GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council’s Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988)

On:
Tuesday, 27 May 2008

Held at:
St James’s Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

STEPHEN ANDREW SPENCER BM BS 1976 University of Nottingham
Registration No: 2305893

DAVID PATRICK SOUTHALL MRCS 1971 Royal College of Surgeons of England
Registration No: 1491739

MARTIN PHILIP SAMUELS MB BS 1981 University of London
Registration No: 2732178
(Day Eleven)

Panel Members:
Mr D Kyle (Chairman)
Mrs V Brickley
Mrs S Hollingworth
Dr T Okitikpi
Dr M Sheldon
Mr A Forrest (Legal Assessor)

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MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hempsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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THE CHAIRMAN: Good morning, everybody. We continue with the case of Dr Spencer, Dr Samuels and Dr Southall. Mr Forde?

Cross-examined by MR FORDE

Q Good morning, Mrs Henshall. I am going to be a little time with you but not as long as Miss O'Rourke who has covered much of the ground I was going to cover. If you need a break will you let me know? I want to ask you, as Miss O'Rourke did, a little about your involvement of others in this case and in particular the media. I think you and your husband have always believed that Patient 7 died as a result of the CNEP trial and that Patient 6 is brain damaged as a result of the CNEP trial. Is that correct?
A Yes, I did say yesterday it was a contributory factor, yes. I cannot say CNEP actually did this but certainly taking part in the study left them disadvantaged so that they were damaged or dead.

Q I think we are in agreement. You regard, let us make sure we get this absolutely right, CNEP as having contributed to the death to the Patient 7 and having contributed to the brain damaging events so far as Patient 6 is concerned?
A Yes, I do believe that, yes.

Q You have always believed that from the moment you told the Panel you knew they were involved in the trial?
A I do not know when I actually, you know, when it first occurred to me that that is what had happened. I think it was just something that evolved from everything that I had seen, read, heard and the doctors I had spoken to. I could not say exactly when that happened. It was not overnight or anything like that.

Q You see we have not seen any opinion from any paediatrician indicating that Patient 7’s death was caused by CNEP. Are you telling the Panel that you have an opinion which states that in terms?
A What? Other than my own?
Q Yes.
A No, not really.

Q In relation to Patient 6 I have seen a report which I shall come to a little later from Mr Newell or Dr Newell which indicates that he could not see a link between CNEP and Patient 6’s brain damage. I think that is correct, is it not?
A He could not see - from the neonatal records he could not identify something significant enough because he had not seen the earlier ultrasound scans and things like that. There was too much missing. Had not seen the nursing Kardex. He said he had not got enough information to say whether or not that had happened then.

Q I will have to put those documents to you specifically but that is your answer, is it, you think that in some way Dr Newell’s opinion was qualified because he did not have a complete set of notes?
A Yes, possibly and because, of course, like, you know, the effects of CNEP are not well documented and are not known to this day because there is so much unpublished data.
Q You have enlisted the support of the media in order to try and place into the public domain your strongly held belief that it damages children?
A No, that is not why I did it. I explained the other day while we first went to the media. I just wanted to know whether there were any other parents that had been involved in the research trial without their knowledge as well or whether I was the only one. That is why we contacted the media. Everything else has just happened since.

Q That might have been the reason for your initial contact but for the last ten or more years you have been very keen to keep the plight of Patient 6 in particular in the public domain via the media, have you not?
A We have been approached most of the time but it depends what is going on. There has been a lot going on, has there not? It is a matter of public interest. If there is an internal inquiry or a hospital Trust inquiry on things like that you would be very, very lucky to keep that quiet, would you not?

Q You have told this Panel that you think there ought to be a public inquiry?
A I do believe that that should have happened right at the very beginning. I think Mary O'Rourke said that did I feel guilty about the amount of public money that had been spent. To some degree I do slightly because I think the public money would have been best spent on a public inquiry because the inquiries we have had to date have been too fragmented and have not been able to deal with the entirety of our complaint. Yes, I do believe there should be a public inquiry.

Q Can we deal with some of the complaints that you have made historically. I think it is fair to say that you feel a considerable degree of bitterness towards these doctors?
A What? Are you asking me or telling me?

Q I am asking you whether that is the case. Looking at your letters and the quotes in the press you feel a lot of personal animosity towards the three doctors involved in this hearing, do you not?
A I suppose over the years I have been upset at the way we have been treated since, you know, just for asking questions about our own children's care and the way we have been dealt with I feel bitter about that but, yes, I suppose I might do, yes.

Q You do. You feel bitter, let us not beat about the bush, towards these doctors, do you not?
A You would, would you not, if you thought - if you held them responsible for what had happened to your children and it was not good then you would, would you not?

Q When we are looking back at your evidence we need to bear in mind, do we not, that you first of all feel bitter towards these doctors and, secondly, have a strongly held belief that individually or in combination they damaged one of your children and caused the death of another?
A I think the fact that they were in the trial and the way that disadvantaged children that is what happened. I do not say they purposely set out to do anything like that, of course they did not but it did happen, it is a fact that it happens; one is dead and one is brain damaged, they were in the study. I do believe it happened whilst they were in the study, so what else am I to believe?
Q You see, as a result of that strongly held belief you have been prepared to make some extremely serious allegations against these doctors, have you not?
A I just say it as I see it really.

Q What do you think the most serious allegation is that you have made against these doctors?
A I do not know.

Q You do not know?
A I think they are all serious.

Q You have accused them of dishonesty, have you not?
A Yes, I do think they are dishonest, yes.

Q You have accused them of scientific fraud?
A Yes, I do think it was scientific fraud, yes.

Q You have accused them of monetary fraud?
A Possibly.

Q Not possibly. You have written in terms. This is a bundle I have been given of everything you have written to the GMC and anybody else that will listen and I can read on page 91, for instance: “We have evidence of literary fraud, scientific fraud and, indeed, monetary fraud”?
A Yes, I think we went into the detail of this the other day as well because if you apply for something under the guise of something it is not and then you acquire money to do that then that is fraud, yes. That is what I believe anyway. That is how I see it.

Q You have been prepared to go a lot further than that in your allegations against these doctors, have you not?
A Like what?

Q 27 January 1998 you wrote to a Mrs Sudlow who was the Chairperson of the Community Health Council and, again, in the bundle we have it is pages 111, 112.

MS SULLIVAN: Shall we just let Mrs Henshall have a bundle so she can follow it?

MR FORDE: That would be sensible. I do not think the Panel have this bundle.

(Shall we just let Mrs Henshall have a bundle so she can follow it?) Page 111 in the middle at the bottom of the page and 112. Do you have that?
A Yes.

Q If you go to the second page you suggest that the Trust is corrupt on the first page and then you go on to say this: “Doctors should not be allowed to lie.” Do you see that?
A Yes.

Q Do you stand by that?
A Yes, I do.
Q You think these doctors have lied?
A Yes, I do, continuously.

Q We need to know your attitude when we come to assess your evidence. What about this:

“We have accused these doctors of murder, fraud, actual bodily harm, etcetera, and yet they are still free as we speak to carry on without worry of any recompense”?

A Yes, we are concerned about the lack of accountability for their actions, yes.

Q Before we deal with that concern, are you still accusing these doctors of murder?
A I believe that my child died for the benefit of the study and I do believe that they did not put her interests first, so yes, that is probably murder. I cannot think of anything else you can call it.

Q Have you told the police that it is your strongly held belief that either in conjunction or individually these doctors are responsible for murdering Patient 7?
A I have not reported murder to the police, no.

Q Why is it you feel that it is appropriate to write in those terms to the Community Health Council?
A I am free to have opinion of my own and you are free to write that opinion down, so why is it inappropriate?

Q If you cannot see that that may be of assistance to those of us who need to look at your evidence but you are prone, are you not, to using emotive language such as “experimentation”?
A It is a pity the doctors did not use that type of language when they were putting what treatment my daughters were going into, then I might have understood it better but it was an experimental procedure so why should I not use the word experiment.

Q You are quite happy it seems, even today, to stand by your suggestion and assertion that these doctors are guilty of murder? You stand by that?
A Yes, I stand by that.

Q When you the case came before the Court of Appeal - and we have the judgment for everybody's note as C4 - you were maintaining a number of serious allegations against these doctors, were you not?
A Will you say that again?

Q When your judicial review came before the Court of Appeal you were maintaining a number of serious allegations against these doctors, were you not?
A Yes.

Q One of them, just one of them in a list of ten that the leading judgment listed was that these doctors performed unnecessary Caesarean sections specifically in order to ensure an adequate supply of premature neonatal babies for the trial?
A It was something that was suggested to me by a medical expert. I discussed the other day that there was a possibility of multi-party action because there were several parents that had gone to use the same solicitors for damages for their children. When the expert looked at the obstetric records he said that he found a pattern running through and he could not say why the clinical decision was made.

B Q Name of that expert, please?
A I think it was O’Hare.

Q John O’Hare?
A I think so, yes. You will be able to find it because the child that we mentioned the other day he did the obstetric report for her too.

Q Do you think it might have been John Hare rather than O’Hare?
A I cannot remember. I am sorry, I cannot remember.

Q Anyway your evidence is this that he saw a pattern which you are prepared to elevate to a solid allegation against these doctors that they performed unnecessarily Caesarean sections?
A My opinion came about, (a), because of that and, (b), because I know the other children. I have spoken to their parents. Obviously I have seen medical records with them and we have not been able to come up with a good clinical reason for about five out of the seven that were not children that had Caesarean sections including my own.

Q I need to analyse this with you for a moment, if I may. You and other parents have analysed notes and as non-medically qualified people you cannot see an adequate reason for Caesarean section, therefore you have concluded it was unnecessary. Is that fair?
A No. We have not done it on our own. We have obviously consulted over it.

Q Who have you consulted apart from Mr Hare?
A I have spoken to lots of different doctors.

Q You have told us hundreds. I suggest that is another example of exaggeration on your part.
A I have spoken to many, many doctors over the course of fifteen years.

Q It is not hundreds, is it?
A I have no idea how many exactly, I was not counting but lots. Not one or two. Not 20 but more, much more. At one time as an example we rang every neonatal teaching hospital up and down the country to find out where CNEP was being used and in what mode and whatever. I think I mentioned that the other day as well, so yes, there is a fair few.

Q Mrs Henshall, you are on oath. I do not want to be unfair to you. You may use hundreds just as an expression but it is not accurate, is it, to suggest that you have consulted hundreds, which I take to mean more than 200, of paediatricians or doctors?
A Yes, it would not be accurate to consider 200. I did not say 200 but there was lots. I cannot say how many exactly, I was not counting, I am sorry.
Q It is probably less than 100, is it not?
A It could be. I really do not know.

Q The effect of your allegation in relation to the Caesarean sections is this, is it not?
That if any of those children died, having had an unnecessary Caesarean section
performed upon their mother, and that was linked to their death, that would be another
murder, would it not?
A I do not know. I have not really considered it that way. I suppose it would
depend on the circumstances, would it not?

Q You also have accused doctors of forging signatures, have you not?
A Yes. I have spoken to other parents that have said definitely, you know, they are
forged so, yes, I have repeated that.

Q It is not just other parents. You have been very coy about this and you were when
Miss O’Rourke was asking you questions. You accused Dr Kate Palmer of forging your
signature, did you not?
A No, I did not say she forged it. I just said … what am I supposed to say when I
have absolutely no recollection of signing these things? I am told that my babies are in
one research project, then I am told they are in another. I do not know to this day how
many research projects they were in and I am sure if I discovered another research project
they were in a form would be produced with my signature on it, of that I can be
absolutely certain.

Q We will come back to that topic in a moment. Can I just ask you to explain part
of your answer? You said you were told that your daughter was in one research project
and then another. Are you distinguishing between NIRS and CNEP or is there some
other project that you want to tell us about?
A I am not personally distinguishing because I think they were supposedly part of
the same, but obviously they are being split up now. I do not understand why that is. I
do not know. I do not understand what you are asking me.

Q I was trying to explore your answer where you were saying that you apparently
were confused about which trial your daughter or daughters were entered into.
A Yes. Obviously it was confirmed to me that my daughters were part of the CNEP
and RDS trial. Dr Hughes from the Ethics Committee confirmed that for me. But then
some time down the line when we had medical records and everything it became apparent
that when I asked Dr Spencer about all the extra monitoring and why was that not done
on [Patient 6], he said to me that was because it did not come in until the end of the trial.
In fact, they repeated that the other day and in fact I contradicted him by saying that
actually Patient 7, my other daughter, had near infrared because I could remember it, I
had stood by while they did it, so I do not understand how that is a separate research
project or what project she is in because I have since asked for all the information on that
project and what she was in and I was sent three different lots of information on near
infrared of which I cannot see she fits the criteria for any, but maybe that is just me not
being medically minded enough, I do not know.

Q One of the difficulties for you, I suggest, is that all this happened such a long time
ago. Would you accept that?
A It might be more difficult for other people than me, because, as you know from the bonding questionnaire, I have been raising concerns about it for a long, long time. Of course, you know, you forget things and you remember things perhaps differently or whatever, but, you know, I did have a concern quite early on and I was trying to get a picture of what was going on back then.

Q Would you accept that over this time period memories fade?
A Yes, of course memories fade, yes.

Q Do you sometimes find it difficult to discern between that which you can remember as happening at the time and that which you have since discovered?
A I think sometimes I accept that my memory does not always match up with what I am seeing written down, not necessarily by me, like in medical records and things like that, perhaps I remember it differently, but then, you know, that is memory for you and it depends what your perception was at the time, I suppose.

Q Would you accept that if the medical staff, and I include the nursing staff, wrote a contemporaneous note before they had any knowledge that you were going to make the complaints that you had, that that is likely to be more accurate than your memory?
A No, not necessarily. There are lots of mistakes in the nursing records and things like that because a lot of the time the nurses write them retrospectively and they do not always get the times and things right, or events really. I think in some of our medical records it says that “Dad visited with the siblings” and it was at times when it would not have been possible, so, you know, everyone is human and everybody’s memory can be fallible, but ---

Q But that is likely to be far more accurate if written within minutes or hours than your recollection now when you tell us you did not get the notes for many years.
A No, not necessarily.

Q You do not accept that?
A No.

Q You see, what you tried to tell this Panel, and I am looking at Day 9, page 55 of the transcript, was that you were one of those, I suggest, extremely rare people whose memory gets more accurate as your complaint evolves.
A I do not think that is what I did actually say, but ---

Q Let us have a look at it together then, shall we? Day nine, page 55 between letters F and H. Miss O’Rourke just above letter F asked you a question. In fact what she is suggesting is you were:

“Taking on board other people’s accounts of their experience?”
A I did ask them what their experience was, yeah. That was the whole point.

Q You see the reason I ask you is this: the question surely becomes, when someone talks to as many people as you do, learns of
other people’s experience, meets with lawyers, and indeed discusses with doctors and experts, it can sometimes unwittingly happen that your account that you have given now today, 14 years later, is coloured by what some other people have said to you, or something that you have read somewhere, or something that some expert has said, or that somebody else has said, and it has influenced you?”

You said this:

“I am sure that there would have been some influence, and I am sure that there would have been - you know, our complaint would have evolved. Of course it has evolved, because we have learnt more and more as we have gone along. It has probably got a lot more accurate”.

A Yes. What I meant by that was because, you know, when you do see things - I mean, like, I could say, “Well, such and such” - I cannot really give an example.

Q What you have done, I suggest …

A Yes, I agree.

Q … is you have taken on board the views and opinions of those that you have sought, of parents sympathetic to your cause and you have woven it into a rather poor recollection of events at the time.

A What, that I have taken other people’s experience and made them my own? Is that what you are suggesting?

Q Everything you have read, the inquiries you have been through, the Griffiths Inquiry, the reading for this case, the reports, you have absorbed and you have then either deliberately, because you have been accused of lying, or unwittingly, as Miss O’Rourke was putting to you at this part of the hearing, taken that on board and made it part of your own recollection.

A I do not think - I think, like I say, the first statement I ever made was when my daughter was about 2½ years old so I do not think I would have to do that. When I say “evolved”, the thing I mean by our complaint has evolved is that I have learned a lot more. Our complaint has not just gone about the clinical care of my children, it has gone about the way the whole trial has run and the inconsistencies with how it is written down on paper and how it was passed and the protocol to how we actually found that it did run in real life. That is what I mean by evolving.

Q But what you are here to do, Mrs Henshall, is to tell this Panel what you recollect about events in 1992.

A Well, I have.

Q I am suggesting to you, as you were to tell the Panel, and it is at the bottom of page 76, if you want to have a look, on day nine you said this:

“Sorry if I have absorbed it over the years”
and that was a reference to many of the people that you have seen and assistance that you have had. Can you see the very real risk that either deliberately or honestly you have distorted the past by taking on board the views of others? Do you countenance that as a possibility?

A Well, then any inquiry would be a nonsense, because that is how they are set up, to get out the truth about what went on and they have to absorb what people say and make an opinion, so that does not make any sense to me. I do not understand what your point is. Surely, that is how you get to the truth, by doing an inquiry and taking on board and seeing what is backed up by one and what is not backed up by another. That is what you do. You take evidence and you listen to what people say and things like that. You cannot help but form an opinion, can you?

Q Yes, but your role is not to have an opinion. Your role is to tell this Panel - I see you - you have been grinning away throughout this hearing. This is serious for these doctors, Mrs Henshall.

A It is very serious for me too.

Q It is not a laughing matter.

A I know it is not a laughing matter, but what I do not understand is why you keep attacking me and saying that I am not entitled to have an opinion.

Q No. You are here to tell the Panel what you recollect and I am trying to discern recollection from opinion. You are not an advocate for the anti CNEP brigade at the moment. You are here to tell people what you remember. Can you do that? Is it something you can do?

A Maybe you should stop attacking us parents that went through this instead. Why cannot you just try and get to the truth which is what this is about? You are going on at me for not taking it seriously but actually you are here as a defence to these doctors. You have asked me to come here and tell you what I know and what we found out along the way and that is what I am doing and, I am sorry, if you want to just keep insulting me because that is your only defence then go ahead, but I would rather stick to the facts.

Q I am trying to get you to do that rather than to express opinions. Can we attempt to move on and I want to try and deal, if I can, with you with a discrete topic which is your lucidity at the time that you were consented, we say, in relation to Patient 6 and I am struggling at the moment to understand the interaction between your memory and drug therapy, so can you try and help me with that as a discrete topic.

A Right. First of all, to avoid any confusion, I am saying I was not asked to sign any consent form or given any randomisation speech or anything like that about the two different treatments. I cannot tell you because I do not believe anybody came to me to ask for any sort of formal consent other than what I have described. The only thing I commented about was the fact that my daughter went into CNEP at six hours of age and I do not believe that at that time I would have been medically fit to have gone through that process and remembered it anyway. I am not saying that is what happened, because I have no recollection of anything like that. You keep telling me that is what happened but I cannot honestly say or comment about that because I do not know, I do not remember any of that.

Q There is a difference, and I want to explore this as a topic with you before we
A come to the notes and the specifics, between not remembering and accusing people of fabricating consent forms. Do you understand the difference?

A Yes, I do.

Q I want to try and understand what you claim happens to you when you are given anaesthetics, morphine and the like.

A Right. In our family there is some condition, and I do not know what it is called, because it has not been examined formally, but my sister, my mother, myself, two of my sons, my daughter Patient 6, when we have had operations and we do not know to this day whether it is anaesthetic or whether it is the morphine or whatever - I am allergic, I know, I have been told, to NSAIDs and aspirin, and there is something that happens. We sleep basically a lot afterwards. It takes us a long time to recover, it takes us a long time to get it out of our system. I think they have decided it is something metabolic, but we do have lucid moments which is, you know - I cannot explain it. It is just the way we are. We are in and out of consciousness but take a lot longer than normal to come round.

Q Again, because I have seen some documentation which I will put to you a little later, who do you say has made this diagnosis in relation to this fluctuating lucidity?

A Nobody has made a diagnosis. It is just always mentioned. We always have to see the anaesthetist before we go in for any exam. The last time it was mentioned was the last operation I had. They just send the anaesthetist up to see you and they say, “Oh, we believe you had problems with your last anaesthetic” or blah de blah de blah, you just explain it to them and then they just decide on what course of action they are going to take to make sure that you are okay basically.

Patient 6 had to be ventilated when she was even given chlorhydrate, so I do not know what it is that happens, nobody has ever really explored it. It is just a management thing.

Q So we ought to be able to find, ought we, because you had had, I think is it five children before Patient 7…

A Yes.

Q …throughout your notes…

A Six, I think.

Q …something on the anaesthetic record or chart indicating that you have a problem with fluctuating lucidity? Yes? Was it identified prior to the birth of Patient 7?

A I do not know.

Q It is rather important, is it not, to know, given that you cannot remember signing consent forms?

A I do not know whether it has ever been - I do not that it is ever documented. You just have a chat – they do not write everything down, you know. If you look in the medical records you will find there are massive gaps throughout the day, so it just depends how vigilant they are being with their record keeping, I suppose.

Q Let us have a look at how you described it on Day 10, if you have got the transcript, at page 3. It is just below letter D. Mrs Henshall, whilst you reading that long answer between D and F, can I make my position clear? I am giving you an opportunity
to countenance the possibility of having forgotten certain things and procedures. That is what I am trying to do. Let us have a look at this together, shall we? You say:

“Recently I had another operation”

and then you deal with speaking to the anaesthetist and you deal with a metabolic problem and aspirin and allergies and then you say this:

“I came round and spoke to the staff on the recovery”

- ward, I think that should be –

“Whilst travelling back to the ward, I was completely out of it; I do not remember that journey at all.”

You must have had a journey, though, must you not?

A Yes, of course.

Q But you do not remember anything about it?

A No.

Q Then you say you were unconscious and then you seem to have overheard a discussion about Hartmann’s fluid and then you tell the Panel that you interrupted and you remember interrupting?

A No, I was told afterwards. I do not remember interrupting, I was told afterwards. In fact, the nurses remarked on it to me.

Q I see, that is how we should read it, so you were told by nursing staff that you had interrupted but you had no recollection of it?

A No.

Q Do you accept, therefore, the nursing staff were correct in telling you something that you could not remember? You have no reason to doubt them?

A No, not really, no.

Q Did you or did you not?

A My husband was present at the time.

Q Who was present?

A My husband was present at the time.

Q He was able to confirm the fact, was he, that you had this conversation that you could not remember?

A No, he was present when the nurse was telling me.

Q Right. What I was asking you was whether you accept now from the nursing staff that you had a conversation which you could not remember?

A Yes.
Q They were presumably telling you about this conversation on the very day that it happened?
A Yes, they did, yes.

Q Do you accept that if your recollection here is correct, you are the kind of person who can involve themselves in conversations and actions at or around the time of anaesthetic and later have no recollection?
A Yes, I did explain that that is what happens, yes.

Q So can you countenance the possibility in relation to patient 6 that you had a conversation with the female doctor whose clothing Ms O'Rourke took you through you described with accuracy, but you cannot now remember it?
A No, because I do remember what she said to me. I have said what she said to me.

Q You remember bits of it, clearly, but our case is that in relation to Patient 6 you gave consent for Patient 6 to be entered into a trial. You are aware of that, are you not?
A No, I was not aware of it at the time. I am aware of it now.

Q You are aware of what our case is? Our case is that you gave consent for Patient 6 to be entered into a trial. You understand that, do you not?
A Yes, I understand that is what you are saying, yes.

Q You have been very coy about whether or not your signature has been forged but you accept that your signature is on the consent form?
A I am not trying to be coy and I take exception to that, because I can only tell you what my recollection is and I have reiterated that and my recollection is that I was never asked to sign any form for CNEP and I was never given any explanation. You say that actually it was randomisation but I was only ever approached for [Patient 6] to be entered into CNEP as was my previous child.

Q This is what we need to just unravel and keep your answers a little shorter, if you can. I am asking you something rather simple. On Day 10 at page 3 between letters D and G you give a lengthy answer about the fact that you are the kind of person who, when exposed to anaesthesia or certain other drugs, has a failure of recollection?
A No, I did not say that.

Q That is what this answer means, does it not?
A No, actually, I did not say that. I said that I had lucid moments where I remember things and then I can be unconscious. That is not a failure of memory. If you are unconscious you are unconscious. Nobody expects you to remember things, would they, if you were unconscious?

Q Already you have debated with Miss O'Rourke the high improbability of the doctor who took your consent getting you to sign a form when you are unconscious. You do not think you could sign a form when you are unconscious, do you?
A No.

Q No, so let us assume, for present purposes, you were conscious when you signed that form?
A But I did not sign any form. I was not asked to sign any form.

Q I am suggesting that you may have had a failure of recollection of the sort that you describe here. Do you countenance that possibility?
A I really do not know. I really do not know. I doubt it.

B Q But it is a possibility, is it not?
A I suppose so.

Q Can I ask you now to close the bundle relating to the transcripts for the time being and go to our medical records bundle which we have at file 2? I want to ask you first of all about Patient 7 and you will find her notes behind tab 4. Do you have that?
A Yes.

C Q What I want you to do first of all is to turn to page 13 and this is a doctor whom we will later come to know as Dr Aru. Do you remember Dr Aru?
A No, but I remember Dr Arumugan.

Q Ok, same one. Your pronunciation of Sri Lankan is better than mine. Let us just have a look at this lengthy note together. On 12.12:

D “27 wk gestation, premature baby – birth weight 819g.”

A I think that is all correct, is it not.

Q Were you then 26?
A I presume so, yes.

E Q Sixth pregnancy:

“A Bad obstetric history. 3 miscarriages & 4 premature delivery 28 wk, 28, 30, 32.”

F Accurate?
A Yes.

Q “Spontaneous rupture of membrane x 5 days”?
A Yes.

G Q Then we now this child was delivered by a lower section Caesarean section.
A Yes.

Q And then:

“Electively intubated (difficult intubation)”

H And then the APGAR scores, which you are now familiar with?
A  Yes.

Q  Were you familiar with APGAR scores in 1992?
A  I cannot say as I was that familiar with them, no. I know they were given a score but I would not have known what that meant.

B  Q  Were you familiar with bradycardias, or bradys, as you have described them, in 1992?
A  I think so.

Q  That is not another piece of after-acquired knowledge?
A  Sorry?

C  Q  It is not another piece of later acquired knowledge?
A  No. When you are on the – I think I acquired it throughout that time while I was looking after my children, because if your baby is having bradycardias then you fill in a brady chart and whoever it happens in front of you fill it in, so I would have filled in like that and signed it if she had had one in front of me.

Q  What we can say, I think, and agree upon, is that you were a very experienced, high inquisitive, highly protective mother in 1992?
A  I would describe myself as that, yes.

D  Q  Then we get the examination and management and then two lines from the bottom – or three lines from the bottom of the chart – an asterisk:

“CNEP consent obtained from father.”

E  Do you see that?
A  Yes.

Q  If you go over the page:

“Randomised for CNEP trial at 3.05”

F  - a rather precise timing. Do you agree?
A  Yes.

Q  A different hand?
A  Yes.

G  Q  Then a head scan age four hours is said to be normal. If you go to page 19 at the top, we see the consent form. Do you recognise that as your husband’s signature?
A  Yes.

Q  You are not suggesting this is a forgery
A  No. Carl says he signed a form.

H  Q  It suggests, does it not, that the aims and procedures of the clinical investigation
had been explained and that participation in the study is voluntary and “he/she may withdraw at any time of his/her own accord”.

Do you see that?
A Yes.

Q Then it ends:

“I hereby give my fully informed consent to the person named above taking part I this clinical investigation”

and it is signed by your husband?
A Yes, I believe it is, yes.

Q Then the doctor signs that the nature of the investigation has been explained?
A Yes.

Q We have already looked at the shorter version of the Patient Information document but that was stapled to this document, I am instructed, as a separate matter and given to your husband or any other parent. If your husband read that form before signing it ---
A Can I just make a point on that?

Q Yes.
A When you say it was stapled to these forms and then given, so you would have had to have taken the staple out, would you, to give that piece of paper to – so on the originals there should be staple holes on all these?

Q Yes, all right.
A Well there was not on ours.

Q If you have got the original of the Patient Information Sheet please furnish us with it?
A No, I did not say the originals of the Patient Information Sheet. I said the original consent forms that we went to see.

Q I am told and, as you will appreciate, it is 16 years ago, that it may have been a paper clip but in some way the Patient Information Sheet was attached to this consent?
A You know, you would have pulled me up for being that inconsistent.

Q I am sorry, I was not there. What I want to ask you is this, do you accept that if your husband read that form he would have been left in no doubt but that this was a trial? Look at the title, top of the page. What does it say?
A Yes, “Consent by proxy to conduct of a research investigation” but he is not saying he read it, is he?

Q We do not know. I am just asking you whether you would accept - because I will have to ask him about this - that if he read that and the study title “CNEP trial” he would have been left in no doubt but that this was a trial?
A  If it was filled in at the time he was asking to be signing it, possibly.

Q  If we go over the page we have got the nursing note, 11.30 when Patient 7 is admitted and then under 1: “Dad, brothers and sisters united. Dad spoken to by Dr Aru & consent for CNEP trial given.” Do you see that?
A  I do and actually that is the reference I made about like inconsistencies and things wrong in the medical records because the brothers and sisters were not there. Why would you take brothers and sisters to a unit when your wife is having an emergency Caesarean with a very poorly baby. They were not there.

Q  That is as you recall things. It is timed at 11.30 but more importantly if that note is accurate so far as the CNEP trial is concerned and we have now seen, just to remind you, page 13 a reference to the CNEP trial; page 14 a reference to the CNEP trial; page 19 a consent. Now here on page 20 we have a nurse saying that consent for the CNEP trial was given. Do you see that?
A  Sorry, where are you looking?

Q  I am looking at the first and second lines under the entry number one on page 20 in the nursing note: “Dad spoken to by Dr Aru & consent for CNEP trial given”? A  Yes.

Q  “Photograph & explanation of [Patient 7’s] condition given to mum. Will visit on way up to ward.” Then at 21.50 you are recorded as visiting and being seen by Dr Morgan:

“Baby was randomised into CNEP and is now in pressure.”

On full ventilation. These notes continue to record your visit, if we go to page 21, I think this is the 14th, it may be the 13th actually, 21.00 hours:

“Parents visited. All equipment explained and reassurance given. Debbie is moving to our family unit tomorrow.”

Do you see that?
A  Yes.

Q  Do you recall the equipment being explained to you?
A  It was explained many, many times, you know, how it worked and things like that because we asked lots and lots of questions, so, yes, I do, yes. It was never explained as experimental to me though.

Q  It must have been, must it not, because you have told us you were a protective and inquisitive mother?
A  Yes, I was.

Q  You have told us that the appearance disturbed you because you had never had a child who had been ventilated before?
A  That is right.
Question: You saw her head coming out of the one tank which surrounded her body and a head box around her head?
Answer: Yes, that is right.

Question: That was a dramatically differed appearance to some of the other babies in that high dependency unit, was it not?
Answer: Yes, I was explained it was different. I have given an account of that.

Question: You knew it was different, you could see the other babies who were not having the same treatment and do you recall see the teddy-bear sign which said some babies were receiving standard treatment and were not in the CNEP trial? Do you recall that?
Answer: No, I do not recall it because I do not believe it was on any of them. On that point as well yesterday it was made out that that was only on the standard treatment incubators but, again, I reiterate if you look at the BAPSCAN article that Professor Southall does said where he first brought up this poster he is referring to them as being on both the treatments whether you were in one or the other.

Question: The one thing you know, Mrs Henshall, is at relevant time Professor Southall was not working at North Staffordshire, was he?
Answer: Well, no, he was not.

Question: You know if he is describing anything, I am happy to defer to your knowledge of this, that is probably describing the hospital where he worked?
Answer: Maybe.

Question: Why maybe, Mrs Henshall?
Answer: What I am saying is I do not know.

Question: Why are you trying to give this Panel the impression that the question I have asked you is incorrectly posed?
Answer: Because I do not, you know, you are trying to give the Panel the impression that we could not possibly have not known about this trial because there was information and posters everywhere but actually there was none of that. Professor Southall said that that is how it was. He does not make it clear that that is only how it was in his hospital. He infers that that was how it was everywhere and that we could not possibly have not known but that simply was not the case as we have got photographic evidence to prove.

Question: I am just trying to be fair, Mrs Henshall, by suggesting that Professor Southall is probably describing the hospital where we worked.
Answer: Perhaps he is. You know better than me.

Question: Can we carry on with the nursing note because I want to understand your evidence in relation to this. We see on page 21 a visit, this is against seven o'clock: “Mum visited during the night.” Do you recall being on the family unit at any stage?
Answer: I do remember being on the family unit, yes.

Question: If you go over the page at 13.00 there is a note: “Parents and siblings visiting.” That is one:
“2 Remains poorly in CNEP.”

The pressures are changed. Then there is clearly a difficult conversation when you were told that the prognosis was not good and that is also signed. Do you see that next to “NB”?

A Where are you looking?

Q The problem numbers and then there is:

“NB prognosis for [Patient 7] at present not good. Problems explained...”

Obviously very upset. Then at 16.15 Dr Aru is said to have had a conversation with you about poor prognosis. Do you recall that?

A He had spoken to me but he could not have spoken to Carl because Carl was not there. He had taken the children home. He was not back by then.

Q By what time?

A What time did he take the children home?

Q Yes.

A They would have visited for a while, I should not think they would stay much more than half an hour, they were very, very young. I cannot say for an absolute certainty but I would doubt that they stayed too long.

Q There is every possibility, is there not, that the doctor spoke to both of you before your husband took the other children home?

A No, I do not believe he did, no.

Q Then at nine o'clock you apparently are both seen by Dr Jugnu. Do you recall that?

A Yes, that was the lady doctor I believe that was, well, if that is her name, I believe that is possibly the lady doctor that was looking after her at the time when I described like that I had turned around and told her off for messing. She waited with me and we both waited for Carl to come back to the hospital and he did and then it was when he arrived that we both said, yes, okay and they showed us to the room, the flat, the double room on the neonatal unit where you can go and they brought her to us, yes.

Q Do you recall having a conversation with Dr Spencer in the early evening about how ill Patient 7 was?

A I thought the conversation I had with Dr Spencer was around about two o'clock in the afternoon because I rang home. Carl had gone home and I rang home and said, look, you know, and I do not think he believed me that things had gone so bad because he had been in and he had seen her. I asked him then if he would bring some stuff in for her and he did not bring it back in because I suppose with not being there he could not get over how quickly things had changed.

Q You see, if you go back to page 17 there is a clinical note of a conversation as against a timing of 18.00 on 14 February 1992?
A  Yes.

Q  That suggests that Dr Spencer spoke to both yourself and your husband about the problems that Patient 7 was suffering?
A  I do not remember Dr Spencer ever having a conversation with both of us about it. My recollection is that I was on my own.

B  Do you again countenance the possibility that your recollection is faulty or are you suggesting that the nursing staff and at least two doctors other than Dr Spencer whose notes we see have fabricated, manufactured or forged these notes?
A  I am not suggesting anything like that. I am just telling you, you know, what I remember.

C  But do you accept that where there is a note made at the time when there was no complaint by you that it is likely to be more accurate than your recollection?
A  I could not say because I have already pointed out, you know, instances where it was not very accurate, so how do you expect me to - I do not know because I did not write the note, did I?

D  Let us try again. Do you accept that when a member of the medical team has timed a note and written detail about conversations and clinical observations those notes are likely to be more accurate than your recollection or not, Mrs Henshall?
A  It depends how accurately it was written and when it was written and whether it was retrospective or not. I notice in the margin next to it there is something there, a time that is scribbled out and then it is re-written.

E  It looks like a six which is changed to the 24 hour clock, 18.00. There is nothing sinister about that, is there?
A  I am not making out it is sinister. I am just saying you, do you know, I really do not know. You are asking me to comment on things that I really do not know anything about.

F  I am just asking you as a common sense proposition whether or not you accept that where there is a timed, detailed note from a member of the medical team it is likely to be more accurate than your recollection?
A  I would have to say no, then.

MR FORDE: Sir, I am about to move on to Patient 6 and I notice the witness has been giving evidence for an hour, so I wonder whether we can have a short break because I will not finish that patient in 15 minutes.

THE CHAIRMAN: Yes, we will have a 15 minute break now.

MR FORDE: Thank you.

(\textit{The Panel adjourned for a short time})

MR FORDE: Thank you, sir. Mrs Henshall, could I ask you to have available not only the big bundle behind tab 5 which has got Patient 6’s notes but could you also take up the
transcript for day 9 and go to page 13 which is your evidence-in-chief, so when Ms Sullivan was asking you questions. Do you have that?

A Yes, I think so.

Q I want to just explore with you another possibility in terms of your motivation regarding these complaints. If you have a look at your answer which begins just above letter B you indicate your desire prompted by your boys, no doubt, to have a daughter because you said that they were asking “Where is our baby? Where is our sister?”

A I had already got a daughter but I wanted another one for her because she had got five brothers.

Q My mistake. You said this:

“I sort of blame myself because I thought if I can just get – if I can be sensible and just not go on my feet after so many weeks and things like that and I discussed it at length with the obstetrician…”

You had had a number of premature babies and it would appear that one of the options you discussed was complete bed rest from a relatively early stage. Is that correct?

A Yes.

Q Was that something which was difficult for you to achieve given the size of your family at home?

A Yes, it was. I do not think we discussed complete bed rest with Baby 7. It was with baby---

Q Baby 6?

A Yes, because obviously of what had happened. I did explain I had been lulled into a false sense of security or I felt that way really because all my other premature babies had done really well, they had had no problems with their breathing and they were alive and well and neurologically intact and everything so I do not think I started looking into it deeply until Patient 7 died.

Q We can see just above letter E:

“Mr Redmond, the consultant obstetrician who they sent me to see, promised me that he would look into why I had premature deliveries and that he would book me in at 26 weeks and he was determined he would get me near to term.”

That was the plan?

A Yes. With Patient 6, yes.

Q Again, it may be common sense but with six other young children difficult to get bed rest at home?

A Well, yes.

Q Because some of them were of school age, I think?

A Yes, just about, yes.
Q And meals and shopping and the like?
A Yes.

Q So was the advice that you were given to remain in hospital from about 26 weeks until term?
A No. The plan was to get me at least past 28 weeks and, you know, he said basically he had won the lottery if he got me to 32 weeks because of my past history. That is what they wanted to do, until she was viable basically.

Q Look over the page, D9/14. Ms Sullivan is still questioning you.

“So you get to 26 weeks and are you then admitted for bed rest?
A Yes.”

Then you are given medication and were you allowed home at 32 weeks or did you take your own discharge?
A No, I was told that I could go home because they had got me past a viable date and their advice was if she was born the next day she would be fine.

Q Presumably you were told when you were to get home to try and take things easy.
A Yes. I had been mobilising and everything in hospital. I was not on complete bed rest. Towards the end I was allowed to get in and out of bed and nothing had happened, so it was just take it easy really, yes.

Q Because what you then say at the bottom of that page:

“So they asked me if I wanted to go home and I said, well, I was a bit dodgy about it but if they felt that I would be okay then I would love to see my children again”.

A Yes.

Q “And it was quite hard on Carl so that is what we decided we would do”.

As I read that answer, and correct me if I am wrong, when you say “I was a bit dodgy about it” were you thinking it might be better for you to remain in hospital because of the demands of your large, young family?
A I do not think it was anything to do with the family as such, it is just that whilst I was at … they had said to me that anything could happen. If I went into labour and anything did happen then you live half an hour away from the hospital, blah de blah, and so obviously I did not want anything like had happened the time before when my waters had gone at home and I sat around for a while and was not treated and then got an infection. I suppose there are loads and loads of things that help make up my mind really. I wanted a good outcome for the baby and I wanted to give the baby the best chance and it was a balance between whether it was sensible to sit there and carry on until 40 weeks or whether that was realistic or not and it was felt that it probably was not realistic.
anyway, so if they were happy to let me home then basically I trusted them that that was okay to do.

Q  Do you think now you should have remained in hospital?
A  That is impossible to say. I could just have easily laboured there. I do not know. I did not go into labour when I went home, so I do not know.

Q  Do you think now that you overdid it at home?
A  I wish I had not gone shopping but then I would hardly call that majorly overdoing it.

Q  When you went shopping, and I will come to your evidence about that in a moment, were you fully participating in that shopping expedition – getting groceries, loading trolleys, pushing trolleys, carrying things?
A  We did not get that far actually because we had only been out for about half an hour and you have got to get there and whatever.

Q  Did you get there by car or did you walk?
A  I think we got there by car.

Q  If you go over the page to D9/15B you said, I think that should be “I had a really good weekend” possibly, but anyway:

“I had stayed on the settee with my feet up and Carl, I probably added to his problems because he was running round after the children and me now at home and I felt a bit guilty. There was nothing in the cupboard, nothing was done. I was feeling guilty about it so I said we need to do a bit of shopping and Carl said, well, I will go and it, you stay here. I insisted that I would be okay for a little walk and we went out and I was not there half an hour basically and I do not know whether it was because I had been flat on my back for so long and had not done much walking but I got backache and I started to ache and I just thought I need to get home.”

Then you said that you had noted that you had a small show, which was

“obviously not a good sign, especially with me”.

That was after you had been walking, it would appear from that answer, around a great deal more than you had in hospital.

A  No, not necessarily.

Q  You say (I just remind you of your answer):

“I do not know whether it was because I had been flat on my back for so long”

which I took to be a reference to the 26 to 32 weeks
“and had not done much walking”.

A I had not done much. You are only allowed to go to the toilet and back and up to where you go and have your dinner and back and things like that, so I had not done a great deal of walking, that is true. I suppose, yes, I did do more walking that day than perhaps I had done for a long time, but then again I was reassured that so long as I took it easy if I did go into labour she would be fine, so …

B Q What I was asking you is whether you now regret having taken that shopping expedition? (Pause)
A Probably.

Q Do you think that may have contributed to your daughter’s prematurity?
A That is impossible to say. I did not labour, did I, from it? I think perhaps what contributed more was that I panicked and went straight back into hospital and then my panic set off whatever event that led to her being delivered prematurely.

Q Just going to the bottom of that page we are on, D9/15:

“So did you elect to have a Caesarean?”

A Yes, I do, yes.

Q Then over the page you describe the anaesthetic that you were to have and you say this:

“That was part of the deal because they said if it was a planned one rather than me having a general where I would be out of it again and possibly poorly afterwards I might like to have a spinal this time so I could be awake and be more active afterwards and have more hands on with my baby and that was the pay off and that is why I agreed basically.”

A That is what they told me, yes.

Q The idea of the spinal anaesthetic as against a general anaesthetic was that you would remain lucid and able to participate rapidly in the care of your baby.
A That is what the plan was, yes.

Q Are you saying, as you have suggested in relation to a general anaesthetic, that you have this reaction to a spinal anaesthetic which affect recollection?
A I have no idea what it is a reaction to, as you put it, but I have been told that it is more likely to be opiates because of the NSAID and aspirin allergy. It is all linked apparently.

B I think what you are saying, and correct me if I am wrong, is that you think it is possible that even a spinal given to you might affect your conscious level or appreciation of things going on around you.
A No, I doubt it, because it does not affect your conscious level, does it?

C I am asking you, you see, because you say later on ---
A Well, it does not make you unconscious or anything like that, the spinal.

Q What you say if we go down the page, having recollected arguing with your husband about the name:

“Q So you had a Caesarean. Were you given any medication afterwards for any reason?
A Yes, I was given morphine for the pain and stuff like that. I was quite out of it.”

I took that to be a reference to being quite out of it following the Caesarean section.
A That is right, because I had been given morphine by then.

E Again, help me. Is it the Caesarean section spinal that you say made you out of it or is it the morphine that made you out of it or a combination of both?
A I have no idea, but it was most likely to be the morphine, is it not, because … I do not know. I have just always been like that after an operation.

Q You have always had morphine, have you not, as well with other pregnancies?
A Other Caesareans, I suppose, but I have had three Caesareans.

F There is nothing noted about this reaction to morphine in your notes, is there?
A No, because it was not decided that it was a reaction to morphine at that time. Just like they had not looked into why I deliver prematurely, they had not bothered to look … you know, basically it was coincidence, some people apparently are more sleepy than others after an anaesthetic. That is how it was described to me. Not any big deal or anything, just that that is how you are and that is how it affects you and that is how it is going to be. It was not a medical emergency or anything. They were not concerned about me as such. I was just very sleepy.

Q But as I understand the sequence of events on page 16, you had the spinal, your husband was able to stay with you …
A Yes.

Q … because he had not been there for other Caesarean sections, one assumes, and
A

witnessed the birth.
A Yes.

Q Then you are able to argue with him about a name, yes?
A Yes, because they were asking us. When the babies are born they put little name tabs on their hands and feet and they were asking us what we were calling her and I said Zoe and he did not like that so in the end they put Baby [Patient 6]. In fact I have got a photograph of her with her name tab on and it does say on there … not Baby [Patient 6]. Baby Davis. It has got it on there.

Q We will come to the timing of the name in a moment if we need to explore that, but I just want to understand this. You were able, according to your evidence, to have an argument with your husband about the naming of your baby shortly after the Caesarean section. Have I got that right?
A Yes.

Q So you were lucid at this stage then.
A At times, yes, as I have explained lots of times.

Q I have to suggest it is not at times, that you were thoroughly able to argue with him, as you have suggested, immediately following the spinal anaesthetic and the Caesarean section about names.
A Yes, we did have a conversation about names.

Q Of all people, your husband would not take advantage of your semi conscious state to force you to name a child in a manner that you did not agree to, would he?
A No, I doubt he would do that, no.

Q You would expect him presumably, more than anybody else, to say, “I do not think you are with it at the moment, Debbie, let’s have a chat about this in the morning”.
A You will have to ask him about what his thought processes are, I do not know.

Q But you are not suggesting that at any stage he expressed to you, are you, concern about your conscious level or state?
A He was pretty used to me by then.

Q Used to you being unconscious?
A He is used to me being in and out after an anaesthetic, yes.

Q Let us just have a look at some of your past records together. I have got a copy for my learned friend. I will try not to burden the Panel with it, but if I need to then we have got other copies. We have had a look at some of your obstetric notes with Patient 7 to see what happened with morphine. I wonder if we could ask you to look at those with us. (Same handed to witness and Ms Sullivan) I am sorry, this is Patient 6. These are your notes whereas what we have in our big bundle are the post natal notes of [Patient 6]. The first entry:

H “On admission observations stable. Morphine 10 mg required at 2125”.

D11/25
Do you see that? First page, second line?

MS SULLIVAN: I cannot see it either. I wonder if we have got the right pages here.

MR FORDE: Can I just see what it is that you have been handed? *Same handed to Mr Forde* I see what has happened.

MS SULLIVAN: It might help to number the pages.

MR FORDE: Yes, I know. *Same handed to witness and Ms Sullivan* The single page is what I needed you to have with 1292, 2120, 1 “admitted to ward”.

MR FORDE: Can you see “Morphine 10 mg required at 2125”, second line.
A Yes.

Q By 2300 you are said to have “feeling + use of legs”. Do you see that?
A Yes. Can I just make a comment? I have never seen this before ever. Why have I not been given a copy of these records? I asked for full disclosure of all my medical records.

Q We got these from the GMC so you are better off directing that question to Ms Sullivan as part of their unused material.
A Okay.

Q I am assuming that you consented to us having them. *The witness shook her head*
A I have not seen them before.

Q Anyway, what is recorded at 2300 on, we believe, 14 December, it is 11 o’clock, so your baby was born at four minutes to seven:

“Debbie has feeling + use of legs – taken down to see baby for a short while.”

That is at 11 o’clock.

“Baby in headbox with 40% oxygen. Registrar spoke to Debbie about baby & she has agreed that baby go in the ‘trial’ (negative pressure)”.

Do you see that?
A Yes.

Q Are you saying you have never seen this note before?
A No, but, you know, I did not have a full set of medical records, so … in fact I have not got a full set to this day, so, you know.
Q What would appear to be the case is that by this stage you have had one dose of morphine, 10 mg …
A Yes.

Q … at 25 past nine and you are noted as consenting to the fact that your baby, Patient 6, go into the trial at 11 o’clock, so an hour and a half later you are being consented. That is a small therapeutic dose of morphine. Are you suggesting that that is enough to affect your conscious level or recollection?
A It does not say here whether that is the only one I have got or ---

Q We are going to deal with the others, because if you look at 0145 you are given morphine, 10 mg, intramuscularly, IM. By 3 o’clock you are passing a good amount of urine and you are tolerating fluids. Then at 5.20 you are given 10 mg of morphine. At 5.45 your child is noted as being in the CNEP tank and by 9 o’clock in the evening (this is day two) you are mobilising well. There is no more morphine being given. You are being given a distalgesic for pain. Do you see that?
A Yes.

Q What do you say about the nursing note (never mind the consent form which we shall come to in a moment) which records clearly that you have consented for your child to enter the CNEP trial? Is that a forgery?
A It does not mention consent or a consenting process. All it says:

“Registrar spoke to Debbie about baby & she has” ----

Q “& she has agreed that baby go in the ‘trial’.”
A Well, I agreed that the baby should go into negative pressure, that is absolutely true, but I did not write this note, did I, so I would not necessarily … that does not prove that I knew it was a trial, does it? That just proves that they knew it was a trial.

Q We have got “trial” in inverted commas, there is a reference to you agreeing to your child going into the trial. I am asking you whether you think that is a forgery.
A No, I do not think it was a forgery. I do not know. I would not know, would I, but that is not the point, is it?

Q What is the point then, Mrs Henshall?
A I have just explained to you, the way she has put that there, she has agreed that the baby go into the trial (negative pressure). She has wrote that. Basically she is saying that she knew it was a trial. She is not saying I knew it was a trial. I did not know it was a trial and I have told you that I did agree for my baby to go into negative pressure, so I do not know what your point is.

Q You are prepared to agree, is this correct, that you have a recollection of agreeing that your child go into negative pressure?
A Yes.

Q You recollect that?
A Yes.
Q Who did you reach that agreement with?
A A lady doctor who came up to see me.

Q So am I to understand your evidence in this way, that you recall having a discussion with her about your child going into CNEP?
A Yes, I asked the staff on the maternity unit if they would get the doctor to come and see me because I was not able to go down for myself at that time and they did get a doctor to come up and see me and she did speak to me and it was her that said to me she was requiring assistance with her breathing, it was only minimal and that they wanted to – I had had a child that had already been on CNEP and so I knew all about it and they preferred to use that method, was that OK with me?

Q So a definite discussion about CNEP but no discussion about the fact that it was a trial. That is your evidence, as I understand it?
A Yes, that is exactly how I recall it, yes.

Q You have always held to that view that there was no discussion about it being a trial?
A No.

Q You earlier this morning were prepared to countenance at least the possibility that your recollection was faulty? Yes?
A Do you know, I cannot say, I can only tell you how I can remember it and I have told you how I remember it. I do not accept that I did have that conversation. I think with the state I was in and how anxious I was about that baby, if they had said to me, “It may be this or it may be that” and they were not sure, I think I probably would have been a lot more anxious. I think the fact that they told me what they wanted her to go in and why and I accepted that, just told them to look after my baby and make sure she was all right.

Q I am not disputing that. In common with many parents you may have taken from this conversation that which you wished to take – “Do the best for my baby, keep her as well as you can, look after her like she is one of your own.” That would have been your general philosophy, would it not?
A Yes.

Q I am simply suggesting to you that like many parents – and as we shall be putting to Dr Stimmier there have been numerous studies – there may have been other things said to you that you simply do not recollect now?
A At no time ever was IPPV mentioned for Patient 6, ever. I was only ever offered the CNEP. I was told that that is what they wanted to use for her.

Q The problem I have with this being your recollection is that the person consenting you would not have known – and you know this now because of randomisation – whether or not your child was going to go into CNEP?
A Oh yes, they did.

Q They did not.
A

Yes, they did.

Q They did not know.
A Yes, they did.

Q Those consenting were simply consenting and the randomisation was done later?
A I do not believe that.

Q They are lying about that?
A Yes, I believe – yes.

Q OK.
A Misrepresenting the truth.

C

Q It is a lie, is it not?
A Yes, it is a lie.

Q They are also lying are they when the nurses clearly recorded that you consented to a “trial”?
A No, that is not what it says there, actually. Are you reading the same thing as me?

D

Q I am reading something which says:

“Registrar spoke to Debbie about baby and she has agreed that baby go
in the trial (negative pressure).”

A She wrote that because she would have known it was a trial.

E

Q I see.
A Not what – she has not spoken to me about that or anything, had she?

Q She appears to be recording…
A Maybe that is what she believes.

F

Q …her witnessing of your agreement with the doctor at 2300 hrs?
A So she witnessed that, so you are telling me that she was in the room as well now?

Q I do not know, it was so long ago, but what she has recorded is your agreement that your child enter a trial?
A She has recorded her understanding of what had been told to me. That could have been the lady doctor going down and said, “Right, OK, yes, Debbie says it is OK for her to go into negative pressure” blah de blah. She would have known it was a trial. I did not.

Q This looks like a conversation with you, does it not?
A No.

Q
"Debbie has feeling and use of legs. Taken down to see baby for a short while."

Who would have told the nurse writing this note that you have feeling and use of your legs, apart from you?
A They were asking. I was asking to go down and they were asking when it was – I do not know, do I?

Q They were asking questions and recording your answers?
A I do not think they were. There is no...

Q “Have you got feeling in your legs?”
A …speech marks there, is there?

Q “Have you got feeling and use of your legs, Debbie?”
A That is not a conversation, it is just---

Q “Yes, I have.” “We will take you down not see the baby”, recorded. “The baby is in a head box. The registrar has spoken to you.” That is the import of that note, is it not?
A Why would they ask me if I had got feeling in my legs or have a conversation of that sort? They were just...

Q Because you had had a spinal.
A I know. It would have been obvious if I had got feeling in my legs, because I could move them, wouldn’t I? They would not have to ask me.

Q I see. All right.
A You are making out it was a conversation and that is my point, basically.

Q I am suggesting ---
A I do not think that note says it was a conversation.

Q All right. I think it is a reasonable interpretation after nearly 16 years, but you disagree?
A One minute you are saying you do not know because you were not there and now you are telling me that that is reasonable to believe that and actually it is not because you do not know, you were not there and I am saying there was not a conversation like that...

Q Tell me about morphine.
A …and I was there.

Q You say you have this reaction to opiates. Do you ever request morphine for pain relief?
A I do not know.

Q Would you like to look at another page of your notes regarding Patient 7 and there is a note at 1710 which I would like you to be shown, please. (Same handed) One for Ms Sullivan and one for the shorthand writer. Again, have you seen this note before? These are your notes?
A  I could not say but – I do not know.

Q  What we see is that your baby, Patient 7, was transferred to the NNU, visited by your husband, you were admitted to recovery – this is following a Caesarean section so you probably could not remember much of this. Then we have your facial oxygen discontinued at 12.30. You are admitted to the ward and then at 1710,

B   “Morphine sulphate 15mg intramuscularly given for pain relief on request.”

Do you see that?
A   Yes.

C  Q  Do you think that happened, when you had the Caesarean section, that you requested morphine?
A   I probably requested pain relief. I probably would not say, “Oh, give me morphine.”

Q  It does not look as if you said, “Do not give me morphine because it affects my conscious level” either, does it?
A   I have already explained, I did not know that at the time, whether it was that. I still do not know to this day which one it is, do I? It has just been discussed that it is possible it could be and that was not until I saw the anaesthetist at my last operation, which was many years after this, so I would not know then, would I?

MS SULLIVAN: There is also a reference to morphine at twelve o’clock.

MR FORDE: Yes, thank you.

Q  Morphine sulphate 15 mg given intramuscularly – that is next to number 2 at 12.00 noon, so five hours later you are given a second dose, it would appear. That is in relation to Patient 7, I am reminded.

Let us look together, then, at the notes behind tab 5 in our file 2 and these notes are, in contrast to the ones I have just asked you to look at, Patient 6’s notes rather than your maternal notes.

The first page is a summary completed on 14 January 1993, so this is after - your daughter would be a month old. She had been discharged on 7 January. She was pre-term, less than 35 weeks, and her APGAR, you have told us, was 8 at five minutes, resuscitated with suction only, 32 weeks gestation and she had perinatal respiratory distress syndrome, ventilated for two days, CNEP for five days, oxygen for six days.

Then if we go over the page you were keen, under the “Comments” section, to have the baby home despite needing feed by an OGT – that is a gastric tube. She coped very well with this and by discharge the baby was taking some breast feeds also. A hearing check was normal. Do you agree thus far?
A   Yes.
Q Then if we go over the page to page 3, we see the APGAR score at one minute, middle of the page, was 6 and at five minutes was 8. Your baby did not need – I am just checking because I do not want to mislead you – she did not need intubation at birth. Then if we go to the bottom of the page:

“Comments

Admitted preterm with RDS [respiratory distress] ventilated – randomised for CNEP trial now in air.”

Do you see that?
A Yes.

Q Signature E Jones on the 7th of the 1st – that should be 1993, not 1992, but not an uncommon mistake in the first month of the New Year.

Over the page we have got your past obstetric history. Nothing noted about a reaction to opioids, is there?
A No.

Q Then if we go to the nursing notes, I would like you first of all to look at page 12 at the bottom right. Do you have that?
A Yes.

Q We can see “RDS [arrow] CNEP.” Do you see that?
A Yes.

Q Then page 13:

“[Patient 6] needs to be with her family, photos and handouts.”

Do you see a tick by “handouts”?
A Yes.

Q It is a tick. I suggest that that may be a reference to not only the Patient Information Sheet but the handout in relation to CNEP. Do you recall ever getting that?
A What handouts would they be?

Q There were some on the ward?
A There were what?

Q Some on the ward?
A Was there?

Q Never got them? You never got them?
A No.

Q Sure about that?
A Absolutely positive of that, yes.
THE LEGAL ASSESSOR: What are the handouts you are talking about, is what the witness asked. Could you give her a brief description? (Pause)

MR FORDE: I am having that found. It is something which may have been – and you will appreciate my difficulty after all these years – shown to parents at the time of consenting. That was the procedure and we are going to be asserting that the fact that there is a tick means that it was shown to this particular – likely to have been shown to this particular – patient. I think it may be in bundle 1 but I can return to that.

Q Can we then go on a few pages, please? Page 16 – this is part of the nursing care plan. You will see 2:

“[Patient 6] needs help with her breathing so she will remain pink”

and then that is a nursing responsibility.

“Observe breathing pattern and rate.
Administer 02 as necessary.
Record saturation and vital signs.”

Do you see that?
A Yes

Q Do you say the nurses did not do that?
A They did but they did not take any notice when I kept saying about her colour, if that is what you mean.

Q Because my understanding of your evidence – and it is probably best explored with others – is this right, that you believe your child suffered twelve hours, is this correct, of brain damaging hypoxia, and lived?
A I do not know how long she suffered hypoxia. It depends what degree of hypoxia you mean but she was certainly struggling to breathe for twelve hours, yes.

Q You think that such hypoxia as we may or may not be able to identify with Dr Stimmler was causative of your child’s brain damage?
A I believe that.

Q I just want to see how multifactorial the causation scenario is. It is partly caused by CNEP, partly caused by a period of periods of hypoxia. Is that correct?
A Both one and two are the same because she was not coping in CNEP alone, she had to go on to IPPV as well when she had a sudden collapse and that was because she had spent a long time hypoxic.

Q OK.
A So she had tired, basically, and had a total collapse and then she had to go on to IPPV and of course she did improve.

Q That is your causation theory and am I also right in thinking, because we will need
to explore this in a moment, that you believe that the appearance on the first scan indicates a brain damaging event?
A I believe that it indicates that she is having a small bleed, yes.

Q Do you believe that contributed to her brain damage?
A Possibly. Well yes, actually. Yes, I do.

Q OK, so bleed, CNEP, periods or a period of hypoxia. Anything else that may have contributed to her brain damage?
A I do not know.

Q What about the mere fact of her prematurity?
A The fact that she was premature means that she was susceptible to brain bleeds and hypoxia but you can manage a 32 week baby requiring minimal assistance without them having brain damage, can’t you?

Q What about the fact that this brain damage was probably acquired before birth?
A I do not believe that.

Q You do not accept that?
A No.

Q We will come to those who told you that?
A No, they have not told me that. They said that they did not have the evidence in front of them to say “Yes” or “No” and that timing was the problem because of the lack of notes that they had had. I think we went through that yesterday.

Q It is not just a lack of notes, is it? The best advice that you have been able to get, if we are going to deal with this topic now, is that your child, Patient 6, sustained brain damage somewhere between 25 and 35 weeks?
A Yes, that is what Dr Newton wrote but when we actually went to see him he said that, he showed us her scans and everything and he said that from the gap that was existing around her brain he knew that it must have happened between 32 and 35 weeks and he could not be more accurate than that.

Q He has been far more accurate than that and it has always eventually come down to a time prior to birth in writing, has it not?
A No it has not, no.

Q Very well, let us deal with this now, shall we? Within that bundle could you first of all turn with me to our page 237? As you pointed out, Dr Newton has the advantage of having scans which have now been lost and this is how he was interpreting them at the time and he said this in terms:

“It appears to me they show signs of periventricular leucomalacia, with thinning of the corpus collosum anteriorily, along with frontal atrophy. The absence of baso-ganglia change makes it more likely than not that these appearances were sustained prior to 35 weeks gestation.”
That is a letter of 28 March.

A He goes on to say:

“The findings are in keeping with an hypoxic ischaemic insult.”

Q Yes, that can happen in utero. It does not have to happen once a child is born but you have decided selectively only to accept that theory on the basis that it happened after Patient 6 was born?

A On the medical advice I have been given if that had happened in utero and certainly from the time that you are suggesting right at the very end then she would not have been born with such good APGAR scores, she would have shown neurological problems. In fact, they were looking for neurological problems in children before they went into CNEP because that was an exclusion criteria, then I would suggest there is more evidence to say that she was born okay and then went on to -- I think he calls it later on “an acquired brain injury”.

Q The problem is that you cannot sustain that case on a balance of probabilities, can you? You know that is your difficulty with bringing an action?

A I do not have to because I am not the medical expert but---

Q You cannot find anybody who is prepared to go to court and say this child was brain damaged between her birth and 35 weeks, can you?

A Professor Stimmier says that.

Q I do not think he does.

A That was my understanding of it.

Q He is not of the appropriate discipline either. You know you need a neuro radiologist which is what Mr Newton is. Let us have a look at what he said in fairness to you on the topic at page 244, he is a neurologist, I apologise. He is reviewing with a neuro radiologist, they are the correct sub-specialty:

“They confirm with my own findings, in particular the involvement of a thalamus with a lack of lentiform findings does not make an acquisition of the disorder before 35 weeks most likely.”

Then his final word on the topic is page 245, May 1995:

“I was able to meet up with Henshalls today as planned…”

so this is his record of a conversation that you tell us he had with you when he told you that this was acquired brain injury post delivery. It says nothing of the sort:

“I explained the MRI scan findings were very much in keeping with [Patient 6’s] problems being due to nerve cell injury related to prematurity rather than this having been a cerebral dysgenesis.”

So he is placing prematurity as his primary diagnosis.

“I also mention the pattern of findings of the basal ganglion meant
"I think these findings together with her asymmetry make it more likely than not that this motor impairment is acquired rather than genetic in origin."

You have taken that to mean acquired post-birth, have you not?

A Yes. That is how it was explained to me, yes.

Q Be that as may neither of us are neuro radiologists but the one thing we can be sure of is if this is a record of his conversation with you he is not telling you this injury was acquired after 32 weeks gestation, is he?

A It is clearly not a record of his conversation with me because there is lots in there that is missing if it was a true record of our conversation.

Q "I was able to meet up with the Henshalls today as planned"?

A No consultant writes every word down. They have not got---

Q "I explained that the MRI scan findings were very much in keeping." He is having a conversation with you. You are there?

A Yes, I was there but it is not like when you have got the typist here, you know, he will not say everything that was said.

Q You would expect him to say though, would you not, I explained to the Henshalls and I am prepared to be cross-examined on the subject---

A I doubt it.

Q ---in support of their legal action that this was acquired post-delivery?

A No, I do not think he would do that because I was not going to him as part of any legal case or anything like that, it was just a normal clinic appointment. It was well
before so why would he speak in legalistic terms and why would he go to that much document --- he would not bother doing that, would he?

Q Why did you tell this Panel that there was conversation with him, which we will look for if it is not that letter, where he told you this was acquired post-delivery?

DR SHELDON: Page 233.
A Yes, that is the one, yes.

MR FORDE: This is many months before what I have suggested is his final version but this is the reference to ballooning, yes?
A Yes, this was the very first time that he assessed Patient 6 along with all her scans and everything, yes.

Q Nowhere here is he attempting to date or time the damage, is he?
A He does actually make reference to it saying that basically to date it then you need to have an MRI scan, yes, to see if it backs everything that is said on there really.

Q Did he do an MRI scan?
A Yes, an MRI scan was done, yes.

Q We know, therefore, if 233 is the discussion of the films or ultrasounds that he had by the time we get to 245 he is giving a view based upon the full clinical picture because he is explaining the MRI scan to you?
A Yes, you can see how he is thinking because he says here---

Q I am not interested in how he was thinking in January. Let us look together at 246. By then he has the scan that he is saying he needs in January to make a diagnosis?
A You are being very selective. You are not allowing me or the Panel to go through the whole letter which explains the true picture. What you are doing is picking out the bits that are pertinent to you but actually you are asking me how I got that impression and I am trying to show you that and it clearly says here that full perusal of her neonatal notes, neonatal notes, not my anti-natal notes:

“...looking in particular for evidence of acidosis, prolonged hypoxemia and hypertension that might in turn give a clue as to the timing of any haemorrhage may help clarify this…”

So clearly he is thinking that if there is something in there that shows what he is saying there then that is the line he is going down.

Q Mrs Henshall, you are said in this letter to have very fixed views on the classification of cerebral palsy dictating an approach to therapy, so you were well read on the subject. By time we get to page 245 in May 1995 he has reached a settled diagnosis with an MRI scan?
A Can I answer your first statement first? When you say he is referring to --- you are saying that I had read up on cerebral palsy. I knew generally about what cerebral palsy was like but when he is saying specific to brain areas therefore dictating a specific approach to therapy what I was saying was did she need to have physio; should she have had it earlier; would it have made any difference to her outcome and such like and I was
complaining basically to him that the delay in diagnosing her; would that have made any difference to her approach to therapy and basically what he was saying was I had got very fixed ideas about it because I had read books on CP and what you do when you find a child has got CP and what sort of treatment they have and things like that.

Q He might be and I am not going to suggest that you have not got fixed views, it is one of the reasons that we are here. What I am asking you to accept is that by May 1995 when he was explaining the MRI scan to you?
A Which one?

Q Page 245, five months later or thereabouts he was giving his final word on the subject?
A Yes.

Q So it is not very helpful to the Panel to try and clutch, as you do, to the high point of your case which is page 233?
A It says here again here, I do not know your point because it says:

“I explained the MRI scan findings are very much in keeping with [Patient 6’s] problems being due to nerve cell injury related to her prematurity.”

Not to before birth or anti-natal event, an unexplained anti-natal event or anything like that. To her prematurity. So that suggests after birth.

Q No, it does not. Look at what he says, 25 weeks gestation to 35. She was born at 32.
A Exactly. Prematurely.

Q Happened before 35 and after 25. That is the best he can do?
A He is saying a nerve cell injury related to her prematurity, so that is going a bit further than that actually, is it not?

Q So we ignore, do we, for the purposes of your thesis the next sentence where he is actually being time specific?
A He was more specific to us and he, you know, says prematurity, he does not say an unexplained anti-natal event, does he? If she was not born then he would have said anti-natally. He is referring to an event that has happened; that she was born prematurely. It is due to that prematurity rather than having been a cerebral dysgenesis. To me that means once she is born and then an acquired injury.

Q It is another example of the highly selective way in which you choose to read correspondence before you make allegations. Common sense, Mrs Henshall, last opportunity. What is the time period that he is giving in that letter for the probable injury to your daughter's brain?
A He is saying that -- it says:

“I mention that the pattern of findings in the basal ganglia meant that this injury happened before 35 weeks and after 25 weeks gestation.”
He is talking about the basal ganglia in particular there, is he not? He is not talking about the entire thing. In fact, I think in one of his letters he does make mention to, you know, he says that basically even if somebody was already damaged they can still go on to acquire further damage and he put that to us as a possibility as well so.

Back to the notes, please. The notes of Patient 6. I would like to take you basically if I can to page 61 at the bottom. Nursing notes. You were casting doubt when Miss O’Rourke was questioning you upon the validity of these notes. I will remind you in brief terms what you said: it took you several years to get the notes therefore you are suspicious of their validity. Is that correct?

The thing I am suspicious is about is the name there. If you look at these notes on the first day it is [Patient 6] and she did make the comment that she had been very clever to not only guess the name but to guess the name spelt rightly. If you look at the entries where the nurse is writing at the majority of the times they write [Patient 6] and all the through the other records as well, so when you are saying, well, did this nurse do this or did that nurse do that it would not take much really to change the name there, would it?

We will examine that because we must because you were contemplating complaining about the nursing staff despite the complimentary terms in which you wrote about them in your feedback form, which we will come to in a moment. If you want to look at names together we have [Patient 6] under number 2 [Patient 6]. Yes?

Yes.

Which is how her name is spelt?

Yes, it is, yes.

[Patient 6] in the next line which is an incorrect spelling but the more conventional one?

Yes.

Have you ever come across another [Patient 6] spelt with an F?

No.

Can you understand how easy it might be for the nurse to spell her name conventionally at times and in the way you spell it at other times?

Yes, I can. The point I am making is the first day that she was born is the day I am contesting. After that of course they had her name but there is nothing stopping them going back and writing her name in afterwards as has done in several of the medical records that are in here. You know, originally the wrote “Girl Davies” or whatever. Then they go back and change it once they knew her actual name. That has happened loads throughout the records.

We do not have the originals available to us in this hearing but I just want to understand---

You can see because sometimes they cross it out.

There are no crossings out on this page.
A  Not on this one, no.

Q  It looks are if you have got one nurse first entry; another nurse, second entry; the next entry I think is probably the same as the first entry because it looks like the same signature; then another nurse at 6.55; different hand, different signature at 8.30; different hand and different signature at 15.10 and so on and so forth. What I need to understand, Mrs Henshall, because you have not been unafraid to make allegations, are you saying that these notes have been written after the event to support the doctors’ case?
A  I am saying that her name has possibly been put in on the first day, yes. Just on that first day. They would have had it after that. On the first day I say it is impossible for them to have had it because we did not call her that then.

Q  You may have forgotten when you named her? You had the argument about Zoe, did you not? You recall that?
A  Yes, we did, yes. Baby’s names tapes, we have got photographs of those with that on, Baby Davies and she did not have it there so. Would you normally ignore the name? The log book, the CNEP logbook when they supposedly phoned through for randomisation does not have her name either.

Q  We have got the first mention of Patient 6’s name in these notes timed at 22.30 which is four hours or so after her birth. Right?
A  Which is supposedly when you sought randomisation, so why would you not have her name then?

Q  If you have a look at the note timed 06.35 when you were visiting the baby it is suggested that the baby had already been randomised into CNEP?
A  That is at 6.35 the next day.

Q  That is the timing of the note.
A  The only time that you would had to have changed any of that there is them two entries there on that first block of --- after that it was Patient 6 and they did know it was Patient 6 so it is just that first paragraph really where you would have had to---

Q  That you are querying?
A  That I would query, yes. After that they did, so it would not be a massive thing to do. It would not be hard, would it?

Q  Why would they do it?
A  To refute the fact that I was saying they could not possibly have had her name at that time.

Q  That is such a vital thing? You are accusing these doctors of murder and you think that somebody went back into the notes to put your daughter's name in to prove that you were inaccurate about when you named her?
A  Well, possibly, yes.

Q  You honestly believe that could be the case, do you? Something as trivial as the timing of the name?
A  Unless it was written retrospectively like they do, yes. You are saying it was
written at that particular time, so if it was written at that time I am saying I did not name her at that time so I do not know how they could have that unless you are saying that they took consent for CNEP at a later time but you are not telling me when and you cannot tell me when.

Q  Difficult after 16 years.
A  Difficult anyway if you did not.

Q  Let us investigate that as an allegation, shall we? We have got the relevant consent form in our bundle at page 19 at the top right, sorry, I have been looking at Patient 7’s notes. Bear with me for a moment. I am trying to find your CNEP.
A  Excuse me, do you mind while he is looking if I just pop to the toilet?

Q  Of course, yes, that would help me as well. *(The witness left the room)*

THE LEGAL ASSESSOR: Mr Forde, it may be in volume 1, tab 3, page 390. *(The witness returned to the room)*

MR FORDE: I am grateful to the learned Legal Assessor. We have found your consent form but it is in another bundle, so you may just need to look at our file 1 and go back to page 390. It is about 30 pages from the very back.
A  I have got it.

Q  You were asked a number of questions about this form by Miss O’Rourke and I do not want to labour the point, but this form, I think you agree, bears your signature.
A  It looks very much like my signature, yes.

Q  Do you agree that it is your signature?
A  Well, you know … Probably.

Q  Probably. Thank you. The difficulty you have is in understanding how your signature appears to be on that form, is that correct?
A  Yes.

Q  You have used words such as “manufacture”. I really need to understand (I do not want to take you back to the transcript) what it is you are saying about your signature probably being on that form.
A  Right. Well, I could not be clearer. I am saying basically that I was never asked to sign a form, a consent form for CNEP. This appears to be a consent form for CNEP and I do not understand therefore why my signature is on it and I cannot give you any explanation for that at all.

Q  If you were never asked to sign a form for CNEP and your signature appears on this form then would you agree that somebody somehow must have placed your signature on this form?
A  No, not necessarily. I think we discussed all the possibilities.

Q  That is the first possibility, is it not?
A  That is one possibility, yes.
Q Somebody maybe has taken a bit of tracing paper from another consent form and reproduced your signature on this form.
A I would not say that was the most likely possibility.

Q So what is the most likely possibility then?
A Perhaps that they got me to sign this form, me thinking it was for some other procedure maybe or at some other time or perhaps without reading it for something else, I do not know.

Q You countenance now, do you, the possibility that you signed this form but you did not read it?
A No, I did not say that?

Q I thought that is what you just said?
A No, I said one of the possibilities. You were asking me to say what other possibilities could there be and that is what I was saying.

Q Let us just see if we can reach some agreement. Are you now countenancing the possibility that you signed this form without reading it?
A No, I am not saying that.

Q So that is not one of the possibilities then.
A I do not know what they are because what I am saying to you is that I do not know how that happened.

Q All I am trying to explore with you are possibilities.
A Yes, but there is no point exploring that with me because I cannot … you are asking me on oath to say what I know to be true and I cannot say I know how that happened. I do not know how that happened.

Q I am not asking you to say that you have 100% recall or that you are certain. I am asking you whether you countenance the possibility now after all these years of signing that form without reading it.
A If I thought it was for another procedure, maybe. I do not know.

Q If you thought it was for another procedure would that be a procedure involving you or your child?
A I do not know, do I? I cannot say that, can I?

Q Do you countenance the possibility of your signing the form but forgetting, having forgotten that that is what you did after some time?
A I doubt it and you are asking me to speculate on things that I really have no knowledge of.

Q I am not asking you to speculate. I am asking you to consider a number of possibilities, one of which is, as we have already been through your fluctuating lucidity (Day 10/3) that you signed this form but you simply cannot remember now signing it.
A I would have had to have been asked to sign the form because it would not have
been automatic, so I do not believe that is the truth, no. I was never asked to sign anything. I was just told that is what they want to use on my child and I said, “Yeah, whatever, do whatever is best for my baby”.

Q You know I suggest that is what you took from the conversation, but if you read this form can we go through it together. Do you see it makes it quite clear that it is a consent in relation to a “research investigation”?

A That is what it says on the top of the form, yes.

Q The title of the research is “CNEP”.
A Yes.

Q Then the clinician is a Dr Stanley.
A Yes.

Q Who is now Dr Newell. She is signing to say that she has explained the nature of the investigations to you, is she not?
A If you say so.

Q That is what it says, does it not?

“A confirm that I have explained the nature of the above investigation to the above named relative/legal guardian”.

A It has also got a piece on the form where you are supposed to fill in where it says “to take part have been explained to me by Dr ….” Surely if that had been the case she would have made me put her name there to say that ---

Q She may or may not have done.
A She has got no proof that she had explained it unless I had signed that, so if she was going to go to the bother of getting me to sign a consent form to say that she had explained that to me then why would she not have got me to sign that bit as well? I do not understand that. You are saying that they rigorously did this thing and that they have kept it all for all these years and all that and yet clearly she has not said ----

Q What is missing is she has not put her name in the first paragraph ---
A She has signed a form.

Q Has she?
A She has signed a form and she has not signed that it was her to explain it to me, so I find that very strange.

Q She has, because what she has done is she has put “Name of clinician: Stanley” and then:

“I confirm that I have explained the nature of the above investigation to the above named relative/legal guardian”

and she has put “Name: Stanley” and her signature and a date. This is a doctor signing to
say she has explained the investigation to you.

A What are you asking?

Q Let us just see. In 1997 she made a statement and she says that she would have explained in general terms how your child was, that your child required extra oxygen for breathing, that you would have had a photograph, which we can see was given at the time of the nursing notes. That she would have explained that the hospital was involved in a study looking at the best way to provide ventilation for premature babies such as [Patient 6] who required extra support to help them. She would have explained the study was called CNEP, what it stands for and how it operates.

“I would have shown them a picture of the equipment and also a picture of the baby inside the equipment. The next stage would have been to explain the aim of the study was to see if the CNEP equipment had any benefits over the conventional treatment. I would then have explained that CNEP had been used in trials in our hospital since 1989 and had also been trialled in a London hospital. I would have indicated at the time there was no way of knowing whether CNEP had advantages or disadvantages over conventional treatment. At the end of the trial we would be able to compare the outcome of babies in CNEP to the outcome of babies that were treated conventionally”. *(Document not provided)*

A That is a very comprehensive conversation and I cannot see that I could forget anything as long winded as that, do you?

Q “I would then explain that if they agreed to their baby being involved in the study then [Patient 6] would be randomly allocated to either CNEP or to carry on with the conventional treatment. I would have expressed to the parents they were not under any pressure to take part and if they did not wish to be involved in the CNEP trial this would not affect the care which Patient 6 would receive from the hospital. I would have explained that if they agreed to the trial but were later unhappy at any stage they would be able to pull out and Patient 6 would go back to having conventional treatment and this would not jeopardise the baby’s care in any way. I would then have advised the parents that if they had any questions or if they wished to have more time to think about this they were clearly allowed to do so.”

A There was never any conversation about conventional treatment. She was not having oxygen at the time when they offered CNEP and they said that was the treatment that she was going on. They did not say there was anything alternative to that or whether she could go on this or she could go on that. They just said that that was the treatment she was going on, so it was a choice between nothing or that. That conversation never took place like that and in fact I think if you read the top of that statement by Claire Stanley she actually says that she does not recall taking my consent at all and she would not because she did not in that way.
Q Yes, but she recalls how she would have consented and insofar as that is her honest recollection she is another person who must be lying.

A You say that my interpretation of events has been coloured by what I have read and things like that, so if she could not remember and she had to go back and look at “Oh, how was it we were consenting?” then that is what she would be saying, would she not?

Q She is honestly saying she does not have a detailed recollection, but she is also, because she had been involved in consenting by this time, she tells us in that statement, for 18 months or so as satisfied as she can be that she would not put her name to that form unless she had gone through her usual process.

A And I am saying that if she had gone through that process I would not have put my name to any form and did not.

Q I thought you had agreed it was your signature on the form.

MS SULLIVAN: I think in fairness she said she cannot recall this particular case.

MR FORDE: Yes, she does, and I have not put it on any other basis. We will no doubt have the chestnut of mums remembering and doctors consenting hundreds, but the point remains, Mrs Henshall, that this doctor says she would not have put her name to that form unless she had gone through that process, so she must be lying.

A She must be lying, yes.

Q Just to pick you up on one matter, according to the note at page 61 in the other bundle at 2230 your child was given oxygen as her saturations were down.

A Head box oxygen.

Q You said she was not on oxygen at the time of the consenting.

A I meant like when you talk about the conventional therapy or CNEP you said that she would have explained both procedures to me and I thought you meant IPPV. That is how I see the standard treatment, IPPV versus CNEP. That is what I thought you meant.

Q You were giving the impression that it was CNEP or nothing, so, in other words, a child with poor saturation levels would effectively have been left to die if you had not agreed to CNEP. That is the impression you were trying to create, was it not?

A No. She said that she was tiring and she needed some assistance and the only assistance that she was talking about was CNEP because she said she only required minimal assistance, she was just tiring, they did not want her to collapse and I had had a baby on CNEP before so I knew all about it and that is the method that she would prefer to use and, yes, fine, you know. It was a casual conversation like that. It was nothing like the procedure that you are asking me to believe went on.

Q That is what this doctor is going to say, that she did, and I am suggesting you simply have not remembered out of kindness to you, but I also have to suggest, as Miss O’Rourke suggested to you, that you are not telling the truth about this.

A Well, you know, why would I lie about that?

Q Because you have always believed that CNEP injured your daughter.
A Yes.

Q You feel guilty about going on that shopping expedition and you want to ensure that she has damages to look after her when you are no longer able to. That is your motivation.

A So what you are saying is that I think deep down I am responsible for what happened for [Patient 6] and I am just looking to deflect that responsibility on to somebody else.

Q You used the word “guilty” in your evidence last week.

A You feel guilty about all sorts of things with your children. I feel guilty that I even got pregnant in the first place. I know I have premature babies. It is something that you live with, but it is not always justified.

Q You feel guilty that you consented to your children going into CNEP at all, do you not?

A I do feel guilty that I verbally consented for my children to go on to CNEP, yes, I do, because now with the information I perhaps should have had at the time there is probably no way that they would have gone on it. Yes, of course I feel guilty about that, I should have asked more questions, I should have been more aware perhaps, but, you know, what I am trying to explain to you is that I perhaps was not in a position to be able to make that informed decision given the circumstances.

Q The form suggests that you are giving informed consent, does it not?

A Well, you know, if you have not been in a clinical trial previously or ever had any knowledge of one or whatever, how would you know what informed consent meant anyway?

Q This is again something I suggest is after acquired knowledge. You did not know what informed consent was as a concept in 1992, did you?

A No.

Q If you go to page 22 of the notes this is the second time that we find in the notes of consent for CNEP and it is signed by Dr Stanley as she then was, now Dr Newell.

A In this same bundle?

Q In the same bundle behind tab 5, page 22, bottom third of the page.

A There is not a tab 5 in that bundle.

Q It is file 2. I am sorry if I misled you.

A What number, sorry, was it?

Q Page 22, bottom right.

A Right, I have got that page.

Q It says: “Reviewed at 4 hrs”, 40% oxygen in the headbox with 94% saturation levels. I am not going to debate blood gases with you, I will save that for Dr Stimmler. “Consent for CNEP obtained” tick. “Randomized to CNEP”. Signed by Dr Stanley.

A She did have consent of a form, did she not, because she had asked me if it was
okay to put her in CNEP and I said yes, so she had verbal consent. It does not mean to say it is anything like the process that you are suggesting and it was not.

Q She said this in 1997:

“Consent in this case was obtained and I wrote ‘Consent for CNEP obtained’ in the notes and have ticked this. Once consent had been obtained I would then have called the on-call consultant and he would have indicated whether or not the patient had been randomised into CNEP. The consultant would have been either Professor Southall or Dr Martin Samuels. I would then have spoken to the midwife or nurse in charge of Patient 6’s care who would have arranged for the necessary procedures to have been undertaken”.

A I would comment on the fact that she has put “consent for CNEP obtained”. That is how I remember it too.

Q I see.
A She was not saying consent to a randomised trial one way or the other, she was saying consent for CNEP.

Q The form makes it clear that it is a trial but you do not recall signing it.
A No.

Q She is lying about this as well presumably.
A Well, no, she did have consent for CNEP.

Q But not consent for a CNEP trial.
A No.

Q Your evidence is, as I understand it, throughout the time that Patient 6 was involved with CNEP you had no idea it was a trial.
A No. I knew that it was a new treatment and they were looking at it and they were trying to introduce it into this country and things like that, I had been told all of that, but I had no concept of what a trial was, whether it was experimental, what that meant at all I had no concept of, so if I had had the type of conversation that you are suggesting that I did have I perhaps might have known a bit more about that, but, no, I did not have any concept of what “trial” meant.

Q As I have suggested to you already, either your recollection is faulty or you are not telling the truth about that. Can I just ask you about your evidence in relation to when you say you discovered it was a trial?
A Yes.

Q One of your affidavits suggests February 1997. The evidence you gave to this hearing was 1996. Can you help us with which year, please?
A Well, can you show me where it says that and I will tell you.

Q I believe it is your affidavit for the General Medical Council in 2000. Paragraph D11/47
29, page 275 of our large bundle of your involvement with the media, the GMC and others. It is internally numbered page 11 of your affidavit:

“I found out some information in” ----

MS SULLIVAN: Can she just have a look at it, first of all.

MR FORDE: I will give her the page in a second if need be.

“I found out some information in February 1997 which suggested that Patient 7 and Patient 6 had been part of a clinical trial”

and that seems to be 1 November 2000, so it was the one in support of the complaint that the GMC took four months to give us, so it is between 265 and 284 in that large bundle of documents. Do you remember the one that has got the letter in it accusing the doctors of murder? It is that bundle.

MS SULLIVAN: Perhaps Mrs Henshall could just get it, first of all, and then she can see. It is there. Page 275.

Q 275 is the relevant part and I will try and find the part of the transcript. What you said – this is Day 9 page 29, for everybody else’s benefit and possibly yours – at letter F, having seen Dr Newell in December 1995, you went to see him at St James’s Hospital and you told him – this is letter B page 30, day 9:

“I told him he must be mistaken because my children had had the very best treatment that there was to offer and the unit had been fantastic. I was absolutely brainwashed into believing that.”

Then you say that he indicated a breakdown in communication and then Carl recalled signing “some form for our previous child to go into it” – it is not clear from your answer whether you are suggesting “into it” includes trial rather than CNEP. Then you say:

“‘No way, no, absolutely not.’
I never signed for CNEP treatment. Why would I? I was not asked to.”

Then you start debating the Ethics Committee. That is what you were saying. In December 1995 you get the report. I was assuming that your meeting with Dr Newell would have taken place long before February of 1997 – some time in early 1996. Would that be correct?

A Yes, it should be there. It should be in the paperwork somewhere, the date. I cannot remember the exact date.

Q We do not have a date. I am afraid after all this time – we would love to see his notes of the conversation but twelve years on that is a forlorn hope. Doing the best we can, we have a copy of the report which I may come to in a moment, which is December 1995, with a covering letter from him where he says he knows you will be disappointed but he is not prepared to help you establish causation. I am assuming that you had a
meeting with him shortly after you received that report?
A He does not say that at all. If you are going to quote somebody who is not here will you be accurate, please, because he does not say that at all.

Q Right, OK. Can I ask you first of all to help me with when you saw him and then I will get the letter and I will read you the relevant portion.
A I do not remember the exact date without it being here in front of me. I am sorry, I have not got a photographic memory.

Q Do you accept it must have been long before February 1997? Anxious mother pursuing litigation, by the time you saw Dr Spencer on 18 March you were involved in litigation. We have asked for the files so we can see what statements you were giving at the time – no joy. We would love to know whether or not you were telling Dr Newell you knew it was a trial – destroyed, we are told. Did you see him before February 1997?
A I cannot remember. I have not got it in front of me so I cannot tell you. I do not remember exact dates, I am sorry.

Q You are saying you cannot recall having received a report in December 1995, whether or not you saw this doctor before February 1997? Fourteen months, Mrs Henshall. Did you see him within 14 months of the report or not?
A Carl has got that report in there if you want him to have a look.

Q We have all got it and it is dated December 1995, which was the date that Ms Sullivan put to you. I am asking you whether you now have a recollection of seeing him before February 1997?
A I cannot remember what date it was exactly that we saw him without it in front of me, sorry, I rely on paperwork the same way as you do.

Q You do not, you see. You do not rely on paperwork when you tell this Panel you have a clear recollection of nobody handing a consent form to you for you to sign, even though we have got the paperwork. You say it did happen?
A You asked me what my recollection was and I told you.

Q I am going to try once more because I think you are being deliberately evasive.
A You are referring to a specific report and a specific time. It was one visit years and years ago. How would I remember the exact date without it in front of me.

Q You are struggling with dates after all this time, are you?
A Everyone struggles with dates after a period of time, so what?

Q You cannot help me as to whether or not--
A I could if you would let me go and get it.

Q The report does not matter. I could show you the report. Ms Sullivan was correct when she told you it was dated December 1995. The impression I got from your answer, Day 9 page 29 and 30, was that shortly after receipt of the report you had a meeting with this doctor at St James’s Hospital, where we know he works?
A Yes.
Q Do you agree it was shortly after you got the report?
A Yes.

Q Might it have been before you got the report? It seems unlikely?
A I really do not know. I know that we had a telephone conversation with my solicitor at the time who said that he had had a report, it was not favourable and he suggested that we go up and see the doctor in question because there were things in it that we probably were not aware of that we needed to speak to him about and that is what we did.

Q OK, so, it was post- December 1995, because that is the date of the report. Is that correct?
A I do not know. I have not got it in front of me. I believe you.

Q Accept from me that the report is dated December 1995, for one moment. Ms Sullivan will no doubt correct me if I am wrong. OK?
A Yes, OK.

Q Is it likely – and if you cannot remember do say – that you saw Dr Newell shortly after he compiled his report?
A Yes, I think that was the reason why we went down there, to discuss the report with him.

Q Would you agree that the high probability is that you therefore discussed with him, you say for the first time, the fact that your children had been in a trial, in early 1996?
A Yes, possibly. I am not sure whether it was around about March/April time.

Q It certainly was not February 1997, was it?
A I think I was probably referring there, February 1997, to the confirmation from Mr Hughes, the Ethics Committee, when he confirmed that they were part of it because I was still arguing, wasn’t I, that I did not believe – that was the conversation with James Newell, that he was mistaken, my children had not been in it and we did not have that confirmed until Mr Hughes from the Ethics Committee confirmed it for us and we only knew Mr Hughes from the Ethics Committee because James Newell was the one that said to us it would have gone through an Ethics Committee and you would have had some information and perhaps you should go and speak to them and ask if your baby certainly was part of it.

Q All right. Let us look. 1 November 2000, page 284. This is a sworn affidavit so you know that it is a serious document that has to be accurate, do you not?
A Yes.

Q If we look at paragraph 29 again, you say:

“It was only by contacting the local Ethics Committee that we found this information out.”

A That we had it confirmed, yes, that he would…
A
Q "It was only by…” – that is not right. You have been told by Dr Newell a year before?
A I did not believe him.

Q You did not believe him?
A No. I argued with him that my babies had had the very best treatment available.

B
Q They did get the very best treatment available.
A No they did not. It has been discontinued because it does not work for patients in RDS, so they did not, clearly they did not, otherwise everybody would be receiving it would they not?

C
Q Yes, it has been used and still is used for other indications.
A Not for RDS and my children had RDS?

Q Yes but you are the reason it stopped?
A No, I am not.

Q Because of your vocal, public, ill-informed campaign?
A No, I am not. We went through that yesterday didn’t we – the other day, I mean – and there was no way that I, just me on my own, would get that treatment stopped. No way. They would have to have medical evidence.

D
Q What this gentleman said on 8 December 1995, writing to Mr Evans, is as follows:

E "I enclose my report concerning Patient 6. I think Patient 6’s parents will be disappointed to read my report. The standard of care and note keeping in Stoke was commendable. At no time was there evidence of negligence or care of a poor standard. There was also no evidence of under or over ventilation, nor of any prolonged periods of hypoxia. If the period of collapse leading to ventilation at about 18hrs had been the cause of Patient 6’s problems, then I would have expected it to be followed by a more severe illness, neurological symptoms and might have expected changed on the ultrasound as I have discussed.

In conclusion, then, the small intraventricular haemorrhage is likely to occur at that time but would not explain Patient 6’s current symptoms. It is more likely that the brain abnormality apparent on early ultrasound and subsequent CT was due to some undiagnosed and unexplained antenatal event’’

F

G - so prior to birth.

H "Causation therefore is hard to prove.”

That is what he told you?
A That is what we were told, yes.

D11/51
In fairness to you he went on to say he had not then seen the original cranial ultrasound CT or MRI scans but we have gone already to Dr Newton.

So following that letter and report you had a meeting with him?

With Mr Newell?

Yes.

Yes.

Dr Newell. At St James’s Hospital?

Yes.

You had already received a copy of the report?

I suppose so, yes.

You had written on it before the meeting with things you disagreed?

No, I took it with me and wrote on it afterwards from when we had had a conversation and what we had said, I went through the report afterwards.

You wrote on this report before you had the meeting, did you not?

After we went to see him and we went through the report in detail.

Because there were things on the report that you disagreed with and we have got your annotations everywhere?

Yes, there were things I disagreed with but after I had spoken to him, yes.

No, these are things that you quite clearly wrote before you had the meeting?

Why “quite clearly”?

You are on oath. Your evidence is when did you write the annotations I see on this report?

After we went to see him and we went through the report in detail.

Right.

With her medical records, because up to that date we had not got them. He had got them.

He had had the records?

That is right.

You had them?

So it was some time after actually that we actually wrote on that because we had to have copies of her medical records. We had not got them at that time.

We have no way of telling whether they were sent to you because the file apparently has been destroyed, but again I am going to ask you, because you are on oath, is it your evidence that when your solicitors got your daughter’s notes, which must have
been prior to instructing this doctor because he refers to them, that you were not given a copy as well?
A No, I was not.

Q This inquisitive, push, pain in the neck mother, as you have described yourself, did not even bother to look at them. You have been pushing for them since 1993, if you are to be believed?
A Yes. I did not have them before we went to see him because they had had to send them off to them. They had not photocopied them or anything like that, if that is what you mean. I did not actually receive a photocopy of them until after when I insisted that I had them so I could go through the report because it was not in our favour.

Q Right, so are you then saying that you had the notes available to you before you had the meeting with Dr Newell?
A No, I just said that. He had the notes, Mr Newell had the notes.

Q I thought you just said you went through the report with the notes?
A Yes, after we went to see him.

Q After you went to see him?
A Yes, and I got a copy of the report and the notes and I asked for a copy so that I could go through his report because I disagreed with him.

Q How long after the meeting with Dr Newell did you annotate this report?
A I do not know because I do not know when we received the notes, how long after.

Q Your best guess, please?
A I do not know.

Q In 1996 or some other year?
A I really do not know. I cannot remember.

Q That is a convenient loss of memory. Could you have a copy of the report, please? (Same handed) Sir, we will get copies for the Panel in due course, and a copy of the covering letter of 8 December 1995. On what is designated page 3 of the report, it has got 630 at the top, the report;
   “….is based upon the statement of Mrs Deborah Henshall, previously Davies”

G he seems to have mis-spelt it as well –
   “and the medical records of the Staffordshire Maternity Hospital relating to Mrs Henshall’s pregnancy and confinement and Patient 6’s subsequent neonatal and paediatric care.”

So he had the notes?
A He had the notes, yes.
A  Q  But you say you did not?
    A  No.

Q  You cannot tell me, if we go to 631 at the top, internal page number 4, you cannot
tell me when you started scribbling on this report?
A  It was after we saw him when we got a copy of the notes.

B  Q  The reason I am suggesting it is before is, perinatal history, the last sentence:

   “Mrs Henshall remained in good condition during her Caesarean
section and made a good recovery afterwards”

   and you have written, “blood pressure dropped dangerously low. Remained low for a
long time.”

A  That is what I was told, yes. that is why I was in recovery for so long afterwards
and that is why I was cold, that is why I was wrapped in a space blanket, that is why I
vomited. That is what I was told.

Q  So you knew that then before you got the notes?
A  What do you mean?

Q  You said you were told, one assumes by the nursing staff?
A  I was told at the time while it was…

Q  So you were told in December of 1992?
A  What? That I had suffered low blood pressure after the Caesarean?

E  Q  Yes.
    A  Of course I was---

Q  This is after the birth of Patient 6.
    A  That is right, yes.

Q  He said you made a good recovery and you queried it and said, “No, my blood
pressure dropped dangerously low and remained low for a long time.”
A  I could not understand where he had got that from because I was poorly
afterwards.

Q  You must have made that note before the meeting?
A  Why?

Q  Because you had knowledge of the fact you are telling us?
A  Of course I had knowledge in 1992.

Q  So why would you wait until after the meeting and you tell us receipt of the notes,
to write on this report something you knew already?
A  Because I was not – after reading this when we come back, I was not concerned
while I was going to see him about – I was not asking him as a paediatrician to tell me
about my antenatal or postnatal care. I was asking him about my baby. Nothing to do with me.

Q You went through these notes possibly aided by somebody with a medical qualification, this report?
A No, actually, it was aided by medical text books. I got them all afterwards because I wanted to understand how he came to the conclusions he did.

Q You did this, I suggest, before the meeting. Let us look at the next page, Respiratory Problems. You have written at the top:

“poor blood oxygen over a period of time, blood acid for three days.”

Where did you get that information from?
A From a neonatal mode vecum (sic) NRC Roberton wrote it. In fact we took it to the meeting with Dr Spencer. He will tell you where I got it from because he knows how many sheets and things I took in with all blood gas results and everything that I had gone through then.

Q Then you have written, “Metabolic acidosis”, is that supposed to be.
A Yes.

Q Or metabolic something?
A Acidemia. Metabolic acidemia, yes.

Q Then:

“Saturation 96%. This was and went as low as 63%.”

Did you get that from the notes or was it something you knew at the time of the meeting?
A We had got the notes by the time I was writing on here, yes.

Q Most interestingly, the notes record:

“Consent for CNEP obtained and then he explains what CNEP was. I assume that Patient 6 was born during the randomised trial of primary CNEP management of RDS [respiratory distress syndrome] which was taking place at the time. Patient 6 was randomised to receive CNEP”

and you have written:

“Patient 6 was asked because our previous baby had been on CNEP trial.”
A Yes, because that is how it is referred to there.

Q Sorry, just think about your answer.
A Yes.

Q CNEP trial?
A Yes.
Q You knew that patient 7 had been involved in a CNEP trial?
A He is telling me that she is in a CNEP trial so that is how I know there because I am commenting on what he is writing there, but he also says, “I assume that Patient 6 was born during the randomised trial of primary CNEP”, so if I had already known that and I had told him that or referred to that in my statement, he would not have to assume – he would know.

Q Oh, so the statement that he refers to at page 2 of the report may well have had information from you prior to December 1995, the date of the report, that you knew your daughter was in a trial?
A No, that I knew my daughter was in CNEP.

Q You have just said “trial”.
A No I have not.

Q You have just said---
A No I have not. You said trial and he says trial. I did not say trial.

Q What have you written here?
A I wrote, “Patient 6 was asked because our previous baby had been on CNEP trial.” That is with me going through these notes here where he is saying that she is in the CNEP trial and I am saying she was asked because our previous baby had been on CNEP. I was not suggesting that because our baby had been in a trial either way. I am actually suggesting there that she was asked because the previous baby had been in CNEP. Not one way or the other.

Q You have used the word “trial” and you knew before this report was---
A I used the word “trial” because it is in that paragraph and that is what I am responding to.

Q You knew before this report was commissioned, I suggest, and before you saw Dr Newell and therefore back in 1992, that both your children were involved in a trial?
A No, that is ridiculous. Why would he have to assume that she was in it if I told him that she was?

Q Where did you tell him that she was in a trial?
A Where did I what? I did not tell him. He told me.

Q Mrs Henshall, you knew all along?
A I knew she had had CNEP. I did not know it was trial. Nothing there says that I knew that was a trial before reading this report. Nothing at all.

Q Other than what you have written - the word “trial”? A No, that was written after we had seen him in response to this. I mean, how could I write it before? I have not got the report.

Q You could write it before if you knew all along she was in a trial which is what I am suggesting to you. Was it written before the so-called confirmation in February
A 1997 and the Ethics Committee?
A Let us go to where he says there has been a breakdown in communication. Why would he say that if I knew all about the trial and I was telling him I knew about the trial?

Q I do not think this report talks about a breakdown in communication, does it?
A There is somewhere in it, yes. Unless it is like the letter that we got further to it because I did a report of my own. All these scribbled notes on here I put in a report and you know I do that because you have seen it loads and loads of times and sent it back to him and said do you think you could be mistaken about this or mistaken about this because we have looked at this and we have looked at that.

Q You have got, for instance, at page 13: “You have not seen the scans that Dr Newton & team have examined and he disagrees totally as he states there is evidence.” Dr Newton’s letter we have looked at, or letters from page 233 onwards. They are dated I think 1995---
A Can you stop and go back---

Q Hang on---
A --- you are saying all these facts to me and I cannot follow it all in sequence. You are going to ask me in a minute to answer this, this, this, this. Can you just do one at a time?

Q To write that comment you had to be in possession of the Newton letters on page 13, did you not?
A To write that comment I would have had to have seen Dr Newton’s letters?

Q Yes.
A No, I met with him and we spoke. I would not necessarily have his letters. I would not have letters until I got the medical records.

Q You had the records and you know you had the records?
A I did not have the records.

Q Dr Newton and team. You have not seen the scans. “He states there is evidence”, not told me, states. That is a reference to a letter, is it not?
A Where is that?

Q Page 13. “There was no evidence of this.” He is dealing with if Patient 6 had suffered an hypoxic insult during her period of neonatal intensive care:

“I would have expected the first ultrasound to show increased periventricular echoes and by the time of the second scan at 15 days, changes would have been more easily visible with appearance of cysts. There was no evidence of this.”

You have written:

“You have not seen the scans that Dr Newton & team have examined and he disagrees totally as he states there is evidence.”
You must have had Dr Newton’s letters that we looked at at pages 233, if you want look at them again, in file 2, 244 and 245.

What you are asking me is when I wrote that comment did I have the medical records? Yes, I did but that was not when this --- I did not have them before this was written. I did have them afterwards, that is when we went through with the notes and everything, yes. I did say that.

That was long before. This is the point I think you wanted to make. It is not communication in relation to CNEP, it is communication in relation to the changes in the ultrasound scan. Look at page 14. Yes?

Yes.

“It is my opinion that [Patient 6’s] parents should have been told of the changes on her ultrasound scan.”

This would not however, have led to the suggestion that she might have suffered such severe long-term problems and would rather have been to reassure that the changes seen on her neonatal scan are those seen commonly…”

and then to give you a taster of what is coming after lunch that is what I shall be suggesting to you:

…and usually not followed by adverse neurological sequelae.”

So that is what you thought of his opinion in relation to the ultrasound scans?

He had not seen them, had he?

He had gone on the report which I am afraid is all we have got because the scans are missing.

Mr Newton did not and he was telling me something entirely different. That is why I believed it was rubbish because I had medical evidence to the contrary.

We are not going back to that. You cannot possibly still maintain that Dr or Mr Newton was telling you that your child suffered on a balance of probabilities a brain damaging injury post-natally? You are still maintaining that, are you?

Yes, I am. He was saying---

That is fine for my purposes.

He described it as a slow suffocation.

That is another emotive term. You have talked about children being strangled to
death by CNEP.
A He described it that way, not me.

Q Strangled to death – is that something else that permeates your letters?
A Yes.

MS SULLIVAN: I am sorry to interrupt but I think the shorthand writers are having difficulty when the witness and counsel talk over each other.

THE CHAIRMAN: I think that is probably right. Mr Forde, have you reached a point where it would be a---

MR FORDE: I am looking to the shorthand writer to see if that is a problem?

THE SHORTHAND WRITER: It is when you speak over each other.

MR FORDE: All right.

THE WITNESS: I apologise.

MR FORDE: Sir, I am going to deal with the scans after lunch, if that would be reasonable?

THE CHAIRMAN: So now would be an appropriate moment to break?

MR FORDE: Yes.

THE CHAIRMAN: We will break for an hour and come back at quarter to two.

(The Panel adjourned for lunch)

MR FORDE: Sir, we are endeavouring to get for you at the Legal Assessor's invitation a copy of the report of Dr Simon Newell and also the maternal records dealing with prescribing of morphine. We will make sure you have those in time for your Panel questions. Good afternoon, Mrs Henshall. Can I ask you a couple more questions on the Newell report. We were trying to see whether or not you had been in possession of the notes at the time that you made a reference to your daughter being in a trial. You tell us that the annotation about blood pressure was something that was known to you; about your blood pressure dropping dangerously low without you needing possession of the notes?

A No, I did not say that. I said that those --- I have written this on here after we have got copies of the medical records but after we had been to see Newton. Not before.

Q You know I am suggesting to you that it was long before but I just wanted to explore with you at the moment what you knew without seeing the notes, so you knew, you were telling us, that you had been in recovery because your blood pressure had dropped. You knew that in 1992?

A I was in recovery because I just had a Caesarean section but my blood pressure did drop during the Caesarean, yes.
Q You knew that was the reason, you told us, you were cold and shivering back in 1992?
A Yes.

Q You then told us in relation to the next page, 5, respiratory problems that the metabolic acidemia was something that you culled from, was it a report of Cliff Roberton?
A No, it was his book. On one of my many conversations with the teaching hospitals around the country to see who knew anything about CNEP and where it had been and whatever I asked if there was anything that we could refer to to help us out with the medical side of everything and they said the best mode vecum(sic) they knew was N R C Roberton’s book and they gave us a reference and I went and got it and that is what we were using.

Q Just say that phrase again? The best?
A The best reference basically for us to use so that we could check on the like appropriate --- what was appropriate care. He said that basically --- in this report he had said that she had received excellent care, blah de blah de blah, and we wanted to check it out really, so I asked what would be the best reference that we could use to check on aspects of her care, clinical care.

Q There was a Latin phrase that you used which I was going to ask you about because it appears elsewhere in the documentation we have.
A Yes, I was told that it was the best mode vecum(sic) which I was told that basically that was their Bible. That is what they went by. That was what most junior doctors would refer to if they had a problem or whatever. That is what I was told.

Q Are you saying mode mecum?
A Sorry?

Q What is the phrase you are using?
A Mode vecum(sic).

A M-O-D-E V-E-C-U-M?
A Yes, probably mede, mode, whatever.

Q But you are not a Latin scholar yourself?
A No.

Q Can we take it if there is documentation where there is a phrase vade mecum, which does mean a leading text or work, is to be found in your documentation that denotes assistance from somebody? Or do they speak of little else in Staffordshire?
A Sorry, what was you saying?

Q We have a bundle which we have handed to the Panel which is DA1 and one of the things that had interested me was the extent to which you had been assisted in making your complaints. This was explored by Miss O'Rourke in detail. Do you recall whether you had help and if - for the benefit of everybody’s note, page 38 of DA1, this phrase or
series of words appears after you criticise Dr Spencer for concentrating specifically on blood gas measurements you say this:

“Any neonatal vade mecum will advise measuring blood pressure regularly and assessing perfusion by clinical assessment, core-peripheral temperature, capillary filling, skin colour and measuring acid based status.”

Do you recall writing that?
A I would have to see it because it has probably been a long, long time since I wrote it but if you say I did.

Q I do not know if the exhibit has found its way on to your table but you can look at my copy. It is the first full paragraph under note 4. If you want to go back a few pages it might be easier for you to work out what document this is. This is one of your GMC responses I think. (Same handed) (The witness read)
A Yes. What are you asking me?

Q It is just the phrase, I was wondering whether vade mecum --- were you assisted in writing that response?
A Only by the book that it came from.

Q So are you saying that you have lifted that straight from Roberton?
A Yes, in fact, Dr Spencer told me off for that when I met with him because I was quoting out of that a lot and I had got these charts that I had made from that where I went through every blood gas measurement and everything once we had got the neonatal records and checked them against these and what should have been and what should not have been. He actually made the comment that, you know, I was not a neonatologist and I said, no, I was not and reading a book does not make you a neonatologist and I said, no, but the book was written by a neonatologist and it is supposed to be this vade mode vecum vecum whatever and I explained to him what that book was and everything and then interestingly after that we wrote to Dr Roberton because we found out who he was and we wrote to Dr Roberton and asked him if he would assist us further and he wrote back to us saying that actually he was acting for the Trust; that they had contacted him and so we were beaten to it there.

Q So that is where you have got the phrase from, from Roberton?
A Well, no. Not necessarily. I cannot remember whether it was him or whether it was the person that actually told us to go and get that, you know, that that would be the book to --- where you would find what you needed basically and I cannot remember which---

Q The only reason I am suggesting you may have copied it is because you, for understandable reasons, transpose the letters of the two words involved. You said mode vecum rather than vade mecum, so it looks to me as if you have lifted that straight from a text book. Be that as it may. I want to explore with you with Newell’s report that which you knew without recourse to the notes. On page 6 of the report, which has got 633 at the top, you make some notes about the Patient 6’s colour. Do you see that?
A Yes.
Q Which, again, is something you observed at the time?
A Yes.

Q Then the next page there is a discussion about the follow up at the bottom of the page and failure to get to your daughter to appointments in May, June, August and September?
A Which page?

Q You have written “Spasms were dismissed as temper”, that is page 7. That is something you knew without recourse to the notes, was it not, because that is when you were going to out-patient clinics?
A Sir, I have got copies now. It may be easier for the Panel to follow. I do not know what number we are on?

THE CHAIRMAN: D5.

MR FORDE: Thank you. It is a covering letter that I put to the witness first and then the main report from page 2 onwards. It is internal number 5 of the report, bottom right, second paragraph under respiratory problems but has the annotation “[Patient 6 was asked because our previous baby had been on CNEP trial.” Then on page 8 you have made some annotations about the Child Development Team experience.

“I explained that her reaction to the children was adverse and she did not like the milling around”.

Do you see that?
A Yes.

Q That is something that you experienced ----
A Yes. She had got an over exaggerated startle reflex and I said that was exacerbated because there was always lots of activity in our house, so if anybody would run past her or run towards her or anything like that she would startle like really strangely and I just thought that was something I had not seen before in any of my other children.

Q Then on page 10 he is deposing a question which he answers from your point of view unhappily in the hospital’s favour:

“Was there any perinatal asphyxia?”

and he has put this in the second paragraph, second sentence:

“Nevertheless at 32 weeks gestation I would expect an episode of perinatal hypoxia sufficient to explain Patient 6’s subsequent problems to have been evident”

and you have written “Ignored”.
A That is right. I was referring to the amount of time that I had tried to grab somebody to come and observe her colour and rightly so because backed up by Carl Bose.
A
---

Q You say that. You know we have got no way, have we, of knowing whether this conversation took place and you are not suggesting Dr Spencer was there during the conversation you had with Carl Bose, are you?
A Ask him. He remembers because I spoke to him.

B

Q Dr Bose or Dr Spencer?
A I have spoken to Dr Bose since. He is one of the people I rang up and spoke to, one of the doctors I rang up for advice.

Q When did you speak to him last?
A Quite a while ago. Not long after we had found out that it was a research trial and whatever and I was speaking to him about events, asking him what his role was.

Q He is back in America but I am told he may be happy to come and give evidence.
A Yes, I spoke to him in America, in North Carolina, yes.

Q Can I just ask you a little bit more about these annotations. Under “18 hours intermittent positive pressure ventilation was added for a period of a further 19 hours” (this is the top of page 11) you have put “Too late”.
A Yes, it was too late. I believe it was too late. I believe by then she was probably already damaged, yes.

Q Yes, I know. We do not need to explore this again. You think she has been damaged by CNEP. Then you have got in relation to oxygen saturation:

> “These levels constantly fell below 26%\textit{(sic)} whilst watching [Patient 6] after” something “episodes”.

Is that correct. I am sorry, 86%.
A Whereabouts?

Q It is the last entry just above the last paragraph.
A Yes, I see it, yes.

Q Yes?
A Yes.

Q Okay?
A Yes.

Q Again, something that you recalled rather than needing to consult the notes?
A I remember when it went down below a certain level then the alarms would go off and that is when I was taught to either switch them off or someone would come in and either reset it or you would try to say this is what had happened and then I either tickled her feet … I was taught to either tickle her feet or whatever.

Q As I said, I am in difficulties because you are not suggesting this is a Dr Spencer
mandated treatment mode, are you?
A  No.

Q  It was nurses that were telling you this, is that right?
A  Yes, it was the nurses, yes, that I was having to speak to. You did not see the doctors, only on their ward rounds or if there was a major problem.

Q  Thank you. Page 13. You pose a question, first of all, about conclusions and further investigation. Then you are querying, despite this doctor’s expertise, whether or not there is a cyst seen on the ultrasound.
A  Yes. That was something that we had seen written by Dr Spencer. Dr Spencer had said that with hindsight had somebody better qualified looked at the ultrasound scans then they may well have picked up that there was an area of periventricular echo density or something like that and maybe that would be a cyst or maybe it would not.

Q  Again, it is difficult for us when you recount, I think we have not heard this or seen it in a witness statement from you, after this length of time, but you are not there annotating it as a possibility of cyst, are you? You are writing it down as “Could have been a cyst”. That is what you would like to believe, is it not, that this is a cyst that developed by the time of the first or the second scan, but after Patient 6 was born?
A  That was in response to when Newell was saying that you would expect to see cysts and it would look like this and when I saw the explanation of what it looked like in the future then I said maybe that could have been a cyst, but, you know, I am not a neurologist and I do not know. If you ask me now I would say that probably was not a cyst, because cysts take about three weeks to develop after the insult and I would say that would have been too early to have seen any cyst.

Q  He says, does he not, seven to ten days and he goes on to say, and we have dealt with this already …
A  It depends what you read.

Q  … that there was no evidence of this. You annotate that you have not seen the scans that Dr Newton has seen, yes?
A  Yes.

Q  Then on the top of the next page:

“It was not however negligent to fail to do a scan prior to 8 days”.

You have put “Why not?”
A  That is because the protocol stated that a scan should be done prior to entry into the tank, once every week thereafter and once on discharge, so actually Patient 6 should have had a total of five scans and she had only had two that I knew about.

Q  We will have to look at the protocol with Dr Stimmler, but that is your recollection. Then this is interesting:

“Interpretation of the ultrasound scans as showing changes which would not lead to an adverse neurological outcome was appropriate.”
These results should have been shared with Patient 6’s parents.”

You have put:

“Parents not told and also ultrasound should have been followed up”.

Yes?

A Yes. The advice I have been given is that any adverse neurological ultrasound should have been followed up.

Q It is the basis of the charge which we can see quite clearly is generated based upon your opinion of what you should have been told but we will come back to that in a moment, but at the moment I do not see as we go through anything, including your “rubbish” annotation on page 14 which required you to have the notes in front of you. Most of these notes, it appears to me, are notes that you could have made without having the notes in front of you.

A I would have been a bit clever, would I not, without notes in front of me to know whether ---

Q No, because it is all anecdotal. It is that “I was ignored. Nobody took any notice. They did not look at her colour”, all the things you have told us and in fact many of them are not in the notes and that is your complaint, is it not?

A You are saying I had the notes well prior to this, so what is your point?

Q Either you had the notes prior or if you did not when you made the annotation on page 5 that “Patient 6 was asked because our previous baby had been in the CNEP trial” you knew, as I suggest and have suggested, throughout that both your children were entered into a trial.

A I did not know until they told me.

Q Can we then deal with the ultrasound scans themselves because you have complained about the quality of information that you were given? I want to understand your evidence. I have read your witness statement and you have given evidence about this already to the Panel and, in fairness to you, it may be sensible to take you to it. It is D9/27.

A Before we move on to the next point can I just say that when you say there was no evidence from those scans of damage or when he says that there is no damage, when we were talking the other day about the child that had the out of court settlement, her scan reports are identical.

Q You may well say that. I have not seen them. That is not what this inquiry is about.

A Well, I have got them.

Q I am sure you have got them. You have got more documentation than anybody else, but we are not here dealing with that child. If you want me to cross-examine you upon what I suggest is your misleading evidence on the point I will, because that settlement was not reached in relation to CNEP.
A I did not say that. You asked me what my evidence was and why I come to the conclusion that those scans showed damage as it was occurring. You settled out of court and those two scans that she had are identical to my child’s two scans, even to the timing and the part and I can show you that and I can demonstrate you that ---

Q Yes, but we are not here in a clinical negligence trial where you are going to be awarded damages. We are not here debating that case.
A Exactly, thank you.

Q I do not even know whether we are entitled to cross-examine given issues of confidentiality, but you are happy, I suggest, to introduce that case in a thoroughly misleading way.
A Well, it is not misleading. You are asking me where my evidence is and where I am coming from and that is why … you know, I can only tell you that.

Q Can we concentrate on your own children. D9/27. Question at letter C:

"Was it at that point that you became aware of some brain scans that had been performed in hospital?"
A Yes”.

This is when you say you had an outpatient appointment. Your witness statement makes it clear that you had a discussion at the time that either a scan or scans were done with somebody. Is that the accurate position?
A I am sorry, say that again.

Q Yes. This question is predicated upon the basis that you did not know that your child had had a brain scan in hospital, that is not the charge, but you in your witness statement make it clear that at some point at the time that the ultrasound scan or scans were taken you had a discussion with somebody about them.
A No, I did know that my child had had head scans.

Q Right.
A I did not know that Patient 7 had, but I knew that Patient 6 had because I was there at the time.

Q The only charge we are concerned about relates to Patient 6.
A I did not know the results of those.

Q What is the important matter we need to deal with now, because I want to make sure I have understood your evidence correctly, because if we look at the bottom of page 27 you are taken to the ultrasound scan reports, because we do not have the scans:

“Were you told the outcome of the scans?”
A I was just told that they were normal and that she was fine. Nothing to worry about.

Q Who told you they were normal?
A I think – well several people. I asked the radiologist at the time
and I also bought it up with Dr Spencer just in passing when they come around and do their rounds I said---

Q What did he say to you when you brought it up?
A ‘Fine. She is absolutely fine. Not a problem’.

Q Had you any idea that there was any problem at all?
A No.”

Okay?
A Yes.

Q Right, so as you are aware, Dr Newell thinks you should have been told about the scans but you were aware that the scans had been done, is that correct?
A I was aware that they had been done, yes.

Q I want to just explore with you your awareness. 22 December 1992 was a Tuesday, we believe. Are you able to confirm that?
A No.

Q You recall which day of the week your daughter was born on though presumably?
A Monday, I think.

Q Monday, you think.
A I think so.

Q 14 December 1999 you think was a Monday.
A I think it was a Monday.

Q So the 15th would have been a Tuesday and the 22nd a Tuesday, all right?
A Yes.

Q Just help me with this then. We have only got the report, you see. We do not know when they found their way into the notes. Are you satisfied in your own mind that you were present on 22 December when the first ultrasound was done and if you cannot remember do say?
A I was present for most of the time, so I should imagine so. Yes, I think so, yes.

Q Do you recall the female ultrasonographer that we know reported, Ettinger or Ettingar?
A Egginton, Dr Egginton.

Q I am sorry, Egginton.
A Yes, I do.

Q Do you remember her as female?
A Yes, I do.

Q Do you remember being in the room with her when the ultrasound was done?
A I was not allowed to stay in the room while it was done. I think I probably arrived just as she was finishing.

Q Did she have any discussion with you?
A I just asked how was she, you know, and she said it was fine.

B Presumably you asked her what the scan appearances were, because you have told us.
A You have got to remember that when you say about like it evolved, back then I was not this savvy with medical knowledge back then. I was just a parent, I still am just a parent, but I know a bit more because I have looked into it. At that time I knew virtually nothing, only what I had picked up from what the doctors and nurses were telling me.

C You would not, as you appear to now know, have been able to understand or discern the meaning of a report that talked of an increased density on the left suspicious of clot attached to the choroid plexus and in association with mild lateral ventricular dilatation?
A No, I would not have been able to do that at that time, no.

Q That is at our page 161. Were you present for the second scan which was reported as showing mild symmetrical dilatation of the lateral ventricles?
A Unless it was done while I was asleep, I spent pretty much all my time apart from meal times on the unit, so if it was done in normal hours then I probably would have been present, yes.

Q Can we take it that up to and including Patient 6’s discharge on 7 January 1993 the probability is that you would have been or tried to be around for all important procedures, scans and the like?
A Yes. You were not allowed to remain at your daughter’s bedside for everything. If it was something invasive like they were putting a line in or something like that then they would take you out if it was going to be distressing or something or if you were in the way, but for the majority of things if I was not getting in the way or whatever they would let me stay, yes.

F As you have told us, you were yourself highly inquisitive and you wanted to know what was happening with your daughter at all times.
A Yes, most of the time, yes. You did not always ask the doctor. You relied a lot on the nurses’ information because the doctors were in and out and seeing lots of children, so you did not necessarily question them a lot. If they were staying around your baby for any period of time, which they did not if they were not a problem, they would just flit over and go to the next baby, but if they were around you asked and if not you just relied on what the nurses were telling you.

G Just help me with this. At the top of our page 28 on day 9 there is a question:

“Who told you they were normal?”
A I think – well several people.”

H Can you be a bit more specific? You say you asked the radiologist at the time and that is
Q  But you say this:

“I also bought it up with Dr Spencer just in passing”.

A  Yes. The next time he would come round I would probably say, you know … I do not know exactly word for word what I said, but I would have asked him how is she doing.

Q  Were you in the habit of reading your daughter’s notes?

A  You did not get much opportunity to read your daughter’s notes actually, because they generally either had them at the nurses station or kept them in the thing on the end of your … when they went into a cot they were sort of there, but, no, not overly, no. Occasionally I would try and have a peep, but you did not get much opportunity to really and anyway I probably would not have understood them at that time.

Q  You cannot recall with any precision the conversation you had with Dr Spencer.

A  No, I do not remember with precision.

Q  Do you recall where the conversation took place?

A  That is obvious, by the side of her cot, because you did not see the doctors unless they come to your cot. You did not wander around the unit to other people’s cots, you stayed with your own.

Q  He is struggling to recall after this time any conversation with you about this scan at all, but he was to write on the subject closer to events and I would like you to go behind tab 5 in our file 2 and go, if you would, please, to page 212. In fact, in fairness to you, I think we probably ought to start so we can see how this develops in correspondence at page 208 which is a letter from Dr Haycock, another female doctor, to your general practitioner, I believe, Dr Bradbury. Do you have that?

A  Yes.

Q  So this is in 1994. Patient 6 is the therapy group being discussed in the first paragraph ----

“There was a long discussion towards the end of the interview regarding the relationship between [Patient 6’s] current neurological findings and the ultrasound scan findings at ten days of dilation of the lateral ventricles consistent with haemorrhage. There was also discussion about the use of ventilation in Patient 6’s neonatal care and I suggested --- it might be helpful for them to speak to Dr Spencer on these aspects of her care. I think that part of the reason for this conversation was to look for reason and blame for Patient 6’s condition.”
Are you telling this Panel that absent the notes – because the whole part of the case, this part of the case the Panel are dealing with is a failure to tell you about abnormality at the time? Absent the notes, which you tell us you did not get until after the December 1995 report, how were you able to have a discussion with this doctor about the ultrasound scan findings at ten days?

A  Because when we went to the twelve month – she was actually 13 months by the time we got there but when we went to the twelve month – follow up appointment, we saw Dr Morgan and not Dr Spencer and it was – I gave this evidence the other day but it was discussed at what level she was operating at and I asked him if she could have cerebral palsy and it was Dr Morgan that turned round and said it is a possibility due to her brain bleed on the prem unit. I said no, no, no, I was there for the scans and I was told they were normal and it was him that told us what the difference was.

Q  I see. In fairness to you, that is Day 9 page 27 you deal with the Morgan conversation, but another doctor who aroused your suspicions by linking the small haemorrhage to your daughter’s current condition, yes?

A  Another doctor?

Q  Yes, because you told us about Newton?

A  Oh yes.

Q  Although we search in vain for damage post 32 weeks, but telling you it was before 32 weeks and now Morgan is telling you that there is a relationship between the haemorrhage and brain damage?

A  No, I think this is before we saw Newton, was it not? Have a look at the dates. I cannot tell you straight off but I think this is before we see Newton. I think it was after these conversations and whatever that she said that we should see a paediatric neurologist. I think you will find that.

Q  All right, we will check that now but we are now in June 1994 and you told us that you thought you saw Newton when your daughter was 13 months?

A  No, Dr Morgan when she was 13 months.

Q  I am sorry, OK, so Morgan is the first person, is this right, in early 1994, who gives you the information that there may have been a haemorrhage?

A  Yes.

Q  Right. What then happens if we look at the next page, 209, this is Dr Haycock writing to Dr Spencer where she is recording that you are telling her that you were told that the scan was normal. Do you see that?

A  Yes.

Q  “My impression”

- and this is something I explored with you –

“was that much of this discussion was prompted by mother’s concerns
that she may be in some way responsible for patient 6’s disability.”

How did she gain that impression?
A I suppose by having her prematurely, I suppose at the time I was thinking – I really do not know. I do not know what she means by that.

Q OK. Then we have got a letter at page 210 which appears to be a duplicate of the previous page but I think it has come from the records. This is the one that is received by Dr Spencer and he has written, “Offer appointment Tuesday morning 11.30.”
A Yes.

Q So we have got two copies of it. Over the page he writes to you, page 211, and then he writes to Dr Haycock saying that on the first occasion you cancelled the appointment and on the second occasion did not attend and he says this:

“I would note that Patient 6 had mild symmetrical dilatation of the lateral ventricles and at one stage there was the possibility of a clot attached to the choroid plexus on the left side. These ultrasound changes could be considered virtually normal in a preterm infant and would not, in any event, be associated with an increased risk of handicap.”

That was also Dr Newell’s view, was it not?
A Yes it was, yes.

Q So the reason we are here at the moment in relation to scans is your complaint that a doctor 16 years ago did not tell you that there were potentially mild changes?
A Sorry, what did you say?

Q That is what the charge says?
A Yes, I should have been told it was abnormal because it is abnormal.

Q Right. What he then thought he may have said, because you can imagine it is a struggle for him to recall – page 213 – he writes to Haycock and he says:

“These ultrasound changes could be considered virtually normal in a preterm infant and would not in any event be associated with increased risk of handicap. Therefore, it is quite possible that the parents were variably told the scan was normal or that it showed minor abnormality only and this may have led to some of their concerns.”
He cannot remember any conversation with you after all this time but do you accept that the second scan on 29 December from your knowledge – and if it outside of your expertise do say – was more reassuring than the first?
A No.

Q Do you accept that it is not uncommon for preterm infants, from all your reading and researches, to have this ultrasound appearance?
A I accept that they are prone to brain bleeds, yes.

Q You, however, regard it as causative, do you not, of her current condition?
A I do, yes.

Q The experts that we have seen do not but you still do?
A Actually I would say that Mr Newton does.

Q Yes, back to that, but anyway what would you have done if you had been told there was a mild abnormality but it was the sort of thing that people saw in preterm infants?
A I do not know. I cannot speculate on that.

Q The answer is nothing, is it not? It is just another little bit of information about her condition?
A I probably would have insisted earlier on that she was followed up better because when I did try and highlight the fact that my child was not progressing normally physically, I was reassured again and again and again, and perhaps I would not have been reassured or would not have allowed myself to be reassured had I known that earlier.

Q Of course you know there were a number of appointments that you did not manage to attend, which is understandable given the number of children that you have?
A No, we did not attend the appointments on the time that it was first given to us but I did say as well on evidence, and we have got the reports from all the times that we did attend, there was four appointments that we did attend; it just was not when the appointments were first sent to us. We rearranged those appointments and they are all in there.

Q We have got a whole stamp of DNAs…
A I was working.

Q … but be that as it may, I am just trying to explore how serious this is, if it happened at all. It is not being told of a mild abnormality which appeared to have been resolving itself by the time of the second scan. That is your complaint?
A No, it is not.

Q That is what the charge says?
A That is your interpretation of our complaint and that is not our complaint. I do not say that it was a mild event.

Q That is probably better explored if he is up to it with Dr Stimmler, because he is
not a neuroradiologist.
A Exactly.

Q We understand your position. You are strongly of the view that this, as I have suggested to you, not unusual minor bleed is in some way associated with your daughter’s current condition?
A It is not confined to just the minor bleed because, as it was explained to me, it was from a slow suffocation, a hypoxic ischaemic encephalopathy, a prolonged flare which caused PVL which is a recognised event and does cause cerebral palsy of her nature and that is what the neurologist has told me was the cause even before we started any litigation, so I feel like I can rely on his opinion.

Q Yes, this is what you say he told you. He has never gone into print on the subject that we can see in our documents?
A Yes he has. You have read the letters.

Q If your interpretation of them is that that shows a causative encephalopathy caused by slow suffocation, which appears nowhere in the letter, then so be it. I can show you a letter but in September 1993 there were three defaulted clinic appointments involving yourself and Patient 6.
A Yes, I know, I have explained that.

Q The health visitor had to go to the house and stress the importance of keeping appointments?
A That is what it says in there but actually we rearranged them all and I have got – you cannot deny that I went to the appointments because I have got the reports from those appointments. Do you want to see them?

Q No, thank you.
A There you go.

Q Can I then ask you, because it seems we are not going to make any more progress on the ultrasound, you will have noticed that slow suffocation does not appear either in the Stimmel report or in the charges, does it?
A Slow suffocation was how it was described to me, what a HIE actually is, and a prolonged flare. That is what a slow suffocation is. They are not talking in laymen’s terms because they are talking to other doctors but if you ask a doctor to explain to you what a HIE and a prolonged flare is, they will tell you it is a slow suffocation.

Q Again, just so we understand your, it would appear, almost expert opinion, you think that this all occurred postnatally?
A Yes, due to prematurity, he says, yes. Not antenatal changes.

Q 25 to 35 weeks does not matter because we just focus on the word “premature” which can only be used once she is born. That is the thesis, is it not?
A You know, he does say to look in the neonatal records of any evidence of hypoxemia and there was evidence of hypoxemia.

Q There is no evidence in your daughter’s notes of brain damaging hypoxia?
A Is there not?
Q Is there?
A Yes, there is.
Q We will explore that with Dr Stimmler, if you do not mind. You were part of the steering committee when the outcome of the CNEP trial was looked at by, among others, Professor Marlow, were you not?
A Yes, I was.
Q You know that the conclusion of that report was that CNEP had not been shown to have been causative of any harm to any of the children in the trial?
A It was not about looking for causation. It was only about looking for a trend.
Q You have looked in vain, I suggest, for causation. I am asking you whether I have accurately summarised the conclusion of the Marlow report, or do you want me to read you the conclusion?
A It would be pointless just reading the conclusion. You would have to look behind the study. If you read just the conclusion of every study then you would get a misguided picture, would you not, such as in the RDS paediatrics paper. If you just looked at that then you would not know what had been reported before. You cannot say that actually it was OK. The summary has always got positive spin on it.
Q I see.
A If you look behind that summary and look into the actual details of what was found, then perhaps you might have better picture.
Q This report which went to the Lancet on 1 April 2006 is at best inaccurate and at worst a sham?
A No, if you read the whole report then it is representative of the children that they actually looked at and it does not say that there was no damage in any of the children that they looked at. There was five as opposed to one which has got serious disability.
Q Let us ---
A You do not let me finish any of my points, do you?
Q Yes but you have made this point--
A You are asking my opinion and I am telling you...
Q Mrs Henshall---
A … and you just jump in.
G Mrs Henshall you are convinced – we all know this – that all of those five children were damaged by CNEP. I am suggesting to you that there is not a single study or a single respectable paediatrician that believes that to be the case. Do you agree?
A How can you speak on behalf of all paediatricians in the country?
H We are waiting for a report saying that CNEP damaged children?
A Nobody has looked into whether CNEP damaged children. In fact, the only
people that have looked are these three here and they are hardly going to tell you that it damaged anybody, are they?

Q One case of neck chafing, I think?
A No, it is not just one case. Why would you need to do head scans on all dead babies in the CNEP trial if you were not concerned that there was an increased incidence of cranial ultrasound abnormalities? That is not normal treatment, that is not normal care. That is not a normal investigation to do in all cases and that was done in all these babies. If they were not concerned about that, why would they go to that length and where is that report?

Q It is good medicine, to make sure that the trial is being properly undertaken. A model trial, you will be hearing from others, including Professor Hutton. You have read that report, have you not?
A I have.

Q You must have been very disappointed by it?
A I am very disappointed in it, yes, I am very disappointed in it because she ignores the fact that it does not work in the real world. I have already told you, I have already shown you where the scoring system ---

Q It does not work in your world, does it, and yours is the only world it does not work in?
A Why do you not let me finish what I am saying so you can understand where I am coming from?

Q Because I am not going not give you a propaganda platform.

MS SULLIVAN: I think she is entitled to finish what she is saying.

MR FORDE: She is not answering the question that I am putting to her.

THE WITNESS: What is the question that you are putting to me?

MR FORDE: I just want to know whether you think the Marlow report is wrong. I am going to read you some extracts from it and see whether you agree or disagree?
A I already said that the Marlow report was not wrong.

Q Right, well let us just see. What they did was, they looked at the randomised trial, correct?
A Yes.

Q They looked at 133 of the 205 survivors between the ages of nine and 15?
A Yes.

Q The results from 65 complete pairs were available to them?
A Yes.

Q They assessed cognitive function and disability as a paediatrician and
psychologist using standardised tests?
A  Yes.

Q  They found no evidence of poorer long term outcome after neonatal CNEP whether analysis was by original pairing or by unpaired comparisons?
A  No statistically significant but if you look at it and you look at the results yourself and see that there were five as opposed to one in the standard group children who were severely neurologically damaged.

Q  The figures in Stafford were identical, whether it was IPPV or CNEP?
A  No they were not, there were five extra.

Q  There were not.
A  Show me then.

Q  There were not.
A  Show me then.

Q  I am not going to debate statistics with you but I just want to get my understanding of why you are so adamant that this is damaging. As far as you are concerned, despite the babies in the trial being premature and suffering respiratory distress syndrome, which can kill babies, can it not?
A  If it is severe enough, yes.

Q  That every single injury suffered by a child in the trial – is this your standpoint? – was caused not by prematurity or other physiological factors, but by CNEP?
A  No, I do not say that. I say if you look at the two groups and you look at the incidences of a problem or not, then it is more prevalent in the CNEP treated groups, so what are you supposed to believe? Such as renal failure – if you consider that five times higher incidence of renal failure was in the CNEP treated infants, they will say that is not statistically significant. I would say that was an area of concern. If you look there was a 50% increase in cranial ultrasound abnormalities in the CNEP treated group. I would say that was significant to me as a mum because my child was one of those. That should be of concern. It was of concern to them. It should be of concern to the medical profession.

Q  Of course it is of concern but nobody is seeing a statistically significant link. Sick premature babies have renal problems, whether they are in CNEP or not, do they not.
A  They have a five times higher incidence in CNEP than they do in---

Q  You are talking extremely small figures. 244 children altogether, 16 standard treatments with difficulties and 22 in CNEP. The statisticians – do you defer to them or not? – say that is not statistically significant. That is how research works, Mrs Henshall?
A  Yes, that is why I am complaining about how research is undertaken in this country because I do not think it is right, I do not think it works in the real world and I think it hides – you can make anything look statistically good on paper. Statistics will say exactly what you want them to say. How it works in the real world is something else, is it not?
Q Thank you, I am not asking a question along those lines but you have had your say, I hope to Ms Sullivan’s satisfaction. Can I just ask you finally about your assistance from Nicholson? We are able to produce and I am happy for the Panel to have it – an extract in 1998 from his Ethical Bulletin. BMJ, I apologise, it is a letter.

THE CHAIRMAN: D6, Mr Forde.

MR FORDE: Thank you. In the bundle of your involvement with the GMC and others we have an attendance note in which again you appeared to cast doubt on and it is at page 155 at the bottom of that bundle, the large bundle of your correspondence. You were asked about this by Miss O'Rourke and you appeared to cast some doubt upon its accuracy but it looks as if Dr Lohn and Sarah Stanley spoke to you on 10 February 1999 and what solicitors do when they have these conversations is they make a note of them and these are called attendance notes. That is why it says “MSL…” that is Dr Matthew Lohn “…and SJS attending Mrs Henshall by telephone.” You are concerned about many things. You describe the Trust as having ulterior motives; delaying the sending of consent letters, so they are part of the conspiracy as well, the Trust? Forgers and fabricators as well, is that right?
A That is not what it says in there.

Q I am asking you.
A That is not what it says.

Q Is that what you believe?
A What? That they are forgers and---

Q Fabricators, the Trust.
A Fabricators?

Q Yes, deliberately holding up things.
A I think they have misrepresented the truth.

Q Is this delaying the consent letters that is mentioned here as a result of your belief that they were busy writing them after the event?
A No.

Q Concern raised about Dr Spencer using infrared on healthy babies?
A Yes. That was because my sister was approached to go into a research project while she had just had her newborn baby and it was to do with different temperatures and cooling of the limb just after delivery and using near-infrared to measure the changes in the blood volume or blood flow but she rang me quite upset about how she had been approached and said could you come down here. When I read the leaflet I still felt it to be quite misleading and it talked about near-infrared as a useful monitoring tool and I knew that it was still only in the developmental stages and was not a useful tool at the time, so, yes, I did put in a complaint about that.

Q Yes, well, that is hardly surprising. Then the paragraph that I am interested in about Richard Nicholson who has been in contact with the GMC. Do you see that?
A Yes.
Q "Mrs Henshall admitted to having spoken to him of her concern regarding the health authority’s delaying tactics."

Did you have such a discussion with him?
A I cannot remember. I may have.

Q Let me try and jog your memory. BMJ 1998, D6 we are calling it, right-hand column. Have you been given that yet?

"Students must be taught more about ethics"?

A Yes.

Q It talks of sorrow and anger:

"…caused by doctors to real, live people that self regulation must address."

We know that you are recorded as telling Field Fisher Waterhouse that Dr Nicholson is a supporter of your action and a campaigner against self-regulation. Is that an accurate way of describing him?
A That is not a phrase uttered by me, no.

Q Is it an accurate way of describing him?
A What? As a campaigner?

Q He does not like self-regulation, does he?
A I do not know. Does he not?

Q He goes on to say:

"Patients with all their emotions have to be at the centre of self-regulation - not some mechanically performed peer review. Johnson’s editorial may read well in the corridors of medical politics but it gives no comfort to patients trying to deal with the General Medical Council."

So he is not a fan of self-regulation. He is not a fan of the GMC?
A So what?

Q You were aware of that, were you not?
A I think I probably became aware that he was not a fan of the General Medical Council.

Q Happy to be your hand-picked expert, however, appearing on behalf of both yourself and the GMC?
A So what?
A
Q Does that cause you concern?
A No.

Q Do you doubt his independence?
A Independence in what way?

B
Q His ability to give an independent view of the ethical profile of this case?
A He has got an opinion as to whether it was ethical or not. I do not think he thinks it was ethical. I have got no problem with that because I do not either but I am here giving evidence, am I not? I am sure you have hand-picked your experts to give the opinion you want.

C
Q We are hoping we do not need any, Mr Henshall. Moving on, this is you, is it not:

“Last week I met a couple who had just been told that it would take the General Medical Council at least 12 months to decide whether to start disciplinary proceedings against a doctor. A year or more, that is, not from the time of their complaint but from delivery of a dossier that they had assembled at its request. The dossier consists of nearly 1000 pages of evidence supporting their complaint that one of their children died and another was left severely brain damaged as a result of being used without their consent in a research project.”

That is what Nicholson is writing to the BMJ. That information he got from you?
A Yes.

E
Q That meeting that he described was a meeting with you?
A Yes.

Q This is dated 19 September 1998. Can you help us now as to when you first met Mr Nicholson?
A I cannot remember the exact time when we first met but he was doing something or other to do with ethics and we said can we meet you and I went---

F
Q “Nor does the editorial give hope that the General Medical Council will better fulfil its statutory responsibility for medical education so that doctors will be trained not to abuse and misuse their patients”?

A What?
Q That is his view, it would appear?
A Yes.

Q Is that something that you believe has occurred here?
A Yes.

H
Q Then critical of the GMC:
“…instructed medical schools to teach medical ethics over a decade ago. Yet it has still not withdrawn approval from those schools who still have no regular medical ethics teaching one of which (Middlesex/University College London) is right on its own doorstep.”

He concludes:

“If leaders of the profession are incapable of recognising the centrality of patients their experiences to self-regulation this extraordinary privilege will be taken away from us.”

How many times have you met Richard Nicholson since that letter was written in 1998?

A  I think I have only ever met him once.

Q  He is going to be giving evidence. I shall be asking him the same question, so think.
A  From what I remember I only met him once.

Q  You have met him on one occasion in 1998 as he suggests?
A  I could not tell you when it was, to be honest.

Q  Are you saying to this Panel you have not seen the man for ten years?
A  I have seen him on the telly.

Q  Face to face?
A  No. He does not visit me or anything. I do not go visit him or anything. I have spoke to him.

Q  Can you help me with the final part of this attendance note:

“It was discussed that Mr Nicholson’s pressure towards the GMC would not necessarily assist the progress of the enquiry.”

What were Field Fisher Waterhouse saying to you about Mr Nicholson as a supporter of your cause?

A  I do not know. You would have to ask them.

Q  You cannot remember because it says it was discussed?
A  No, I cannot remember.

Q  Any telephone contact between yourself and Mr Nicholson since 1998?
A  I could not say when --- I cannot remember the last time I spoke to him, to be honest.

Q  Any e-mails or letters?
A  There may be. Carl usually picks up the e-mails, so you will have to ask him about that.
Q When do you estimate the last time was that you received an e-mail?
A I really cannot remember. A while ago.

Q One year, two years, five years?
A I really do not know.

Q Cannot remember?
A No.

Q Do you think it is possible there has been e-mail contact recently?
A No, I do not think so.

Q I am just reminded of one other matter that I can touch upon very briefly and it is the questionnaire which Miss O'Rourke has already put to you at some length. Remember your bonding questionnaire?
A Yes, I do.

Q I just want to understand. Your case is yet another document did not find its way to you. That is at our page 378 in file 1 behind tab 3. The covering letter. Somehow you have returned your bonding questionnaire because it is 379 onwards to the Trust. No, yours is actually 391 onwards but looking at the letter:

“We would greatly appreciate your completing this questionnaire and returning it to Theresa Wright in the envelope provided.”

You say you did not get this letter?
A No, I was given it by hand when Sister Halfpenny came out to see me on the follow up of my baby around about six weeks, I would say, and she sat with me and we filled it in together and I handed it back to her and she took it.

Q I have to suggest to you that you did get a copy of that letter. Be that as it may. If we look at your bonding questionnaire and contrast it with your current complaints. You were telling the Panel about problems with access, seals and pressure changes temperature. First question:

“Given the severity of your baby’s illness did you feel that you had less access to your baby than you would have liked?”

A little less access”

you have written?
A You have to remember I am filling this form in after Patient 6’s care, not Patient 7’s.

Q No, I am asking you about it. I make it quite clear at the top that it is Patient 6.
A Yes, well, you know, the instances that you are referring to was with Patient 7.

Q So you did tell us it was an improved tank for your second child involved in the
trial, did you not?
A It was on a different incubator base.

Q Then you appear really to be expressing fairly minor concerns and then on page 393 we have got a very lengthy handwritten appraisal and you say:

“Having had previous babies on special care, two of which have been nursed in the CNEP tank and four in the usual incubators.”

Did you mean two other than Patients 6 and 7? Or were you meaning Patients 6 and 7?
A No, I meant others. When I talk about four in the usual incubators I mean my other children.

Q You say having had previous babies, two of which have been nursed, the two is a reference to Patients 6 and 7?
A Yes, of course.

Q I just wanted to check. You have experienced both forms of nursing. You can see the differences from a mother’s point of view?
A Yes.

Q You thought CNEP was a necessary evil. A lot less stressful in the long run. Treatment was more effective?
A Yes, because that is what I was told, yes.

Q No, this is not recalling what you were told. This is your impression of CNEP?
A Yes, from what I was told.

Q You are not just parroting.
A Was I a neonatal expert at this point? At all? It is the impression I got from having spent time on the unit and what I was told. I do admit to being brainwashed, I called it, did I not?

Q You have been brainwashed, you have been duped.
A I have.

Q Probably hypnotised but this is your document and you are disavowing it, are you? You are saying we should regard this as part of the brainwashing process?
A No, not necessarily. I do complain about certain aspects of it, do I not?

Q I will come to that. It is mainly to do with staffing levels, you are complimentary about the nurses whom you were later to try and have disciplined?
A No, I reported everyone that was on the paediatrics papers that took part in the trial because at that particular time I did not know who was responsible for what, just that it was not run as it was intended to do which is what I was complaining about, so it is not for me to decide who is clinically responsible here or criminally responsible or whatever. It is whatever investigations take place thereafter. I am just a parent. I have not got that power.
A  Q  You will complain about everybody that is named without any compunction, without any concern for their careers?
A  If it was defendable they would have defended it by now. It would not have gone on as long as it has done.

Q  It is the doctors’ fault that we are here in 2008, is it?
A  I did not put my children in it, did I?

Q  You say, and I want to understand this, that you thought the treatment was more effective. Is it your evidence---
A  No, I did not say I think it was more effective.

Q  “I feel it must be a necessarily evil as, in my opinion, the process was a lot less stressful in the long run---”

A  I think that sums it up, does it not?

Q  “Treatment being more effective than in a normal incubator.”
A  That is---

Q  Just let me finish my question. You are contrasting the experience that you have had with four babies in normal incubators and the two that you had in CNEP?
A  Right, I will take you through that then. It says here:

“I feel it must be a necessary evil...”

that does not suggest that I think it is absolutely fantastic and wonderful. That is that I have got concerns. I think it is a necessary evil because I am being told that the process is less stressful in the long run, treatment being more effective. I am being told at this particular time that my children are receiving the very best, most effective, proven treatment that there is.

Q  Pause there. I have got a question for you. I want you to be very careful in your next answer because you are on oath. You can see in that document that you use “I”, and you talk about your own “opinion”. Do you stand by that last answer?
A  Yes.

Q  That is your honest evidence, is it?
A  I think so if I am understanding what you are asking me.

Q  You realise that credibility is an issue in this case, do you not? Who is to be believed?
A  I do not see it is down to belief. There is enough documentary evidence to prove whatever, is there not? It is not just a case of, you know, you are lying or she is lying. It does not rely on memory. There is enough factual evidence here. There is enough documentary evidence here to support our case.
Q: I am glad that you feel it is so strong. I must press you on this. Is it your honest evidence that in the comfort of your own home with a neonatal nurse or health visitor, six weeks after the birth of your daughter when you write: “I did find the CNEP tank somewhat restrictive”, so that is a personal view. Yes?
A: Yes.

Q: Then the next sentence you described it as a necessary evil but less stressful in the long run and that that the treatment was more effective, that we are to regard that as something you were told rather than a view you honestly held?
A: It says:

“I feel it must be a necessary evil as, in my opinion, the process was a lot less stressful in the long run, treatment being more effective than in a normal incubator.”

I was describing it as an incubator and a normal incubator does not give any assistance, whereas the CNEP incubator was giving them assistance to breath. That was how it was explained to us. Mary O’Rourke pointed out how we were told about how it would assist their breathing and help them to breathe unaided without IPPV and such like so I think that is summing-up exactly what we were told about it.

Q: I am going to try once more and then I shall sit down, because the Panel have to assess your credibility. Are we to read those two sentences as expressing a personal view that you held at the time or are we to read them as being an interpretation of that which you were brainwashed into? I want you to think about your answer before you give it.
A: It is not as black and white as that, I am sorry.

Q: It appears to be. To the informed reader you are expressing a personal view.
A: It was a personal view based on what I was told at the time and what I believed at the time, yes. That is what I have said, is it not?

MR FORDE: Very well, Mrs Henshall, that is all I have for you.

MS SULLIVAN: I think Mr Forde was going to ask Mr Henshall about.

MR FORDE: No. I was not going to ask her about it. I said the tick indicated there was an information leaflet and I think it is the information leaflet that you find in part from 356 onwards. I will just check. For my learned friend’s benefit it is 356 to 364 available on the ward. 355 is the information leaflet that would have been stapled or clipped to the consent form. By way of example, you would get 354 with 355 in some way attached to it. I hope that makes things clear. Hopefully you will recall the handout tick. I am simply suggesting that the handout is likely to have been that document.

THE CHAIRMAN: Are you happy with that, Ms Sullivan, because that does accord with my recollection as to the way the matter was introduced?

MS SULLIVAN: Yes, I can ask about it in re-examination.
MR FORDE: Let me see if I can just find the nursing note so that we are all orientated.


MR FORDE: I am very grateful to the Legal Assessor. Page 13 behind tab 5 in file 2 can be cross referenced to 356 to 364. Also, sir, I note the time. We have got copies of the maternal morphine prescribing and I probably ought to show it to my learned friend before she re-examines. I wonder whether we could perhaps have five or ten minutes just so that she is satisfied that she has got the documents I have referred to.

THE CHAIRMAN: Yes, certainly, this would be a good point to have the afternoon break, so we will break for quarter of an hour. We will say twenty past three to come back.

MR FORDE: Thank you. If she is happy with them then I am happy for her to speak to Mrs Henshall about these documents as well and then we will have them handed to you.

THE CHAIRMAN: Very well. Subject to anything that arises you have finished now.

MR FORDE: I have finished, sir.

THE CHAIRMAN: Mr Foster?

MR FOSTER: No questions, sir.

THE CHAIRMAN: We will break now until twenty past three and if you have any re-examination, Ms Sullivan, we will commence that when we come back.

(The Panel adjourned for a short time)

MR FORDE: Sir, the position is that Ms Sullivan is happy with the documents going to you but she has pointed out, and I think she is correct, that we may not have got them in strict chronological order because part of the date is missing on the left hand margin, so if she is happy to continue whilst we get the bundle in the right order then I will then tell you when it is ready to be handed to you and she can re-examine upon it if she needs to.

MS SULLIVAN: Sir, can I just say at the outset that I think everyone will find in Panel bundle 1 behind tab 3 (perhaps I could just ask Mrs Henshall to get it for us as well) that your page 394 is just a duplicate of page 393, I think you will find, so can I suggest that everyone takes out 394 and I will give a replacement page. It is not new material because it appears elsewhere in the bundle, so everyone has seen it before, but it is much better that we have the right things in the right places. (Same handed)

Re-examined by MS SULLIVAN

Q Perhaps we could just stay with that same bundle a moment and just go back, please, to page 355. Did you see that particular leaflet at page 355 when either of your children was receiving CNEP treatment?
No, I did not.

Again, turning on to page 356 through until I think 364 did you see that at the time, either in the form of having been given it or seeing it on the ward?

No, I did not. I could not have, because it had not been produced then.

You have been asked a number of questions about whether you had assistance with your medical terminology that you have obviously acquired over the years and I wanted to ask you this, Mrs Henshall. Could you just indicate for us how it is that you have acquired such knowledge, from what sources?

Basically, as I have said before, from everything these doctors have written. I carry around a medical dictionary, the Roberton book that I have said. There is another more recent model book that we have got at home and I check that against the internet and people I speak to. From a number of sources really, but mainly just from study.

Over how many years have you been studying this subject matter?

From when we found out that our children were part of the research project and we acquired our medical records, since then really.

Let me deal with that then next. When was it that you discovered that either of your children had been part of a trial as opposed to receiving CNEP treatment?

Not until Dr Newell indicated it to us and then I still did not believe him and I finally had confirmation off Mr Hughes from the Ethics Committee of North Staffs.

I wonder whether you could just turn in the bundle of statements. This is not something that the Panel have, but you have it in front of you, Mrs Henshall. It is a file with various different statements in it that have been made by you and your husband. Have you got that one to hand? It probably is just blank on the front as opposed to having a number.

Yes.

Mr Forde asked you about one particular document. I wonder if you would just turn, please, to page 275. That is the numbers in the middle at the bottom. Do you see there at paragraph 29 he referred you to the first sentence in which you say that you found out some information in February 1997 which suggested that Patients 7 and 6 had been part of a clinical trial and I wanted to ask you this. You say there that you found out information in February 1997. Can you help as to when it was that you first contacted the local ethics committee in order to try and find out information?

I would have to look back at the letter. I have got a letter which I wrote to Viv Hughes when I found out who it was and it would have been that time. I have got a letter with me.

I wonder if you would just turn on in this bundle to page 527. This is I think page 527. This is I think an e-mail sent by your husband to someone at the General Medical Council, would that be right?

Yes.

Can I ask you just to look at the penultimate paragraph on page 527 and just to the first couple of sentences of that paragraph.
A  Yes.

Q  It refers to a date of 20 March 1996. Do you see that, the second paragraph from the bottom? It starts about there being a few interesting coincidences and then refers to the date of 20 March 1996.
A  Yes.

B  A reference to this being when you and your husband visited the hospital for the first time unannounced to speak with the Ethics Committee.
A  Yes.

Q  Does that assist you at all in recollecting when it was you first approached the Ethics Committee?
A  Yes. That says 20/3 which is ---

Q  20 March 1996.
A  So it would have been just before that.

Q  Of course, we know that Dr Newell reported in December 1995 and you said that you had a meeting with him some time after his report to raise the various issues that you had with him.
A  Yes.

Q  When you refer at the page we were looking at earlier, page 275, to 1997, what were you discovering at that stage? Is the date there correct?
A  I am not sure really, because I would have thought that that was supposed to be '96. I would have thought that was more likely to be '96 and certainly I did say March/April time I thought, so I would have thought that was '96.

D  Basically how soon was it after speaking to Dr Newell that you made your first approach to the Ethics Committee?
A  It was not long after, it was not too long after.

Q  I wonder if you would just take up file 1 again behind tab 3 and go to page 390. You indicated in the course of questioning that as far as that signature was concerned that is on the form there, Mrs Henshall, that that is probably your signature.
A  It does look like my signature and I did go and visit to see the original and that as well looked like my signature.

Q  Just to be clear, what is your recollection about giving consent in relation to Patient 6?
A  I gave verbal consent to allow her to go into a CNEP tank, not for a trial. I did not have any conversation about any trial or research or whether there would be any different treatments or whatever. I knew before I went down on to the unit that she was going to be in CNEP and that is what I understood that they were asking me.

Q  As far as your recollection is concerned about the time when your daughter was named (this is Patient 6) because you indicated why it was you thought you had not named her until later, can I just ask you, please, to look at page 373 in that same bundle.
A  Yes.

Q  We see right at the bottom of the page there (this is part of the CNEP log of the randomisation of the babies into the trial) is an entry on 14 December 1992 timed at 2330 and then the name of the caller is given there which I am not entirely sure what that says there and then the patient’s name is indicated there as F/I which I assume means female infant and then a reference to your maiden name, albeit spelt incorrectly.

A  Yes.

Q  Staying with Patient 6 again, you indicated to us that after you gave birth to Patient 6 and you had a spinal anaesthetic for Patient 6 that your recollection was that your blood pressure had dropped and your temperature …

A  Yes.

Q  … and that you needed to be wrapped in a blanket of some sort.

A  Like a foil space blanket thing.

Q  Again, if you just have a look at this, please, and there are copies of this for everyone as well, these are again part of your obstetric notes which everyone has seen. (Same handed) Perhaps it is better to let everyone have a copy and then we can follow it.

THE CHAIRMAN:  This document is separate from any of the bundles?

MS SULLIVAN:  It is, sir, yes, so it should have a C number.

THE CHAIRMAN:  C12.

MS SULLIVAN:  Thank you.

Q  I think everyone now has a copy, so just so we can see what it is, Mrs Henshall, first of all it is a chart for your preoperative care in December of 1992, so in relation to Patient 6, and if we look in the box in the bottom left-hand corner we see reference to your temperature there, your pulse and also your blood pressure, so we see temperature is I think 36.6, pulse 102, blood pressure 150/70.  I think that is all we need concern ourselves with at the moment.

Then if we turn over the page we see your postoperative condition and if we look now at the second box down under “Maintaining safety” there, it makes a reference to your blood pressure, which is now 115/50, your temperature is described as low and there is reference to a space blanket.  Then that seems to be on admission.

Then on transfer again a reference to blood pressure of 110/55, pulse 71, temperature 36.  Does that accord with your recollection of your condition postoperatively?

A  Yes, it does.

Q  I just wanted to ask you a couple of matters in relation to Patient 7.  I wonder if you could just take up again the files, file 2 behind tab, page 22.  Do you recall you were asked a number of questions in relation to Patient 7 about whether Dr Spencer had spoken just to you or to you and your husband and you indicated that your recollection was that
he had just spoken to you?
A Yes, that is right.

Q On a particular occasion?
A Yes.

Q Could I ask you, please, to look on that page, page 22, at the long note that appears for the first entry at 7.00 am and go right down to where it says “NB” in the margin and refers to the prognosis for Patient 7. Do you see that? “Prognosis for Patient 7 at present is not good?”
A Yes.

Q Then it indicates thereafter, “Mother s/b Dr Spencer” and patient 7’s problems explained. Does that accord with your recollection of speaking certainly on an occasion alone with Dr Spencer about Patient 7?
A Yes, it does.

Q When you were being asked questions about what the CNEP tanks looked like for your daughters and what was there by way of information, and I know you say there was no information, you made reference to photographic evidence, but do you have photographic evidence in relation to your own children of what the CNEP tanks looked like at the time when they were in them in February and December of 1992?
A No, I do not. I was never given any photographs of my baby in CNEP.

Q I know we have a photograph of Patient 7 in the medical records which you will have seen but that does not really show the position?
A No.

MS SULLIVAN: I have no further questions. If you would just wait there, the Panel may have some for you.

THE CHAIRMAN: Mrs Henshall, that completes the questions that counsel have for you and the Panel members have an opportunity now to ask questions if they have any. As you have been giving evidence for quite a long time, I am going to take an opportunity with the Panel just to consider whether we have any questions and the ambit of them, which will not take very long but I am going to do that now, so if I could ask everyone to leave and the Panel will stay here and we will call you all back when we are ready.

STRANGERS THEN, BY DIRECTION FROM THE CHAIR, WITHDREW

STRANGERS HAVING BEEN READMITTED

MR FORDE: Sir, I do not know whether you will need these documents for your questions but I now have in order – and the Tippexing bottom right is because we have changed the pagination – first of all the note relating to Patient 7, or this witness’s pregnancy of Patient 7, the 1710 note about a request for morphine and then the other pages that I referred to. I have given Ms Sullivan and her instructing solicitor copies. Could I ask for those – I think D7?
THE CHAIRMAN: Yes, D7, Mr Forde, thank you. *(Same handed to the Panel)*

Thank you all for that opportunity. Mrs Henshall, the purpose of Panel questions is seeking any areas of clarification out of the evidence that you have given and, of course, you have been asked and answered a lot of questions first by Ms Sullivan, then by Miss O’Rourke and Mr Forde and then again by Ms Sullivan, so it was useful for us before embarking on our questions just to reflect on whether there were specific areas of clarification which we thought we wanted to raise with you and we have done that.

There is a matter which Dr Sheldon, who is the medical member of the Panel, would like to ask you about.

**Questioned by THE PANEL**

DR SHELDON: Good afternoon, Mrs Henshall. I am a general practitioner. There was one area that we would like clarification on. We are talking about Patient 6. In file 2 behind tab 5 are her medical records. We spent some time looking at page 61, which was the nursing record shortly after she was born. My first question is, in the days before she was born did you and your husband talk about what sort of names you might give? First of all, did you know it was going to be a girl or not?

A No, we did not know.

Q What sort of discussion did you have about what sort of names you might give?

A Actually I wanted to call her Allison at first and then for some reason that just changed. It was Allison and I think for the boy it was going to be something like William John. We did discuss names but it was basically on the day where I decided I wanted to call her Zoe. I do not know where it came from.

Q On the day when she was born or before she was born?

A No, on the day she was born. When she was actually born.

Q When she was actually born?

A Yes. You know how you look at a baby and you have got a name in your head and it just does not fit.

Q Carl was there at that time, was he?

A Yes.

Q Did you have any discussion with him at that point about a name?

A He just said no way, he did not like that name. I think probably because it was the first time he was hearing it and he thought where had that come from. He did not like it.

Q Did you discuss other names?

A I think at the time he was probably insisting on Allison because that is what we had chosen, but I did not like that and I said she did not look like that and so I do not think it went on for very long; obviously I was not very well.

Q The delivery was at seven o’clock, was it not?

A 6.30- ish, I think, or five-to seven. Between then, yes.
Q So by four hours later that same evening had you had further discussions with Carl about what name you were going to call her?
A No, I think he probably had left the hospital by then.

Q Did you have any discussion with the nursing staff, because they must have said to you, “What are you going to call her?” What did you say to them?
A They did keep asking me, what shall we call this baby, but at the time I was still insistent that it should be Zoe.

Q When did you change your mind on that?
A When he came back the following day and we discussed it again.

Q So it was on 15 December?
A Yes.

Q You discussed with Carl again. At what sort of time was that?
A I am not really sure. I suppose when he came to visit – it would have been in the morning.

Q So by the time of 3.30 when the record is here, mum and dad have visited and then the correct name is put?
A Yes.

Q You would have said to the nursing staff at that stage?
A Yes, probably. Yes.

Q You had never seen the nursing records, of course, when you were a patient? It is not something that you would have seen?
A No, not really, no.

Q So we need to ask any questions of the nursing staff as to what their normal practice was. The slight query I have is that you feel that someone went back and corrected particularly that top entry on that page, the one dated the 14th at 2230 hrs because by then you did not know what the name was?
A No. It is the only explanation I have got, really, because, like I say, all the other documentation, all the doctor’s notes, everything else refers to her as Girl Davies and I have noted that in places they do go back and cross out the “Girl” and then write her name on top and things like that once they know, but---

Q I suppose my confusion is that under problem number 2 on that page the name [Patient 6] is spelt correctly but then on 3 the name of [Patient 6] again appears but spelt in the incorrect version?
A Yes, it is very strange being it has been written by the same person, by the looks of it.

Q It would be strange if they were going back to change something that they would not change all of them. Do you see what I mean?
A Yes I do, unless it was just missed or something. I do not know.
A

Q  As far as you are concerned it was during the morning of the 15th that you finally decided on the name and that spelling?
A  Yes, it was the next time I saw Carl.

Q  And you communicated that to the nurses during the morning of the 15th?
A  Yes, when we went down to visit her.

B

DR SHELDON: Thank you very much.

THE CHAIRMAN: That was the only point of clarification. Are there any questions arising out of Dr Sheldon’s questions?

Further cross-examined by MISS O’ROURKE

C

Q  Because it is not just as Dr Sheldon put to you page 61. If you would like to look at 171 and 173 in the same file. Do you have page 171?
A  171, yes.

Q  I think we see it is the same nurse as has written the note at page 61 and you will see she has written on the left-hand side:

“Patient 6 needs to be with her family but is being looked after on the unit until she is well enough.”

You will see it is signed on the 14th of the 12th 1992, the same signature, and you will see there is a name there. Under the next column across “To breathe” and again the name, “needs some extra oxygen to remain pink” and then the name again, “needs headbox, oxygen, needs to be nursed, CNEP” and you will see again the next signed date 14.12.92 and then in the last column over, “To feed” - again she has written the name albeit spelt incorrectly – “by mouth” and signed it again. If you look on 173, the immediate left-hand side, “[Name] needs help to maintain her temperature so is being nursed in an incubator.” Again signed and dated by the same person, 14.12.92.

When she went back or somebody went back to amend these records, to write in the name of the patient, they will have done it not just in two places on page 61 and they will have done it five times on pages 171 and 173. Quite an elaborate going through the notes and correcting them in several different places, as opposed to the alternative which is Patient 6 had her name before 11.30 that night when she was randomised into CNEP?
A  I do not believe she did.

G

Q  I am sorry?
A  She did not.

Q  The more likely option, really, in terms of possibilities, other than an elaborate conspiracy involving a nurse who would have nothing to hide, is that you are telling a lie and you have made up the name story in order to back yourself up when the press found out that you had signed the consent form? That is the truth of it, is it not?
A  No.

H

D11/92
MISS O'ROURKE: Thank you.

THE CHAIRMAN: Mrs Henshall, that completes your evidence. Thank you very much for the assistance you have given over the past few days. I imagine you will be staying in the hearing as you are free to do but you are released from that chair now.

(The witness withdrew)

THE CHAIRMAN: Ms Sullivan, given the time my inclination is to rise now and resume tomorrow morning with your next witness.

MS SULLIVAN: Yes, sir, that seems a good idea. It is late for someone to be starting to give their evidence.

THE CHAIRMAN: I take it that will be Mr Henshall?

MS SULLIVAN: It will be Mr Henshall, it will, yes.

THE CHAIRMAN: We will start with Mr Henshall tomorrow at 9.30 and then may be during the course of tomorrow or Thursday you and your colleagues will be in a position to give us an indication to see where we are in terms of timetabling?

MS SULLIVAN: We are liaising about the likely progress.

THE CHAIRMAN: Thank you all very much. We will meet again tomorrow at 9.30

(The Panel adjourned until 9.30 a.m. on Wednesday, 28 May 2008)
GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council’s Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988)

On:
Wednesday, 28 May 2008

Held at:
St James’s Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

STEPHEN ANDREW SPENCER BM BS 1976 University of Nottingham
Registration No: 2305893

DAVID PATRICK SOUTHALL MRCS 1971 Royal College of Surgeons of England
Registration No: 1491739

MARTIN PHILIP SAMUELS MB BS 1981 University of London
Registration No: 2732178

(Day Twelve)

Panel Members:
Mr D Kyle (Chairman)
Mrs V Brickley
Mrs S Hollingworth
Dr T Okitikpi
Dr M Sheldon
Mr A Forrest (Legal Assessor)

MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hempsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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FITNESS TO PRACTISE

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THE CHAIRMAN: Good morning, everyone. We continue with the case of Dr Spencer, Dr Southall and Dr Samuels. Ms Sullivan.

MS SULLIVAN: Sir, could I call Mr Henshall, please?

CARL HENSHALL, affirmed
Examined by MS SULLIVAN

Q Mr Henshall, would you start by giving the Panel your full names, please?
A It is Carl Henshall.

Q As we know, you are the husband of the previous witness?
A That is right.

Q When was it that you got married? Which year was it?
A It was 1994.

Q We know as well that you were, along with your wife, also a complainant ... in this case?
A That is right.

Q And that you are the father of the two children about whom your wife was speaking over the last few days, Patients 7 and 6?
A That is right, yes.

Q You will find, Mr Henshall, still there in front of you, just a little reminder of which baby is which because it is difficult sometimes to remember the numbering, I know.
A That is right. I made sure it was still here.

Q I am going to ask you first of all, please, about Patient 7 because she was born first, as we know, on 12 February of 1992?
A That is right.

Q She died on 14 February 1992?
A That is right.

Q I do not need to go into as much detail with you about what happened initially because, of course, we have heard that from your wife. Just to summarise, I think it is the case that you took your wife to the hospital to North Staffordshire on 7 February ... of 1992?
A Yes.

Q I think actually I think she went in the ambulance and I followed her because her waters were going. I think we called an ambulance. She went up there, I followed her in the car because obviously we had other children we had to think of, so I had to get someone to come and care for them. It did not actually take myself but I followed on as
quickly as I could, yes.

Q Fine. She was then admitted?
A She was admitted, yes.

Q You, of course, as you said, you had the other children to look after?
A That is right.

Q So you left your wife in hospital but visited regularly, I am sure?
A As often as I could actually, whenever visiting hours and babysitters would allow it, yes.

Q Then I think on the evening of 11 February, did your wife telephone you and say that she was going to have a Caesarean section early the next morning, the 12th?
A She did, yes, yes.

Q Did she indicate why that was?
A I think the doctors were more worried that infection may be getting to the unborn baby and it would be detrimental, so I think they just decided better out than in at that stage.

Q Did you go to the hospital the next morning, 12 February?
A I did, yes. Because she had telephoned me the night before I was able to arrange child care for first thing, so I was able to get up there for I think nine o’clock that morning.

Q But I think she was not taken to theatre straightaway; you were with her a while?
A No, I think they had an emergency in that morning, so I think Deb then was put like second on the list. I think it was more 10.30, quarter-to eleven, something like that, when she actually went for the operation.

Q We know that on this occasion she had a general anaesthetic?
A That is right, she did, yes.

Q But you were not present therefore whilst this was happening?
A Not in the theatre, no. They have what they call a fathers’ room, which is half way - the theatre is one end of the corridor and the neonatal unit is the other end of the corridor and about half way along there is a room what is called the fathers’ room where you can go and wait until everything has happened.

Q So you waited there until Patient 7 was born?
A That is right, yes.

Q Did you see her being taken from the theatre? That is Patient 7.
A I did, yes, because, like I have just said, the theatre is at one end of the corridor and the neonatal unit is the other, so they had to wheel her past me. She was in a normal style incubator then with the tube in her throat, yes.

Q Yes. Had you seen a tube in the throat of any of your previous babies?
A No, I had not, no.

Q Did you go with the incubator to the neonatal unit?
A I followed very closely behind, yes. I think I might have waited a minute or two just for someone to come out of the theatre to tell me that everything was okay with Deb. I followed down very, very closely behind the incubator.

B Q Where did you spend the next couple of hours?
A When I first got to the neonatal unit, there was a young Asian female doctor who was trying to put a cannula in Patient 7’s arm. She had had two attempts and had not done it. I think I was making her a bit nervous standing there so she asked me to leave, so I popped back to the recovery and basically spent the next couple of hours doing just that, in between Deb and the recovery and Patient 7 on the neonatal unit, just basically pottering about and feeling like a spare part, to be honest.

C Q How was your wife at that time when you were going to the recovery room?
A She is normally very sleepy after any anaesthetic and surgery. She had had a child previously by Caesarean section. She becomes very sleepy and every now and then she will sort of come around, speak to you and then she will fall into sleep again. There is not much I could actually - that is why I said I felt like a spare part; there was nothing I could do on the neonatal unit for Patient 7, nothing really I could do for my wife in the recovery. I felt I wanted to be there at the time. I needed to be there.

D Q Yes. Then after spending some time in the recovery room, did you accompany your wife to the ward?
A I did on that occasion, yes. I was able to go up on to the ward and see where she was and make sure she was settled before and I decided I needed to go home.

E Q So you decided you needed to go home?
A Yes, I think by that stage then I was starting to think about the other children. I had left them for quite a while that morning. In fact, someone else had taken them to school that morning for me, the ones that were of school age. I thought, you know, there was nothing else I could do at the hospital. Debs just needed to sleep off the effects of the anaesthetic and the painkillers. Patient 7, as far as I was concerned, was just stable in an incubator; there was nothing I could do there. I thought my place then was back at home with the other children, just let them know what had happened.

F Q Approximately what time of day would you have gone home? If you cannot say ---
A I cannot say with any certainty. I have a feeling it was after lunch, mid-afternoon, because I was thinking I need to be back before the children come home from school.

G Q On your way out of the hospital, did you go to the neonatal unit?
A I did. I was not going to and I did not plan to. By then I realised I had left my coat hanging up there, so I popped into pick up my coat. While I was there I just went and - basically to just let the nurses know that Debs was now up on the ward and that I was going home and that I was basically about if they needed anything and just basically to say, you know, “Is everything okay?”

H D12/3
Q Yes, and how was Patient 7 at that stage?
A The only nurse that was around her incubator was - I think, like I have described many times, it was a mature looking nurse who was wearing a blue uniform with like a white check pattern on it. She had a red belt and red epaulettes. That stuck out in my head because all the other nurses on the unit were wearing like a loose-fitting blue smock. I automatically thought because this nurse was wearing a different uniform, she was more mature looking, that she was a more senior nurse.

Q When you say more mature looking, what sort of age are we talking about?
A I would say she was probably in her 40s. That sort of age. I just basically said to her, “I am going home now. My wife has gone up on the ward. Is everything okay?” Her basic comments were, “Your daughter is quite stable at the moment. She has not passed” - I cannot remember whether she said “much” or “any urine” at that stage, but there was obviously a concern about she had not passed any urine.

Q Were they checking that to ---
A Yes, they were. What they had done, they would just lay her on a nappy. They had not fastened the nappy, they just lay her on the nappy and they were observing for any signs of urine. They also said that at nappy change time - because they changed the nappy periodically whether they were soiled or not - at nappy change time they would actually weigh the nappy to see if there was any signs of any urine that they could not see by eye.

Q You described how Patient 7 was in an ordinary incubator. Was that the case when you saw her now when you left?
A Yes, she was still in the same - well, not the same incubator, sorry, the same type of - obviously she was in a transport incubator, what they brought her down from the theatres in, but it was the same sort of type where her whole body was inside and she still had a tube in her mouth.

Q Yes, I was going to ask you that. She was still being ventilated via the tube?
A Yes.

Q Was anything said to you about the type of ventilation that was being used?
A That was the other concern that this nurse raised, that they were worried about the type of ventilation she was on. Bear in mind this is the first one of our children that had been ventilated. I was completely ignorant as to what the problems were.

Q What did she say to you were the concerns about that type of ventilation?
A She told me that what they were actually doing is they have a pipe down my daughter’s throat which in itself could cause damage to the windpipe. Then they were blowing air into her lungs under pressure, which could have caused damage to her lungs and it could even overinflate and rupture the lungs. She then went on to say, “We have this new kind of gentler treatment that we are trialling” - sorry, not trialling - “that we are using on the unit. It works by just a negative pressure around your daughter and helps them breathe more naturally. Would you like your daughter to have this treatment?” I mean, of course I said, “Yes, I do, yes”.
Q Where had this treatment come from? Did she tell you?
A I think America was mentioned. I think America was mentioned. I could not say with any certainty whether at that time America was mentioned or whether that was something I heard subsequently. I will not speculate that she mentioned America at that time, but it could have been.

Q You said you agreed to your daughter receiving this treatment?
A I agreed to her receiving the treatment, yes.

Q Were you asked to sign anything, Mr Henshall?
A I was asked to sign - the nurse just said, “You just have to sign - there is a form saying that she can have this treatment”. She went away for a couple of seconds. She came back with the form, as I remember it, on a clipboard. She just said, “You need to sign your name - print your name and sign your name here”, which I did. I did not read the form because I did not think I needed to. She just told me what I was signing for, so I signed it. I mean, I was quite anxious at that time as well to get home, as you can imagine. There was lots of things going through my mind about the children at home, Deb up on the ward, Patient 7. So if you have just been given an explanation by, you know, a member of staff on a neonatal unit, you basically accept what they tell you.

Q I am just going to ask you, please, just to take up file 2 a moment. It says “Panel Bundle File 2” on the outside, hopefully. Someone will help you. Just turn to page 19; that is the numbers in the top right hand corner.
A Yes.

Q We see there a consent form which bears your name, Mr Henshall?
A Yes.

Q Dated 12 February 1992?
A Yes.

Q Is that your signature?
A That is my signature, yes. The printed name is my writing. I do not think any of the other writing on that form is mine.

Q No. We see reference to the name of a doctor below ...
A Yes.

Q ... your name and signature. Do you see that?
A I do see their signature, yes.

Q Have you any recollection of a doctor?
A No. As I said, the only doctor I saw on that unit at that time was the young Asian doctor who was trying to put the cannula in Patient 7’s arm. That was straight after birth.

Q Was that a male or female doctor?
A That was a female.

Q You said that you did not read anything that you were shown on the clipboard?
A No, I did not, no.

Q Were you given any documentation to keep about the treatment that Patient 7 was going to receive?
A Nothing at all, nothing at all. Just a very brief explanation, as I have already said, and then asked to sign this form obviously. I could not even tell you - you know, if you had just shown me the form and said, “Did you see this form?” I would have said no, but that is my signature, so obviously it was this form I was being asked to sign.

B Q Were you at any later stage given or shown any documentation about the treatment?
A Nothing at all, no.

C Q You mentioned earlier the fact of a trial. Were you actually aware at that stage that your daughter was part of a trial?
A No, not at all. It was never ever made - well, I was going to say never ever made clear; it was never even mentioned that this was part of a trial.

Q Were you told anything about the treatment, any risks or anything of that nature?
A No, only about the ventilation she was on when she came out of the theatre. That was the only risks we were told about, the risks of lung damage and windpipe damage. As far as the CNEP was concerned, we were - there was nothing - it was kinder gentler treatment.

D Q Yes, now you have indicated that you married your wife in 1994?
A 1994, yes.

E Q Did you in fact have parental responsibility strictly for your daughter?
A Well, at that time I had no idea whether I did or not. Obviously subsequently, no, I did not have parental responsibility for my daughter at that time, no.

Q As far as your understanding was concerned, what treatment were you expecting your daughter to receive after the conversation you had had with the nurse?
A I was expecting to receive the CNEP treatment because that was what was I was being asked to sign for.

F Q Had you any idea that there was a randomisation process involved?
A No idea, no.

Q How long did you spend there before you went home in the neonatal unit in the process of signing the form and hearing about the treatment?
A I would say - sorry, was this from when I come to get my coat and before ---

G Q Yes.
A I was quite anxious to get home, so I would say I was there for five minutes maximum. I had literally gone into pick up my coat and say goodbye. I was quite anxious to get back home then, so it was very quick.

H Q Was that what you then did? Go back home to your other children?
A Went straight home after that, yes.

Q Did you come back to the hospital at all that day? So we are still on 12 February.

A I think I came back in the evening then towards - I think I left Deb for the whole day to recover and came back in the evening just for a visit, yes.

B Q When you came back in the evening, did you and your wife go and see Patient 7?  A Yes, we would have done, yes.

Q When you went to see her that evening, what sort of ventilation was she receiving?

A She was on the CNEP tank then, which - I mean, it was quite a shock to see her come from the theatre on the ventilation because that was something totally different, but then to see her on the ventilation and in the CNEP tank as well, it was just really - I was taken aback by the whole - that is the feeling I remember, being in there looking, just being sort of stopped in my track, “What is this?”

Q Just describe how it looked to you.

A You could hardly see her in it, to be honest. There was like portholes all over it and then her head was one end and if you wanted to look at her body you had to come to the other end of the tank. It just looked really, really horrific. You know, but that is just impressions. I am not saying, you know, because it looked horrific it is horrific. It is just the impression you had at the time.

Q Yes, but could you see her head properly?

A There was lots of equipment around and her head was just sticking out one end and the tubes are there, she had the bonnet on. It was very difficult to - you know, seeing what she looked like, things like that.

Q Were any concerns expressed about her condition by the nursing staff at that stage that evening?

A I think again they were just concerned she had not passed much urine. That seemed to be the only concern, really. I think everything else was, you know, as they would expect of a child of this prematurity, just that she had not passed much urine.

Q No doubt you went home that evening again after that visit?

A Yes.

Q Did you visit Patient 7 the next day? So we are now 13 February.

A Yes, I would have visited the next day.

Q Do you remember who you went with the next day?

A I think it was Deb’s mum that came with me that day. She was quite excited about seeing the new baby. I think it was Deb’s mum with me that day.

Q When you went to the hospital, where was your wife?

A She was down on the unit, on the neonatal unit. She spent most of the time on the neonatal unit with all the children, to be honest.
Q Is that why you went there?
A Yes. I think when we got to reception - I cannot say what I did, honestly, what I did. I usually went to reception first, see if Deb was on the ward, rather than go up the stairs then come all the way back down, because the neonatal unit is on the ground floor. I tended to head for the neonatal unit to check she was not on the ward first.

Q When you got to the neonatal unit, how was Patient 7 doing that day, the 13th?
A Again, very much the same. There was not a great deal of concern about her. They were slightly more concerned then because she had not passed much urine, but they said sometimes it can take a couple of days for babies’ kidneys to kick in. It was something to keep an eye on. The nappy was left open. All the time she was in there, the nappy was left open, looking for signs of urine all the time.

Q Was your wife concerned about her?
A I think she was a bit anxious because she was obviously quite a bit sicker than the previous premature children we had had. I think she was a little bit anxious, but not overly anxious. She was not - she was not - it is difficult to describe how she was, obviously. Obviously she has got concerns. She got concerns because Patient 7, like I said, was a little bit sicker than our previous premature babies who had done really well, but she was not overly concerned. She had a lot of confidence in what the staff were doing at the time.

Q Did you stay long that day, the 13th?
A I could not tell you exactly for how long I stayed. I tended to, you know, get as much visits in as I could around looking after the children at home. So I would - the morning visiting times, particularly for Deb up on the ward we did it, but we had open access to the neonatal unit, so could just tend to get there after I dropped the kids off at school, spend an hour or two with Deb and get back home to the children and then, hopefully if I got a babysitter, come back at night-time.

Q Now the next day, so by the time we get to 14 February, how concerned were you then about Patient 7?
A I think this is when things did start to deteriorate a bit, and there was a lot more concern around the ward. Deb was a lot more anxious then and a lot more concerned.

Q What did Patient 7 look like at this stage?
A She seemed a little bit jittery, to be honest. It was difficult for me, because I did not have much confidence in my abilities with her, because she was so tiny and I am not the - you know, I am quite clumsy with my hands at times. I have big hands. I am a coal miner, so, you know, I did not tend to have much to do in the way of Patient 7’s care. I tended to leave that up to the nurses and to Deb, who was a lot more confident than me. I tended to stand back and did what I was told, or little things I picked up by myself, but I remember her being jittery. That is what stuck out, because she did not seem to like being touched and things like that.

Q Yes. I think you left in the course of that day, again, to go and look after the other children, Mr Henshall?
A Yes. We had - I mean, at the time, we had - this is February ’92, so we would
A have had a ten-month-old and a two-year-old who had to get - you know, rely on the rest of the family to look after for me while I popped up. I had to keep shooting back home and making sure everything was okay, or taking them from one grandparent to another aunty, and things like that, because I did not really think it was appropriate to take them up to the hospital with me. I may have taken one or two of the older children up on one of the night-times, but the young ones, no.

B By the time we reach the early evening of 14 February, did your wife ask you to come back to the hospital?

A She did. I think I was at my mother’s, who was looking after - probably one of the children. She managed to get in touch with me there. Yeah, she was quite tearful. I think I had not long got to my mother’s, actually, when the phone rang. She was a bit tearful and asked if I could come back.

C Do you know what sort of time that was, approximately? If you do not, do not guess?

A I could not say for definite. You can imagine at that time it was, like, really hectic for me, you know, trying to keep home life as normal as possible for the children when mum is not there, and then, at the same time, I am trying to spend as much time up at the hospital with them as well and Patient 7. The time scale, basically, is bit of a blur to me, to be honest. I just remember I was dotting about here, there, and everywhere, you know, and doing what I could.

D Did you go back to the hospital, given what you were told?

A I did go back to the hospital after Deb had telephoned me. It is a bit off-putting to me. I did go back to the hospital, yes. I remember, when I got to the hospital, there seemed to be a lot of people around Patient 7’s incubator. As I walked into the unit, Deb was crying, and she walked across to me. There was a very large, again, Asian male doctor... (Pause)

E Is it putting you off?

A It is actually, yes.

F Mr Forde, I am sorry, you and Dr Spencer are distracting the witness.

G Well, I find that absolutely incredible. We are whispering. If he is that easily distracted, then I have to say I am extremely surprised. I suspect a point is being made.

H It is not the first time. This has happened on a number of occasions. I know the need to take instructions and I sympathise with that, but the witness does need to be able to concentrate on what he is saying. We all do, really.

MR FORDE: If we had been speaking in the way I am speaking, I could have understood. As I have indicated, we were whispering. If it is impossible for us to have a whispered conversation whilst witnesses are giving evidence because my client is obviously anxious to give me instructions when things are being said that he may not necessarily agree with, then I will just have to ask for an adjournment on every occasion.
THE CHAIRMAN: If you can just keep the distraction to a minimum, because the witness is saying he is distracted. Point or not, if you could just whisper quietly and also not move and gesticulate.

THE WITNESS: I will try to ignore it.

MS SULLIVAN: Yes. We had got you back to the hospital, Mr Henshall?

A Yes.

Q You were describing, I think, how your baby was, Patient 7, at that time.

A Yes. I think I said when I got back on to the unit, Deb was crying. She came across to me. She had been talking to a large Asian male doctor who, I remember, had a goatee beard. He came across within - Deb introduced me as her partner. He gave us a very brief talk about, you know, Patient 7 was not very well at this time. They were quite concerned about her prognosis. He mentioned things like, you know, cerebral palsy. I do not know the exact words he used, but they are the sort of words I picked up. I remember he mentioned cerebral palsy then or other disabilities. Basically, I think the advice was given it may be in the best interest to stop treatment which, at that time was just - you know, I had just come - I had sort of left - the last time I had left the hospital, I was not really leaving with any great concerns. I was only really aware of the kidney problem, and then I am coming back to be basically asked to, you know, switch the life support off for my daughter. You know, to me, you cannot just hit them with that, really, so Deb and I needed to speak about that. I think we decided that we wanted to carry on for the time being.

Q You decided you wanted to carry on with treatment for your daughter.

A Yes.

Q You have talked about speaking to an Asian doctor?

A Yes.

Q Did you speak to any other doctors, do you recall?

A No. None at all, no.

Q Did there come a time that evening when you realised how sick your daughter was?

A Yes. I think it just sort of became, you know, inevitable that she was not going to make it. I think Deb and I then just said, you know, if it is futile, then, you know, what is the point of carrying on?

Q Yes.

A The staff arranged for us to go into the - there is a flat on the neonatal unit where parents can stay overnight. Well, I think the flat there is more for if the father needs to stop overnight, or people from far away, but they arranged for us to go into the flat. They said they would take all the monitoring equipment and everything else off Patient 7, and then they would bring her to us in the flat and we could have a cuddle - at that stage, we had not even had a cuddle. We were not able to get out of the tank or nothing at all.
Q They took her out of the tank and brought her to you?
A Yes, in the flat. They asked us if we wanted to bath her, which we did. I just remember I filled the bath up and tested the temperature of the water and I just looked at Deb and thought what am I doing? That was just the sort of things you do, still being a parent at that time for your child, are you not?

Q Yes. Obviously she died shortly after?
A She died - I think she was certified dead, actually, in the flat. It was a lady Asian doctor who came and listened to her heart rate and said, “There is no heartbeat now,” and certified her dead at that time.

Q Did you understand at that stage why she had died?
A Not really. We were under the impression that it was something to do with infection. We thought, you know, because that seemed to be the reasons the obstetricians were giving full delivery. They were worried about infection given to the baby. We just assumed it was more to do with infection than anything else.

Q We know that no post-mortem was in fact carried out?
A No. We did ask if - because there seemed to be quite a delay in releasing the body for funeral, and so we asked if we could do the post - I think it was actually Deb’s mum who rang up and asked, because she could see how anxious we were getting, but no post-mortem was done, no.

Q That is all I want to ask you about Patient 7.
A Okay.

Q I am now going to turn to Patient 6. We heard from your wife that she wanted to get pregnant again.
A Yes.

Q And that happened. We also heard from her about how the plan was that she would go into hospital so that she could try, if at all possible, to get this baby to full-term.
A That is right, yes.

Q We heard, Mr Henshall, that after 26 weeks, once she got to that stage, she went into hospital for bed rest.
A Yes.

Q And stayed there for, I think, about six weeks?
A Six weeks, yes.

Q Then at 32 weeks, she came home?
A That is right, yes.

Q And we heard about a shopping trip.
A Yes.

Q Just tell us about that, briefly.
A Well, she had been in hospital for six weeks, hardly being allowed to get off the
bed at all. I think the odd trip to the toilet, or a trip for the bath, that was about it. That is all they would let her do. She had come home. It was on the understanding that she was still going to rest and she did, for the whole weekend, rest. On Monday morning, I think one of her sisters - because her sisters lived quite close, they would come up and they would look after the younger children. I said, well, while your sister is here, I will go out and do some shopping. We need some shopping, so I will go out and do that. Deb said she wanted to come with me. We had a bit of a discussion about whether it was right. She was, well, you know, I am only going to be half an hour around the local supermarket, so I should be all right. I think as soon as she had been on her feet for about five or ten minutes, she was saying, “I think I need to go back home now. I think I need to go back home.” That is what we did, that is what we did. I remember saying - when we got home, she was complaining of her back aching and everything, and then she had a show, which I think worried her then. I think she thought, well, I have done so well to get to this stage, I am not going to jeopardise anything now, so I think she sort of - “Look, I am just going to have it checked out,” you know, “make sure everything is okay.”

Q Did you take her to the hospital on this occasion?
A I did on this occasion, yes. One of her sisters was still around, so they were looking after the children, so, yes, I thought it best. She was not complaining. You know, her waters had not gone at this stage. She was only complaining of a bit of backache, things like that, so I thought, yeah, the quickest ease - I will just take her up and then I can be with her.

Q When she did get to the hospital, what was it decided should happen?
A Well, they monitored her for a while and trying to say that she was in labour, and Deb was arguing, saying, “Well,” you know, “I do not feel like I have been in labour. I have been in labour enough times to know when I am in labour.” They were talking about contractions showing on the monitor, but I cannot remember if they actually showed us these contractions and things like that. Deb said she was not in labour and her waters had not gone, or anything like that. I think Deb was of the mind that she wanted to, you know, hang around a bit for a few more weeks.

I remember it was referred to in her obstetric notes, something about a trial of labour, because she had had two Caesareans and Deb was adamant when she got pregnant again she wanted to labour this time, if she could. So it was talked about, a trial of labour, any complications, you know, it would be straight in for a Caesarean. There was lots of discussion about whether it was right to trial her, because I think if you have had Caesareans before, there is a chance that your uterus can rupture if you go into labour. It was not that long after she had had a previous Caesarean, so I do not think the obstetric registrar was too keen on a trial of labour.

He had asked if we wanted our child that night. Well, is that not our decision, really, you know. You know, we cannot make that decision. Then it just sort of got agreed that Deb would have an elective Caesarean, because that was probably in the best interests of her, the best interests of the child and then Deb also said it was in my best interest, because if she had an elective, it could be done with spinal anaesthesia and then I could be in the theatre as well, so it was just sort of - that was the sort of deal that was, you know, brokered out at that time.
Q Ultimately, the decision was that there would be an elective Caesarean with you being present in the theatre?
A That is right, yes.

Q And your daughter, Patient 6, was born on 14 December of 1992.
A Yes.

Q So, Mr Henshall, you were present in theatre, I think, all scrubbed?
A Yes.

Q Although, I think you did have to leave at the very end stages?
A Yes. I was not allowed in at the very start while they set Deb up. Then I was asked to come in when everything was ready. There was a screen up just past Deb’s head, so that I could not actually see - well, suppose so, I could not see what was going on, but I could see over the screen. She was already anaesthetised and everything then, you know, she had the spinal in. I was just sat by her head. I watched Patient 6 be born, basically, basically delivered by Caesarean. I watched them break Deb’s waters and all things like this.

Q Could you see much of Patient 6 when she was born? How did she look?
A Yeah, I saw them pull her out. Yeah, I saw them pull her out. I think she - they clamped her, cut the cord and there was a paediatrician in the theatre who whipped over to the side of the theatre. I could not see what he was doing. Then he just brought her back to us, wrapped in a towel, sort of hung her over us and said, “There you are, you have a little girl,” and then he ran off down the corridor, so - I mean, it was like glimpses, you know. I saw the hands go in, they pulled her out, clamped the cord and then they were off. Off she went, more or less, really. You know, it was - how she looked, I could not really tell you. You know, it was just like a quick glimpse. I did actually manage to see my daughter being born.

Q Was sterilisation discussed at that stage?
A Yes, we discussed this with the consultant obstetrician. Deb said previously that she wanted this to be the last one. Contraception, nothing had worked. She did not want to be in this position in 12 months’ time. He was reluctant to make any specific note for contraception. He said because you have lost a premature baby before, you might change your mind after you have given birth. Deb was adamant on the table. She wanted to be sterilised. I think it was the registrar who had done the caesarean. He asked two or three times, “Are you sure?” “Are you sure?” He fetched a form which Deb signed and then he asked how Deb wanted it done. He said “I can cut and tie the tubes. We can burn ends, or” and there was something else. Deb said “I want you to do all those and send a piece of tube to pathology to make sure it has fallopian tube in. I do not want any more children now”. When we got the reports back they had done everything. I was sat there while they were doing the sterilisation and I remember them burning the ends of the tubes because I could hear the noise and see the smoke coming off.

Q How was your wife at that stage, when signing that form?
A When she signed that form she made her point clear that she wanted to be sterilised and she was okay. It was afterwards. I do not know whether it was because she had had an anaesthetic and it was a spinal anaesthetic, but she started to talk about feeling
sick. I wondered, and I mentioned it because I could see over the screen and was telling her things that were going on. Obviously she could not feel pain and did not know what was going on. I could see Debs and was describing what was being done. I probably should not have done that and I wondered if that was what was making her feel sick. I stopped doing that. Then the anaesthetist said “You should not be feeling sick” and gave her an injection of something and said that should stop her feeling sick. Then she started feeling cold and her blood pressure dropped. I think the anaesthetist made a comment about how low the blood pressure was. That he did not believe that reading. She would have been dead if that was true. After that I had to leave because they were finishing off and taking the screens off and I was asked to go to the fathers’ room and wait.

Q You did that. When you next saw your wife after she left the theatre, how was she at that stage?

A She was quite, if I say poorly that gives the wrong impression. They were obviously very concerned about her. Deb was lying there as if asleep, but they were obviously very concerned about her. There was a nurse with her who would not leave her at all. She had covers over her and then I think they put a space blanket on her. They were constantly monitoring her blood pressure. You could obviously tell that the nurse was really concerned about her condition. They kept her on the recovery ward for longer than I remember with the previous two children. I do not remember, she seemed to be a lot longer. They were quite concerned. I do not know why they would keep her in the recovery a bit longer because of her blood pressure and temperature, whether it is because they have better resuscitation facilities there than on the ward… But they were quite concerned, the staff were. Deb was just Deb after surgery. She was asleep. She would wake up now and again and say something and then go again. (Mr Forde and client left room)

MS SULLIVAN: I do not know if you want me to pause for a moment or carry on?

THE CHAIRMAN: I assume that if Mr Forde wishes to go out with his client then he can do so. Please carry on.

MS SULLIVAN: (To the witness) Having seen how your wife was in the recovery room, did you go and see Patient 6 in the neonatal unit then, Mr Henshall?

A Yes, I did.

Q What sort of incubator was she in?

A Just the normal incubator, the same as everyone else on the unit.

Q Was she in CNEP or anything like that at that stage?

A No, she was just breathing for herself. I could not say for definite whether they were giving extra oxygen to the incubator, but she was breathing by herself. She was obviously a lot bigger than the previous couple of children we had had. She just looked a normal baby. I remember she had lovely big fat cheeks on her as well. That was the first impression I got, these lovely big fat cheeks.

Q Again you have your wife in the recovery unit and Patient 6 in the neonatal unit. Are you going backwards and forwards between the two again?

A Backwards and forwards. I probably spent a bit more time with Deb this time.
because I could sense there was some concern about Deb, and I was probably a bit more worried. After seeing Patient 6 I was probably a bit more worried about Deb than I was about Patient 6. I think I spent a lot more time just in the room with Deb. There did not seem a great deal of point in speaking to her because she was asleep for a long time. Occasionally she would wake up with comments and then be gone again.

Q I was going to ask you to describe her state of consciousness as you were able to observe it?

A I have seen her four times following surgery. At times it is quite comical because I could be stood there talking to the nurse, thinking Debs is asleep and she will just join in the conversation. Then be back asleep again. Sometimes she can remember what she said, sometimes she cannot remember what she said. It is strange. When we spoke with anaesthetists, not necessarily just about Debs - we have obviously had other children who have had to have surgery for different things - Debs made this point clear that there is perhaps something that runs in the family, because her sister and mother have a similar problem. The anaesthetists seem to understand the situation. In fact, we have got one son who is in the armed forces. He has never had surgery but because we have made the Army aware that there may be this condition, the Army understand the condition. They make sure it is on his dog tags that there maybe a reaction to general anaesthetic, there may be a reaction to morphine. As far as I can see, this is a recognised condition.

Q On this occasion with Patient 6, when your wife was eventually taken back from the recovery unit to the ward, did she go on to the main part of the ward?

A On this occasion I did not accompany her to the ward. When they said they were taking her to the ward I was happy then because I could see there was an improvement. Her temperature had obviously come up by then. Although she was still cold there was an improvement. It was quite late at night, so I just decided I was going to go. They would take her up on to the ward. I was happy they would settle her on the ward.

Q Did you see her on the ward?

A Not that night, it was the next day. She was in a room, not a six-bedded room, just her in a room.

Q You see her the next day having gone home to deal with the family at home. When did you go back, the morning or later?

A It would have been mid morning because again I had to get the children to school and arrange for somebody to look after the younger children while I was up there.

Q Where do you go, the ward or the neonatal unit?

A Again I would probably ask if Debs was up on the ward or down on the neonatal unit. I could not say with any certainty where she was on that occasion. Knowing Debs she was probably on the neonatal unit.

Q When you go there, how is Patient 6? How is she being treated when you see her on this day, 15 December

A She was on CNEP then. I suppose it was not so surprising to me, the sight of it because we had had a previous child on it. She was on the CNEP again. I am thinking we are back to the same where we are looking here for a head and here for a body and not being able to see a great deal.
Q Were you approached in relation to consent for Patient 6?
A No, I was not.

Q Were you told at any stage that this treatment was part of a trial?
A No.

Q Do you stay at the hospital on that day, on 15, or do you go back home again?
A I cannot say with any certainty. My normal pattern would be to stay at the hospital as much as possible, but then I would have to go home because there are other children at home. I have to still take care of those. I cannot rely totally on friends and family to have them all the time. I would be darting back and forwards to the hospital at every opportunity.

Q Did there come a stage when your daughter, Patient 6, was not just on CNEP but was being ventilated as well?
A Yes, there was. Particularly for Deb that was really upsetting considering what happened to Patient 7 before. I was worried at the time but I was trying to be comforting for Deb.

Q Where you made aware why it was necessary for her to be on IPPV as well?
A I think the only recollection I have is that she had started tiring so they thought she needed extra help and were going to give her the ventilation.

Q What was her colour like at this time?
A I always remember her being quite dark in colour. When I went back particularly on the morning of the 15 she looked quite dark, but I did not really question it. I knew Deb was a bit concerned about her colour. I thought she looked a bit dark. I was not as experienced as Deb with premature babies and did not really have much to compare her with because you are not really allowed to go and look at other children on the children. I thought she was a bit dark. Obviously Deb was concerned about her colour.

Q We know she was ventilated for a while. When you went back the next day was she being positively ventilated then or was she back in the CNEP?
A No, when I went back the next day Deb was down on the unit. As I walked on the unit Debs greeted me with a big smile and saying, she is not on the ventilator, little money key. “Oh, great, does that mean she is improving?” “Put it this way, she does not need the ventilation now. She is doing okay.” I remember Deb was quite upbeat at that time. I think Deb then pointed out the colour and I said “Yes she does look a bit pink and not so dark now”.

Q And she reminded on CNEP for a number of days?
A Yes, I think about three or four days.

Q In terms of naming Patient 6, when, according to your recollection, did you agree on the name for her that we see in her notes?
A It was the next day on the 15. We had not really - we had two girls previously. We got names for girls and for boys ready for those and then we had sort of run out of girls’ names that we could both agree on. So we never settled on a name for a girl. If it
was a boy I remember I had a nickname Billy. It was a reference to some television programme. So I always said if we have a boy can we call him Billy. So Deb agreed William. She said that I could call him Billy if I wanted. So we had a name for a boy, but we never settled on a name for a girl. Even in the theatre they were asking us what names have you got. We said “Billy if a boy but do not know if it is a girl.” Deb said “I like Alison or Zoë” I said that I did not like either of those names, so we never settled on a name. We said we would wait until after and then see. Then obviously Deb was not capable of discussing names until the next day. That is when we discussed it. Obviously she must have sat by the cot side before I got there and came up with a name, what Patient 6 is called now. When she mentioned it I thought yes, I quite like that name. When she mentioned the name Zoë I just thought the name was a bit harsh. When she said Patient 6’s name I thought it was a nice name. It seemed to suit, it was a nice soft name and seemed to suit her. I thought I like that. Then Deb cannot have anything in the conventional way, so she insisted on the “F”. We have a couple of kids who have their names spelt in the non conventional way.

Q She remained on CNEP for a number of days. Did you care for her during that time? You have described how your hands were a bit big for the tank?
A Yes, because she was a larger baby I did help up a bit. The nurses were not always too keen because the portholes had cuffs around them to keep the negative pressure when you hands are in there. Because my wrists are a lot bigger than Debs, they were worried I might stretch the cuffs and then Debs would not be able to keep a negative seal. I did yes. I was encouraged to more by Debs. She said “You need to”. It was nice to be able to take part in the care of my daughter at that time because I had not been able to with Patient 7.

Q We know that Patient 6 was having difficulty with feeding?
A Yes.

Q And that she had a tube?
A Yes.

Q I think you were taught how to use that, you and your wife?
A Yes, we were taught how to check the tube was in the right place. You put like a little syringe, draw a slight bit of liquid out of the stomach and test that that was acidic, so you would definitely know the tube was going into the stomach. Then how to hold - you have a syringe with expressed breast milk. Debs was very keen on the children having breast milk. You would put in a syringe and take out the stopper and then allow it to run in. We did that. Debs obviously is a lot more experienced than I was with premature babies and I think they went on to teach Debs how to pass the tube itself. That was normally up to the nurses. We were just told you must check before every feed that the tube is still in the stomach and Debs was taught how to pass the tube as well.

Q Once Patient 6 was discharged home you had visits from health visitors as well?
A Yes, she was discharged and still being tube fed. We had regular visits from the community neonatal midwife. I do not know her exact title but Sister Halfpenny.

Q We know there were a number of appointments after Patient 6 had been discharged from hospital to see how she was developing and for the doctors to see how
she was developing. There were appointments at three-month intervals?
A Yes, there was. I remember the follow-up appointments. Because not long after, I say not long after it was probably four or five months after Patient 6’s birth that Debs went back to work because she was getting too anxious about Patient 6 not attempting to do anything. She wondered if her being a bit over anxious was contributing to that. She was expecting probably too much. So she went back to work and I took on the responsibility of bringing up the children. There was an appointment at three months which Debs took her to. I think that was with a female doctor. I definitely remember taking Patient 6 to two appointments with Dr Morgan. Then there was the final appointment Deb took her to with Dr Morgan where the first reference to any problems, neurological brain bleeds, on the unit was referred to. Although we may have had to cancel or rearrange some appointments we did attend the right amount of post-natal appointments.

Q Your recollection is three, six, nine and 12 month appointments?
A Around about that. The six and nine months ones might not have been spot on. I remember that we had to rearrange some. I remember on one occasion I think I was up the hospital on three occasions in two days when Patient 6 had to see the eye surgeon. We have got another son who is diabetic, and his appointment fell on either that day or the next day and then Patient 6 had a post-natal appointment on one of the same days as well, so it was quite a hectic couple of days for me that was.

Q Can you remember when the first mention of cerebral palsy was made and by whom?
A After the sort of twelve month appointment where the first reference to brain bleeds was made, it was decided to - I think the wording as Deb said was, “We will get the team into you”, which is about the child development team, and we had an appointment with a Dr Mali, who did an assessment. It was Deb that took Patient 6’s assessment and she said, “Yes, there is definitely a disability there. Call it cerebral palsy if you like”. Then she arranged follow-up physiotherapy and for us to attend the child development centre and things like that.

Q I am going to take you forward now, Mr Henshall, if you do not mind, to the time when you see Dr Newell. Do you remember that?
A Yes.

Q Do you remember when that was?
A I know we had had his report and I think his report we got just before Christmas time in probably about 1995, I think. I think 1995 is the date on the report. We got it just after ---

Q That is right, December 1995 was the date.
A Yes, and I think it was just before Christmas time. So although we had a quick - I imagine in a household with so many children, Christmas time, build to Christmas time was really hectic. Although we read his report, we would not really have taken much of it or done much with it at that time. We knew that there was the offer of going to meet Dr Newell as well. We did not really do much with the report until then. I remember it was still cold when we went to see him so it was probably towards the end of the winter,
probably February time I think when we probably actually went to see him, perhaps.
I could not say with any definite - I just remember it was cold still.

Q  So that would have been in the early part of 2006 after the report ---
A  1996.

Q  I am sorry, you are quite right, 1996, that you would have met with Dr Newell?
A  Yes.

Q  When was it that you became aware for the first time that your daughters had been
part of a trial?
A  It was just in discussions with Dr Newell. I mean, at that time we had no real
knowledge of - Deb was an experienced mother of premature babies and knew her way
around a neonatal unit. As to the actual technicalities of prematurity and neonatal care,
we were really ignorant of that, so Dr Newell explained one or two things to us, such as
things like blood gas results and the significance of those and things like that. He went
through that with us and things like base excess. We were debating points with him as
best as we could at that time. I think he said, “What did you expect from an experimental
procedure?” to which me and Deb both looked at one another and Deb said, “What do
you mean, experimental? My daughter has had the best treatment”, because that is what
we were led to believe at the time. That was the first time - and then he went into
explanations about how a trial should run, how a randomised trial should have run, which
is what he is trying to explain this was, you know, which at the time was just completely
alien to us. We had no idea what he was talking about. He did his best to explain it to us
but ...

Q  Had you any awareness of Ethics Committees until then?
A  No idea. Not at all, no.

Q  As part of his explanation, were you made aware of trials being approved by
Ethics Committees?
A  He did tell us that we should contact the local research Ethics Committee because
they should be able to give us more information on the trial. I think that is what we
eventually did. It might have been some time afterwards because I think our main thing
then was to, hang on, we need to look more into our daughter’s care and such.

Q  Yes. You say you did in due course contact the Ethics Committee?
A  Yes.

Q  Did the Ethics Committee send you some information which they said you should
have received as part of the trial?
A  They did, yes, they did. They sent us a patient information leaflet which they said
was the one that they had for this trial and this is the one we should have seen at the time.

Q  Yes, I am just going to ask you, if you put file bundle 2 to one side, just take up
bundle 1 a moment. If you go behind tab 3, Mr Henshall, pages 336 and 337, you can
just start with 337 a moment.
A  Yes.
Q Was that what you were sent by the Ethics Committee?
A That is what we were sent by the Ethics Committee, yes.

Q If you turn back to page 336, have you ever seen *that* at any stage whilst your daughters were in CNEP?
A No.

Q Again, if I can ask you to turn on, please, to page 341, in the top right-hand corner ...
A Yes.

Q ... that is said to be a negative pressure trial information booklet for parents and it goes on until page 364. Did you ever see *that* at any stage whilst your daughters ---
A No, we did not and we could not have done because we have since found out that that was not produced until certainly the end of ‘92/beginning of ‘93.

Q Did you at any stage meet with any of the doctors here about your daughter’s care, with Dr Southall or Dr Spencer?
A Following the - yes, we have met with Dr Spencer. We went and met him in his office. That was after we had - I think it was after we met with Dr Newell and after we had done some research ourselves, you know. We had a couple of appointments which we turned down because we just did not feel in a position to go and speak to him at that time, but we did subsequently go and see him, yes.

Q Can you remember what he said to you at that stage?
A He just thought that Patient 6’s neonatal care had been uneventful, the blood gases were not particularly significant; he had seen a lot worse than that. We had quite a debate with him and kept referring to the book we had at the time. Eventually he just said he did not think we were getting anywhere, he did not see the point. We should have had an appointment with Dr Samuels the following day but we were told that that was cancelled.

Q So you did not meet with Dr Samuels at all ---
A We did not, no.

Q On another occasion you met with Dr Southall?
A That was a lot later, yes. A lot later on, yes.

Q In relation to Patient 6, I just want to ask you this, please, Mr Henshall: in terms of the scans that your daughter had, were you aware of the results of them at the time?
A No, I was not, no. I was like dotting backwards and forwards to the unit and I was not there all the time. I relied on Deb for a lot of that, you know, just to keep our eye on Patient 6 and just report back to me whatever she thought. I was not aware of scans at the time.

Q Not aware of them at all?
A No, I might have been aware that scans had been done, but I cannot particularly say that I knew what the results were and things like that.

Q When you met with Dr Southall at a later stage, did he give you any information
about your daughters?

MR FORDE: Dr Spencer.

MS SULLIVAN: No, Dr Southall. It was Dr Southall. (To the witness) I think you said you had a meeting with Dr Southall?

A The meeting with Dr Southall was - it was when the GMC stopped our case and just before we went to judicial review because there was no complaints pending so he could meet us then, but that was like a lot later. We had got a lot of information by then.

MS SULLIVAN: I have no further questions, but there will be some more for you at some stage.

THE CHAIRMAN: Miss O’Rourke, are you going first?

MISS O’ROURKE: Sir, I am going first.

THE CHAIRMAN: This could be a convenient moment to have a morning break if that would suit you.

MISS O’ROURKE: Sir, I can assure you my cross-examination is not going to be 20 minutes or half an hour, it is going to be a number of hours.

THE CHAIRMAN: Yes, I thought that was probably the case. We will take a quarter of an hour break now and come back at five-to eleven.

(The Panel adjourned for a short time)

THE CHAIRMAN: Welcome back, everybody. Miss O’Rourke.

Cross-examined by MISS O’ROURKE

Q Mr Henshall, can I deal with one of the last things that you said just before the break? You said about the meeting with Professor Southall, as he then was, “It was just before we went to judicial review”. That is what you said. Is that right?

A That is right, yes.

Q Can I just ask you about the “we”? In fact, the position is you did not participate in the judicial review, as I recall it. The proceedings were brought on behalf of your wife alone. Was there a reason for that?

A It was - you would have to ask our solicitor at the time. I think they just thought it was easier to put in Deb’s name rather than mine or a joint one.

Q Was it anything to do with the legal aid position?

A What do you mean the legal aid position? In what respect?

Q Deborah got legal aid for the judicial review proceedings. In other words, she did not fund it, you did not fund it.

A Yes.
A

Q Would it have been anything to do with the legal aid position that the proceedings were taken out in her name rather than yours?
A No, I am just as entitled to legal aid as she is.

Q I was just going to ask you about that. You do not currently work. Is that right?
A I am not currently employed. I would not say I do not work.

Q Not currently employed. When were you last employed?

Q That was as a coal miner?
A Coal miner, yes.

B

C

Q You were made redundant, were you?
A Yes, I finished on redundancy/ill health. I had severe chest infections at the time that would not seem to clear up. The pit was closing round about that time so ...

Q So when you took objection to me saying you do not work, you said, “I do work but I am not in employment”, what work do you do?
A I am a full-time carer for my daughter. It is a 24 hours, seven days a week job, basically.

Q Which daughter, Patient 6?
A Patient 6, yes.

Q But is not Patient 6 in full-time schooling from, what, 8.30 in the morning until four in the afternoon?
A Yes, and during which time I am still on-call for her. If there are any problems in the school, I am still on-call for her.

Q I think your wife described herself as a full-time carer too?
A We have another son who is diabetic. He is what is called brittle diabetes. She is down as his carer because, again, she has to be on-call for him.

D

E

F

Q Right, and he is in his 20s, is he?
A Yes, he is in his 20s, but he is still brittle diabetic. That is not discriminated by age.

Q Just on that, we have another son - in fact, you are the father of Patient 6 and Patient 7 and one other girl?
A Yes, that is right, yes.

Q Your wife has five other sons by some other father?
A Yes.

G

H

Q In fact, as I understand it, you and your wife have been together - when you were asked a question by Ms Sullivan about when you married, you in fact became your wife’s boyfriend in mid-1990, shortly after she had split from her then husband?
A  That is right, yes.

Q  Indeed, when your first child together was born, she was in fact still married? She is described in the medical notes as married but separated?
A  Probably, yes, probably.

B  You sat here I think throughout every word of your wife’s evidence?
A  Yes, I would imagine so, yes.

Q  She gave evidence in the witness box for three full days?
A  Yes.

Q  Did you disagree with anything that she told the Panel?
A  Not particularly disagree, no, no. I thought ---

Q  Did she get anything wrong? Did she answer any of the questions wrongly from your perspective in terms of how you remember it or in terms of explanations she gave?
A  I would not say she answered anything wrongly. She answered them as honestly as she could from how she remembers it.

C  From your own recollection, your own involvement and the many discussions you have had with her over a period of time, did she say anything that you thought, “No, that is not quite right. I might need to correct it”?
A  Not really, no. I think, as I said, on the neonatal unit Deb was there a lot more than me. She had a lot more awareness of what was going on. Particularly with Patient 7 I took a complete back seat because I had no confidence in handling or anything like that. So, no, why would I question her recollection? A lot of things she was talking about I would not have been there for anyway.

D  I am giving you the opportunity, Mr Henshall, should you wish it, to take it, to dissociate yourself from some of what she said. I am taking from your answers that you do not dissociate yourself from any of the answers that she gave on evidence?
A  Such as? Which answers?

E  I am going to come in due course to the specifics of them. You will recall, because you sat here, I accused her of lying about the consent form. I accused her of lying about when Baby 6 was named. I accused her of lying in respect of what she alleges about documents in other matters. You, presumably, are adopting her evidence because you have told us you cannot specifically recall anything you disagree with or anything that you would like to change?
A  That is fair, yes.

Q  Is that right?
A  Yes.

Q  So if her evidence includes lies and the Panel should ultimately find they are lies, you are adopting the lies as well, are you?
A  I am adopting the lies?
Q: Yes.
A: That is only your assumption that they are lies.

Q: I have made the point to her that she is telling lies ---
A: That is ---

Q: When we get to half-time in this case I will be making a submission to the Panel, so that you know it and have an opportunity now to comment. I will be saying to the Panel that your wife is a liar and I will be asking them, at half-time submission, to find there is no what is called sufficient or credible evidence to take this case forward to part two because it is founded on the evidence of someone who lied on oath. Now, I am giving you the opportunity to dissociate yourself with what she said and, finally, after all these years, come clean. I am taking it you do not want the opportunity?
A: I do not want to dissociate myself with anything she said and I do not think I need to come clean, as you put it.

Q: Let us go and examine it and see what you have to say. You are one of the complainants in this case?
A: I am, yes.

Q: This case has generated a load of documents? Yes?
A: Yes.

Q: Have you read all the documents in the case?
A: I have probably read them at some time, yes.

Q: You have read all the witness statements of all the witnesses that ---
A: Oh, sorry, sorry. I thought you meant the documentation that we generated. No, we have not seen all of the witness statements that have been put on behalf of the prosecution. No, not at this stage.

Q: Why not?
A: Because I think we have been open to criticism that we could have tailored our evidence to fit in what those people were saying, or we could have influenced those people. Until we had actually given evidence, I think our legal team has taken the view that perhaps, for the reasons I have outlined, so we are not open to criticism, it is probably best we do not see all those witness statements at this time.

Q: Which ones have you seen?
A: All we have seen is the one from Professor Hutton, Professor Stimmler, and Dr Nicholson, and I think a statement from Kate Palmer.

Q: Right, so you have not seen the witness statement from Claire Stanley?
A: We have seen ---

Q: She calls herself Claire Newell now, I think.
A: We have seen a witness statement from Claire Newell in the past. I cannot remember if our legal team showed us a new - I cannot say whether - I am not sure they have.
Q Did you not want to see it? Did you not say it is important we see what she is saying, because, after all, Deb is going to have to give evidence about the same thing, about the consent form?
A We knew what she was going to say, anyway, because we have seen a previous statement that she has made. So if she has made a new one, it is obviously going to say the same as the one before, so I think we knew what it was going to say, anyway.

Q How do you know what it is going to say, because somebody might change their evidence? They might have a chance to reflect upon it and say something different, so how do you know?
A We did not know for any doubt, or any certainty. We thought we knew what it was going to say.

Q You thought you knew what it was going to say. Then should you not say to Ms Morris, “Can I see the statement of Claire Stanley-Newell so that we see what she is going to say about this consent form, because this is obviously going to be a very significant issue in this case?”
A Well, perhaps I could, but Ms Morris and Ms Sullivan will probably have their reasons why they did not want us to see that. They have showed us the things they want us to see.

Q Do you want to think carefully about that answer? Your wife, of course, gave the same answer. She said, “We did not see any of the witness statements.” Then when we got further in her cross-examination, she repeatedly quoted me from the statement of Claire Stanley.
A I do not ---

Q She kept saying: but Claire Stanley said this and this...
A Yes, because I told her.

Q ...it was from her witness statement.
A I told her we had seen a previous statement of Claire Stanley’s.

Q Not, it was not the previous statement. She quoted from the current statement.
A Well, I cannot say with any certainty I have seen the current one or the previous one.

Q Let us ask you about a much more and pertinent statement relevant to you. Have you seen the draft witness statement served on us in this case in respect of Dr Aru, or Dr Arumugam?
A No.

Q You have not?
A No.

Q You have not seen what Dr Arumugam says about taking consent from you?
A No.
Q And you did not ask to see that?
A I did know he was making a statement. I was not told he was making a statement.

Q You were not told that Dr Aru was on the list?
A No.

Q Do not worry, it is another statement I have seen.
A Sorry, another statement from someone else who says they have taken consent from me? Because you said ---

Q I have seen a statement from someone who has taken consent from you?
A But not Dr Arumugam, who was purported to take consent from me?

Q Yes?
A Sorry. Sorry. You have just said you have seen a statement of somebody who has taken a ---

Q Not a GMC prosecution statement.
A You have just said you have seen a statement off somebody who purports to have taken consent off me, but it is not Dr Arumugam.

Q No, sorry, it is.
A Oh, so it is a defence statement?

Q Yes.
A Right. Okay.

Q We have seen lots of letters written by you and your wife. I think you have seen the file...
A Yes.

Q ...it is thick, A4 file full of statements, starting to write letters in about 1997 and writing letters right through for a period of ten years. Yes?
A Probably, yeah.

Q Most of those letters have your name and your wife’s name on them. Very few of them are written with one name only?
A Yes.

Q Who wrote the letters?
A Probably I have wrote the majority. I would not say - I would not know how much of the majority, but we have both written them and we have both put our names on because we will tend to read one another - not always, we will tend to read what one another has written, agree with it or say, “Perhaps you should change something.”

Q And make changes, as appropriate. In other words, if one writes it and the other looks at it, somebody will make a change if they think it is appropriate?
A Yes. It is more to do with how it reads, because you might write something and think it reads one way and someone else might read it and think, well, actually, it reads
another way, and make sure you get the point across that you want to make.

Q So if both your names go on the bottom of it, it means you are both happy with the contents of that letter?
A If both of us has signed it, probably, yes. I mean, not necessarily. Again, you know, it depends what the circumstances are. I might say to Deb, “I have written this letter. Do you want to sign?” She might just sign it, say, you know, having confidence in what I have written and I might do the same with her. Just because we both got names on it or both signed does not necessarily mean we have both read it.

Q What, you would not read a letter that is going to go to the chief executive of the Trust or to the General Medical Council, or to your MP? You would not read it before signing it?
A Probably, yeah, but I cannot guarantee I have read everything that Deb has written, and she probably would not guarantee she has read everything I have written.

Q But you would want to read it, because it is important and you are putting your name to it.
A I probably would read it.

Q You would appreciate the significance, because over that ten-year period, you have written letters to some fairly important people? Yes?
A Yes.

Q You have written to, I think, three secretaries of state for health?
A Yes.

Q Frank Dobson, Alan Milburn. You have written to Baroness Hayman as well, I think.
A Yes.

Q You have written to a number of MPs, Llin Golding, now Baroness Golding, being one.
A Yes.

Q You have written to the General Medical Council?
A Yes.

Q The UKCC, as was?
A Yes.

Q You have written letters to The Nursing Times, the editor of the BMJ? Yes?
A Yes, yes.

Q You have written a number of letters that you know were going to go into print or you hoped would go into print, in particular, in the BMJ...
A Yes.

Q ...and various other newspapers, even The Sentinel? Yes?
A Yes, yes.

Q You would want to be sure that what you have written is accurate, because it has been disseminated to important people who may act upon it?
A Yeah, yeah. In that respect, yeah.

Q So if there was something wrong, you would have said to Deb, “That is a mistake. I better correct it”?  
A We would probably comment on one another’s letters, yes. Do not necessarily get the facts wrong, which is just like I said before, sometimes how you word them, it comes across ---

Q It looks like most of them have come off a word processor, so if they have come off a word processor, it is easy to correct them if somebody reads them and says there is something wrong there?
A Yes.

Q Now, I want to ask you about civil litigation and proceedings. You first instructed solicitors in 1994.
A That is right, yes.

Q They were a local form in Stoke James A Evans?
A That is right, yes.

Q As I understand it, contact has been made with them by Ms Morris, from Eversheds, to find out - or with some solicitors who have acted on your behalf to find out if we could have available, for example, the instruction letter to Dr Newell?
A Yeah.

Q And whether we could have material that would have been sent to Dr Newell with the instruction letter? Yes?
A Yes.

Q Was that contact made by Ms Morris or was that made by you and Deb?
A It was made by me. Ms Morris asked if I could do it, it would probably be quicker.

Q Who did you contact?
A I contacted James A Evans, spoke to the secretary there. I went through - I got the case reference number. I gave her that. I told her that - I think there were three specific things that we needed. She called me back, probably half an hour, three-quarters of an hour later and said they had looked for it, and it had been destroyed. It had been sent to Birmingham and destroyed.

Q The position is, of course, James A Evans were your solicitors for a period of three years. You then sacked them as your solicitors in 1997, did you not?
A Well, we moved solicitors. I think sacking is a bit harsh.

Q I think there is an article in one of the papers somewhere, I am sure I can put my
hands on it, that says you were thoroughly dissatisfied with the service they were giving you, so you moved solicitors and you went to Challinors Lyon Clarke?
A That is right, yes.

Q I think I have seen some correspondence between those solicitors, saying, we were dissatisfied with what you were doing?
A Yes.

Q You moved solicitors because you did not think they were getting it right, they were not advancing the claim on your behalf?
A I think one of the problems I had with James Evans is he was more or less a single practice. We did not - we could not always contact him when we felt we needed to. We did not think - we had gone to James Evans originally because we thought that, one, you had to go to solicitors to get hold of your medical records at that time, but, two, we had seen him in the local press and on the television, because there had been some cancer case that he had headed as a multi-party action, so it was just a name we knew, so we went to James Evans for that reason.

Q When you moved solicitors, did not all the papers move from James A Evans to the new solicitors? Did you get all the documents and have the Legal Aid certificate transferred and the documents transferred?
A I have no idea what, because we just instructed Challinors to take on our case and they do all the contact with James Evans. As to what papers moved, I have no idea.

Q Have you called Challinors to ask them if they have the documents and indeed the papers? Have you called them to ask them if they have got the letter of instruction to Dr Newell?
A I have not, no. No.

Q You then, I think your wife said, went from Challinors to Russell Jones & Walker.
A We moved with the solicitor, moved from ---

Q Moved with the solicitor.
A Yes.

Q Then the same solicitor moved again to Irwin Mitchell.
A Well, one of the solicitors moved to Irwin Mitchell. We went to Irwin Mitchell for the judicial review proceedings, not the ---

Q Were Irwin Mitchell ever instructed in the civil proceedings?
A Not on our behalf, no.

Q When was the last time a firm of solicitors was instructed in this civil proceedings? Was that Russell Jones & Walker?
A That would be Russell Jones & Walker.

Q Have you contacted Russell Jones & Walker to ask them if they have the instructions to Dr Newell among the documentation?
A No, I have not.
Q You have not. Now, when each of these solicitors in turn was running the litigation on your behalf, you were presumably getting copies of some of the documents?

A Some of the documents, yes.

Q It appears from Dr Newell’s report that your wife made a witness statement that was provided to him.

A Yes, she did. Yes.

Q She presumably would have been sent a copy of that witness statement by the solicitors to check and sign before it was sent off to Dr Newell?

A I have no idea she was sent at all. She went to his offices and read it and signed it.

Q There was not a copy given to you?

A Well - I mean, as you can see, we have kept all the paperwork that we have ever been given and that we have not got, so ---

Q Well, that is what I was going to ask you because I have watched you now for four or five days trailing in and out of here with two big suitcases full of stuff, that I am sure is not your clothing and personal hygiene items, but is more likely documents. Yes?

A That is right, yes.

Q Okay. Do you have, among those documents, documents relating to the civil litigation?

A There is solicitors’ letters, yes.

Q You see, none of that has ever been disclosed to us. I do not know whether you are going to claim legal professional privilege for it. If you are, then tell us, and I will respond by saying, “What have you got to hide?”

A I am quite sure that the letters between solicitors was disallowed to the PPC, because I am sure it is in the bundles that we received back.

Q There are some letters that we have seen that relate to solicitors. We have also seen, obviously, Dr Newell’s report, and we have seen some other material, but what I am asking you is this: what we do not appear to have seen, or someone will tell me I am wrong and I have overlooked it, is the witness statement that Dr Newell very clearly had from your wife in order to comment, as he does, including, as we know, he comments in the report about the CNEP trial.

A Well, we obviously have not been given a copy of that, then otherwise we would still have it.

Q Why do you say that?

A Because we would...

Q Have you trawled through your.

A ...still have it.
A Q Have you trawled through your two suitcases to see what other documentation you have from the civil proceedings?
A Sorry. Say that again, please.

Q Have you trawled through your two suitcases to see what other documentation you have from the civil proceedings?
A We have looked - I was asked by Ms Morris if we did have that statement and we did have anything to do with the Legal Aid. I looked through all the documentation that we have, both in our suitcase and at home, and we have got nothing. Then when I have contacted James Evans, they do not have it; it has been destroyed. So I do not know what more I can do personally.

Q Call Russell Jones & Walker.
A I can do that if you want me to. I can try and contact - make contact with them.

Q Let me ask you this: you say that Irwin Mitchell were never instructed on civil proceedings on behalf of Patient 6. Is that right?
A Not Irwin Mitchell on behalf of Patient 6, no.

Q The last time solicitors acted on behalf of Patient 6 for potential legal proceedings was Russell Jones & Walker?
A Russell Jones & Walker, yes.

Q What time did they stop acting for you and Irwin Mitchell started acting for you? 2004, something like that?
A Irwin Mitchell were first approached when our case was first thrown out the GMC. We went to ask advice on judicial review to Irwin Mitchell’s, but then GMC reopened the case when they found the 600 papers, so that would be the first time we approached Irwin Mitchell’s.

Q What I am trying to find out is when is the last time that somebody did any work on a file that related to the civil proceedings, in other words some lawyer? Would that be Russell Jones & Walker?
A That would be Russell Jones & Walker, yes.

Q What date would that be?
A When they ---

Q 2002, 2003?
A Yeah, probably something around that time.

Q Then it is likely they are going to have the documents, because solicitors have rules that oblige them to hold documents for a period of about seven years.
A Okay.

Q Let me ask you this then: you had a Legal Aid certificate to investigate a claim against the Trust? Yes.
A We have had several, yeah.
Q  You have had several. Do you have one right now?
A  A Legal Aid certificate to investigate?

Q  A claim for Patient 6...
A  No.

Q  ...against the Trust?
A  Not ---

Q  When is the last time you had one?
A  Well, that would be the same time again, with Russell Jones & Walker.

Q  2001, 2002?
A  Yes.

Q  You have seen Dr Newell’s report. Have you had other experts’ reports prepared in the context of the civil litigation and the several Legal Aid certificates that you have had?
A  Yeah, there has been two others, perhaps three.

Q  Who are they? Do you want to give us the names of the people?
A  Am I ---

Q  No reason not to give us the names.
A  All right. Okay, if there is no reason not to, I just did not know if I was going to breach some sort of confidentiality. It was a Dr Michael Weindling, who was a neonatal expert. There was a Dr Lewis Rosenbloom, who was a...

Q  Paediatric neurologist.
A  ...paediatric neurologist, and I think they also consulted - but I are not sure if he ever put a written report through - there was a paediatric neurologist up at Liverpool Hospital, his name I cannot ---

Q  Lewis Rosenbloom lives in Liverpool.
A  Yeah. It was the neuroradiologist that...

Q  Neuroradiologist ---
A  ...she works with, yeah. I cannot think of his name off the top of my head.

Q  We will probably come up with it on this side of the room fairly shortly. Have you got copies of those reports?
A  Yes, they should be in the bundles somewhere. Yeah, yeah.

Q  So you have probably got them in those two suitcases in the back of the room?
A  Probably not. Probably at home.

Q  You can bring them from home tomorrow, if need be?
A  I would think so, yeah.
A: Now, I am guessing that none of those people in any way supported a claim on behalf of Patient 6 and that is why your Legal Aid certificate was ultimately discharged. Is that right?
A: Ultimately, yeah. They could not time the actual event. That was the trouble they had. They could not time the event because there was not enough head scans to actually make a definitive timing.

B: I am not going to agree with that, that it is nothing to do with that. I am going to suggest to you that a number of them probably said to you the damage may well have been caused in utero.
A: What they could not ---
B: Before 32 weeks.
A: What they could not say is whether it was caused in utero or post-natally. They could not time the event.
B: Indeed.
A: You know, the civil action is on probabilities, so they could not come up with a probability, either way.

D: That is fine. Why do you not come clean, tell The National Press, The Observer, The Independent, Daily Mail, The Sentinel and Stoke, that you currently have - and let us deal with them in turn, the following: firstly, no Legal Aid to bring any proceedings on behalf of Patient 6. Why do you not tell them that?
A: I think we have told them that.
B: Oh, have you? Where? I have not seen it.
A: Because they have not reported it, does not mean we have not told them.
B: Why do you not tell them that you have got no solicitors or barristers supporting any claim?
A: We probably have told them, but again, it is not - I cannot tell them, “You will write this in your paper.” That is up to them what they write.
B: Why do you not tell them that you have no paediatric expert support, whether it be paediatric neurologist or paediatrician in support of a claim?
A: Well, that all goes in hand in hand with saying we have not got any civil action, which we have told the press, when they have asked us to send to them. The fact they have not reported is their prerogative.
B: Why do you not tell the press in an open statement, or do you want to do it now, insofar as the press are interested in reporting what is being said ---
A: Well, I think I have just done it. I think I have just said that we have not got the civil action.

Q: Let us just reel it off to make sure they do not miss it: that you have no Legal Aid to support a civil claim; no legal support from barristers or solicitors confident in the field; no paediatric expert evidence, and, as a consequence, no sustainable claim that Patient 6 was brain-damaged as a result of CNEP. All of those are true, are they not?
A I do not think we have ever said she was brain-damaged as a result of CNEP per se. I think we have said that it is part of being the trial that we think has caused her damage.

Q I am going to take you, in due course, to where you have continued to make statements to the press and we will just see what you have said. I want to ask about Patient 7 in the same vein.

A Okay.

Q You have got no supportive expert evidence that Patient 7’s death was in any way caused or indeed contributed to by CNEP or indeed by any negligence.

A I do not think we have ever taken out a clinical negligence claim on behalf of Patient 7.

Q I know you have not, but that is not the same as - your wife yesterday sat here and said in answer to a question from Mr Forde that Patient 7 had been murdered by these doctors. Is that your view? I asked you this morning...

A No.

Q ...if you went with her evidence; did you wish to disassociate yourself from any of her remarks? That included not just answers she gave to me, it included answers she gave to Mr Forde and, indeed, to Ms Sullivan. Do you wish to disassociate yourself from that contention?

A I think the word “murder” was probably the wrong word to use. I would say that. It is not the sort of language I would have used. I think she - you know, it was the wrong word to use.

Q What about suffocating your baby?

A Well ---

Q Is that a better word?

A Well, I think for - in the case of baby 6, where there is evidence to show she was left hypoxic for, I think, a period of 15 hours, then the term suffocation is probably a justified one.

Q Right. By David Southall?

A I did not say by David Southall.

Q Did you not? Do you not remember the letter you wrote to the chief executive of the hospital where you said Professor Southall suffocated your baby, because I am going to show it to you in due course?

A I wrote that letter?

Q Yes.

A We levelled that allegation directly at Professor Southall?

Q Absolutely.

A Okay. I will wait to see that letter then.
Q Let me just ask you about David Southall before I move on to some of your other allegations. Let me just deal with the following: firstly, you agree David Southall was not involved in the clinical care of either Patient 6 or Patient 7?
A Not directly, no.

Q Well, not even indirectly, or is your evidence he was indirectly involved?
A Well because he had made some decisions about how the CNEP trial was going to run, which ---

Q Such as?
A Well, I think he was one of the people who come up with the protocol for the use of CNEP and was one of the people who was pushing for the use of CNEP, so I think without that, then she would not have gone on CNEP, so...

Q Is that right.
A ...I think indirectly.

Q Is that right? He was not involved in any clinical decision making of either child going into the tank that would have come about as a result of some clinician talking to you and your wife agreeing. He was not present for any of that?
A He was not present for any of that, no.

Q There is no evidence anywhere that he gave any advice in respect of how to treat them when in CNEP?
A No.

Q There is no evidence he gave any advice as to when they should go in and how long they should stay in and when they should be taken out of the tank?
A No.

Q There is no evidence that he gave any advice to any clinician on any aspect of query of the treatment of any child?
A I could not say that with any certainty. I have seen letters where there is the opportunity to contact either Dr Southall or Dr Samuels for any problems. Whether people contacted I do not know.

Q There is no evidence?
A No, but the opportunity could have been there but I could not see.

Q There is no evidence. In other words this Panel has to decide not on speculation, which you are great at and your wife is even greater at, they have to decide on evidence. There is no evidence that Dr Southall had anything to do with either of your two children?
A No, that is true.

Q Why do you keep telling the media he does? Is it exploitation of his name and his fame?
A I think you are misrepresenting us. We have made it clear that we do not particularly hold Dr Southall clinically responsible for our children. What the press
choose ---

Q Where have you made it clear because I have not seen it?
A We made it clear in discussions with the press and discussions with people like the Griffiths inquiry, even the GMC.

Q Could you show me something, because I would love to see that, where you have made it clear?
A To whom?

Q The GMC, the Griffiths inquiry or to any of the press. I would love to see some letters saying that Professor Southall has not got responsibility here and we are pretty upset that his name has been abused by the press. I would like to see you writing to the press and saying sorry we need to correct this, you mentioning Professor Southall, that in fact he was never involved with our children?
A We have made it clear to the press.

Q Is that right?
A Yes.

Q They have ignored you?
A Yes, and they will carry on ignoring us. I think only yesterday we were told by a press officer that they will only cover this hearing as long as either my wife, myself or Dr Southall are giving evidence because that is all they are interested in. That is the press.

Q Does that concern you, that you are being used to get at David Southall when it is not justified?
A It depends on whether you say it is justified. I do not like the fact it is all concentrated on Dr Southall throughout the press. I do not think that is right, no.

Q We will look in due course at some of what you said to the press and some of what you wrote in particular about Dr Southall. Let us go back to civil claims. On what you say we should not therefore have read in the press from about 2002 or 2003 about the fact that you are going to bring a multi-million pound claim on behalf of Patient 6?
A I could not say for definite that that is when our civil litigation ended. What the press choose to print after that... You are insinuating that we have control over exactly what the press print. As you and your client will rightly know, you do not. The press print what they want.

Q You can now confirm that all civil litigation is at an end and so the statement by your wife about waiting for Patient 6 herself to be of age and claim when she is old enough to understand, is simply not right. You hit a dead end, a brick wall, the claim is dead in the water and is not going to be resurrected?
A That is not my choice. My daughter is coming to an age where she can make decisions for herself. If she decides she wants to resurrect a complaint for civil litigation that is her prerogative. If she wants to do that I would support her in doing that.

Q She will hit the same brick wall. She will find that the experts do not support it and the legal aid will not waste any more money on it?
A That is as may be, or the evidence will come along that can prove one way or the other. You cannot speculate on that. That will be her prerogative, her right.

Q What evidence?
A I said some evidence may come along, I did not say there is evidence coming along. That will be her prerogative, her right if she chooses to do that.

Q On a question I asked you earlier about work and employment and whatever else, you have put in what must be thousands of hours into writing the letters you have done?
A Probably.

Q And attending meetings?
A Probably.

Q And you went to meet some of the Bristol families and you have been at public meetings with other parents here, involved in CNEP?
A We have had meetings with other parents on CNEP.

Q You went with one mother - I can write her name down on a piece of paper to protect her confidentiality - to the hospital to look at her records for her child?
A Which parent? I have been...

Q I will write it down on a piece of paper. (Same handed)
A Yes, I did. Yes.

Q You did. So in other words, you have not just investigated Patient 6's - I do not think there is any problem with the Panel seeing it, I think that it is best we do not say it in public as I do not know what that mother thinks about her child being mentioned. She initially was a complainant to the GMC but her complaint was screened out.
A It was screened out.

Q You have involved yourself and given up time to follow up not just her, I think you accompanied some other parent or got involved in letter writing for some other parents. You describe yourself in one of the letters as campaign coordinator?
A Yes.

Q So you have told us about your obligations as a full-time carer for your daughter, but you have had the time on your hands to get involved in running a campaign that has included you giving interviews on TV, on radio, to the press, posing for photographs and generating a file full of letters?
A Yes.

Q And getting involved in other people’s and other parent's issues?
A Yes.

Q And involved in other issues. I think you were involved in the covert video surveillance issues on Professor Southall?
A No.
Q: Did you receive and send emails to Brian Morgan on such matters?
A: We received them off Brian Morgan. We did not do anything with it. We did not sent anything back apart from Brian, we are not interested. That might have been an email back.

Q: What about Penny Mellor?
A: What about Penny Mellor?

Q: Have you ever met her?
A: I met her on one occasion and that was at this building at a previous hearing to Dr Southall’s work. The reason we came to that, it was the day the decision was being read out. At the time we were taking judicial review proceedings and we thought it was important that we find out as soon as possible what the decision was going to be because that affected our judicial review.

Q: Have you communicated with her?
A: Not really no. She telephones us. She sends us emails, but we try not to have much to do with her, no.

Q: She knew you had approached the Coroner in Stoke. How would she know that?
A: It probably came out in the press.

Q: No, because you told her?
A: It probably came out in the press or somebody else might have told her. I do not know.

Q: I will give you an email later to look at and we will see about that. You felt able, willing and you have had the time to do, it to devote hours and hours per week to a campaign against these doctors and in respect of CNEP?
A: To campaign against these doctors?

Q: Yes.
A: I think that we have had a complaint against these doctors. We have campaigned to have CNEP discontinued as a treatment for bronchiolitis. We campaigned on CNEP. I see myself as a campaigner because, as you say, I got involved in lots of issues around health and disability at the time, so I have no problem referring to myself as a campaigner.

Q: You do not think that all that effort you put in could have been used for gainful paid employment?
A: For gainful paid employment? At the same time who would have looked after my daughter? If I am not employed, I can do these things when it suits me.

Q: Ever heard about working from home? All this energy and articulacy that you have devoted to writing lots of letters and making false allegations you might have used it more profitably to earn money to support your family and not be living on benefits?
A: What is wrong with living on benefits? I think that I am doing what is best for my daughter. You cannot just use the comment just because I am on benefits I am not worthy to be here complaining.
Q No, I am not. I am just saying that you spent an awful lot of time and energy making allegations, most of which have had to be withdrawn?
A I do not agree they are all false.

Q Let us run through the serious allegations you have made and see how many you are still sticking with even if the GMC are not. Allegations that these doctors performed or were involved in the performing of unnecessary Caesarean sections in order to produce babies from their trial. Do you maintain that allegation?
A I think that has come from an obstetrician who was looking at the patterns of delivery.

Q You made it. You adopted it. You wrote it in a letter to the GMC. You wrote it in a letter to Matthew Lohn at Field Fisher Waterhouse? Do you stand by it or not?
A I think there is evidence there and it should have been looked into so yes I stand by it.

Q You stand by it. That is a serious allegation you are making. Allegations that these doctors were involved in monetary fraud in respect of this trial?
A I think as we have said, there are lots of letters that refer to who has funded what. When the actual paediatrics paper came out some of those people were not listed there as funders. People who deny funding it are listed there as funders. I think that needs looking at.

Q You maintain that?
A I think there is some sort of monetary fraud or impropriety going on somewhere. It is worth noting that a side trial was the near infrared where I think you will find that the lead professor of biomedical engineering at Keel was jailed for monetary fraud as part of that.

Q Forget them. We are talking about these doctors here?
A I think we alleged monetary fraud in part of the research trials.

Q You alleged monetary fraud in a complaint letter to the GMC naming these three doctors. Are you alleging monetary fraud on the part of David Southall?
A I think it needs looking into.

Q The answer is you are?
A Yes.

Q The further allegation was forging consent forms?
A I think there are consent forms that look as though they have been forged.

Q That is not the question. Listen carefully to the question. They are not tricky. Are you alleging there has been forgerly of consent forms by David Southall?
A I know what you are saying because we had to come to the General Medical Council and name doctors and then put allegations. We thought that there might be some sort of investigation into those allegations. There has not been a lot of investigation up until Miss Morris got involved. It was left to us. Some of those complaints had been
screened out before Miss Morris got involved. We were not in a position to investigate. We were hoping that an investigation would be done by the General Medical Council or other bodies but actually it has not been done. But, there is definitely one consent form I have seen, where the name on it is not one of the parent's names. It is the parent’s surname, it is the wrong initials and it is nothing like her signature. That really should have been investigated.

Q I am concerned about your complaint to the GMC. You know enough because you have been in the process now for eleven years. You first lodged your complaint in April 1997. You take up a lot of GMC lawyers’ time, first with Field Fisher Waterhouse and subsequently at Eversheds, and of course there has been a judicial review. So you know that GMC proceedings involve individual doctors and individual responsibility. There is no such thing as GMC proceedings against the Trust. If you want to bring a civil claim against them that is another matter. I represent one doctor and I am asking you in respect of him and the notice of inquiry for which you were the complainant, are you alleging that David Southall ever forged anything, consent form?

A We cannot say with any certainly what David Southall has ever forged a consent form. What we can say with certainty is that there is at least one consent form that is forged.

Q That is why I said “Please listen to the question”. Nobody else is here. There are three doctors here. There is no corporate body to make an allegation against. You have to make allegations against individuals. I am asking you whether you are standing here and saying that David Southall forged any CNEP consent form.

A I think he could have done.

Q Which one did he forge?

A I am saying that he could have done.

Q How are you saying he could have done?

A There is a forged consent form and there are a number of people who could have forged that consent form. I am not in a position to say which one it is. I have told you why it came out in the allegation because we were hoping that there would be an investigation.

Q Why are you saying it could have been him. You said there are a number of people who could have forged it. Tell us why you are saying he is one of them?

A Because Dr Southall was one of the people who has came out in the media and said that there were consent forms for every child. So if it turns out there is not a consent form for some children then he has a reason why he would want to produce one, as have other people.

Q That is the evidence for forgery against him?

A That is the evidence for an allegation.

Q Do you understand the seriousness of the allegations that you make? Do you understand when you make allegations against professional people of repute that is a very serious thing. You should not just do it willy-nilly, you should have a proper basis on which to do it?
A I think we did have a proper basis. There is without doubt a forged consent form.

Q You are aware of the laws of libel. If you were not saying it in these proceedings, if you were saying it outside Dr Southall would be able to instruct solicitors to sue you for libel?
A Yes.

B Q You are saying that he could be involved simply because he said there is a consent form for every child in the trial?
A Yes.

Q Who else? You have said other people could be involved. How many others? Dr Spencer and Dr Samuels?
A I do not think Dr Spencer spoke out in the press hardly at all about it.

Q So he is absolved from forgery?
A Not really, he would still have reason to do it. You are asking me now to speculate and name somebody who has done it. All I am saying is that there is one forged consent form. Who has done it I do not know, but I know that lots and lots of people, and people who work at the Trust who have come out and made statements could have.

D Q Is this one consent form part of your complaint to the Staffordshire Police back in 2001?
A It was, yes.

Q The Staffordshire Police kicked it out?
A They said that forging a medical consent form is not criminal fraud.

E Q No, they did not. The Staffordshire Police said, and I will read you the bit from their statement. The Staffordshire Police said that they had leading counsel, that means top Queen’s Counsel, to look at it and there was not evidence to sustain your allegations and it fitted with what they had always said?
A Could you point me to that letter because I think that it says a lot more than that. Could you tell me where in the bundle it is?

F Q It is not in the bundle.
A It needs showing because it says more than that. It talks about does not constitute fraud in the criminal sense of the word, or something like that. That is what it says. What they were telling us was this needs to go to the GMC not the police. They talk about you need monetary gain to be criminal fraud. What we were being told was that criminal fraud needs some sort of monetary gain. They could not see where the monetary gain in forging a consent form for a medical trial. That was the sort of explanation we had.

G Q I suggest that they were much more categorical. I read the words to your wife. I hope I will be able to turn them up in a second. They used the words very clearly that they had gone to leading counsel and the outcome was the letter to the chief executive of North Staffordshire Hospital from Staffordshire Police:
“Leading counsel has concluded that whilst their outcome can still be looked at when to hand, there is now no need for the police to await the result of the GMC inquiries simply because there is no evidence which could conceivably satisfy the Crown Prosecution Service’s tests over (1) sufficiency of evidence, and (2) being in the public interest to prosecute. He has carefully considered what, if any, criminal offences are revealed to date, but has been unable to identify any. As far as the specific criminal offence of forgery, as defined by statute not the dictionary, is concerned, he has expressly also concluded that there is no prospect in all the circumstances of ever proving that this particular question defence was committed either. This has confirmed Staffordshire Police’s long-held position on this matter. In consequence Staffordshire Police will be taking no further action in respect of the six complaints received.”

A He does mention criminal fraud several times ---

Q Yes, and that is what you go to the police for ---

A Sorry?

Q Is not forgery a criminal offence?

A Well, apparently according to the counsel there, there are two types of forgery. Forging a consent form does not constitute a criminal forgery as defined in statute as I think they say there.

Q That is not correct and you know it.

A Why is it not correct?

Q The point is this: the Trust investigated it; the police investigated it; the General Medical Council investigated ---

A The police took counsel opinion on it and decided there was no criminal fraud. They did not have handwriting experts, nothing like that involved in it, did they? You cannot say they actually investigated it.

Q Let me ask you about that. I asked your wife about an organisation called MLI and whether in fact you had been involved in the instruction of this organisation called MLI who were now going to investigate this forgery. Were you involved?

A In the instruction of them?

Q Yes.

A They were looking for funding avenues so that they could investigate on our behalf, yes. I do not think they ever got the funding so they could never actually do anything for us.

Q Let me now take it much more directly. You have talked about this one other form for one other parent. We are not concerned about that. I am concerned to know about your two children and the consent forms we have seen, one of which was signed by you and the other of which was signed by your wife. Were either of those forged?
A My form is not forged. My wife’s form, it is one of the possibilities we have come up with because she has no recollection of ever being asked to sign a form or sign a form. I have no reason to doubt her.

Q Let us just clear away the muck around that and come straight to the point. Are you alleging that David Southall forged or was involved in the forgery of your wife’s signature on that form?

A We are going around in circles again ---

Q Yes or no. It is a very serious allegation and he would like to know and as his lawyer I would like to know too.

A For a start, we are not definitively alleging that that form is forged. If it was forged, going back to the previous discussion about forged consent forms, David Southall is one of a possible number of people who could have done it. Who - you know, I am not in a position to say. I have told you why we put the allegation in and the procedures that have to come before this Panel means that we have to name doctors, but we were hoping there was going to be some sort of investigation into this.

Q So he is on a list of suspects for it?

A Basically, yes, that is probably a better way of putting it, yes.

Q It is best that we know so that I can obviously deal with it now in cross-examining you about what you said at various stages. Let me put to you our case in summary and it is this: you went mouthing off to the press about CNEP in ‘97 claiming this was a trial and we never knew about it and our children were put into this trial and we never gave any consent. Suddenly you were ---

A Hang on ---

Q Just wait ---

A No, sorry, because I just need to pull you up on something there because you are saying that we said we never gave consent. That is correct to a trial. The fact I have signed that form does not mean I was giving consent, and particularly informed consent, to a research trial.

Q We will come to that in a moment.

A Okay.

Q That is why I asked you questions a little earlier on about do you read documents before you sign them and do you read carefully when you are putting your name on a document and you answered that you did.

A No, I did not say that. I said sometimes I do not. I may not do.

Q We will come to that in a second. Let me summarise what our case is so that you understand it and then I will move to it in some more detail with examples. Our case is that you went off to the press and said, “We never consented to our children being in a trial and this has taken us all by surprise and this is outrageous”, et cetera, et cetera, and the press listened to you ...
A ... and reported it. Then suddenly here were the consent forms with your signature and your wife’s signature on it and the words “study”, “clinical investigation” and “research” all over them. Suddenly you were looking rather foolish in the eyes of the press, so you take the line, “Oh I signed it and I never read it because I was too distressed at the time”. Your wife takes the line, “That is not my signature. It must be manufactured”.

B I do not think I have ever disputed that I signed the form, even before ---

Q But the minute you got caught out ---

A Caught out in what way?

Q Caught out because you said, “I never consented to my daughter going in a trial” ---

A No, I never did.

Q Here was a form that blatantly, on its face, in seven places, made it clear that this was some sort of trial or study.

A And you can prove I have read that form, can you?

Q Let us look at the form.

A Can you prove I read it? Just because I have signed on the bottom of it does not prove I read it. It just proves I signed on the bottom of that form.

Q Let us get the form out and look at how you could have missed it. It is behind divider 4 in file 2. I think it is page 19. Do you have it?

A I have it, yes.

Q What did you read? Not read a single word of it?

A Not a single word.

Q You did not read a single word?

A Not a single word.

Q How long would it take you to read this document if I asked you now to read it top to bottom? What is it going to take? 60 seconds?

A Possibly something like that, yes.

Q Yes?

A Yes.

Q So you did not even give it 60 seconds worth of attention?

A No.

Q Is that your writing where it says “NAME” and then it says “CARL HENSHALL” in block capitals?

A That is my writing, yes.

Q As you wrote it you presumably read the word “NAME”?

D12/44
A I was pointed to where I put my name.
Q Were you?
A Yes.

Q Somebody actually put a finger and pointed it?
A Well, it was - (Witness made a pointing gesture) name, sign.

Q No, you said in your evidence, I listened carefully and I have read your statement, “I was handed a clipboard with the form on it”. So how did you know where to put your name?
A What, so because I have it in my hands no one else can point at it?

Q You said, “I was handed a clipboard”. You did not say somebody put their finger. We can see there is no little “x” - sometimes when you get a document to sign someone puts an “x” sign that says, “Sign here”. How did you know where to put your name?
A Because it says “NAME” there and I was probably pointed towards it.

Q You had to scan down the document in order to see where it wanted you to put your name?
A No, because I think it is quite obvious where you put your name.

Q Is it? Because there is one down below that says name. How do you know which one is the name of parent and which one was the name of the doctor?
A Because obviously I was pointed to where to put my name and signature.

Q You were, were you?
A Well, I must have been.

Q By who?
A By the nurse who gave me the form.

Q Why do you say you must have been? It is not your evidence up to now. The evidence up to now was, “I was handed a clipboard and told to sign”. Because I was told to sign. I was told to put my name and signature on it.

Q Right, well, how did you know whether your name was going in the bit that says “Carl Henshall”, as opposed to the bit down below, because there are two places that say “NAME”? Unless you had read the bits above, you would not know which one of them you would put your name to.
A I did not read the bits above. I did not read any of it.

Q So it was pot luck that you put your name in the right place?
A No, it was not pot luck. I was shown where to put my name.

Q By whom?
A By the nurse.

Q That is first time today you have said that.
A No, it is not, it is probably the second time because I said it just five minutes ago.

Q In other words, the first time we hear that account that somebody literally handed you, what, a clipboard like this with a finger right on it?
A Possibly, yes.

Q Why not then put a little asterisk next to it?
A I do not know. You would have to ask the nurse why she chose to do it that way.

Q There was not a nurse. You are telling a lie.
A I am telling a lie?

Q Yes. You were seen by a doctor, Dr Arumugam?
A You were on the unit at the time, were you, and saw the doctor speaking to me?

Q No, I ---
A Was anybody else in this room on that unit ---

Q I have seen the notes made contemporaneously by clinicians as to Dr Aru speaking to you as to the consent and as to Dr Aru and somebody else ---
A I have seen the contemporaneous notes as well, yes.

Q So ---
A Are you saying those notes are 100 per cent accurate?

Q We are going to come to that in a minute and there are allegations about that. You say now somebody, this nurse, pointed her finger at the very spot where you signed?
A Mmm.

Q You did not read even the three words up above?
A No.

Q You did not see them as you wrote “CARL HENSHALL”?
A No.

Q How come?
A Because I was not interested in what it said, to be honest.

Q Really?
A She explained it to me.

Q Really? You were not interested to see what you were signing in respect of a daughter that you were very worried about?
A I had just been told what I was signing for.

Q How did you know?
A What do you mean how did I know? So I should have just doubted what I was told even whether it was ---
Q Let us just look at how many opportunities you had on this form to find out what this was about. Firstly, “CONSENT BY PROXY TO CONDUCT OF A RESEARCH INVESTIGATION”. Would you agree with me if you read those words you would have been on inquiry at the very least as to what this is, what is a research investigation?
A Possibly. Possibly.

Q That is opportunity number one. Opportunity number two is the word “STUDY”, the next line?
A Yes.

Q Opportunity number three is where it says, “CNEP trials”?
A Yes.

Q The word “trial” is used?
A Yes.

Q Opportunity number four may be where it says, “NAME OF PATIENT/VOLUNTEER”, because you would wonder why you were a volunteer?
A Yes.

Q Opportunity number five is the next sentence, “The aims and procedures of the clinical investigation ...” Yes?
A Yes.

Q “... in which the person named above is to take part ...” So it suggests you are taking part in a clinical investigation. You would agree that is opportunity number five. Yes?
A Possibly, yes.

Q “... have been informed about the possible benefit to him/her” of any risks. Then next one, jumping down, “I understand that participation in the study is voluntary”. That is opportunity number six.
A Yes.

Q “... may withdraw ... if that is my wish. Withdrawal will not affect the future care ... he/she will receive”. Yes?
A Yes.

Q Opportunity number seven, it might be said, or at least it would put you on inquiry, is where it says it “may be disclosed to Drug Regulatory Authorities”.
A Yes.

Q So you might say why are the drug regulatory authorities involved because that seems a bit unusual?
A I might have done, yes.

Q Then opportunity number eight is, “I hereby give my fully informed consent to the person named above taking part in this clinical investigation”. Yes?
A Yes.
Q Opportunity number nine would be just above the doctor’s name, “I confirm that I have explained the nature of the above investigation to the above named relative/legal guardian”.
A Yes.

Q Right. You did not see any of those nine sets of phrases or words when you put “Carl Henshall, father” on that paper?
A No.

Q In order to write “CARL HENSHALL” and your signature and “father” - and is the date written by you as well?
A No. I said that I think as far as I can see the only two details I put on there are the name Carl Henshall and my signature. The writing “father” does not look like mine and the numbers do not look like mine.

Q Okay. How long did it take you to sign the form? 20 seconds?
A Probably not even that. To write your name and sign is seconds, yes.

Q You see, I am going to suggest to you that it is a complete and utter lie that you did not look at this form when you signed it. You did look at it and you knew very well it was a research investigation, study or trial.
A You can say that if you want but you have nothing to substantiate that. I did not read that form. I did not see the need to read that form. I know it is stupid. I know I look back now and it would be the last thing I would do now, sign anything without reading it. At that time, under those circumstances, given the explanation I was given by somebody I trusted at the time, then I had no reason to read that form ---

Q That is my number two because it was not a nurse. You were given that form to sign by a male Asian doctor.
A I did not see a male Asian doctor on that unit until the final day, on the 14th.

Q Well, I thought you told us you saw a male Asian doctor with a goatee beard which ---
A Which was on the 14th.

Q The next day?
A No, on the 14th that was.

Q 14th?
A Yes.

Q I want you to look at page 13 in the bundle, I think it is.
A The same bundle where the consent form is?

Q Yes.
A Page what, sorry?

Q 13. Just tell us, firstly, what time do you say this nurse approached you and you
signed the form? What time of day?
A It would have been a couple of hours - I mean, it was probably a couple of hours, I was dotting off backwards and forwards ---

Q A couple of hours after what?
A After the birth.

B Q The birth? Well, let us just see if we can get the time of the birth of patient - this is Patient 7. I think she was born in the morning, was she not?
A She was born about ten-past eleven I think in the morning.

Q It was within the next couple of hours that you were asked by this nurse?
A I would imagine so, yes.

C Q And you signed the form?
A Yes.

Q If you want to look on page 13 now.
A Yes.

D Q “12/2/92”, that is the date Patient 7 was born?
A Yes.

Q You will see somebody has written “12.00 noon”?
A Yes.

Q And underlined it?
A Yes.

E Q That person has then written some notes about Deb, has dealt with the delivery, has then dealt with an examination of Patient 7. Yes?
A Yes.

Q And then management investigations, various things of that sort. You see down the bottom, “CNEP consent obtained from father”?
A Yes, I see that, yes.

Q Do you see a signature?
A I do, yes.

G Q The signature of that person who has written the note is identical to the signature of the person on page 19 who has written - it is the same name as on page 19 as the person who says, “I confirm that I have explained ... the above investigation”?
A Yes, I do see that, yes.

Q So that note, is that note forged?
A I do not think it is forged. I think he has wrote that, yes.

Q So you think he has written that?

D12/49
A

Q You think he has written that ---
A At twelve noon?

Q Yes.
A Okay.

Q You think he has written that and, yet, it was not him that approached you or saw you ---
A No, it was not him that approached me. I mean, are you saying that the whole of that page is 100 per cent accurate?

Q Well, I am not saying 100 per cent accurate. I could possibly say that. I am saying that doctor signed that note saying “CNEP consent obtained” ---
A You are saying everything he has put there is what he believed at the time?

Q Well, let us deal with it in another way ---
A No, because it is an important thing here actually because you are talking about consent, “CNEP consent obtained from father”, and a note made at twelve noon, which is less than an hour after my daughter’s birth. Why is he taking consent for a research trial less than an hour after my daughter’s birth when the consent process should not have been - she should not even have been assessed as being ready for that trial until at least two hours of age and the consent should not have been taken until round about I think four hours of age.

Q What I am going to suggest to you is it happened before three o’clock.
A That is not what it says there. That says twelve noon.

Q No, that it when the first part of the note is written ---
A No, it is not. There is no other signature. There is one signature at the bottom of the form and all the handwriting is the same hand. There is one time. There is one signature, so you have to assume that all that was written at one time.

Q You do not, Mr Henshall ---
A I do not?

Q And you probably know enough about medical notes that often what happens is a doctor at the end of a shift or at the end of a particular session may write a note timing when they came on shift, when they started or when the baby was admitted, and this looks like this is the first note for Baby 6 in terms of being admitted to the paediatrics.
A Right.

Q Let me ask you this ---
A Can I just point you to the nursing records then as well?

Q Forget that for a second and let us worry about ---
A No, because it focuses all on the same point actually, because the nursing records, which I think are - right. This is page - I am not sure, 20 I think. It looks like page 20.

D12/50
Yes, it is page 20. The first insert there is time 11.30. Then there is a note, “[Patient 6] admitted to NNU”, then, “I. Dad, brothers & sisters visited. Dad spoken to by Dr Aru & consent for CNEP trial given”. That is at 11.30. That is 20 minutes after her birth.

Q  No, it does not and that is why I say you are twisting it in terms of what ---
A  Why am I twisting it? There is one time entry. There is one signature. There is not a signature for the top bit and then the rest has been added.

Q  Mr Henshall, it is going to be a matter for the Panel to decide and they are going to hear, or likely may hear, evidence from doctors and nurses who know about the writing of notes ---
A  My point ---

Q  Just hold on a second ---
A  Can I just make my point first?

THE CHAIRMAN: Mr Henshall, if you are speaking at the same time as Miss O’Rourke, the shorthand writer has an incredible difficulty getting down what is said. Could you wait for the question to be asked and then give your answer?

THE WITNESS: I apologise.

MISS O’ROURKE: (To the witness) The Panel has medical expertise available to it. It may well hear from medical witnesses. It has a medically qualified member upon it. They, as Panel members, will have dealt with medical cases before and they will form their own views about how doctors and nurses write notes and whether when they write a time that is the start of the session with nurses or doctors. That is not a matter for you to deal with. What I am suggesting to you is that Dr Arumugam has written a note, “CNEP consent obtained from father”, and has signed it. It is the same signature, or it looks pretty much the same signature. This is on page 19.
A  Yes.

Q  Let me ask you this: are you saying if Dr Arumugam signed page 19 and wrote, “I confirm that I have explained the nature of the above investigation to the above named relative/legal guardian”, that that doctor has made a false declaration with that signature and that statement?
A  Yes.

Q  So that doctor has lied?
A  If you want to call it lying, yeah.

Q  He has lied on a consent form?
A  I said earlier what I have thought.

Q  No, just take it through. He is lying on a consent form?
A  Yeah, he is lying on a consent form, because he is not the one...

Q  Right. What reason...
A  ...who approached me.
A  
Q  ...would he have had to do that at the time?  
A  Well, the scenario I have come up with, and this is just pure speculation.  I had gone on to that unit, saying that Deb had gone up on to the ward, I am going home.  They had identified that Patient 7 was a candidate for the CNEP.  So they needed a consent form signing.  If Dr Arumugam or no other clinician was available at the time, I was asked for consent by a nurse who had just got Dr Arumugam to come to sign it after, just saying she had explained it, can you sign it because I cannot.  

B  
Q  Let us follow this through, then.  At the time you appended your signature to it there was no writing down the bottom, saying Dr Arumugam?  
A  Probably, not, no.  

C  
Q  What do you mean, probably not?  
A  Well ---  
Q  Was there or was there not?  
A  Well, as I have already said, I have not read it.  I did not read the form.  I just remember signing a form for treatment.  

D  
Q  You do not remember whether anybody else’s signature was on it when you signed it?  
A  No.  
Q  What about the nurse who gave you the clipboard and took it back from you; did you see the nurse sign the form?  
A  No.  

E  
Q  So Dr Arumugam’s signature could have gone on the form before you signed it or after you signed it?  
A  Well, I suppose it is possible, but it still does not prove that he was the one who spoke to me.  
Q  It does prove, though, when he signed it, he made a false declaration, because, on your account, he never gave you any explanation.  
A  Well, he did not give me an explanation, no.  
Q  Why would a doctor - what interest would this doctor, back in January 1992, when the outcome for Patient 7 is not known, when it is not clear which part of the trial she is going into, why would he make a false declaration and put himself at risk with his professional body and others besides, saying, “I have explained it,” when he has not?  
A  Well, you would have to ask him that.  

F  
Q  The more likely explanation is that he signed a true declaration and you are telling us a pack of lies?  
A  That is not the more likely one at all.  

G  
Q  It is absolutely the more likely one, Mr Henshall...  
A  No, I totally disagree.
Q ...because Dr Arumugam, you can think of no reason why he put his signature on there and make a false declaration, can you?
A Sorry, I have just come up with a possible scenario, that ---

Q That is a false declaration.
A Well, it is still a false declaration, but...

Q Why would a doctor ---
A ...I am not - I am not alleging anything malicious in that, it is just that it was ---

Q You what?
A Well, I know it is ---

Q You are alleging ---
A It is a serious allegation, but I am not saying it was done maliciously to con me or anything like that. I am saying it was just that, at the time, they needed somebody to consent for CNEP. I was going home. They probably could say I was quite anxious to get home, so it was done quickly.

Q Right. You are making a very serious allegation, you are saying ---
A I am not making a serious allegation.

Q Yes, you are.
A I agree it is a serious allegation, yeah.

Q Mr Henshall, you are suggesting a registered medical practitioner, with absolutely no motive at all to lie, has written on a form, “I confirm I explained the above investigation,” has written it in the notes and has caused the nurse to write in the nursing note you helpfully pointed out, “Dad spoken to by Dr Aru and consent for CNEP trial given.” You have ---
A It is 11.30.

Q Forget the time. A nurse had written ---
A Yes, forget the time, so it does not suit you.

Q A nurse has written a note, so you are suggesting all of those people did that, with what motive?
A What do you mean with what motive?

Q What motive did Dr Aru have to put himself at risk of being caught out for a false declaration, as opposed to...
A He probably.

Q ...the motive you have for telling a pack of lies for potential financial gain and because you have been courting the press for years with lies, and you cannot now, even now...
A Financial gain?
A  Q  ...stand up and tell the truth, and say to the press, “Yes, I lied.”
A  Sorry, where is my financial gain that you have just referred to.

Q  You have been trying to get a compensation off the ground and kick-start it. You have been telling the press you are going to get millions.
A  For me?

B  Q  Your daughter.
A  Well, it is not ---

Q  For your family.
A  Then it is not financial gain for me.

C  Q  It is for your family.
A  That is financial gain for my daughter. No, it is for my daughter. It is not even for my family. It is for my daughter, because I believe that she was damaged through negligence.

Q  Your scenario that the doctor would have to fill it in, why could not the nurses have done it? Nurses were taking...
A  Because ---

D  Q  ...consent ---
A  Because the uniform I described, that is the uniform of a student midwife, I have since found out, whether it would have been inappropriate for her to countersign that, I do not know.

Q  Well, it is nonsense. It is, first, nonsense that you have remembered in detail the uniform, but secondly...
A  It is not detail.

Q  ...it is nonsense that a student midwife - a midwife, not even a paediatric nurse - a midwife was going to talk to you about this trial.
A  It is nonsense?

E  Q  Yes.
A  Why is it? Why is it nonsense?

Q  This is a paediatric ward now your daughter is on. Yes?
A  Yeah.

F  Q  So what is a midwife doing there?
A  I do not - I thought - I do not know. I do not know, but...

Q  It is nonsense that this trial ---
A  ...that is the usual ---

G  Q  You have read lots of stuff about this trial. You have seen the list of the 34 people who took consent, and you know there were no midwives involved in it, there were no
student midwives.

A I know that, do I?

Q Yes.

A Right.

Q Do you not? You have read all the stuff.

A What stuff is that?

Q The investigation of how many people took consent, the consent audit done by the Trust in 2000, the list of the consent forms and the identities of those who took consent.

A That is just going by what signature is on the form. Where is the actual substantial...

C Q You are suggesting...

A ...evidence about.

Q ...that this trial was having to fall back on student midwives in a paediatric department, are you?

A I am saying the uniform she was wearing was the uniform - well, the uniform she was wearing is worn by student midwives.

D Q You can remember what somebody was wearing 16 years ago, but you cannot remember...

A Well, I ---

Q ...a single other thing on the form?

A Well, I can remember lots of things. What you are asking me is - what you are suggesting is I can remember little things and not other things. But, actually, what I am saying to you, I have got quite a good memory of what went on there.

Q Right.

A I have explained to you why the uniform has stuck in my mind, because it was unusual compared to what the other neonatal nurses were wearing.

E Q Let us come to some of your other lies for that day. The next one is this: you were told that your baby was going into CNEP and you had it explained to you that this was the safer, gentler treatment. Yes?

A Was not told the baby was going into CNEP. It was inferred that they wanted to use CNEP on my child. That was the explanation. I did not say that I was told.

F Q Let me just check your witness statement for a second and see what you were saying there. You wrote your own witness statement, did you not?

A No, I think we had ---

Q It has got your own footer at the bottom. It says 12 December 2007, Carl Henshall. It is not on the Eversheds’ face nor is your wife’s. It is done on a face of your own ---

A I think they were actually written by Luisa Hunt at Russell James & Walker. She
helped us to put them into some sort of format.

Q That is your solicitor in the civil litigation?
A Yes.

MS SULLIVAN: I think there may be some confusion as to which document we are talking about.

MISS O’ROURKE: I am talking now about the statement that we had served on us as part of the GMC proceedings. It says 12 December 2007 ---
A Part of these proceedings?

Q Yes.
A This is what had been done by ---

Q Carl Henshall. It has your own footer...
A Okay. Right. Sorry.

Q ...and your wife’s had your footer on it as well.
A Okay, yeah.

Q I am suggesting it has come off your word processor, certainly looks like and it is therefore written by you?
A Probably. Yeah.

MS SULLIVAN: Could he just have it in front of him a moment if you are going to ask him about it?

MISS O’ROURKE: Has somebody got a copy? Mine is, I am afraid, marked and annotated.

THE WITNESS: On page what, sorry?

MISS O’ROURKE: Page 2, paragraph 5. Paragraph 6, she went on to explain:
(Document not provided)

“They now had a new, kinder, gentler, more natural form of ventilation from America which removed the need for the pipe, worked by enclosing the baby’s chest in a tank and creating a negative pressure by pumping the air out. This would then cause the baby’s chest to rise and fall and as such the baby would take in air more naturally. They knew this treatment to be better. They would like to put Patient 7 on this ventilator if that was all right with me. Of course I agreed as I wanted the best for Patient 7. I was concerned about her well being. The nurse brought me a form and a clipboard and told me where to sign, date and print my name. This I did without reading what was on it. I now realise this was stupid.”

A Yep.
Q So you are saying she told you that Patient 7 was being put on CNEP?
A No, they would like to put her ---

Q No, no.
A They said they would like to put Patient 7...

Q Yes, and I agreed. “They would like to put Patient 7...if that was all right with me”...
A ...on this ventilator...

Q ...“and of course” ---
A ...and it was all right with me.

THE SHORTHAND WRITER: I am sorry, I can only take one person at a time. I am sorry.

THE WITNESS: Sorry.

MISS O’ROURKE: “They would like to put Patient 7...if that was all right with me. Of course I agreed.” So that is agreement to put her on CNEP?
A To put her on CNEP. Yeah.

Q Now, that is lie number two or three, depending which way you want to look at it, because, in fact, this was a trial that randomised and the decision as to whether or not Patient 7 was going to have CNEP was not yet made?
A I have since found that out, but I do not - I agree - I do not agree, because the conversation was to get my daughter into CNEP.

Q Right.
A The conversation that was had by the side of the cot.

Q The midwife would have - or whoever she was, we say of course it is Dr Aru - had to have got that wrong? Yes?
A Well obviously.

Q If you look on the next page, in the notes at page 14, you will see that Patient 7 was randomised for CNEP trial at 3.05. Yes?
A That is what it says there, yes.

Q And page 371, I think it is in bundle 1, we can turn it up if we need to, but it may be you do not need to turn it up. The Panel may want to. If you look at the fourth block down ---
A I am just looking at the wrong numbers. I will just get to it. Fourth block down, yes.

Q Fourth block down, the first entry, “12/12/92.”
A Yes.
Q “15.10.”
A Yes.

Q “Centre. Stoke.”
A Yes.

Q “Name of caller. Kate Palmer.”
A Yes.

Q We can ask her about that, because, as you know, she is going to be a witness. “Answered by. MS,” that is Martin Samuels?
A Yes.

Q Name of patient, and you will see Patient 7’s name.
A Yes.

Q “[Gestational] Age.”
A Yes.

Q Then percentage of oxygen. Yes? “IPPV? Yes.” Group. 13.” Yes? And then “Infant No.” Do you see that?
A Yes.

Q Infant number is number 1.
A Yes.

Q And “CNEP.” Yes?
A Yes.

Q Now, number 1 means that she is the first of the pair? You know that now, because of looking at it?
A Yes.

Q You know what was happening. There were paired infants. Yes?
A Yep.

Q And she is in pair number 77.
A Right.

Q The other of the pair in pair 77 does not come in until the last entry on the page, “29/4/92.”
A Yes.

Q At Stoke. You see the name of that patient, who is a 26-weeker, and she is the other one of pair 77, and she is listed as pair two, and she gets the standard treatment. Yes?
A Yep.
Q Therefore, whoever spoke to you and took your consent could not have possibly told you that Patient 7 was going to have CNEP, because the randomisation process took place when a telephone call was made at ten-past three and Dr Samuels pulled cards out of an envelope in order to determine which child was going where?
A Did he?

Q Yes. So it would have been impossible. Yes?
A Well - what you ---

Q Unless that sheet is a lie as well?
A You are asking me to speculate on what other people did. Now, if you are saying Dr Samuels definitely pulled an envelope or he was told, well, that is the CNEP tank empty, so we will just put this on CNEP and the next one can go on standard. I do not know.

Q Let us look at probabilities and let me give you a snippet now of my half-time submission. I am going to say to the Panel: there are two possibilities. One possibility is that you are telling the truth, but if they go for that possibility, they will have to find the following: firstly, that a student midwife was somehow or other taking consent for a paediatric trial on a paediatric ward; secondly, that that student midwife did not sign the form; thirdly, that a doctor, who I think was a registrar at the time - yes, registrar doctor in paediatrics would have to make a false declaration on a form saying that he had signed it and explained it; fourthly, the same doctor would have to make a false note on page 13; fifthly, a nurse would have to make a false entry on page 20, and “Dad spoken to by Dr Aru and consent given”; sixthly, whoever explained it to you, whether it be a doctor or a midwife, had to be a psychic and know what Dr Samuels was going to pull out of the card to know that Patient 7 was going to have CNEP; and, finally, that form would have had to have been written up dishonestly afterwards to say that Patient 7 was randomised at ten-past three. And if wanted to add one more just for good measure, it would be that the note on page 14 was also a lie. Now that is one possibility. So, eight or nine lines there, or highly ---

THE LEGAL ASSESSOR: Perhaps you should ask him a question.

MISS O’ROURKE: Right.

Q Here comes the question: the other is that there is one liar, and it is you, and it is you saying that Dr Aru never explained to me, a midwife did, and I was told that Patient 7 was going into CNEP. That is the other possibility.
A No, it is not the other possibility. I have already give you one possible scenario as to how Dr Arumugam’s name appeared on the consent form.

Q And it involves the doctor telling a lie?
A Well, perhaps so, yes. Perhaps so, but that is the possible ---

Q And his reason for doing so?
A Because I was explained the procedure to by a student, who could not - I do not know whether it is legally or procedurally wise, countersigned the forms, so she had to get somebody else to do it, because no other clinician was available at the time when they
needed to get me to sign a form before I went home. The fact that Patient 7 is number 1 means it is easier to decide which treatment to go on, because obviously there was a tank available. It does not involve such a massive conspiracy, as you were trying to make out.

Q There we go. You said you did not have, in answer to a question to Ms Sullivan, parental responsibility for...
A That is right, yeah.

Q ...this child. Did you tell anybody in the hospital that was the case?
A Well, I would have to - I think to Ms Sullivan that I would not have been aware of that at the time. I was not - I did not know what the law was around parental responsibility and that, but the staff on the ward should have known.

Q Even though this repeated reference, both in your wife’s obstetric notes and in the paediatric notes to you being the husband and next of kin being the husband...
A It does not say the husband...

Q ...at the same address.
A ...because we were not married at the time. It could not say the husband...

Q I know, but ---
A ...we were not married at the time.

Q The notes are full of it, reference to you being the husband and next of kin being husband, same address.
A Well, that is wrong because we were not married.

Q Well, was it possible ---
A Well, actually, actually, then, if the next of kin is the husband, I am not sure if Deb was divorced from her other husband then. So - well, the fact is I did not have parental responsibility. I was not aware of that fact, but the people on the ward should have been aware of that fact.

Q Well, I am suggesting ---
A Especially paediatric registrar, if he was the one who was talking to me and taking informed consent off me. He should have been aware that I did not have parental responsibility and therefore that signature has no legally binding.

Q I am going to suggest to you you did not tell anyone, and more than that, it appears that Debs may have been using the phrase husband in reference to you?
A She filled in those notes, did she?

Q No, no. She may have been using it in reference to other details given.
A I do not understand the point you are making, sorry. Can you just ---

Q There are places in the notes, in her obstetric notes, where it refers to next of kin and things like that, and it is husband, and there are other references to husband. It appears, unless...
A But she did not.
...all the nurses and midwives were getting it wrong, that she may...
A Well, obviously she did not write the notes.

...have used the word “husband,” rather than have said partner or boyfriend.
A Well, she just said partner. She did not write the notes, so you cannot hold her responsible for what is written in the notes. She was saying partner. We were partners at the time. It was obvious we were partners, we have got different surnames.

Q Let us move on to the name.
A You cannot - I mean, you seriously cannot suggest that the staff were that stupid to think these are married when they have got different surnames.

Q Why not? Lots of people are married and have different surnames.
A Do they?

Q I think you will find Ms Sullivan has a different surname from her husband.
A Well, why did they not question us on it, then?

Q Mmm?
A Why did they not question us on it?

Q Let us not waste time on that. Let us move on to the name game. I want to understand what your evidence was this morning in respect of when the name was given, and, as I understood it, you say that while you were in the theatre, your wife said Alison or Zoë. Is that right?
A In the theatre?

Q Yes.
A Yes.

Q Waiting for the baby to be delivered.
A Yes.

Q This is now Patient 6.
A Sorry, Patient 6, and we are talking about in the theatre now, and we are talking about baby names. Right. Okay. Yes. The two names touted were Alison or Zoë. I had already told Deb beforehand I did not like the name Alison, and then she kept coming up with Zoë. That was mentioned in the theatre. I said, “No, I do not like that name.” It was not an argument, as was tried to be made out yesterday. It was just like, you know, Deb said Zoë and I said, “No, Deb. You know I do not like that name.”

Q I think I must have misunderstood you this morning. In due course, we can check the transcript, but I wrote a note down that you said it was in the theatre for the first time you said, “We had a name for a boy.” You gave the explanation about Billy or William, but you - “We had never settled on a name for the girl.”
A No, we had never settled on ---

Q “Then when we were in the theatre, she said Alison or Zoë. I then said I did not
like either of those names.”

A We had had a discussion before. We never settled on a name. Those were the two names that Deb particularly liked, so she brought it up again in the theatre. I did not say we had never mentioned those names beforehand.

Q Alison, the first time any of us heard that name, or certainly any of us on this side of the room heard that name was when your wife was being questioned yesterday afternoon by Dr Sheldon.

A Yes.

Q Nobody had ever mentioned before Alison. All your letters and things, stuff you told the press was all about Zoë.

A That is right, yeah, yeah, because as far as I was concerned, we had already dismissed the name...

Q Was it something...

A ...Alison.

Q ...your wife came up with yesterday and you have come out with today to back her up?

A No, no. I mean, Deb has always liked the name Alison. She has always wanted to have a daughter named Alison. It is just that I have never been particularly keen on...

Q But you had...

A ...that name.

Q ...never bothered to mention it to anybody before, it was always Zoë, I think you said.

A It has never really been important or relevant before.

Q Has it not?

A No.

Q Okay. I am going to ask you now the same question that I had to ask your wife, and you will find it in file 2, behind divider 5, firstly, at page 61. “14.12.92,” left-hand side.

A Yes.

Q “22.30.”

A Yes.

Q Item number 2.

A Yes.

Q “Baby needing increasing amounts of [oxygen] now in headbox with 38% to maintain saturation”

- then the name, which is the correct name of Patient 6 -
“continues to have moaning respirations.”

Then number 3 below it, “[The name],” which is the more conventional spelling of Patient 6’s name, “has received her first dose of antibiotics,” and then signed for by a nurse. Yes?

A  Yes.

Q  What are we dealing with here, a clairvoyant and psychic nurse or a forged document?
A  I would say a forged document.

Q  Can I ask you to look at page 171 - same nurse, conventional spelling of Patient 6’s name on the left-hand side and date in the middle, 14/12, the day before you say the name was given, same nurse and signature?
A  Yes.

Q  Next block over, to breathe, and then again the date 14/12/92 and the same nurse. Last column over, to feed, again same date, same nurse and same conventional spelling of the name?
A  Yes.

Q  On page 173, top left-hand corner, an entry under normal body temperature, conventional spelling of the name, signed and dated, same nurse - the same thing, psychic nurse or forged document?
A  Forged document.

Q  So this particular nurse has forged three documents in your daughter’s notes. Can you think of any reason why?
A  I do not know if it is that nurse.

Q  All right. Who has done it?
A  These documents were not available until the Griffiths inquiry was initiated. We continually asked for the nursing records. The hospital trust could not find them and were prepared to have a sworn affidavit that they had been lost. Then all of a sudden they turn up, and they are the only documents where Patient 6’s name is referred to on the first day. It is also worth noting that the first time we mentioned about Patient 6’s name was probably on a Channel 4 news item, the same one where Dr Prowse then released consent forms without our consent. As part of the Keith Prowse hearing it was alleged that the signature for the release of those documents was not the signature of the person who it was purported to be.
A

Q Answer the question.
A I have.

Q I am asking you about these particular pages. Are you saying that they were forged. If so, why? Give us one conceivable reason why that nurse would in six places know the name. That is why I gave my theory, it has to be clairvoyance, psychic or a forgery. You have plumped for the forgery?
A But not by that nurse.

Q Then by whom?
A I do not know.

Q Give us a list of suspects then. Is Dr Southall on the list this time?
A Possibly.

Q He has written on page 61, has he, Patient 6's name under number two and under number three, has he?
A I have no idea if he has written that.

Q Is it possible that he has?
A It is possible in a list of probably 100 people at the Trust.

Q One hundred people at the Trust are all involved in this conspiracy, are they?
A No, 100 people are not. I said is possible. I am not saying anybody is involved. It might be a handful.

Q I would like to see how big the conspiracy is ---
A I have never mentioned a conspiracy.

Q Of course the Panel is used to looking at conspiracies and the Legal Assessor in due course will be able to give the Panel advice on it. The larger the number of people involved, the less likely it is, and there are criminal trial directions on it as to whether there has been a conspiracy. So, I would like to know how many are in it. Is it just these three doctors or is it the chief executive at the Trust, a load of nurses and everybody who took consent?
A I have no idea. How could I?

Q You are the one alleging forgery, I am saying this is a genuine document, written by that nurse at the time.
A You are the one alleging conspiracy, I have never alleged a conspiracy I do not think.

Q I think you have, and we will come to it in due course. So, who forged it?
A I have no idea.

Q It would have to be a number of people involved, would it not? If we look at page 61, it could not be written five years later without getting several others all to sign the subsequent entries?
A Page 61.

D12/64
Q Page 61 does not just have the writing of one nurse on it. If somebody was going to recreate the page now in order to write the name on it, in order to make up these notes in the interim period around the time of the Griffiths inquiry, they would have to get somebody else involved to write the second entry?
A No, they would not.

Q Why not?
A Why would they?

Q So what you are now saying - let me understand it - is that all the rest of the entry is right, but what has happened is that the baby’s name under (2) and (3) has been tippexed out and re-written
A Actually on (2) it does not need to be tippexed out because there is a full stop there. It says:

“Baby needing increasing amounts of O₂, now in headbox of 38% to maintain saturation.”

Full stop. That can have been added in afterwards. The only place where it needed to be changed is on point (3).

Q So it would be added in afterwards. It looks to me like the same writing. The individual in question writes an unusual letter “G”. It looks like a nine, as it goes straight down. So somebody has set out, have they, deliberately to copy that? Look at the word “moaning”, which is in the first line and the word “moaning” which is in the line under two; those look identical to me.
A They do not look absolutely identical to me. The “N” is different.

Q It is a matter for others to look at.
A Exactly. Both “N”s actually.

Q The position is that you are saying that somebody other than this nurse has had to try to copy her handwriting and written this in on a subsequent date before the Griffiths inquiry in 2000.
A Possibly, yes.

Q They would have had to do the same, if we look at pages 171 and 173, in all these places. They would have had a bigger problem because it is the top of the page, the first word of each of those sentences they would have had to tippex out, would they not?
A Yes, they would have to tippex out. Has anybody ever seen the originals of these?

Q Yes, the hospital has, so I understand. The position is this. When I come to my half-time submission to the Panel we have two possibilities. One is that those notes are genuine, made contemporaneously by the nurse who signed her name to them, and that she therefore knew the name of Patient 6 at half ten, eleven, before Patient 6 was randomised into CNEP. If that is right then those notes are genuine and you are a liar and your wife is a liar in the name story. The alternative is that you and your wife are telling
the truth, and the Panel will have to decide is this nurse a clairvoyant and a psychic? That is highly unlikely. We have no evidence that is the case. In which case this nurse has been involved in a forgery, despite the fact nobody can think of any motive or motivation for her to do it or indeed any opportunity, or that it is not her that is involved in the forgery. Somebody else has taken out of the notes and engaged in deliberate forgery, and David Southall is one of the possible candidates?

A One of a number of possible candidates.

Q So if you had a chance to ask the Panel to plump for one of them when I make that half-time submission, you would be saying that it is the latter, the forgery, and David Southall is on the list?

A Yes.

Q While we are dealing with those notes and because it arose out of the evidence this morning. You gave evidence about Patient 6 and about following up with Patient 6 and her attending follow-up appointments. You claimed you had taken her to one and Debs took her to one and that you took her to some others. Can I ask you to look, while we have file 2 in front of us, at page 194 please. You presumably have seen this document before? It is in Patient 6 notes.

A Yes.

Q It is an interdepartmental memorandum from the health visitor to Dr Spencer?

A Yes.

Q It says Patient 6’s name, refer to health visitor following three defaulted clinic appointments. Health visitor then,

“visited the family and stressed the importance of keeping next appointment on 1/9/93. Mother says she will attend.”

A Yes.

Q Do you remember the health visitor coming to your house?

A The health visitors come to the house. I do not remember particularly on this occasion talking about this, no.

Q Do you remember the health visitor coming to the house and saying you had defaulted on three clinic appointments?

A No.

Q Are you saying that this is a false note to make you look like parents that were not that bothered?

A No, I am just saying that I do not remember the health visitor coming to say we had defaulted. I remember we had to change a number of appointments at the time because of how busy our household was. I do remember we had to change appointment times, but I cannot actually remember the health visitor coming and saying you know you really must attend them.

Q If she had, you would have wanted to comply, you would have wanted to turn up to the next appointment? As she notes there, Mother says she will attend 1 September
A

1993?
A Yes.

Q Could you give us any explanation then for page 34? Do you have 34?
A It is intensive care charts on my page 34.

B

Q It is behind tab five. We are now dealing with Patient 6 and not Patient 7.
A I did not realise there were two page 34s.

Q Do you have page 34?
A Yes.

Q To put it into context, if we go back to page 32 you will see 7 January 1993, the
date that Patient 6 is discharged?
A Yes.

C

Q We go on to page 33, which is her first follow-up appointment, which is two
months after discharge?
A Yes.

Q In fact it is two weeks after what would have been her estimated date of delivery
if she had got to full maturity?
A Yes.

D

Q Then at the bottom she is given C3 over 12, which means see within the next three
months?
A Yes.

E

Q She is given an appointment for 25 May 1993. Nobody attended, unless you are
going to tell me that this is a forged and made-up page as well? Otherwise it looks like
they say.

“Did not attend. Send a new appointment.”
A All I can say is that I know that I attended two out patient appointments with Dr
Morgan with Patient 6. One of those was not the one where the brain bleed was referred
to.

Q If this note is right, you failed an appointment on 25 May. So you were sent
another one. You failed another on 29 June, so you were sent another one. You then
failed another one on 11 August. As a consequence they were sufficiently concerned to
write health visitor to call. That is the memo we have seen about the new appointment.
So you are given an appointment for 1 September 1993 at 10.30 am. The note is made by
the health visitor that mother says she will attend. But, oh dear, look what happened, 1
September 1993 you did not attend, so the hospital take the view, probably in accordance
with their policy when you have three failed appointments, no further action. They refer
you back to you GP.
A Then there were subsequent appointments.

H

MS SULLIVAN: There was an appointment on 22 September.
MISS O’ROURKE: If that is the next page it is cut off. It may well be when you are referred back to the GP you get sent back?

MS SULLIVAN: It is page 195 as well.

MISS O’ROURKE: It is a better copy?
A Referred back within three weeks?

MS SULLIVAN: Page 195 shows an appointment with Dr Morgan on 22 September 1993.

MISS O’ROURKE: On my copy we have the date cut off on page 35. There is obviously one in 1993. It looks like it may be the same one. (To the witness) What I am suggesting is that there were four failed appointments.
A All I can tell you is that Deb took her to two appointments, I took her to two appointments. The one thing I will say about the missed appointment on 1/9/93, and I think you are saying there was actually an appointment on the 22nd. That means a letter went from the clinic to our GP, to us, and then an appointment was made within three weeks. That does not seem to read well with how the NHS works. It does not tend to be that quick.

Q It may have gone to the GP, it may have gone to you. It is not clear from the records. What I am suggesting to you is that there are four missed appointments there?
A There might have been four missed appointments, but there were still four appointments taken by us.

MISS O’ROURKE: I am about to move on to another topic. Mr Forde is pointing out to me that it is twenty to one. This witness has of course been giving his evidence now for a while. He also tells me he has a couple of issues that he probably wants to raise. It may be that rather than start my next topic, which I know will take more than half an hour, it may be appropriate to stop now.

THE CHAIRMAN: I agree, Miss O’Rourke. Mr Forde, you want to raise a couple of issues?

MR FORDE: Yes, and I am happy to do so in front of the witness. I am also happy for my learned friend to take instructions from him on the issue. The first is this. In the light of the answers that have been given by the witness as to the state of the civil claim, I have been asking because of the considerable media interest in this case, for the General Medical Council to acknowledge that it is no part of this hearing that CNEP damaged Patient 6 or was responsible for the death of Patient 7. I am still waiting for that comment to be made. I am mystified as to why it is thought that that statement cannot be made in clear and unequivocal terms. That is the first matter for my learned friend to consider, if need be with the Henshalls.

We are somewhat dismayed, if that is the case, that, having requested investigations to be made of previously instructed solicitors on the part of the Henshalls, particularly in relation to the report of Dr Newell, that it was thought appropriate for this witness, whose
credibility is very seriously in issue, to make those inquiries. At paragraph 2.14 of my skeleton argument, which I am sure now seems many weeks ago, I made a request for service of unused material to establish when the Henshalls first consulted solicitors. I am not asking for an instant response, and you may wish to seek the advice of the learned Legal Assessor after the luncheon adjournment, but we, on this side, would like an undertaking that the appropriate inquiries will be made of the solicitors J A Evans & Co, and, if need be, of Mr Evans, if he is still practising and of Russell Jones & Walker by the solicitors instructed on behalf of the General Medical Council.

It is not thought by us to be appropriate that Mr Henshall, given what we regard as the delicacy of his position as regards credibility, to make those inquiries. It is not a duty that should have been delegated in our view to him.

MISS O’ROURKE: Can I just echo that last point because of course the General Medical Council, as this Panel will know, has powers under Section 35 of the Medical Act to require any other person to deliver up documentation. I was concerned the answer would came back - I suspected it was going to be the case, which is why I asked the question - that the question had been raised with the first set of solicitors and not the last set of solicitors. I was concerned, knowing as I do a little about civil litigation, that the legal aid certificate had been transferred and so would the papers, so the question was being asked of the wrong person. I too believe that Miss Morris should now be asking questions of this Louisa Hunt that we have had identified or of Russell Jones & Walker, whatever firm of solicitors last held the legal aid certificate.

THE CHAIRMAN: Ms Sullivan, a couple of issues have been raised there. It probably would not be fair or appropriate to expect you to respond to them immediately. We are going to adjourn now. Perhaps you will consider the point and we can come back to them when we resume at a quarter to two.

MS SULLIVAN: Perhaps we could consider the matter with the Legal Assessor as well at some stage.

THE CHAIRMAN: Certainly. We will break now for an hour and come back at a quarter-to two.

(The Panel adjourned for lunch)

THE CHAIRMAN: Miss O’Rourke.

MISS O’ROURKE: Sir, I understand from Ms Sullivan - and I am grateful to her for the information - that the original notes for Patient 6 are now here. I, for one, would like an opportunity to look at them before I continue cross-examining this witness, because obviously in the light of what he said immediately before lunch about what in your notes are pages 61, 171 and 173 and indeed suggests there is a Tippex or overwriting or a whole new page has been created, Ms Sullivan is content, indeed offered me, that I should look at them.

I have asked her if she will lend her instructing solicitor, Ms Morris, because I would rather look at them with somebody else present to verify that I am not tampering or
touching them or doing anything inappropriate. I think Mr Forde would like to as well, and Mr Foster is nodding his head too.

Sir, what I would ask is if the Panel might afford us - I suspect it is not going to take more than 15 minutes, possibly 20, because it is really those three pages that I would wish to look at. It may be someone else wants to look at, if the notes contain the original consent form, whether someone wants to look at that as well, I do not know whether it is in there or not. I would anticipate that probably what we need is something like 20 minutes.

Sir, I think it would be sensible now, before I finish cross-examining this witness and given I have just asked him about the relevant pages.

THE CHAIRMAN: Ms Sullivan?

MS SULLIVAN: Sir, that seems to be an appropriate course. Can I just mention the two matters that were raised just before we broke for lunch, to indicate that in relation to the documentation relating to the civil claim, Ms Morris, my instructing solicitor, is putting in train steps to contact and track down the person in the file in Russell Jones & Walker, if it is still in existence.

Secondly, the matter raised by Mr Forde in relation to the question of causation and Patient 6 and Patient 7, I have spoken to Mr Forde and to the Legal Assessor about that. Sir, in terms of timing, it seems to me that now is not the right time to be speaking to Mr and Mrs Henshall when Mr Henshall is in the middle of giving his evidence. It is something that we will address thereafter and revert to you as soon as we can.

MR FORDE: Sir, I am entirely happy with that course being adopted. Might I suggest, just out of an abundance of caution, that Ms Morris also tries to speak to Mr Evans, who I think was someone from the administration that Mr Henshall says he spoke to, to just confirm first of all that the file was destroyed and, secondly, that it was or was not transferred to Russell Jones & Walker. Because if he is able to indicate that it may have been destroyed before Russell Jones & Walker were instructed, it may be that speaking to Russell Jones & Walker is a bit of an arid exercise.

I would tentatively suggest that contact is made with the solicitors first instructed and then we see whether there is any need to speak to anybody further down the line.

THE CHAIRMAN: Presumably that seems like a logical process of investigation?

MS SULLIVAN: Yes, we do not really mind. We were planning to work backwards, but we are happy to work forwards.

THE CHAIRMAN: Whichever, but the main point of the exercise is that it will be done by your instructing solicitor. Mr Henshall will have heard that that is what is going to be done and that is how it is going to be done. That deals with that.

MISS O’ROURKE: Sir, can I just confirm in terms of the working backwards or forwards, I, for one, would like someone at Russell Jones & Walker spoken to because if they are the last people who had the legal aid certificate, they should still be holding
documents giving the timescale.

THE CHAIRMAN: Yes, very well. It looks as if the inquiry needs to be made of both.

MS SULLIVAN: Exactly, sir.

THE CHAIRMAN: The point you make about the Henshalls still giving evidence, Mr Forde is happy with that, so that seems to be fine. Let us now adjourn to give you the opportunity - shall we say quarter-past two? That gives you slightly more than the 20 minutes. We will expect to come back at quarter-past two, unless we are given a message to say that you would like a little bit longer.

Could I also say, while I have the floor, that I am intending we should finish at around four o’clock this evening, if that is all right with everyone. We will adjourn now until quarter-past two.

(The Panel adjourned for a short time)

MISS O’ROURKE: Thank you, sir. Sir, can I indicate we are grateful for the time. We have the original records. We also have the original consent forms signed by both Mr and Mrs Henshall. In due course, sir, I am going to be asking for you, the Panel, to have them and to look at them. In the light of having seen them, I do now want to ask Mr Henshall a couple of questions, firstly, about the original consent form and, secondly, about the notes - what are pages 61, 171 and 173. I do not think he has had the opportunity to see them - no. I think the notes are now here. I wonder, first off, if he could be shown the original consent form that he signed for Patient 7. (Same handed) Mr Henshall, that is the original of what we have at page 19 behind divider 4 in file number 2. Yes?

A Yes.

Q Can you confirm that is your signature and your block printing “CARL HENSHALL” on it?
A Yes.

Q Having looked at that original, it appears that the word “father” has not been written by you. It does appear to be a slightly different pen and it is different writing.
A Yes.

Q And also the “12/2/92”?
A Yes.

Q “12/2/92” looks like the same handwriting as the “12/2/92” down the very bottom of the page?
A Yes.

Q If we look at Dr Aru’s note in the clinical notes, you may want to look at the bundle that you have in front of you as opposed to the originals, but I think we have the originals as well. It is page 13. Yes?
A Getting there, yes.
Q The writing of the word “father” looks like it may be Dr Aru’s word “father” as well, although the “f” is slightly different but the “ther” looks like ---
A Are we talking page 13 behind tab 5 again?

Q Tab 4, Patient 7’s notes.
A I am there now.

Q What I am going to suggest to you is that when you said earlier to me that you did not think the word “Relationship, father” and date “12/2/92” was written by you ...
A That is right, yes.

Q ... now having seen the original, I am agreeing with you.
A Okay.

Q Therefore, I am suggesting to you it looks like they are written by the same person and the same pen that wrote down below “Dr Arumugam” and signed and wrote “12/2/92”?
A Yes.

Q You agree with that? This raises the following question, does it not: when you signed and wrote your name, was “father” and “12/2/92” written below it?
A Not as I can remember, no.

Q Then why did you not write the date?
A Because I was just asked to put my name and signature on it.

Q Is that right? You told us this morning you were asked to sign, date and print your name. You also said so in a witness statement written by you on 12 December 2007, you were handed a copy this morning, it is paragraph 6:

(\textit{Document not available to shorthand writer})

“I was concerned about her well-being. The nurse brought me a form on a clipboard and told me where to sign, date and print my name.”

A Obviously I got the date bit wrong. I was not asked to do that.

Q If you were handed the form and asked to write the “Carl Henshall” bit and your signature, surely you would have looked at the line immediately below and thought, “I better date it as well”?
A Not necessarily. Why?

Q The only reason that you would not have needed to do that is because it was already written on the form when it was handed to you, and that is because Dr Arumugam had already himself written his name, his signature, the date, the word “father” and the date and handed you and simply said, “Print your name and sign it”?
A So you are agreeing then - because if you read the line below, “I confirm that I have explained the nature of the above investigation to the above named relative/legal guardian”, so Dr Arumugam could not have legally signed that before I signed it, or else

D12/72
my name would not have been there.

Q He did. He signed it because he was standing right next to you at the time when he handed you ---
A So he made a false statement then you are saying.

Q Well, no, he did not.
A So you are just saying he wrote “father” and the date then I signed, then he signed?
Q Yes.
A Why would he do that? Surely he would fill in all those bits at one go.

Q Well, you tell us otherwise why you signed it and did not then date it.
A Because I was not asked to, obviously.

Q So that is a mistake in your witness statement that (Talk over each other) ---
A It is a mistake, yes.

Q --- of 12 December 2007?
A In when, sorry? 2007?

Q 12 December.
A Obviously, yes, it is a mistake.

Q It is a mistake in your evidence this morning in answer to Ms Sullivan?
A Yes, it is a mistake. I am sorry about that. That is part of like, you know, the lapsed time ---

Q Why not sign it when you see it? Did you not see the word “date”?
A I could not possibly tell you this time away, no.

Q The answer is simple, is it not? Dr Arumugam was with you. He wrote the other bits. You wrote your bit and you did not need to write the date because he had written it ---
A So he wrote his bits first? So he still made a false statement because ---

Q Well, he wrote them first contemporaneously with you he said, “Do not worry, I will fill that in”, but it was all written in the one session. You were ---
A He was not there. It was a nurse that ---

Q Okay. Now pages 61, 171, 173. We have now had the opportunity of looking at the originals. I think you should too have the opportunity. I think it may help, because the notes are all jumbled up, if Ms Morris just makes available to you the pages that are the nursing notes. (Same handed)

MS SULLIVAN: These are Patient 6’s notes?

MISS O’ROURKE: These are Patient 6’s notes. (Pause) You have had a chance to look
A at those pages?
A Yes.

Q You can see that they are original pages from the notes?
A No, I cannot see that. Why ---

Q What, you do not think they are original?
A I have no way of telling that, have I? I do not know.

Q You will confirm that they have no Tippex on them?
A They have no Tippex on them. I would not expect them to, to be honest.

Q So where Patient 6’s name appears, starts the sentence and on other pages of the nursing notes, there is no evidence that it has been rubbed out or Tippexed out or overwritten, is there?
A There is no evidence of that, no.

Q No. Each of those pages has several different colours of pen on it in several different sets of handwriting?
A Yes.

Q The pages, as you have just been flipping them over, they are in fact two-sided pages, although we have them copied as one-sided. Yes?
A Yes.

Q So, if someone was going to manufacturer that document some time between ’97 when you first complained in the Griffiths Inquiry in 2000, they would have to do a fairly elaborate manufacture because they would have to write two sides of notes, they would have to get different pens and they would have to get different sets of handwriting to make those amendments, would they not?
A Probably, yes.

Q So the Panel is now faced with one more on to my list of options, that there was some elaborate conspiracy to take out notes and recreate and rewrite whole pages of them, or the alternative is you and your wife are telling lies about the naming of Baby 6.
A We are certainly not telling lies, that is for certain.

Q So we are back to the clairvoyant psychic, are we now?
A You are back to whatever - I can tell you we are not telling lies. We did not name her till the next day.

Q Those notes are genuine documents?
A I would say no based on my knowledge of when she was born.

Q So someone has made up that page you have in your hand there?
A I would have to say that, would I not? Because we did not name her until the next day.

Q So it is not just in fact as we look through the original notes and the Panel will in
due course have them; it looks like there is about five or six different pages where Patient 6’s name is written with signatures for 14 December?

A Yes.

Q So all of those pages have been manufactured?

A Well, I would have to say yes because we had not named her on that day.

B Q That is fine. If you have to say yes, the Panel will make their minds up. If you could let Ms Morris have the pages back and the Panel in due course will see those and your ---

A Can I just look at these? I did not really have chance. I only looked at that one. I did not have much chance to look at these ones. (Pause) Thanks. (Same handed back to solicitor)

C Q Now in addition to the witness statement that you wrote on 12 December 2007, you made an affidavit when you first lodged your complaint with the General Medical Council. Do you remember that?

A Vaguely, yes.

Q Complaints have to be supported by affidavits. That means that it is not just a statement made by you; you have to go and have it signed and witnessed by a solicitor or a notary public or something of that sort. Yes?

A Yes, we went to a solicitor I think.

Q Yes, you did. You went to a solicitor before somebody D Smart or something, solicitor, 1 November 2000?

A Yes, sounds about right, yes.

E Q In Newcastle under Lyne. At that stage your complaint was against Dr Spencer, Professor Southall, Dr Samuels, Dr Brookefield, Dr Raine, Professor Harvey, Dr Modi and Dr Palmer?

A Yes.

Q I want to read to you - and I can hand you up the page to look at - from paragraph 4 of that affidavit. This is a statement made on oath. You appreciate the significance of an affidavit. Yes?

A Yes.

Q You would have been asked by the solicitor who witnessed it for you to read through the statement and confirm its accuracy before that solicitor would sign it off. That is what an affidavit means.

A Yes.

Q In 2000, events would have been fresher in your mind than they are now today, seven and a half years later?

A Slightly, yes.

H Q You have been asked about the consent form that you signed the original, which you have there, in respect of Patient 7. You say:
“The nurse brought me a form and a clipboard and told me where to sign, date and print my name.”

So you were saying you were being asked to date it?

Q But that was November 2000, was it not? You had seen the consent form by then because it had been made public by Dr Price a number of months before.

A I had seen the consent form, yes.

Q Yet, you were claiming at that stage a nurse was asking you to sign, date and print?

A As I just said, the sign and date is a figure of speech.

Q You do not think it is important to try and be accurate when you are putting in an affidavit?

A Yes, obviously you have to be accurate but obviously that is something that, you know, I did not actually - it did not occur to me that I had got that slightly wrong. It is not completely wrong, it is just slightly wrong. It was just the date bit. I was not asked to do the date bit obviously, or else I would have put the date there, would I not?

Q Next I want to move on to some of your writings and some of the things that you said to the press. (To the Chairman) What we have done, sir, rather than as the last time where I was handing in individual pages and it got confusing, I have put together every page that I want to ask Mr Henshall to look into. It is a little clip of pages of correspondence. I have provided Ms Sullivan with a copy, I think at the morning tea break. I am content if the Panel wish to see it if Ms Sullivan is, but if she does not want the Panel to then I will deal with it the same way I dealt with it the last time: I will ask the witness individual questions about it. We have not copied it yet for the Panel, but there is no problem in doing it. That is the thickness of it. At the moment I have provided it to Ms Sullivan, my learned friends have it and I am about to let Mr Henshall have it. It is really a matter for Ms Sullivan as to whether she thinks I should just leave Mr Henshall with it or whether she has any objection to you, the Panel, having it.

MS SULLIVAN: Sir, I think for the time being Mr Henshall ought to have it and perhaps we ought to see the extent of the cross-examination as to it. I do not think it would be right for you to see a whole bunch of documents if that is not actually going to be the evidence in the case. Perhaps we could just wait and see the extent of cross-examination ---

MISS O’ROURKE: Sir, I will put it in this way: we will give it to Mr Henshall and obviously the shorthand writer as well. Your Legal Assessor has already had a copy and then, dependent upon Ms Sullivan’s view at the end of it, we can make it available for the Panel.

D12/76
THE CHAIRMAN: Yes, very well.

MISS O’ROURKE: (To the witness) Mr Henshall, you do not need to start reading it all because I am going to take you, page by page, through it. There should be one separate page; you can put that to one side at the moment because that is not one written by you. I will come to that in a minute. The balance is written by you or else purporting to quote you. You can tell me whether it is accurate or not. I put them in chronological order.

A Okay.

Q They are numbered, in the bottom right-hand corner. Do you see that?
A Yes.

Q I want to take you, first, to page 1, which is April 1997.
A Yes. ’97?

Q Yes. It looks like someone has written “April ’97.”
A Yes.

Q Is that your handwriting?
A That is my handwriting.

Q That is your handwriting. This is a letter, as I understand it, to the UKCC, written by you...
A Yeah.

Q ...complaining about two of the charged nurses on the case...
A Yes.

Q ...in the study, Theresa Wright and Kate Lockyer?
A Yeah.

Q You say in that letter, the last paragraph on page 1:

“We have officially complained to the Health Authority, the General Medical Council, The Ombudsman...Community Health Council...our local MPs”

- and we are pushing for a public inquiry?
A Yeah. That is right, yes.

Q On the second page of that letter, and this is the bit that I am interested in, after the space for the signatures, it says, “Brian.” Can you tell us who that Brian is?
A I would imagine that is Brian Morgan.

Q And Brian Morgan is a journalist who lives in South Wales?
A That is right, yes.

Q Purports to be an investigative journalist and has been running a campaign against
David Southall for ten-plus years?
A I mean, when you say he has been running a campaign against David Southall, I know he has had an interest in the work of David Southall. I do not know what his motives or what his reasons behind it are.

Q An interest in denigrating the work of David Southall, not an interest in supporting the work of David Southall?
A Well, I mean, Brian Morgan is not here to - I would not like to speculate on what his motives are and what ---

Q Come on, Mr Henshall, you have read a lot of stuff.
A I have read a lot of stuff.

Q Have you ever read a word written by Brian Morgan that has been supportive of David Southall or his work?
A No, I have not, no.

Q No, you have not, so Brian Morgan writes articles denigrating the work of David Southall, and he has been doing it for years?
A Probably, yeah.

Q Why are you sending him a copy of your letter of complaint to the UK Nursing Council?
A Well, as I remember it, around about this time, or perhaps just before it, Brian Morgan had done or was planning to do a story about CNEP, and newspaper editors, being as they are, if you mention something, they like proof of it. We had to do quite a bit, actually, to newspaper editors, and we have also had solicitors from newspapers visit our house to pick up documents of evidence when there has been threats of press complaints, commission and things like that, so I would imagine it is saying that.

Q Why would Brian Morgan in South Wales suddenly have an interest in CNEP?
A I would imagine it is because of Professor Southall’s involvement.

Q Absolutely.
A You have to imagine, way back in ’97, we would not have not been aware of Brian Morgan’s previous work. I think it is fair to say we have not done a great deal with Brian Morgan since...

Q You have done bits.
A ...probably 90s. I mean, little bits.

Q We are going to come in a minute to just what you have done with him, what you have had from him. So Brian Morgan takes an interest in you and CNEP and you exploit his interest because he is a journalist who puts stuff in papers?
A I do not think it is fair to say...

Q Well, let me finish.
A ...we exploited his interest.
Q You exploit his interest, because you want to gain publicity for your campaign, so although you have never met David Southall, although he has never been involved with your children, there is no evidence linking him to anything that happened to your children, or duping you into signing consent forms, or placing your children in the trial, you take advantage of someone who is a known enemy of David Southall’s?
A He was not particularly known in that way to us at that time. The sorts of people he was talking about doing pieces with, were The Independent newspaper or Channel 4 News, who we thought would do a good job and produce something worthwhile, rather than - you know, it was not things like The Sun we were going to and that. We were hoping it was going to be a well-balanced and informative piece.

Q Why, at this stage, are you picking on David Southall? You have got clinicians who you complain about to the GMC who are involved in the care of your children...
A I do not.

Q ...Dr Spencer for one - just wait for the question - Dr Spencer for one, Dr Brookefield for another, Dr Palmer, all of whom have written in your children’s notes, all of whom have seen your children. Why is it that you were targeting David Southall as early as June ‘97 when you have not met him?
A I do not think anywhere this letter says we are targeting David Southall.

Q Right. Then let us look at the next letter, page 3. Is this a letter to Dr Prowse, who, at that time, is acting chief executive of the hospital which employs Dr Southall? Yes?
A Yeah.

Q 3 June 1997. It starts:

“Dear Mr Prowse,

Thank you for your recent correspondence concerning our letter addressed to Professor Southall, 24th April 1997 and in reply to our own correspondence dated 17th April 1997.”

Yes?
A Yep. Yeah.

Q The rest of this letter is about CNEP and Professor Southall. It does not name any of the other doctors. It talks about Professor Southall and his colleagues, and Professor Southall’s involvement, Professor Southall’s work into Sudden Infant Death Syndrome and breath holding in small infants. It is all about David Southall, June 1997. Yes?
A It talks about material available on CNEP, including that written by Professor Southall and his colleagues, so we do mention his colleagues as well.

Q Yes. Nobody else is mentioned by name, other than David Southall.
A Dr Bose is, on page 4, down the bottom.

Q Yes, but not as a matter of complaint?
A Not a matter of a complaint, no, no.

Q No.
A The thing is, this is obviously in response to a letter that Mr Prowse had sent to us, so...

Q The key bit I want to ask you about is on what is numbered page 4, middle paragraph, very long paragraph.
A Yeah.

Q Around about what would be the middle of the page, between the two punch holes.
A Yeah.

Q “Why then [should] he slowly suffocate my child with his machine and lie in order to cover up what had been done?”

Do you see that sentence?
A I do see it, yeah, yeah.

Q That sentence is written about David Southall, is it not?
A I think it was established that me wife wrote this letter.

Q How is it so established? I do not see how ---
A I thought it was in some of the cross-examination that she thought she wrote this letter, and she was pointing out the ---

Q Is your name not there as well? “Yours sincerely, Carl Henshall. Deborah Henshall.”
A My name is there, yeah.

Q It comes from both of you?
A Yeah.

Q So you have adopted it. You have accused David Southall of slowly suffocating your child with his machine and then lying in order to cover up what has been done.
A Well, I think we ---

Q That is as of June 1997. No other doctor has that allegation made, no-one else’s name, none of the clinicians who actually treated your child, put her in the tank, decided when to take her out of the tank, none of the doctors who sought the consent and you say duped you, but David Southall?
A Yeah. I think the inference is that it is the machine that suffocated the child.

Q What, and David Southall designed it, did he?
A Well, he is part of the design of it, yeah. I think he takes a lot of credit for that for redesigning the CNEP tank...
Q Unless you...
A ...along with Dr Samuels.

Q ...had agreed, even if it is because somebody duped you, unless you had agreed, the children would not have gone into the tank. Maybe somebody duped you and that is the person who did the wrong and you should be pursuing them, but that was not David Southall.

A Well, what, the person duped me into lying my daughter into the tank?

Q Mmm.
A Well, I have actually made complaints along that line.

Q It is not David Southall, there if somebody suffocated your child in a machine, it is because you said yes because somebody, according to you, told you lies, but that somebody was not David Southall.

A How can you say that?

Q You have told us you did not see any information leaflets, you did not see anything else about the study, so if he wrote those or any part in those, he has not misled you. The misleading, according to you, has been the person, you say a midwife, who told you this was a safe system, or Dr Claire Stanley, now calling herself Dr Newell, who told your wife, because those are the people who you say did not give us full information, or gave us misleading information, or did not give us the leaflets, or did not tell us what this is.

A Did David Southall take any part in the right of the patient information leaflet...

Q Well ---
A ...that was submitted to the ethics committee?

Q That is not the question. The question is ---
A Well, it is because you are on about lies...

Q You say ---
A ...and lies in that patient information sheet.

Q You said you did not see any such documentation, so it did not influence you.
A No, it did not influence me, but there are lies in that documentation.

Q It did not influence you. You made a decision based on, now you and your wife are saying, in your case, a midwife lying to you and, in her case, a doctor lying to you, so they are the people ---

A But if I ---

Q Just wait. They are the people who caused your children to be in those tanks, you saying yes in response to them?
A Say that again, sorry. If I?

Q You and your wife both gave consent. You have both agreed it. You said it was not informed consent, but you have agreed you gave consent. She says verbally.
Okay, yeah.

You say, in writing, the target should surely be the people who misled you into giving consent that was not informed. That is not David Southall.

I wrote a letter to our local Trust, asking if they could find out the whereabouts of Dr Arumugam, and they said they could not find him.

It was not him either.

No, it was not him. It was not him, no, no.

Why did you want the Trust to find him?

Because of the point you were making where you were saying - and I make the same point ---

Or is it the truth, Mr Henshall, that it was... Dr Arumugam?

If you are asking me a question, let me finish.

Can he just finish that?

I think the letter of complaint regarding Dr Arumugam is just as you were saying, that he had countersigned a consent form, saying that he had explained treatment to me when he had not. I think there is a letter, which definitely we have written, because I have read it, you know, recently, that says just that, that it was not Dr Arumugam that explained this to me, it was a student midwife.

Right. So let us ---

So, basically, the explanation we were being given was being influenced by ---
Q Let us ask about that. You say it was a student midwife took your consent. Do you have any evidence at all to link a student midwife to Dr Southall down in London? Did he train her? Did he speak to her? What did he do to the student midwife?
A Well, who did then? Who would have give an explanation?

Q We, of course, say no student midwife took any such consent, but you claim and swear blind and, whatever, that it was. Where is your evidence to link the student midwife who took consent from you to Dr Southall?
A I have got no direct evidence. How would I?

Q You have got none.
A How would I?

Q Not a scrap.
A How would I?

Q Not only no direct, none. Zero. Zilch.
A How would I?

Q Yes, because it did not happen.
A No, how would I, as a parent, get that sort of information?

Q Therefore you should not make an allegation against Dr Southall and you have not got a scrap of evidence for it?
A I think if you take this letter in context - this is written to the chief executive of the hospital Trust...

Q His boss.
A ...it has not been bandied around to the press or anything like that.

Q It has been written to his boss.
A It has been written to his boss, yeah.

Q Oh, really? It has not been bandied around, it has been written to his boss alleging...
A It is a letter.

Q ...he suffocated your child.
A It is a letter from us - I think my wife did say she wrote this - to the chief executive of the hospital Trust.

Q In 1997, without a scrap of evidence...
A 1997.

Q ...you are impugning the reputation of a professional of international repute, and you...
A Well, I did not know that at the time.

Q ...have got no shame or conscience about it.
A  I did not know that at the time...

Q  Right. Let us look at the next page then. Let us move on, page 6.

THE SHORTHAND WRITER: I am sorry, I did not get the end of the answer. “I did not know that at the time…”?

B  THE WITNESS: What his reputation was.

MISS O’ROURKE: Page 6 and page 7.

A  Yep.

Q  This is an e-mail to you. Yes?

A  Yes.

Q  xxx@xxxx.xxon.co.uk”?

A  Yep.

Q  2 July 1998?

A  Yes.

Q  From Brian Morgan in Cardiff.

A  Yeah.

Q  Addressed to “Carl and Debbie Henshall.”

A  Yeah.

Q  “North Staffs Health Watch.” What is North Staffs Health Watch?

A  North Staffs Health Watch was an organisation we became involved in. It is like an umbrella organisation for people who have concerns or issues with the local health service, and, basically, we came together, we campaigned on a number of issues, mainly around openness, transparency, accountability with the NHS and improvement in services within the NHS.

Q  When did you join that organisation?

A  Oh, we met up with all the members of it at a Trust - annual general meeting, hospital Trust annual general meeting, probably...

Q  When?

A  Probably around ’97-ish, somewhere around then

Q  Did you thereafter become what is described as the coordinator of it?

A  I was one of a number of coordinators.

Q  With your wife as well?

A  With my wife, yeah.

Q  And Ian Syme, who is sitting...

A  Ian Syme, yeah.
Q ...in the row behind your wife?
A That is right, yeah.

Q The gentleman who has been nodding and gesticulating throughout the hearing?
A Yeah.

Q That is the one. Okay, so why is Brian Morgan e-mailing you about CVS, which stands for covert video surveillance, in July 1998?
A Because I think that Brian Morgan was hoping that we would complain regarding this as well. I think he - I think this is sort of around about the time when we sort of realised that Brian Morgan was, you know, taking the sort of interest in Dr Southall’s work, that we were not taking the same interest. There was no way we were going to start complaining on issues that were of no relevance to us. So although he sent us this, I do not think there was ever anything come from it. I do not think we even replied to him, other than, again, perhaps something like, “Sorry, Brian, we are not interested.”

Q The opening words are:

“The history of CVS is complicated. I don’t know how much detail you might need if you were to take this further.”

Q Why was he looking to you to take this further? You had no interest in covert video surveillance?
A Well, exactly. Exactly. I do not know why he was thinking we would, to be honest.

Q “This is an outline. Southall started using CVS in the Brompton Hospital in around 1987.”

It goes on. He is effectively dishing what dirt he can on David Southall, is he not?
A Probably. Probably, yeah. As I say, we did not do anything with this.

Q But you continued to be involved with Brian Morgan.
A Not a great deal.

Q You did not tell him to go away.
A We did not have a great deal to do with him. Our e-mail address was there. He knew our phone number, so he would periodically send us e-mails or even ring us, but as to what involvement we had with him, it was really limited. It was more or less just that, the odd phone call.

Q Did he not set up and facilitate for you an interview such that he and Dave Blackhurst both ended up being witnesses at the Prowse hearing?
A That must be the Channel 4 one. I am not sure what year - what year was that?

Q 2000.
A It was 2000, was it?
A  There again, that was an interview on our complaint, not on a child protection complaint, or anything like that. As we all know, child protection has got nothing to do with CNEP.

B  It was an interview where, again, he was given the opportunity to take a potshot at David Southall and he used you to do so?
A  Well, you might see it like that. We saw it as an opportunity, because the thesis of Joe Raine had come to light then.

Q  Let me take to you page 8 then of this bundle. This is a letter to Dr Matthew Lohn, who is partner at Field Fisher Waterhouse, doubly qualified doctor and solicitor.
A  Okay.

A  Yes.

Q  First-name terms with him.

“Following our meeting on Monday 20th July 1998 here is the requested chronological statement of events which led tot he faxed consent and the unauthorised faxing of Deborah’s medical records.”

Yes?
A  Yep.

Q  This appears now to be a new complaint relating to Dr Prowse and the consent forms?
A  Yep.

Q  You talk about a Watchdog programme and the BBC and Angela Ripon. Yes?
A  Yes. Can I just point something out there? You just said that that Channel 4 interview ---

Q  It is ’97.
A  It is ’97, so, like I say, it was around about that time that we ---

Q  Yes. We see on the top of the second page, which is page 9:

“Tuesday 3rd June 1997. We met Brian Morgan, Kent Barker [from ITN] and a camera crew at our local library along with”

- then the name of another parent.
A  That is right, yeah.

Q  Who is the name that I got you to write down earlier?
A: Yeah.

Q: In that letter, you say there, and I think that is one of the first times that you say it, 25 July 1998, “...we had not named [Patient 6] then and Deb would not have been in any condition to sign [the form] at the time”?

A: Yes.

Q: So you make that allegation, in writing, to the GMC’s solicitor?

A: Yes.

Q: Yes?

A: Yes, because, actually, Dr Prowse agreed that Deb could not have signed that form between two and four hours of age, on camera, under the effects of morphine and anaesthetic. Dr Prowse actually agreed with that point.

Q: I am not worried about what Dr Prowse agreed. I do not represent him. I have got nothing to do with him. He has already had his case, and he had you, effectively, branded as liars in that case. I have got another case when we deal with that.

A: I do not particularly think we were branded as liars, to be honest.

Q: Well, we are going to come to that in due course.

A: Yes, but he is a medically qualified doctor is Dr Prowse.

Q: I do not care what he said. He is not an anaesthetist. It is not relevant. I do not represent him. I do not represent the Trust.

A: Okay.

Q: I represent Dr David Southall, and I am asking you, in respect of allegations that you made, that is the first time that I can trace anywhere that you say Deb would not have been in any condition to sign it, and, by the way, we had not named Patient 6. The reason you are saying it there for the first time is you had previously been peddling the story that she did not sign a consent form at all, and suddenly Dr Prowse is able to produce it, and you have to tell your mates at the press something to cover up, so out comes story number one: we had not named her and Deb would not have been in a condition to sign it.

A: I think the bit about Deb not being in a condition to sign it, we probably made before, being under morphine. But, to be fair, until we had actually seen the consent form, how would we know this has got Patient 6’s name on it? So, therefore, how would we be able to mention that beforehand?

Q: Let us look at the next letter because that gets more interesting. Page 11. It is a follow-up to Matthew Lohn, I think three or four days later. Actually, the same date by the look of it. It looks like it is a second letter of the same date. Okay?

A: Yes.

Q: “Following our meeting on Monday 20th July [1998] here is the requested summary of our complaints...”

- then you name all the people you are complaining about?
A: Yep.

Q: There is eight of them?
A: Yep.

Q: Paragraph number one, “Consent. We deny that we gave informed consent.”
A: Yes.

B: “Deborah did not and could not sign a consent form for [Patient 6] at the time claimed by the researchers. Therefore the form must either be forged or was signed at some other time on the understanding that it was for some other treatment or procedure.”

C: That is right, yes.

Q: Do you stand by the second part of it - that it was signed at some other time on the understanding it was for some other procedure or treatment - and, if so, what other time and what other treatment or procedure?
A: It is one of the possibilities, yes, it could have been.

D: How is it?
A: How is it?

Q: Yes. Let us look at the form. It is file one, page 390. I think we now have the original if you need to see it. You are saying that it is a possibility that it was signed at some other time on the understanding that it was for some other treatment or procedure. You are saying that is a possibility?
A: Yes.

Q: How could that be because what somebody would have had to do would be to cover up with a page of A4 the whole top of the form?
A: Not necessarily.

F: Otherwise it could not be for any other treatment or procedure, because it uses the words “research investigation…clinical investigation…participation in the study…drug regulatory authority”, all the points I took you though this morning. So it could not be for any other investigation. It also uses the title CNEP.
A: Hang on, that may not have been written on when Deb was signing it.

G: But the printed bits would be on it which say “clinical investigation”, “participation” and “study”. So it is not for any other treatment or procedure. Your wife at one stage appeared to suggest in letters or witness statements that it could be for a hearing test?
A: That is a possibility.

H: How could it? That form does not fit a hearing test?
A: If you are walking down a corridor and you have a form thrust under your face saying you need to sign this for the hearing test, you just sign it.
Q Your wife is not saying, as you are saying, the defence of “I did not read it, guff”, your wife is saying “I did not sign it, guff”? That is what she is saying, “I never signed this form”.
A She is saying she has no recollection of being asked to sign it or signing it.

Q Can you be shown the original so you can confirm there is nothing on the form that seems to suggest that there has been a photocopying job done or a tippexing out or a folding over the top of the paper? (Same handed)
A No, we have seen that before, yes.

Q That is the original. There is no tippex on it that you can see?
A No.

Q There is no over writing on it?
A No.

Q There is nothing to suggest that the paper has been folded, stitched together or stuck together?
A No.

Q It looks like it is one piece of paper?
A Yes.

Q With the writing on it, including the doctor’s writing at the top and the bottom - all the one set of handwriting?
A Yes.

Q Are you maintaining that it is a possibility that it was for some other treatment or procedure, or what are you saying - forged?
A There is the two possibilities in the letter. Either it is forged or signed for some other treatment.

MS SULLIVAN: These possibilities are really for Mrs Henshall to answer, as indeed she did because Mr Henshall was not present at the time.

MISS O’ROURKE: I understand that, but he is the author of this letter to Matthew Lohn. He has already agreed that he wrote most of these letters and his wife also indicated that he wrote most of these letters. (To the witness) This is a letter that you wrote and you are giving two possibilities, so it is your understanding that it was forged or signed for some other procedure.

A That was my understanding and is my understanding now.

Q Can you look at page 13. The next page in the clip of correspondence that I have given you. Dr Richard Nicholson. Can you recall when you first met him?
A Dr Nicholson did an interview on I think it was “Newsnight”. This was before we had ever met him. It was him and a lady called Beverley Beech and an organisation called AIMS, who were interviewed about the scene at trial. I might be mistaken but it might have been in the wake of the announcement of the Griffiths inquiry. I might be
mistaken on that. He definitely did a television interview, which is the first time we had ever seen or become aware of him. We did make contact with him after that because obviously we could through the *Bulletin of Medical Ethics* because that is where he was from according to the television screen.

Q You contacted him rather than him contacting you?
A Yes, I am sure we would have contacted him. We met up with him some time after. I could not tell you exactly how long. He happened to be up in Stafford to do an Ethics Committee members' training day and he had a couple of hours in-between the course finishing and catching his train. So we just took the opportunity to go down to meet him and have a chat with him.

Q Mr Forde yesterday showed your wife a letter that Dr Nicholson wrote to the *BMJ* in December 1998. You may recall that. We can dig it out if we need to. In that he makes reference - Mr Forde read it out or showed it to your wife yesterday - to having met a couple. Although he does not name you in the *BMJ* it clearly appears to be you because it says they had one baby die in CNEP and another one brain damaged.
A Yes, that is us.

Q And that these parents have complained to the General Medical Council. That would fit with you. That letter says “I met them a week ago”?
A Yes.

Q Was that the first and only time you met him?
A Not the only time, probably the first time.

Q How many times have you met Dr Nicholson?
A We have actually met Richard Nicholson on three occasions. That was the first time. The next time, I cannot remember whether we contacted him or he had been in contact with us about something. He was passing through Stoke on the train so we took the opportunity to meet up with him for an hour and just have a chat. Then in his capacity as chairman of the Association of Research Ethics Committees he was holding a debate on the new government arrangements for Research Ethics Committees and invited me down to speak as a patient stroke consumer.

Q When was that?

Q Is that the last time you met him?
A I cannot remember if the last time I met him was at the AREC conference or when he came to Stoke. Those were the last two times we met up with him.

Q So you have not met him for five, six or seven years?
A No.

Q Have you been in telephonic communication with him since?
A I may well have spoken to him briefly on the phone. I could not say for definite.

Q What about emails?
A We have not been in email correspondence for a long time. I did try to send him an email a few weeks ago when there were lots of derogatory remarks made about him on websites supportive of the three doctors here. I just thought he might want to answer them, but there was no correspondence back and to. I do not think the email actually got through to him, because I am sure I had them bounce back.

B There was an attendance note I put to your wife and I think Mr Forde also put to your wife with Matthew Lohn at the GMC on 10 February. It appears that it was your wife having that telephone conversation. It appears that she may have used the phrase that “Richards Nicholson is a supporter of your action”. Did you see Richard Nicholson back in 1999 as a supporter of your CNEP case?
A Not as a supporter of our CNEP case. I think this was probably just a bit of confusion, misinterpretation. I remember that he wrote something in the *Bulletin of Medical Ethics* or that he had done a television interview and made some remarks supportive of some of the issues we had raised. I do not think we have ever described him as a supporter of CNEP. I do not think he has ever particularly described himself as that. I think it is more likely that what was said was he was supportive of us and our remarks and that sort of thing, and it has probably got misinterpreted in the conversation.

Q I will not ask you about that. Did you ask him to intervene with the GMC on your behalf to either put in a call to Finlay Scott the chief executive, or indeed anybody else at the GMC?
A No, we have not asked him to do anything like that, no.

Q Do you know that he did phone Finlay Scott or attempted to phone Finlay Scott the chief executive and it was on behalf of your complaint?
A I do know now. He did it off his own bat. We did not ask him to do that. We had probably been speaking to him and complaining about how long it had taken, so he took it on himself to do that.

Q Help me with this. Page 13 in this clip of correspondence is a letter to the GMC from the House of Commons from Mrs Llin Golding MP who was at the time your constituency MP. The last paragraph reads:

“The Henshalls also tell me that they have been given helpful advise by Dr Nicholson”.

Did you tell Mrs Golding that?
A Yes, we probably did.

Q What was the helpful advice he gave you?
A I could not remember at this time. He has given us bits of advice on how research trials should run and how Ethics Committees should be constituted and things like that. So he has given us lots of little snippets over the years or pointed us to where we can go and find stuff.

Q She continues,

“it has been intimated to them that the GMC feels that he is being unhelpful with
his advise. Could you let me have you impressions on this matter as well.”

Did you tell Mrs Golding that it was intimated to you that the GMC felt he was not helpful, that he was being unhelpful?
A I cannot remember being told that by the GMC. I know you have a record there saying they did feel that. It may have been Deb who spoke to him. I cannot remember him saying that.

Q I want to ask you about page 14, 12 March 1999?
A Yes.

Q This is a letter to the editor of the Nursing Times in London. It follows the Nursing Times running a story which said that “Nurses are in the clear over baby treatment experiment”. You were not happy with the story that the Nursing Times wrote?
A No.

Q This is a feature - I will put further examples to you in due course - when you do not like what the press writes or you think they have it wrong you write and tell them so?
A That is the right to reply, I think.

Q Absolutely, I have no problem with that. I establish that as your attitude, so then we can take it that you were happy with press reports in circumstances where you do not write to correct them?
A It is impossible for us to read every story that is written about us or about CNEP trials and correct every single mistake or misinterpretation.

Q You would correct the significant ones, though, would you not?
A We correct some of them if we see them and if we have the time or the inkling to do it, yes.

Q In any newspapers where you had voluntarily posed for a picture and they got it wrong, you would certainly in those circumstances take the time to tell them, “Look hold on you guys, we posed for a picture and you have mis-quoted us”?
A It depends what the quote was.

Q We will look at a few of them in a moment. This one to the Nursing Times, you know say on 12 March 1999, it is the third paragraph:

“I would also like to make firm that it was a trainee midwife who spoke to me about the treatment. She did not state that this treatment was unproven or that it was part of a trial/study/experiment. She did not tell me any of the previous adverse incidents.”
A That is correct, yes.

Q And so you are stating categorically and beyond peradventure that this was a trainee midwife. Why are you saying that?
A Because it was.

Q Did you ask her?
A No, the uniform was that of a trainee midwife..

Q Why do you say that? You have underlined in a letter to the *Nursing Times*, “It was a trainee midwife.” Who told you it was a trainee midwife?
A Nobody told me. That is the uniform she was wearing. The uniform was that of a trainee midwife. Unless you are saying she was incognito that day. Why would she wear the uniform of a trainee midwife if she was not a trainee midwife?

B None of the doctors who work in the hospital recognise the uniform you described as being that of the trainee midwife. So where did you get that from?
A By visiting another friend on the ante-natal wards and a trainee midwife coming into the room in that uniform.

C You know our case. Firstly, the consent was taken by a male doctor, and, secondly, there was no trainee midwife near you? I ask you now to look at page 16. This is a printout from the page of the *Bulletin of Medical Ethics*, March 1999.
A Yes.

Q What I am interested in is the top of the page. It says,

“By fax to C and D Henshall”.

That was in fact faxed to you by Dr Richard Nicholson?
A That is pretty obvious from that.

Q You see it because the fax header says,

“27-04-1999 18:45 FROM: BULLETIN OF MEDICAL ETHICS”.

Then it gives its fax number to, and I presume that is your fax number, that starts 01782.
A Yes.

Q That is your fax number. Then it has your fax header above that, Carl Henshall. You then send it to the GMC on 29 April?
A Yes, that would be right.

F So you were in direct communication with Richard Nicholson as long ago as April 1999 with him sending you by fax, documents, and you were using them in your case to the GMC?
A We were just forwarding everything on to the GMC like we had been asked to.

G Did he know you were using material provided by him to come forward to the GMC?
A I have no idea, but it was a public document anyway so the GMC could have got it. It is not as thought we are breaching confidentiality, it was written in a public journal.

Q The particular article that he has in there is entitled “Yet another enquiry in North Staffs”. It opens with not the words of general inquires or whatever, it says,

“A third enquiry into the work of Professor David Southall”?

D12/93
A  “...and his paediatric department”.

Q  But it is David Southall that he names?
A  That is not us naming him. You cannot level that against us.

Q  Did you know that Dr Nicholson had an agenda against Dr Southall?
A  I do not know that he has, to be honest.

Q  Have you seen what he said to the Griffiths inquiry? Did you read it?
A  I have read it. I cannot remember off the top of my head what he said, no.

Q  Defamatory and derogatory - questioning Dr Southall’s qualifications, questioning his career, questioning how he come to be a professor, and raising all sorts of matters that do not seem to have any connection to CNAP. Did you not think that was strange?
A  It was his opinion. He went there to give his opinion. He was asked his opinion and he gave it, and his opinion was printed.

Q  Did you suggest him to the Griffiths inquiry as someone who might give an opinion?
A  Not to the Griffiths inquiry, no. The Griffiths inquiry was set up and I think it was Professor Griffiths himself who said that anybody could come and speak to them if they had any interest in CNEP and research in North Staffordshire. A lot of people took up that opportunity.

Q  What did you understand when dealing with him in 1997, 1998 and 1999 when you were meeting him, or indeed what you understand now about Dr Nicholson's qualifications?
A  I knew he had been qualified as a doctor but was no longer practising as a doctor. I knew he had worked some time in paediatrics.

Q  At what level? Did he ever tell you?
A  I do not know what level. I was under the impression he had got to either senior house officer, registrar or something like that.

Q  You knew he had never been a consultant?
A  I knew he had never been a consultant, yes.

Q  Did you know that he had no postgraduate qualification in paediatrics? He had a DCH, a diploma in child health but nothing else?
A  No, sorry.

Q  Did that not worry you that you were being given advice by somebody who was not working as a doctor, who had never made the rank of consultant and who had no postgraduate recognised qualification in paediatrics?
A  Did that bother me?

Q  Yes.
A  Why should it bother me? I have got none of them either.
Q But you are taking expert advice from him. Do you not think it is appropriate you take expert advice from somebody who has some expertise.
A I am taking expert advice on medical ethics or research ethics, in which I think that he is quite highly regarded.

Q Did he ever tell you that he had never designed or conducted any research trial, let alone a paediatrics one?
A I do not think so, but there again that is pretty irrelevant really, is it not?

Q Is it? If you are going to criticise someone for designing or conducting a trial, do you not think it would be quite good to have somebody who has been there, seen it and done it in order to criticise?
A Really. So Research Ethics Committees are a waste of time, are they? A lot of people sit on a Research Ethics Committee who probably never designed or run a trial but they are still asked for their opinion day in and day out.

Q They are not asked to give expert evidence against doctors who have designed and conducted a trial?
A They are asked their opinion on the design of medical trials, and they have never designed and conducted a medical trial.

Q That is not the issue, the issue is if you are going to come and give expert evidence, you are entitled to have someone who is your peer give expert evidence to say, “I do this and this is the standard by which it is done, and I can speak to the standards by which it is done”. It is called the law of negligence. Therefore, to come forward as an expert and to criticise designing conduct, do you not think that that person needs to be able to say, “I have seen it and done it, and this is the standard to which I do it”?
A So far as I am concerned, he has been asked to comment on the ethical side of the trial, the application to the Research Ethics Committee. I thought that was where Professor Hutton had been asked to comment on, the actual design of the trial.

Q You told me at the outset of my cross-examination this morning that you had seen what Dr Nicholson had written in this case?
A I have seen what he has written.

Q He trespasses into all areas, and, even in a recent conversation with Miss Morris he complained about the notice of inquiry and that the heads of charge now seemed thin?
A I have not seen that.

Q You have not?
A I have not seen there where he is saying he thinks the heads ...

Q Heads of charge are thin.
A ... of charge seem thin, no, I have not seen that.

Q When you have finished giving your evidence ask Ms Morris to see it because you might find it interesting.
A I mean, that is his personal opinion. That is not something he has discussed with us or anybody else; that is his personal opinion, so I mean I cannot really comment on
that. I do think Richard Nicholson, he edits quite, as far as I know, quite widely read medical journal on ethics. He ---

Q Widely read by who?
A I do not know. I understood he has quite a reasonable circulation.

Q Of paediatricians?
A I do not know. Paediatricians do not choose to read ---

Q People of repute?
A People of repute?

Q Yes.
A Such as?

Q People who have reputations. The paediatric community in this country.
A They are the only people of repute, are they?

Q The President of the Institute of Child Health, Vice President of the Institute of Child Health. The sort of people who wrote to the Lancet in 2006 about the Telford Study. Those sort of people.
A About what - so they are the only people of repute and if they do not read this journal then it is worthless?

Q I am asking you whether the paediatric community - because these three guys that sit down this side are all paediatricians, they are all consultant paediatricians. They have the qualifications to get there and they have the work and experience to get there. You are using as an expert in your case, because you are the complainant, someone who never made it to a senior level in paediatrics and who has never designed and run a trial, to criticise their work. You are saying to me, “Oh, well, he writes a journal. It is quite widely read”. Well, comics are quite widely read; it does not make them authoritative. I am asking you if it is read by the paediatric community or supported by it and, if so, where is the evidence?
A I have no idea, but I would have thought it would have been widely read by the medical profession ...

Q Really?
A ... because it is a medical journal.

Q Where is your evidence for that ---
A I have not got any evidence but it must have a reasonable circulation because it is his main source of income as far as I am aware, so it must be quite widely read to support him. Getting away from the journal, he sat up and chaired the Association of Research Ethics Committees which was why - you know, the meeting I spoke at there must have been about 300 people there who had come for that day. He trains people who sit on Research Ethics Committees. That is his second source of income as far as I know. He must have some good knowledge of medical ethics and research ethics.

Q Did he ever tell you why he came off the medical register?
A  I do not think he did, no.

Q  Did you never ask?
A  The impression I got is because he was more interested in the ethical side and wanted to concentrate on that rather than practise medicine.

Q  That might be why you do not practise; that is a different thing. There are lots of doctor in this country who keep registered with the General Medical Council and remain on the general medical register but do not go out and practise as doctors. Right?
A  Yes.

Q  They pay I think it is £357 a year, something of that sort, as a retention fee to remain on the medical register. There is a difference between not practising and not being on the register. Dr Richard Nicholson has not been on the General Medical Council’s register since February 2000 ---
A  That is his choice I think.

Q  For the sake of £300 he is going to edit a journal that you say is going to be read by the medical profession, but he is not going to be on the medical register? That is not going to give him much status with the medical profession, is it?
A  I have no idea.

Q  Did it worry you that this is a man who had an agenda against David Southall and therefore is not an appropriate expert to give independent expert advice to this Panel?
A  I do not think he had an agenda against David Southall ...

Q  Really?
A  ... because the first time he had ever commented on him was the television interview that I had spoke about earlier ---

Q  How do you know it was the first time he ever commented on him?
A  Because I am sure that is what he tells - because the paper that he was commenting on at that time he had only read just before he got there.

Q  So you believe everything Richard Nicholson has told you, do you?
A  I do not automatically assume people are lying.

Q  You do, you see, because ...
A  No, I do not automatically assume people are lying.

Q  ... you have given an abundance of evidence today that suggests every document is forged, notes are manufactured and doctors tell lies. Dr Arumugam is telling lies.
A  Not without some evidence though.

Q  Not without evidence?
A  Mmm.

Q  So Richard Nicholson is okay even though he is not a registered medical practitioner. You believe what he says but you will not believe a word these doctors say?
A Being a registered medical practitioner means you do not lie? Is that what you are saying?

Q No ---
A That is the point you have just made.

Q Why do you not believe what these doctors say?
A Because I have evidence contrary to what they are saying.

Q Is that right? Where is it? Can we see it?
A Well, it is all here, yes.

Q I would love to see the briefcase, Mrs Henshall ---
A It is not in the brief case ---

Q I would like you to make it available to me overnight. I would welcome the opportunity to read it.
A It is not in the brief case. It is in here as well.

Q In where?
A Yes ---

Q In the bundle the Panel has?
A For a start, I am sure the final day you were cross-examining my wife you agreed that we were told about the side effects of IPP ventilation. I sat there - when we were talking about bronchiolitis you were saying, “Oh well, IPPV does harm lungs, you know that. You were told that”. Well, the only time we were told that is when we were being asked - you are sort of agreeing that we were told that. We were not told any of the side effects of CNEP. We were never made aware of the neck injury. We were never made aware of the problems of temperature control. We were never made aware that there might be higher chance of collapsed lung. We were never made aware of the possibility there is more brain ---

Q I never said you were told about neck injury because we say it is not something you needed to be told to give informed consent.
A We did not need to be told?

Q No, to give informed consent.
A Seriously?

Q Yes.
A I am sorry, Miss O’Rourke, I am sorry, but I do not want to - I do not know if you are a parent or not, but I needed to know about that neck injury as a parent.

Q Why?
A Why not?

Q It had not happened in Stoke. It had not happened with the neck seal that was used in Stoke.
A It had not happened in Stoke? How do you know?

Q Or with the neck seal that was used in Stoke.
A How do you know? You are only going by what you have been told by your client so ... I do not know that.

Q Let us move on to page 17 in that little clip. This is a letter you and your wife wrote to Peter Swain who at the time I think was Head of Fitness to Practise at the General Medical Council. Yes?
A That is right, yes.

Q June 1999. You wanted to hold a public meeting. It was not just CNEP; it was hypoxia and RAST study as well.
A That is right, yes.

Q You were intending to involve in it people from the GMC. Tell us what MCHN is?
A That is Midlands Health Consultancy Network, who were gathering paperwork on behalf of Professor Griffiths for his inquiry.

Q How were you involved with them?
A We gave evidence to the inquiry.

Q Did you give them Dr Nicholson’s name?
A No.

Q So what did you give them?
A We gave them statements and paperwork to back up what we were saying.

Q North Staffs, the Trust, AVMA - what was your connection with AVMA? That is the Association for Victims of Medical Accidents, is it not?
A Yes, we had written to AVMA - I think the letters might be in here, they might not - for their advice and if they could help us in any way.

Q In the civil claim?
A Mainly the civil claim, yes, because that is how we directed them - because apparently they hold names and contact details of a number of medical experts and also solicitors who are specialist trained in medical negligence claims.

Q You then say local police. Why were the local police involved?
A Because of our concerns over the neck injury, I think.

Q So let me just understand that about the neck injury. What were you alleging there? Were you alleging that as being a cause of death?
A We were concerned at the injury. You know, the mark on that infant’s neck was not a natural mark and I do not know of any other medical device ...

Q What did this have to with ---
THE SHORTHAND WRITER: Sorry ...

MISS O’ROURKE: Sorry.

A I do not know of any other medical device that can cause that sort of injury to an infant’s neck, so obviously we were very concerned about that and concerned that we had not been told about that. I think at that time we knew that even the mother of that infant was not completely aware of that injury.

Q Let me ask you this: what has it got to do with you to go to the police or indeed to go to the West London Coroner about a child who was in London that was not your child?
A Because I saw that as my duty.

Q Why?
A To report that.

Q Who were you? You were not the child’s parents ---
A Does it matter ---

Q It was not your hospital.
A So? So, if I see a child in the street with a horrific injury like that, because it is not my child I just walk on by and ignore it?

Q You did not see the child though. You never saw the child or the injury ---
A I saw the photos. That was enough. I would not have liked to see the child ---

Q You saw a photo in a published thesis. Yes?
A Yes. The first people to read it outside the medical profession.

Q How do you know that?
A Because we were the first people to sign on the front of it; it had never been out of the library before.

Q There may have been other copies.
A Maybe.

Q What business of yours was it when that child had parents, when there were doctors in London who had dealt with that child and treated that child, where there was a pathologist who had performed a post mortem on that child, what business was it of yours?
A What business was it of mine? I am a concerned ---

Q To involve the local police, because you said “local police” ---
A Yes, I am a concerned member of the public so I went to my local police with it. I was concerned that the injury that child had received ---

Q What was the outcome of your local police?
A We did give a statement to the local child protection unit.
A  Q  What was the outcome of your local police?
   A  I do not know. They never actually told ---

Q  Did nothing.
   A  They probably did nothing, yes.

Q  Yes. You wasted their time.
   A  I did not think we wasted their time at all. They came and made a statement.
      They thought it was serious enough to come and take a statement off us.

Q  No, they had to because you went and made an allegation but, ultimately, it was a complete waste of their time and they took no action.
   A  I cannot say why they chose to take no action.

B  Q  You wrote to the West London Coroner, you and wife, as busybodies demanding an inquest and the West London Coroner refused. None of your business.
   A  Dr Burton refused and then when Dr Burton was replaced and we had the statement about the post mortem that you have just spoke about, we wrote again. I do not think we totally dismissed them because, as the coroner at the time said, that post mortem should not have been done in hospital. If there was a concern over the cause of that child’s death, it should be reported to the coroner, an independent post mortem would have been done, and rather than Dr Southall and other colleagues going around and discussing the cause of death, the coroner would have - should have discussed the cause of death, what could be the cause of death, not these people.

Q  The pathologist, not Dr Southall, carried out the post mortem.
   A  The pathologist carried out the post mortem but in Dr Raine’s statement he says that a perinatal mortality meeting, which was attended I think by Dr Raine, I am sure he mentions Dr Southall, the pathologist, where they got around and discussed the child’s cause of death. Well, according to the Coroner’s Act ---

Q  Did you not know that is normal?
   A  Sorry?

Q  Did you not know that is normal, where there may be an adverse incident, for doctors to have, they nowadays call them audit meetings, or to have mortality meetings? Did you not know that is normal practice in hospitals up and down the country and has been for, what, 30 plus years?
   A  Not according to the Hammersmith Coroner it is not normal. If there is any confusion over the cause of death it should be reported to the coroner and the coroner will decide. The only way the post mortem could have been done in hospital would be under research. That was her ---

Q  Let us not waste further time on this. Let us establish the following: the coroner never held an inquest on this case?
   A  No.

Q  The police have never followed it up and sought to charge any doctor with manslaughter?
A Not as I am aware of, no.
Q You would have been aware of it if it had happened, would you not?
A Yes.
Q There has been no claim by those parents?
A The parents of the injured child?
Q Dead child.
A Yes, no, they have never made a claim because they do not want to. They ---
Q They have never made a claim ---
A They are just happy that they have one of three triplets alive ---
C And they have never made a complaint? They have not joined in with you in any complaint against ---
A Oh yes, they made statements to the Griffiths Inquiry. They made statements ---
Q No, complaint.
A They made statements to the General Medical Council - no, they do not want to make a complaint. They do not want to do that. That is their choice not to do it. It does not mean ---
Q Despite being whipped up you and your wife?
A They were not whipped up. Obviously they were not whipped up by us, or else they might have made a complaint or been more vociferous if we had whipped them up.
Q Did not you and your wife send them a photograph ---
A She asked us to.
Q She did not. I have seen the letter your wife sent and your wife actually in the letter says, “Do not open it. If you do not want to, get your GP to first because it might be shocking” ---
A Yes, she did ---
Q She had not asked for it ---
A She did ask for it.
Q Please wait. She did not ask for it. If she had asked for if she would not have needed to be given the warning, “Do not open it. I am sorry to have approached you and I do not know whether you have seen this or know this” ---
A I am sorry, I totally disagree with that. If I knew there was a photo like that of my dead child, I would ask for it, but I would still be reluctant to open it and look at it. I think that was the warning that Deb was giving her. You know, you say you want this photograph, but when you have opened it, it is too late to then wish you did not. You know, that is common and I think Deb actually needs commending on that rather than criticising.
Q Did you not think those parents had seen the child when it died?
A Yes, they did but ---

Q Why do they need to be sent a photo by you out of the blue, busybodies like you?
A The description [Mrs W] gave to Deb was that the baby was brought to her wrapped up in towels - wrapped up in a blanket, rather, sorry, with just the head exposed and she never knew that injury. Now, there is no way you can convince me or anybody else in this room that if that mother had seen that injury she would have forgot about it.

Q Can I ask you to look at the second page of that document that you have written to Peter Swain? The second paragraph you are saying you are going to call:

“... certain experts in the various professions to give a lecture and answer questions relating to their topic and these will include statisticians, paediatricians, neonatologists, neurologists and of course medical ethics experts.”

Who were you intending to be the statistician?
A I think we were - I think we called and we were going to invite people. I think we were going to write to a number of people and ask if they would be willing to come.

Q Who?
A At this moment in time I cannot remember who we wrote to. Perhaps a lot of people. I do not know who now.

Q Who were the paediatricians?
A No, I cannot remember.

Q What about the neonatologists?
A I cannot remember. I think we were just going to write to a lot of the units and hospitals and departments around the country and see if they wanted to come.

Q But you were actually saying they were going to give a lecture and answer questions. So you had to know they were going to have something useful to say on this topic, indeed something supportive of your case. That is why I am asking who were they?
A I do not know if we ever actually got to write to any of them because the first paragraph, back on page 17, is just our plans to hold a public meeting. Whether it got past most of the planning stage or much past this letter, I could not really say. I know the meeting never actually went ahead.

Q You then say “and of course medical ethics experts”. Who was that? Was that going to be Richard Nicholson?
A Possibly. He would have been one person we might have approached, yes.

Q You see, if you look at the next page, page 19, in fact it goes rather further in the planning because you actually have the words:

“Meeting to be held at The Moat House Hotel, Eturia. PUBLIC CONCERN OVER PAEDIATRIC RESEARCH.”
And you have a timetable including coffee, introduction from you, presentations, lunch and questions from your wife. Then you have the MHCN, the GMC, the Health Authority, Scope, AVMA, et cetera?

A Yes, but that is still part of the planning stage. I mean, we could have wrote that at the same time as we wrote this letter. We are still saying the GMC are going to attend and then you will know there is a letter where the GMC said, “Sorry, we cannot attend”. That was all the planning stage. It never got past that really.

Q Why not? Because you could not get any experts to support you?

A I do not think we got past that at all. I do not think we wrote to any experts.

Q Why?

A Because we probably did not have time to do it in the end.

Q You have actually identified a venue. You have typed out an agenda. You have a timetable and you have written to the Head of Fitness to Practise at the GMC ---

A Yes ---

Q Surely you got a bit further down the planning line before you would write to him?

A Not necessarily. Why? He is probably the first person we wrote to ---

Q Look at paragraph 3 on page 17.

A On page 17?

Q Yes, first page of the letter:

   “We plan to hand out questionnaires (enclosed) in order to gather certain information for evaluation.”

I think the questionnaire was something like about six pages, so you had spent the time to draft a six-page questionnaire and, yet, this was all that ever happened?

A If you read the final paragraph of that letter, I think you will realise why we were writing to the General Medical Council first:

   “We would appreciate your input and considerations on what may or may not harm our situation from your understanding of the law and such like before we finalise when and where we hold this meeting.”

Basically, that is why we wrote to him first. We sent him the questionnaire, we sent him the agenda asking him first. I would imagine the letter came back to say ---

Q Do not imagine, tell us. Did a letter ---

THE SHORTHAND WRITER: Sorry ...

MISS O’ROURKE: Sorry. Did a letter come back?

A I know the letter came back saying the GMC could not attend. I cannot remember
what their advice was on holding the meeting but I know it never went past that. The venue - because you see the ---

Q  Not interested in the venue ---
A  You did because you said we had a venue and everything lined up, trying to make out we got further down the planning. The RAST study, the lady who had been involved in the RAST study wrote to the Moat House and said that she could get us a room at the Moat House. That is the only reason the Moat House is mentioned there because we knew we could probably get a room there if we needed to.

Q  Mr Henshall, do not dissemble. Answer the question asked, not the one you would like to be asked or not to make a speech. I am asking you did a letter come back from the GMC and, if so, can we see it?
A  I think I have already said a letter did come back and it should be in the bundle because everything is in the bundle. A letter did come back and I know the GMC said they could not attend; it would not be right for them to attend. I cannot remember what the other advice was they gave ---

Q  But they did not tell you ---
A  But it is available. It is not as though we have hid the letter.

Q  We will dig it out overnight.
A  Okay.

Q  But it is not that they told you you could not have a meeting. They said it would be inappropriate for them to participate.
A  I remember them definitely saying they could not participate. I do not know ---

Q  I am suggesting to you it did not go ahead because you did not get any experts to support you: paediatricians, neonatologists, or neurologists.
A  I think it is more likely it did not go ahead because we just did not follow it through.

Q  You tell me when you, over the years, you have had a paediatrician, a neonatologist or a paediatric neurologist, consultant level, someone of repute who supported you in what you say about CNEP?
A  Supporting what we said about CNEP?

Q  Yes.
A  What, the whole of CNEP or CNEP ---

Q  That it is dangerous. That it has killed babies. That it has suffocated babies. That it has brain damaged babies. You tell me where are the ---
A  (Inaudible)

THE SHORTHAND WRITER: Sorry, I did not hear that.

THE WITNESS: I said paediatricians are not going to be required to start using that sort of language, are they, so that is ---

D12/105
MISS O’ROURKE: Just tell me who supports you.
A I think whether they come out and verbally support us, I think in the current climate they would not do that. You know, since the things like Bristol and Alder Hey. I think it would be very difficult for a paediatrician to come out and do that. But, if you look at use of CNEP throughout the country, you know, paediatricians are voting with their feet because they will not use ---

Q Because you scared them off.
A We scared them off?

Q With the successful campaign you ran.
A Yes, yes.

Q Intimidating people and reporting them to the General Medical Council.
A Two parents from the backwater of Stoke-on-Trent have frightened off the whole of the medical profession from using a technique that you are trying to say works and is fantastic? I do not think so.

Q I am going to come to that in the morning, I think. I just want to ask you finally about page 20 and 21, the Cliff correspondence. This is the start of the campaign, is it not? This is a letter written by you, your name first, Carl Henshall. Yes?
A I probably did write this actually, yes. I cannot say for definite.

Q It is written to the Chief Executive of North Staffordshire NHS Trust. Yes?
A Yes.

Q Thursday, 22 July 1999?
A Yep.

Q Picture of a diagram of a CNEP tank up the top?
A Yep.

Q And the word “Risk,” with what looks like tears or drops of rain coming from it?
A Yeah, yeah. It is just a font that we found on the computer.

Q Or is it blood?
A I thought it was just the letters melting, if I remember rightly. The name of the font relates to something like it was melting. It is just ---

Q Is that a name that you made up?
A I think at the time we were sort of asked, rather as individuals writing similar complaint about the similar things, if we could just sort of amalgamate the complaint into one, and perhaps under a name, and this is just the name we came up with.

Q Right. The question I will repeat: was it a name you made up?
A Well, I cannot remember - you know, there was four or five of us sat around. I cannot remember who exactly came up with this name and then who finally decided. I think it was just like a - I could not tell you who came up with that name.

D12/106
Q Okay. The letter starts:

“We are becoming increasingly aware of children who have been treated with CNEP for bronchiolitis and, those who have survived, have subsequently developed developmental deficits due to a brain injury.”

A Yep.

Q Where was your evidence for that?
A Just speaking to parents, parents who have said that their child had had ---

Q Anecdotal?
A Well, anecdotal from parents. I mean, a parent who says that I had this, you know, fit and healthy child running around, developed bronchiolitis, put in a CNEP tank, was never the same child again, then...

Q Let us just establish: anecdotal rather than medical?
A Anecdotal, yes, but, I mean, you cannot say that a parent is not an expert in their own child’s abilities.

Q But are they experts in medical causation?
A No. Well, I am not saying that. I am saying that what the parents were saying, they had a fit and healthy child develop bronchiolitis, went into a CNEP tank, and then was not the same child again. In fact, you know, like, they have got developmental delays, this child changed, and that is a parent who would be an expert in their child’s abilities, noticing a difference pre-CNEP tank, post-CNEP tank.

Q Why is it the CNEP tank is a causal factor? It could be what caused the bronchiolitis in the first place.
A It is not common for bronchiolitis to cause that. This is something totally different.

Q You are a medical expert, in it, are you?
A Well, actually, we do say ---

MISS O’ROURKE: Sir, I wonder if Ms Henshall could stop shaking her head at the back. She has had her turn at giving her evidence. It is now her husband’s turn.

THE WITNESS: I think, if you read the letter, we are not blaming - in that first paragraph, we are not blaming it on CNEP. We are saying they have been treated with CNEP for bronchiolitis.

Q No, you are going way beyond that. You are asserting as if it is a matter of fact, that they have subsequently developed developmental deficits due to a brain injury. You are making that linkage?
A That is what the parents were saying to us, yeah.
Q With no medical evidence to support you?
A Perhaps not, yeah.

Q Yes, perhaps not. Not perhaps not, absolutely not. Then you say:

“As this treatment has never been proven to be either safe or effective in clinical use, we think its use should be discontinued and a thorough audit of children’s outcomes undertaken.”

Yes?
A Definitely.

Q You then go on and the next paragraph says:

“As Chief Executive [of this Trust] you are charged with protecting the public and promoting sound, evidence based practice. If you decide not to carry out the action suggested above then we see this as a failure to discharge your duties. How many more children have to die or have their lives destroyed by this equipment.”

So you are threatening him? You are saying: if you do not do it, this will be a failure to discharge your duty and you better carry out the action we have suggested above. In other words, stop using it. Yes?
A I do not see it as a threat, to be honest. I think we are just strongly pointing out his obligations as we see it.

Q If we look at the second page, page 21, you copy this letter, threatening letter, to four different MPs, Llin Golding ---
A It is not a threatening letter.

Q Well, some people would interpret it as a threatening letter, Mr Henshall. Llin Golding, Joan Walley, George Stephenson and Mark Fisher, four MPs. Yes?
A Yes.

Q The then Secretary of State for Health, Frank Dobson?
A Yep.

Q Cynthia Nash at Midlands Health Consultancy Network?
A Yes.

Q Jane Dunkley at the Community Health Council.
A Yep.

Q Somebody at North Staffs Health Authority?
A Yeah.

Q The General Medical Council.
A Yeah.
Q The General Medical Council’s solicitor.
A Yeah.

Q And All Primary Care Group Chairman.
A That is right.

Q Did you ever actually meet Frank Dobson?
A We did, yeah.

Q A few minutes ago you described yourselves as a couple from the backwaters of Stoke. You had access to the Secretary of State for Health about this matter?
A We wrote and asked. He was visiting Stoke. We wrote and asked if he would meet us, and he said yes.

Q Well, that is the point I am making to you. You had access across this campaign of yours - was he the only Secretary of State for Health you met, or did you meet some of the others? Did you meet Baroness Hayman? Did you meet ---
A No, no. I have met Yvette Cooper, but on a totally separate issue to CNEP. It was part of another campaign with North Staffs Health Watch, but she was only a Health Minister, she was not Secretary of State.

Q Right. Secretary of State for Health at this time would have been the boss of every NHS doctor in the country.
A Yes.

Q The Secretary of State has the responsibility of running the health service. I think it is section 1 and section 2 of the National Health Service Act 1977.
A Yes.

Q So you met the boss of every doctor in the country and you are copying him on letters, saying: stop CNEP right now.
A Yep.

Q You are telling me you do not think you two little people from the backwater of Stoke, who have run a national campaign, you have hit every major national paper report, have you not? The Independent, The Guardian...
A Yeah, possibly.

Q Times, Observer, News of the World, The Sun, I think probably The Daily Mirror seems to be the only one left out.
A I have no idea. Do not know.

Q You have had the BBC, Channel 4 and ITN.
A Yeah.

Q So you have run a national campaign in every - and radio, BBC radio; BBC radio, Stoke.
A Yes.
Q You have run your campaign in every major newspaper, every major television station, relevant stations, and you have had access to the Secretary of State for Health?
A Frank Dobson was a member of Parliament.

Q Not yours, Holborn South.
A Yes, but as Secretary of State that we can still write to, and if he wants to meet with us and speak with us, that is his choice.

Q You did not write to him as the member for Holborn South, you wrote to him because he was the Secretary of State for Health?
A Yes, but we are entitled to do that. We are able to ---

Q You were running a national campaign and you were scaring off paediatricians and chief executives throughout the country. They were going to get a bagful of trouble if they used CNEP and it was going to cost them a fortune, as it indeed cost this Trust. It cost this Trust over a million pounds, did it not, your whole campaign?
A I do not know if it cost the Trust all that. I do not know.

Q Over a million pounds.
A Did it?

Q Yes. On suspended doctors, on the Griffiths inquiry.
A My understanding was that Dr Southall and Samuels was suspended more over their child protection work than the research work, otherwise ---

Q That has not got ---
A Well, our complaints over research, three doctors, but only two were suspended, so where do you get they were just suspended over the research? There must have been something else, as Dr Spencer was not suspended with them.

Q You joined in a campaign with others and so there was a whole flurry coming forward at one time.
A Campaign with others, sorry, on what?

Q Brian Morgan, Penny Miller.
A Never ever ---

Q We have already been there. We will look at it tomorrow.
A I am sorry, I have never, ever made any complaint or comment on child protection because it has nothing to do with CNEP.

Q You joined in at the same time.
A I did not join any campaign. They might have joined in or piggybacked on a complaint of ours. We have never, ever campaigned along with them.

Q Right. We will look at the piggybacking tomorrow.
A Okay.

MISS O’ROURKE: Sir, I notice the time.
THE CHAIRMAN: That is a convenient time?

MISS O’ROURKE: Yes, sir, because I am going to move on to some newspaper coverage tomorrow.

THE CHAIRMAN: We will end for the day and return tomorrow at 9.30. Mr Henshall, the same point that I made to your wife: if you would avoid, please, talking about the case with her or anyone else while you are giving evidence.

THE WITNESS: Okay.

(The Panel adjourned until 9.30 a.m. on Thursday, 29 May 2008)
GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council’s Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988)

On:
Thursday, 29 May 2008

Held at:
St James’s Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

STEPHEN ANDREW SPENCER BM BS 1976 University of Nottingham
Registration No: 2305893

DAVID PATRICK SOUTHALL MRCS 1971 Royal College of Surgeons of England
Registration No: 1491739

MARTIN PHILIP SAMUELS MB BS 1981 University of London
Registration No: 2732178
(Day Thirteen)

Panel Members:
Mr D Kyle (Chairman)
Mrs V Brickley
Mrs S Hollingworth
Dr T Okitikpi
Dr M Sheldon
Mr A Forrest (Legal Assessor)

MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hempsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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THE CHAIRMAN: Good morning, everyone. We continue with the case of Dr Spencer, Dr Southall and Dr Samuels. Miss O'Rourke?

CARL HENSHALL, recalled
Cross-examined by MISS O’ROURKE (Cont)

Q Mr Henshall, we were looking at the thin clip of correspondence and articles that I have given you. Can I take you to page 22. This is an article written by Richard Nicholson?
A Yes, yes.

Q This time in the Sentinel newspaper, I think, rather than his Bulletin of Medical Ethics - it looks like a newspaper?
A It looks like it, yes.

Q It looks like you posed for the photograph?
A We posed for the photograph. I would not say it was at that particular time. Patient 6 looks quite young there.

Q It looks from the headers on that page that you have sent that to the General Medical Council and, indeed, to Field Fisher Waterhouse?
A As we did everything we came across, yes, yes.

Q It looks like from the article that you have given Richard Nicholson an interview in order to allow him to write this article?
A Interview. I did say we had met up and spoke with him about some issues around the trial. Whether you call that interview I do not know.

Q In that article he talks about the dossier that you have sent to the General Medical Council and, indeed, to the junior Health Minister for the purposes of asking for the inquiry. It is the third paragraph down in the first column. Do you see that?
A Yes, he makes reference to a dossier of evidence, yes.

Q But he goes on in that article, having started with CNEP, to then go on and talk about covert video surveillance. Yes? Do you see that at the bottom of the second column and into the third column?
A Oh, right, yes, yes.

Q He goes on to attack in general Professor Southall and North Staffordshire. Goes on to talk about the culture of we know best and CNEP parents being dealt with in that context and then he goes on to talk about North Staffordshire as unique in having a Scientific Merit Committee and a Research Ethics Committee and he goes on to attack effectively the culture at North Staffordshire?
A Yes, yes.

Q Before you sent this article to the General Medical Council and Field Fisher Waterhouse you presumably read it?
A We did read it, yes.
A: So it looks like you sent it on to the GMC and Field Fisher in February 1999? Both of the headers are 26.2.99. Yes?
A: Yes, yes.

Q: You were aware as long ago as 1999 that Richard Nicholson was not independent in this debate about CNEP or, indeed, about North Staffordshire; that he was very definitely partisan?
A: Obviously we were aware he had got an opinion.

Q: No, that is not the question. Very definitely partisan. There is no balance in the article, is there? There is no interview with the hospital or the doctors or any consideration that there might be any other point of view?
A: I think possibly by writing a piece like that he is open to other people’s opinion. The local *Sentinel* newspaper has an excellent right to reply, I think we have about three pages of readers’ letters come in. So he is putting his views out there to be responded to if anybody feels like they want to.

Q: Do you believe in balanced reporting?
A: Yes, of course, I do, yes, yes.

Q: So balanced reporting would mean you put one side and you put the other side and you try to get somebody from a different point of view to comment, or at least to say there are arguments on the other side and they are as follows?
A: That would be on behalf of the editor of the *Sentinel*. I mean, look under the heading “The North Staffordshire baby death scandal highlights the need for tighter scrutiny of medical ethics says Richard Nicholson”. This is not the opinion of the *Sentinel*, this is the opinion of Richard Nicholson. If the *Sentinel* editor thought it needed balancing then obviously he would have gone out and got another opinion.

Q: The importance is, coming to these proceedings, your wife told us - and you tell us if it is your case too - that it was you or her or you as a pair who gave Richard Nicholson’s name to Louisa Morris at Eversheds. Is that right?
A: We were asked by Miss Morris if we were aware of any experts in medical ethics. We actually gave her two names. One person, I think, was unavailable. We did tell Miss Morris that we had spoken to Richard Nicholson, that he had already written on this subject, so there might be a conflict there. She came back to us and said that she had checked it all out and it was all fine. There was no conflict there.

MS SULLIVAN: I think that obviously these are privileged communications.

MISS O’ROURKE: I did not ask that question; he has given the answer.

THE CHAIRMAN: No, I know, but they are privileged communications and I think the witness needs to be aware of that so that he can make his own decisions.

THE WITNESS: Sorry, I did not realise that.

MISS O’ROURKE: He is choosing to waive the privilege. It is his right to say “I do not want to discuss it.”
THE WITNESS: Can I say I am not waiving my right to the privilege, I did not know I had that privilege, I did not know that that sort of discussion was confidential. Sorry, there is a difference there.

THE LEGAL ASSESSOR: The position is this, that you are not obliged to answer questions about confidential dealings you have had between you and your solicitors, who are Eversheds, in this context. I assumed that had been explained to you particularly about some of the documentation we have already seen.

THE WITNESS: Okay.

MISS O'ROURKE: Can I add this, and the Legal Assessor will correct me if I am wrong. If you decide not to answer the questions then I will invite the Panel to draw adverse inferences from your refusal to answer the questions because I will say what have you got to hide in terms of answering questions as to how Richard Nicholson got selected because I cannot see that it is a matter that is going to adversely affect you other than, of course, in the context of claims you are making in these proceedings that he is supporting.

A So I am stuck between the devil and the deep blue? Either I answer the question and waive my right to legal privilege or I do not answer and I get hung out to dry, basically.

Q That is how I am putting it.
A Yes.

Q Back to Richard Nicholson. You may say, as far as newspapers are concerned, that it is up to the editor or someone else to ensure that there is balance in the newspaper. In terms of selecting an expert to give evidence to the Panel, would you not wish to see that expert being independent, not biased or partisan in the matter and, therefore, able to give fair, balanced evidence that reflects all the arguments?
A I think if Richard Nicholson has been asked to be an expert then he is obliged to come at it from an independent point of view in writing his report. I do not think it is up to me to cast aspersions on whether Richard Nicholson has done that. That is totally unfair of you to ask that of me.

Q How can he write a fair and balanced report when he has been on record in respect of this matter for a period of in excess of ten years in the Bulletin of Medical Ethics, the Evening Sentinel, in contacting the General Medical Council and attempting to speak to Finlay Scott and in saying---

THE LEGAL ASSESSOR: Miss O'Rourke, surely that is a question for Dr Nicholson. It would only be surmise on the part of this witness.

MISS O'ROURKE: Except this witness is fully aware of all those matters.

THE WITNESS: I am fully aware of all those matters. I am---

THE LEGAL ASSESSOR: He is not a journalist and he is not a doctor and he is not an ethicist. He cannot say how an expert would prepare his report.
MISS O’ROURKE: Sir, two points. Firstly, he is a complainant rather than a witness and, secondly, his wife told us - and I am assuming he has agreed it as well given he accepted the totality of her evidence - that they selected Richard Nicholson to be the expert in this case.

THE LEGAL ASSESSOR: He has already told you he gave the name.

THE WITNESS: We did not actually select. We gave the name. We did not do the actual selection.

MISS O’ROURKE: I will move on. Page 23 of that bundle is an article in The Independent “We were misled say parents of babies who died in experiment.” Yes?

A Yes.

Q If you look down, it is The Independent 19 February 1999 by their health editor, Jeremy Lawrence. If you look down at the end of the first column?

A Yes.

Q You will see it says, the last paragraph:

“Debbie and Carl Henshall, whose complaint to their local MP, Llin Golding, triggered the inquiry…”,

this is a reference to the Griffiths’ Inquiry:

“…said their consent form had been manufactured.”

E Is that what you said to your MP?

A It would have been one of the scenarios we put forward to her, yes.

Q Then on the next column over it quotes your wife as saying:

“They fooled me not once but twice. I am angry about that.”

F Is that your case, that you have been fooled not once but twice?

A I think it says Mrs Henshall said that and I think she confirmed that she had been fooled not once but twice.

Q I am asking is it your case as well that you have been fooled not once but twice?

A Yes, I do feel were fooled, yes.

G Q Although your wife signed the consent form for Patient 6 you would have been aware that Patient 6 was put in the CNEP tank, indeed, you saw her in the CNEP tank and you were involved in caring for her while in the CNEP tank?

A I do not think my wife has actually admitted she signed the consent form so that is different but, yes, of course, I saw her in the CNEP tank, yes.

Q You will have recognise when you saw it that it was the same that Patient 7 for
whom you had signed the consent form had been in?
A That is right, yes.

Q You knew that you had signed a consent form, of course, for Patient 7?
A For her treatment, yes.

B Q So you presumably at that stage would have presumed that there had been one signed for Patient 6 as well?
A It did not particularly cross my mind as far as I can remember. It was just she was in the treatment.

Q Can I then ask you about pages 24 and 25? This is an article in The Daily Mail.
A Yes.

C Q That it appears that you co-operated with and, indeed, you posed as a family for? Right-hand side, second page of it. 25. That is a posed photograph, is it not?
A It is a posed photograph, yes, yes.

Q More than that, The Daily Mail have a copy at the top, to the left of your head on that photograph, of Patient 7 taken when she is 15 minutes old?
A Yes.

Q The photograph can only have been provided by you?
A Yes.

Q Did The Daily Mail pay you for this article?
A No.

E Q Sure about that?
A Positive, yes.

Q Did not pay you for the photograph or use of the photograph?
A No, no.

Q Were you paid for any of the articles that you did?
A I think there was one magazine article where we were paid a small fee. I think it was sort of organised because we had spent so much money trying to photocopy Joseph Raine’s thesis and it was sort of pay back for that but the actual money received, as I remember, we spent on the children anyway. It was not as though we personally gained from it.

G Q You presumably read this article when it was published?
A Possibly.

Q Why do you say possibly?
A Because I think at this time, that this was around the time when the Griffiths’ review had been made public, you know, that there was going to be a review and I think at that time perhaps every newspaper, television in the country was reporting on us. For you to ask me can I say categorically, yes, I read this one I cannot tell you because there
was so many at the time whether I read this one, whether I scanned through it because I had had enough of reading about them by then, I do not know.

Q If you want to look in the third column?
A Third column, yes.

Q It says, and this is a quote from your wife, or allegedly, and that is why I want to ask you if you remember her saying it or if the Daily Mail made this up and got it wrong:

“Suddenly they approached me and asked me to sign a consent form. We were not suspicious. We thought Patient 7’s death was a genuine tragedy and we just wanted to do what was best for little Patient 6.”

A Yes.

Q Do you remember your wife saying that?
A No.

Q Are you saying the Daily Mail has made this up?
A I am saying the Daily Mail have misquoted, which is perfectly common in newspapers.

Q So you are saying she never said that?
A No, she would not have said that, no.

Q If you had read this in the Daily Mail you would have taken that up with them?
A I certainly would, yes.

Q Did you take it up with them?
A No, because obviously this is one of the ones I did not read or take much notice of.

Q I know your wife, when I asked her about that, did not say she had been misquoted?
A Did she not?

Q No. She said she could not explain it but did not say it had been taken up with the Daily Mail. You did take up with other newspapers things that were wrong, did you not?
A Yes, we had, when we noticed them.

Q You wrote to The Independent, I think, about an article that they ran and you pointed out a number of things that you did not agree with?
A Possibly, yes. You would have to show me the letter.

Q We will get it for you in a second. I am suggesting to you that you did, or your wife did, say it and you did see the Daily Mail and that your story changed subsequently in respect of the consent form to the “I never saw it and it must have been manufactured”?
A That is just conjecture on your part. We did not write the article. I cannot tell you definitely we read the article or took much notice of it, so we were misquoted. She would not say that.

Q Can I take you finally to the last, single document there, a loose page? Have you got that?
A Yes.

B This is an e-mail sent from a lady called Penny Mellor. Have you met Penny Mellor?
A I think we met her once in this building at a previous hearing of Dr Southall, yes.

Q But you have had communications with Penny Mellor and you have had e-mail communications?
A She sent us e-mails. We do not really send many back to her, apart from just to say we are not interested.

C This is an e-mail from Penny Mellor to the media in January 2002 and it is relating to the outcome of an inquest and judicial review of an inquest. It then goes on to talk about the CNEP campaign and the CNEP campaign now looking to open up other inquests – do you see that?
A Where am I reading that?

Q What I am interested in is the second paragraph and they are talking about another parent – I will not name her for confidentiality reasons:

“She as yet has been unable to formalise any complaints to the GMC as the documentation has been needed for the coroner and is currently left out of the hearings against N Staffs Consultants”

and then it mentions Southall et al?
A Yes.

Q Then it says:

“Carl and Debbie Henshall along with many other CNEP parents who have dead children, have now also approached HM Coroner in Stoke to request full inquests into the tragic deaths of so many babies, especially given that parents were not aware it was research and that the CNEP trial had already failed at Queen Charlotte’s in London and horrifically killed other babies.

We are looking to get a ruling of at least death caused by neglect, we contend that death was caused by criminal medical negligence and will pursue with vigour calls for a public inquiry and for a full criminal investigation”

et cetera, et cetera. Two questions. Firstly, is she right when she says that you were now approaching the coroner in Stoke to request a full inquest into tragic deaths in Stoke?
A I think she exaggerated a bit when she said “so many babies”; I think there was ourselves and one other parent who approached on our behalf and, as you can see, she took this other lady to the coroner herself.

Q So you, in 2002, were in fact asking the coroner in Stoke to investigate the death of Baby 7, were you?
A We were asking him to look into it, yes. We were asking if there was post mortems done and to look into the causes of death, yes.

Q And the outcome was?
A One of the causes of death given for Patient 7 was renal failure. The coroner did say – I think it is in a letter as well – that renal failure cannot be put down as a cause of death unless it has been identified and treatment attempted in life because it is more likely then to be a symptom of dying, but he did not think that he would be able to hold an inquest at this time, it was so long after the event – especially that we had had Patient 7 cremated.

Q The outcome was there was no inquest?
A There was no inquest, no.

Q Why was Penny Mellor getting involved in this?
A She was not getting involved with us and the other parent, she was getting involved with the parent that is named on here.

Q She was getting involved and she---
A She was trying to get involved.

Q She has sent this letter to “all media” and she has described herself as “Child Advocate and campaigner”?
A Yes.

Q And she says:

“We are looking to get a ruling of at least death caused by neglect, we contend that death was caused by criminal medical negligence and will pursue with vigour calls for a public inquiry and for a full criminal investigation”

and she goes on about Stoke parents and who they are and what needs to be done. She is getting involved in a campaign that was your campaign – you were the campaign coordinator?

A She was trying to get involved. I think you are being a bit mischievous because I think the “we” in the final paragraph refers to herself and the parent named in paragraph one, nothing to do with my wife and myself or the other parent that had gone to the coroner with us. That is not how I read it at all. This is Penny Mellor trying to piggy-back, as I have said before, on the back of our complaint.

Q Did you know that she had a criminal conviction?
A I know that she has been to prison, yes.
Q For conspiracy to abduct a child?
A I am not exactly sure what the charge was.

Q Which would hardly make her fit to describe herself as a child advocate, would it?
A I do not really have any opinion on it. I do not know.

B Q I am suggesting you were giving her information for her to know what she is saying in the media and you were associating with someone who had a campaign against David Southall?
A I do not think there is any information in there that could only have come from us, it could have come from the media.

C Q Did you know that David Southall was the key person who led to her arrest and subsequent conviction?
A No, I did not. I do not take much notice in it now, to be honest.

Q She did not tell you that?
A No. I do not speak to her.

Q But you exchange e-mails with her?
A I occasionally send her an e-mail just to tell her that we are not interested or it is not important to us if she sends us something.

Q Have you ever heard of a Dr Rita Pal?
A I have heard of Dr Rita Pal. I have actually met her on one occasion, yes.

E Q That is what I was about to put to you, that you met her at a meeting that she was giving a lecture at about events in another ward in Stoke, is that right?
A She was talking about that. It was actually a British Council of Disabled People’s forum, I think, so there was the two reasons we went along. We went along from the disabled person’s point of view and our friend Ian Syme came along with us because he was interested to hear what Rita Pal had said, given his interest in elderly care in North Staffordshire.

Q You were introduced to her because she was raising issues about something else happening in North Staffordshire Hospitals and so you felt you might have a connection?
A I think I have just said it was Ian who was more interested in meeting Rita Pal because of his interest in elderly care and what she was saying about elderly care in North Staffordshire at the time.

G Q Were you not interested because you only had a narrower agenda of CNEP?
A I was not as interested as Ian. I was prepared to sit there and listen to what she had got to say. I did not have much respect for her, I think is perhaps the right word; I was not totally impressed by her and as far as I know did not really make any more contact with her. There might have been an odd e-mail but I cannot really remember any more contact between us after that.

H She, of course, is a supporter of Dr Southall’s?
A  Apparently.  Apparently.

Q  Is that why you were not interested in becoming involved with her and her campaigns and you spoke to Staffordshire because she did not take your viewpoint, did not accept it and supported Dr Southall?

A  I think that her support of Dr Southall, as far as I can see, has only been recently, as in the last two or three years. I do not think before that there has been much from her.

Q  Why do you say that?

A  Because I think I am aware of a number of websites associated with Dr Pal that have only really been in existence, some of them only for the last six months or so, where she has been quite derogatory about myself, my wife, just in support of these doctors. To me it is totally irrelevant, she can say what she wants; she is not important – she is irrelevant.

Q  Penny Mellor, on the other hand, has been writing blogs and websites, wholly supportive of you and giving distorted reviews in particular of this hearing. Are you aware of that?

A  I have seen her website as well, yes. Of course I have. I spend a lot of time on the internet so I come across these things and just look what goes on and check back regularly just to see what has been said just out of interest, but it is not particular important.

Q  The position is this, is it not? You have said all sorts of things, you and your wife, over the years in newspapers, to newspapers, in letters and otherwise?

A  We have, yes.

Q  All of it disparaging of these doctors, none of it complimentary?

A  Possibly not, no.

Q  Nothing commending any of the good work they might have done as doctors over many years?

A  No, because that is---

Q  You have said it all without anybody being able to challenge you?

A  Why nobody challenges?

Q  Because of this. There has been no right of anybody to cross-examine you until now?

A  There has been at least two complaints I know of have gone to the Press Complaints Commission that have gone no further.

Q  But nobody has had the right to question you as I am questioning you now; nobody has had the right to cross-examine you?

A  I have never denied anybody that right. I have always said we are willing to meet and talk about this.

Q  And the press have given you an easy ride, they have not cross-examined you, whether for fear of upsetting the parents who are bereaved for one child and have a
disabled child, so the press have never questioned or scrutinised any of the claims you have made?
A Yes, they have.

Q Who has?
A There is lots of times. I think I gave an example earlier where we had to send stuff to Brian Morgan for an article he was doing or something and the editor of The Sentinel has asked the same – always we have had to provide documentation before they will print things.

Q That is not the same thing as scrutinising what you say. Brian Morgan has been so friendly and used you because he has got an agenda of getting at David Southall. He has not in any way scrutinised whether you are telling the truth about the consent forms or whether you are telling the truth about the naming of Patient 6. Nobody until me now cross-examining you has scrutinised what you have said. The press have given you a soft ride, accepted it and printed it?
A I cannot speak for them. I do not know what they have done.

Q The minute somebody tried to stand up to you, namely Keith Prowse when he found you telling the press things which were false and which he was very concerned were going to affect patients in the area of his hospital, and he said “I can’t let them away with this, they’re saying they never signed consent forms” and so he made them public, you jump up and play the confidentiality card and report him to the General Medical Council?
A The one thing about the Keith Prowse episode is that on that Channel 4 interview there was us and there was another set of parents also claiming they could not remember they had signed. Keith Prowse just chose to pick on us to try and discredit us, not the other parents.

Q Was he not entitled to come out and fight back? If you were telling lies and that is what he believed you were doing, you were saying “We never signed any consent forms”, was he not entitled, on behalf of his hospital and the people who consumed the services at that hospital, to fight back?
A Yes, he was, yes. I think he went about it the wrong way.

Q Why did you (1) play the confidentiality card? What was confidential about it when you had been to the press with every detail about both your daughters? What was this confidentiality card about?
A The forms he released was not about my daughters, it was about my wife.

Q No, it was not, it was a form that was---
A I am sorry, it was.

Q Okay, there was a form as well about your wife. What was the confidentiality card about? You had been to the press, you had told your story, what was your problem?
A What was the problem?

Q Yes?
A It was the way it was done. It was---
A  Q  It was because he was fighting back?
    A  No, it was not because he was fighting back, it was because of the way it was done. He had just gone through my wife’s medical records willy-nilly, pulled out anything with her signature on and faxed it to an open fax in the middle of an office in Channel 4 News, as I understand. Anybody could have picked those up and had a look at them. He had no idea if I was aware of what was on those consent forms. He only chose to pick on us, not the other family, and I think rather than it was fighting back it was because he had admitted that my wife could not have signed that form between two and four hours of age on the television.

B  Q  You not only fought back by playing the confidentiality card, you then instigated as complainants a full General Medical Council hearing?
    A  We complained to the General Medical Council and they decided it needed to go to a full Fitness to Practise hearing.

C  Q  No, you were the complainants in that case?
    A  We were witnesses in that case.

D  Q  No, you were complainants?
    A  We made the complaint and were treated as witnesses.

E  Q  The position is that the General Medical Council Professional Conduct Committee found that he was justified in doing what he did for the protection of patients and public confidence in the system, that he should expose that there were consent forms and that you were not telling the truth to the press?
    A  I do not think that the truth thing came into it.

F  Q  You do not think so. Let me read you an excerpt from what the Professional Conduct Committee said and see if you disagree with that being their Determination. Tell me if I am misquoting it. This is the Determination of the Professional Conduct Committee, and this is addressed obviously to Dr Prowse because he is the respondent practitioner:

    “At the time when you decided to make these disclosures the North Staffordshire Hospital NHS Trust was faced with the prospect that allegations of forgery against doctors practising in the paediatric department were planned to be broadcast on television within 48 hours. Such public allegations would seriously have undermined the trust of patients and their parents in the paediatric department. Such a breakdown of trust would seriously have damaged the standards of medical care provided by the paediatric department. In particular parents of babies and young children would have been reluctant to accept and act upon the medical advice of doctors whom they believed to be guilty of forgery. The best interests of these patients demanded that such allegations which were entirely false should not be made”.


G  "Document not supplied to shorthand writer"

H  A  You are talking about the “entirely false”.

D13/12
Q Yes?.
A As you know, we went to barrister’s opinion on this. One of the question I was asking was, “Does that mean that the allegations we made were entirely false or it was entirely false that there was allegations of forgery being made?” There are two ways of reading that.

Q It does not matter which way it is?
A It does actually yes. Are they saying that we were not actually making allegations of forgery, that it was just a misconception, or that we were making allegations of forgery and they were false, because the General Medical Council had nothing in front of them to prove or disprove the latter.

Q The position is this. The Panel, having heard you and your wife give evidence, having heard you cross-examined by one of my colleagues, came to the conclusion that the allegation of forgery was false.
A No.

Q And that these documents were not forged?
A I just explain that I do not agree. Is that what they came to? In fact they admitted that Dr Prowse had released those documents without consent. He was justified in doing it…

Q Absolutely?
A …of the pressure the Trust was under. Whether the allegations were - I have just said, I do not know. The General Medical Council at that time did not have enough information in front of them. No investigation had been made for them to say that those consent forms were or were not forged. So, my reading of it is that they were saying that the allegations of forgery were not actually being made, it was a misconception.

Q You can twist it what way you like, you went to the High Court by way of an attempted judicial review, which failed, on the basis that this finding by the Panel that the allegation of forgery was entirely false, somehow or other was a reflection on you and your wife. The judge did not give permission to judicially review and said that what the Panel were saying was that she had indeed signed the consent form. That makes the allegations of forgery false?
A It says that there, does it?

Q Yes.
A The Panel were saying that she had to sign a consent?

Q No, what the judge said was that regardless of your arguments that you needed a judicial review because this might affect your wife’s honesty or credibility; in fact what was being said was that the consent form had in fact been signed by your wife.
A Can I see that document, please?

MS SULLIVAN: I think it should be shown.

MISS O’ROURKE: It is notes.
THE LEGAL ASSESSOR: I think we had this discussion last time. I am looking back at my notes and I have put down in the middle of cross-examination of Mrs Henshall, “Prowse hearing transcript of 2001 JR judgment” as a note to myself that we were waiting for that document.

MISS O’ROURKE: We will get it. I should have got it before now. (To the witness) What I am suggesting to you is that your attempt to judicially review failed, the judge refused to give you permission.

A He refused but I do not agree that he said those things that you have put there. I thought he was saying that he just would not prejudice any future hearings.

Q He said that as well.
A Which is wrong because it is being used against us right now.

Q No, would not prejudice any clinical negligence claim because that would have to be brought on the basis of somebody having fallen below the standard to be expected in the treatment they provided, and that had nothing to do with whether the consent form was signed.
A Well…

Q We will get a copy of the consent form and make it available to the Panel so that they can see it. I am suggesting to you that when anybody tries to stand up to you, challenge you or scrutinise the truth of what you say, you do what you did to Dr Prowse, you make a complaint, you put him through a General Medical Council hearing and you start shouting about confidentiality despite the waiving of confidentiality in respect of your daughters and your wife with all the things you have said over the years to the press?
A What was your question?

Q The point is that you do not like it when anybody disagrees with you. You talk to the press who will support you and who will peddle your story and, indeed, your lies. Anybody who fights back you seek to silence them?
A Totally the opposite actually. We would love the doctors to come out and speak to us and respond to us.

Q But you know they cannot because if they do you will scream confidentiality?
A I think Dr Southall has a couple of times made statements, which we welcome. At the end of the day it is about what happened to our daughters.

Q Dr Southall met with you sometime in 2004?
A Possibly around that time, yes.

Q And you took with you Ian Syme from North Staffs Health Watch?
A Ian came as an advocate for us.

Q One of the concerns that Dr Southall had, and expressed to you quite strongly, was the impact your campaign was having on paediatricians choosing what treatments to use and parents choosing what treatments to use - that you were affecting treatments in
A Treatments in this country? That is a lot to put on our shoulders as just two parents.

Q You stopped CNEP?
A I am glad we stopped CNEP. There was no evidence base for it whatever. Dr Southall himself had tried two or three randomised control trials or clinical trials at North Staffordshire Hospital and could not prove it at all. In fact in a letter in the Hall report, he writes himself that he does not think it is going to have any impact on the course of bronchiolitis. It just has to run its course. So he is admitting there. Regardless of that they carried on using it at North Staffs Hospital and then wrote a retrospective analysis trying to praise up how it good it was, but they could not show it in a trial.

Q The paediatric community does not agree with you, does it?
A Where is the evidence? Where is the trial that shows that CNEP works for bronchiolitis?

Q We are not getting to do trials because you are stopping it?
A I am stopping it. I totally disagree. If there was an evidence base for it, and it has been shown to be effective it would be used, no matter what I said. My wife has already told you the example of the MMR. It does not matter how much parents and some even in the medical professional shout about the MMR, it is still being used.

Q You were involved, or your wife certainly was, perhaps you were too in the Telford study that was done by way of follow up in the Queen Mary College in Nottingham in 2005-06?
A Yes.

Q You presumably have read the articles in the Lancet?
A I have, yes.

Q Following it up, and I think that you have seen not just what Telford and others wrote, you probably have a copy of the paper, have you?
A Yes, I have a copy of the paper.

Q Their conclusion, and this was following up North Staffs CNEP patients, was that they:

"...saw no evidence for a long-term outcome after neonatal CNEP, whether analysis was by original paring or by unpaired comparisons, despite small differences in adverse neonatal outcomes. The experience of our study indicates that future studies of neonatal interventions with the potential to influence later morbidity should be designed with longer term outcomes in mind." (Document not supplied to shorthand writer)

A Yes, I definitely agree with that, that longer term outcomes should be a consideration.
Q That they find no adverse effects from CNEP?
A I think again that you are being selective with the text of that. If you look at it more, what they are saying is that they can find no benefit, no worse outcome of the two treatments. When they looked at it more they have come up with the children in CNEP might have slightly higher IQ in certain areas.

Q They also do better?
A No, because there was an explanation for it. I am not sure if it is mentioned in Professor Marlow’s paper, it is certainly mentioned in the thesis. I think that Professor Marlow reiterates it, that statistically more low birth weight children went on to standard treatment, and as in Professor Marlow's opinion IQ is related to birth weight, that would explain why the IQ of children treated with CNEP will be slightly higher. What it could not explain is why there are five times more seriously disabled children in the CNEP treated group than in the standard group. Another side study of that was looking at respiratory outcomes, and the same thing was said there, that although there are no differences, despite what these researchers claimed in their research, in respiratory outcome again more CNEP children showed a severe respiratory disorder than those treated with standard.

Q I disagree with you, but I am not going to argue.
A It is in the paper.

Q Professor Marlow will be a witness in this case, if we get past half time.
A Good because it is in the paper and basically what it is concluding is that there is no difference between the two but if you are damaged by CNEP it is far more severe than standard treatment.

Q Where is the "if you are damaged by CNEP"? There is nothing in the papers to suggest anybody is damaged by CNEP. That is you saying that. Where has any member of the paediatric community said anybody has been damaged by CNEP?
A Nobody has ever actually looked specifically at that. He has looked at trends. He has taken a small number of survivors who came forward. He has looked at trends and come up with no differences apart from in the severe disability or the severe respiratory outcomes. There is only small numbers but again it is showing a trend. It is not statistically significant I know, but it is showing trends. That is all he has looked at. No scans were done of those children. It was basically assessing their cognitive and physical abilities, the respiratory capabilities and comparing the two.

Q We have experts we can put the paper to and the Panel will get the paper in due course and they have medical expertise available. My question to you is, why are you misstating what it says by saying that it says "if you are damaged by CNEP". It did not say that because it does not in any way, shape or form suggest any child has been damaged by CNEP, does it?
A I was probably using the wrong words. I accept I was.

Q It is your version again?
A I have just admitted that I used the wrong phrase.

Q It remains your contention damaged by CNEP despite the fact that there is no
paediatric evidence anywhere to support any child being damaged by CNEP?
A Children treated in the CNEP group, their respiratory outcome is possibly more severe than the standard treated group.

Q The point is that no one says that anybody has been damaged by CNEP. You presumably have read in the same edition in the same edition of the *Lancet* or had provided to you what Professor Griffiths had to say.
A Yes, I would need to see a copy of it if you wish to question me on it.

Q I have a copy here. I can read it to you and then hand it to you?
A Professor Griffiths said as follows:

“Despite what seemed to be an increase in issues related to brain damage when the original trial reported, the longer term study shows that CNEP might, if anything, be kinder on the brain. The paediatric community now has to decide whether CNEP has a place in the care of these babies or whether everything has moved on.” *(Document not supplied to shorthand writer)*

Do you remember that?
A I vaguely remember that sort of comment.

Q So he is somebody who has conducted an inquiry. He is actually saying that the evidence suggests that CNEP might be kinder on the brain. He is medically qualified and that is his interpretation of the Telford article?
A That is his interpretation.

Q And he says it is an issue now for the paediatric community, not for you and your wife?
A Your point is?

Q Let me put this to you and see what you say about this:

“The third week and we can now see the headlines about baby deaths in perspective. They were lurid and misleading and in making such headlines the mass media did not do anyone a good service. It created unnecessary anxiety and did nothing to further the research that might save lives in the future”? *(Document not supplied to shorthand writer)*

A I do not write the headlines, that is editors. What I will say about the media attention around this is, we are sat here now at a Fitness to Practise Panel hearing. So obviously the General Medical Council have some concerns about the issues we have raised. Had the media not got involved in this, we would have been silenced years ago. That is how the NHS works. We got involved in groups like North Staffs Health Watch and other parents were asking us for help on a range of issues, not just neonatal issues and that. They were asking us for help around the complaints procedure. We suddenly come up with what we called the three iii of how the NHS deals with it. Basically they isolate you, they intimidate you and then they ignore you. So without the media keeping this in the public eye then we would not have got here. There are obviously concerns because it
A would not have got here just on the back of a media campaign.

Q I will say two things about that. You provided the quotes for the media to create the lurid and misleading headlines. They may well have taken them but you provided the quotes like “guinea pig” and “experiment”, etc.
A No, never mentioned guinea pigs – hate the phrase, would never have used it.

B Q You were the ones that raised the words “forgery” and “experiment.” You gave the quotes that formed the headlines?
A We put forward – you see, you are sort of trying to say now that we sit down and tell the media exactly what to write. We have put forward what our thoughts are; the media have gone off and wrote the story. If they get it absolutely totally wrong and we pick up on it and we have got the time and the inclination to do it, we will correct them, but we cannot be held responsible for everything the press writes.

C Q Let me come on to, finally, one other article in The Lancet. You presumably read the article written by Professor Alan Craft and Professor Neil McIntosh?
A You would have to show it me. As the Professor Griffiths one you are supposed to be showing me.

D Q Yes, I will show you the Professor Griffiths one. (Same handed) That is the second page. You can look at the first page if you want.
A I think, underneath the bit you have highlighted where actually Professor Griffiths still praises my wife and myself for what we have done.

Q It is not a key point. What he does is---
A It is not the key point to you. It is a key point still, is it not, because Professor Griffiths is still not saying that we were wrong to do what we did.

E Q Professor Griffiths has not been here to hear your cross-examination and the lies you have told about your consent forms?
A That is if Professor Griffiths agrees with you or agrees with me, really, isn’t it? I would like to come back to those lies, particularly the nursing records, if we could, actually. OK, so we are on to this one now. This is the…

F Q Alan Craft and Neil McIntosh. Do you know who they are?
A I have heard of them, yes. I cannot say as I know them.

Q They probably would be two of the most respected people in the paediatric community, being past President and Vice-President of the Royal College of Paediatrics and Child Health?
A Possibly.

G Q Right. They say:

“Southall and the members of his team have come under unprecedented scrutiny --- apart from the findings of the Griffiths Inquiry have not been found wanting. Southall and his colleagues were suspended from practice for long periods. Pressure on them
personally and their families has been incalculable. We must protect patients; we must also find better ways to protect professionals. If we do not medical progress will cease, particularly in controversial and distressing areas.”

I can hand you the page if you want to look at it. They are suggesting that one of the concerns – I will give you the whole article – they also say that this CNEP trial and study received funding only after rigorous independent scientific review by the UK Medical Research Council which gave it an alpha rating and that it has been peer reviewed and not been found wanting.

A I think the Oxford database of perinatal trials – I think that is what it is called – actually said they would have designed the study completely differently. They would not have used the sequential design because they did not think that was as---

Q Some people do it differently. What he said is nobody has found it wanting?

A I think---

THE LEGAL ASSESSOR: The only valid question arising out of that, Miss O’Rourke is what is the witness’s reaction to that article.

MISS O’ROURKE: Yes.

MS SULLIVAN: Perhaps he might just have an opportunity to look at it.  (Pause)

THE WITNESS: My reaction – I have not read it all but I can see the bits you have highlighted – my reaction is that is their opinion, they are more than entitled to put their opinion forward. I respect their opinion; I may not necessarily agree with it. They have not spoken to us so they did not really know what all our concerns were.

MISS O’ROURKE: The point I am making to you is this, and it is a point I made to your wife about that article. What they are saying is this has affected the paediatric community, it has affected research being done. If professionals can be subject to this sort of complaint and the degree of scrutiny and everything that has gone with it, then it is going to affect other paediatricians doing this work and doing vital research?

A I think it is a bit unfair just to put it on the CNEP. I think what we have had over the last few years is a number of scandals in paediatrics which has caused the public to lose confidence. I think you are talking as far back as the Bristol heart surgery, Alder Hey organ retention, the MMR and this is just one of many that has caused the public to question paediatricians. I do not think it is fair just to put it at CNEP.

Q Let us put it more specific. Your campaign has done two things. It has affected public confidence of people and patients in Stoke and this hospital and in particular the paediatric department?

A Possibly, I do not know.

Q It must have done. You have been using Dave Blackhurst at the Sentinel. He has published, I think, more than 90 articles about CNEP and these three doctors over the last number of years?

A Without me going round and speaking to all the people in North Staffordshire and
that I really could not comment on that. What I will say is that it is not as though I walk around Newcastle Under Lyme or Stoke on Trent and everybody knows who I because I have been in the paper talking about CNEP. Very, very few people actually recognise us, so I really could not comment on what the public perception in North Staffordshire is about the hospital at the moment. I do not think the numbers are going down because it always seems to be full.

Q Your evidence has been that you have not written anything nice about them, you have not contributed any positive comments about them or their work. You accepted from me it had been disparaging. There have been 90 plus articles in the Sentinel – that is the local evening paper in Stoke. That must have affected the confidence of patients and the public in these doctors, all three of whom have been consultants in the paediatric department?
A It possibly has but I could not say with any certainty.

Q That is the first thing that you have done, you have destroyed confidence and it may be that the outcome of this enquiry is that that has been totally unjustified.
A It depends what the enquiry – I am not going to try and predict what the Panel is going to say.

Q Secondly, what you have done, according to the paediatric community, is you have stopped research and stopped CNEP in this particular hospital for bronchiolitis and you therefore have deprived other parents of the opportunity of choosing that treatment or other consultants of the opportunity of choosing that treatment for patients?
A Would those parents have been told that there was no evidence base to prove that it worked? If not, then they would not have been making an informed choice anyway, so if the treatment was going to be offered as a front line proven treatment, then I am glad it is not being used.

Q Did you know that the Nottingham group also undertook a follow up study of children treated in Stoke with CNEP for bronchiolitis?
A I do, yes.

Q Do you know that they find in respect of that firstly no evidence of harm?
A I do not think they were actually looking for harm in that because they said they could not see how the harm can be caused.

Q Do you know that they also find the following; that once CNEP was stopped in Stoke the rate of intubation had to go up for children with bronchiolitis from 26% to 82%? Did you know that?
A So 82% of children with bronchitis in North Staffordshire are ventilated?

Q Had to be intubated where previously the rate had been 26% when CNEP was being used?
A 82% of children with bronchiolitis in North Staffordshire are intubated?

Q No.
A Because I think the national figures are something like 1%.
Q  From bronchiolitis and apnoea?
A  Oh, bronchiolitis and apnoea now?  Right, so that is a totally different thing, is it not?  How many people suffer with it?  We are talking percentages – how many actual people are we talking here, numbers rather than percentages?

Q  What I am suggesting to you, that is not the issue.  The issue is that as a result of CNEP having been stopped you had a threefold increase?
A  Percentage wise?  That could just as easily be one person up to three people.

Q  Did you know as well that what happened is that when they were getting CNEP they were only on paediatric intensive care for two days and once CNEP was stopped they suddenly had to be on, if they had bronchiolitis and apnoea, they were now staying on average 7.5 days?
A  No, I did not know that.  How would I know that?

Q  What I am suggesting to you is those are both facts.  The Nottingham group followed it up and the effect was that by you getting CNEP stopped at the hospital you were impacting upon the care and treatment of children and choices for their paediatricians?
A  And lack of informed choice for parents because if they were being told this is a proven treatment when it is not, they are not making an informed choice.

Q  They were not and it is a question of lots of parents, as you know, were very happy with CNEP for their babies?
A  I cannot speak for other parents.

Q  244 children in the study and the group of parents who have complained and have pursued their complaints is what?  Ten?
A  People who have complained or got concerns about it?  there is a totally different thing there.  You cannot say that you have spoken to every parent who has had a child in the CNEP study and there are just ten people who are not happy with it.

Q  No.
A  Because I think you will find there is going to be at least another, I think, 14 or 15 come forward here and I assume with them being prosecuting witnesses they are not going to say that they think it was great.

Q  Have you read their statements?
A  I have not read their statements, no.

Q  Then how do you know that?
A  It is an assumption that a prosecution witness is not going to come forward and say, “I think CNEP is brilliant.”

Q  Do you think many of these parents in any event who are coming forward are coming forward because you started it off and kicked it off in the Sentinel?
A  I think Miss Morris has been very cautious to make sure that these are parents who have had no contact with either myself, my wife---
Q That does not mean they have not read stuff?
A Whether they have read anything in the Sentinel you would have to ask them.

Q Not just the Sentinel – the Daily Mail, the Independent, the Sun, the Times, the Observer, the Guardian?
A You would have to ask them that.

Q Do not worry, we will. So the position is this - you are aware, for example, that a number of patient refused consent to CNEP?
A The study says there was people refused.

Q The study says it?
A Yes. Still collected data on those children, though.

Q Indeed, but---
A So even though they refused consent data was still collected on those children, so refusing consent did not really mean they were not going to be part of the study.

Q They were not in CNEP?
A Still had data collected on them.

Q If parents refused consent, which they did and I think you have seen the enquiry report into it and the details and whatever else, that indicates parents were being given information that was allowing them to make a choice
A Possibly. I could not speak. I was not there.

Q If there were parents who were refusing consent, why would these doctors need to forge consent forms, or manufacture consent forms?
A I do not know, you would have to ask them that.

Q That is your allegation still they were doing that?
A Not necessarily against these three doctors. Like I said, we were hoping there would be an investigation. These are possibilities. Like you said, they are in a list of suspects.

Q Right. You know that there is, in fact, a consent form available – you may say some of them are forged but there is a consent form available – for every child that was in the study?
A I have not seen a consent form so I could not---

Q You have seen the enquiry report?
A Which enquiry?

Q That the Trust itself did in 2000, the enquiry into consent?
A So the Trust did an enquiry into itself and found itself OK?

Q No, the Trust---
A That is what you are saying.
Q No, the Trust did an enquiry into one of its departments and its studies. The Trust is entitled to investigate its own employees, is it not?
A Of course it is, yes.

Q The Trust therefore investigated its own employees and the consent forms in its own study and it found that there was a consent form for every child in the study?
A That us their report, yes. I do not think the Griffiths Inquiry said the same thing.

Q The Griffiths Inquiry, as you know, has been much criticised and Professor Griffiths has now said had I known now what I knew then, then I would have written it very differently?
A And Professor – was it Professor Griffiths or Dr Southall actually criticised his own Trust for not allowing him to reach some documents to look at this enquiry, so the Trust are implicit in that as well.

Q All right, so the Trust are involved in the conspiracy, are they?
A I did not say the Trust were involved in the conspiracy. The Trust were involved in holding back documents from the Griffiths Inquiry according to Dr Southall. Going back to Dr Prowse, he made big play that we had to complain to the General Medical Council. We did because the only other thing is we could have complained to him as the Acting Chief Executive of the Trust for him to do an investigation into himself.

Q I put to you yesterday that the Trust has spent a large amount of money between the Griffiths Inquiry, various suspensions, dealing with a number of the issues you have raised. Did you know that in fact there was a European Union grant of 460,000 euros for the development of CNEP and research? Do you know that was lost as a result of your campaign?
A Was it?
Q Yes.
A No, I did not know that.

Q You did not know that. So therefore the implications of your campaign, if it turns out to have been unjustified – in due course we will hear the expert evidence, are affecting patients in Stoke area, stopping CNEP and affecting patient choices, unnecessarily upsetting other parents and causing them to question agreement to the study that might be damaging when it is not, and huge financial loss?
A I do not particularly agree with all of those.

Q All to further your own ends of trying to kick start a case for compensation when there is no case to be made and you have been told that by medical experts?
A Do you think my motivation is just money?
Q Money, publicity for yourself and your wife?
A Publicity?
Q Yes.
A You see, you have no idea what drives me. You have no idea what sort of person I am. For a start, the publicity, there is nothing worse for me than standing in front of a
television camera and trying to speak. I hate it, I hate every second of it, so publicity, no. If you are talking about money for me I will not and do not want to make any financial gain from any of this. Yes, I would like my daughter to have compensation, I think she deserves it, she needs it. My motivation is that is her - she is the person I have to get out of bed for in the morning to help her get out of bed, she is the person I have to help get on the toilet, she is the person I have to help get dressed every day. That is my motivation. I do not want any money whatsoever from this.

Q Let us examine your motivation in the following two actions. 13 April 2000 the Sentinel reports:

“Professor could be stripped of OBE.

Mr Blair was alerted by Carl and Debbie Henshall, who claimed their daughter [Patient 6], now aged 7, was brain damaged by CNEP treatment.

The couple wrote: ‘We appreciate the OBE has been awarded for his charity work in places such as Bosnia which, on face value, would merit recognition. However, we are concerned…”’

and the Sentinel goes on to report you sent this letter to Downing Street shortly after the OBE was announced. What was your motivation for that then if your motivation is getting your daughter out of bed in the morning and helping her and it is not publicity and it is not money?

A Because we thought it was wrong that somebody who is being investigated by the General Medical Council was being awarded an OBE. We thought it sent out totally the wrong message.

Q Despite the fact that it is for his humanitarian work in Bosnia and Afghanistan?

A I think a lot of people sort of do not see what it is awarded for, they just see an OBE awarded. I think it will send out completely the wrong message of the honours system.

Q It is a very vindictive action, is it not?

A No. Why is it?

Q You are aware that David Southall has done a lot of charity work for years. That he has done work in Afghanistan, he has done work in Bosnia, he has done work in The Gambia. You are aware that he has done a huge amount around the world, so it is said, to help children?

A I am not aware of what he has actually - I am aware he is involved in a charity called Child Advocacy International which does humanitarian work around the world. I have not really looked into exactly what David Southall has done himself in all that, no.

Q Why not? If you are attacking this man and telling the Prime Minister that he should remove his honour and complaining about him to the GMC why not spend a little time just investigating what he actually does do and what good work he has done and what you are trying to stop?
A Because I thought it would send out the wrong message about the honours system for somebody who is being investigated by the General Medical Council to be at the same time being given an honour by the country.

Q Let me ask you about this. Did you in March 1999 e-mail the BMJ about his humanitarian work in Afghanistan?
A Possibly. You will have to show me. Possibly.

B If you did e-mail the BMJ about his humanitarian work in Afghanistan why were you doing that if you have not investigated what he did and what good he was doing?
A You would have to show me the article. I do not know what you are talking about so you cannot expect me to comment on something unless I have got it in front of me and I can read it.

C I am just asking you did you e-mail them about his humanitarian work. Yes or no?
A I have no idea. I know we have e-mails from people who have worked with Dr Southall saying that the complaints in this country are affecting some humanitarian work and I have responded to people saying I am sorry it is affecting your work, that is unfair. I really could not say. I have read things in the BMJ about - I think there was one or two articles about his humanitarian work there which I have read but I cannot actually remember whether I responded to them directly.

D If it was affecting his humanitarian work, these complaints you are making, which we say are unjustified, it was affecting the finance of them and grants and his ability to carry out that work, would that cause you any concern or shame?
A The letter I wrote back to his colleague was that I thought it was unfair but there were serious issues we were raising in this country.

E I want to ask you about the bonding questionnaire. Actually I want to ask you, without looking at it. Did you fill in the bonding questionnaire? Were you present when your wife had it?
A No, I do not think I was.

F Did you ever see it?
A No.

G Were you ever told by your wife that she had filled it in?
A She did tell me she had filled in a questionnaire with the health visitor and basically said that she had wrote a long comment at the end about the particular lack of nursing staff on the ward.

H Are you adopting you wife's version that this questionnaire was handed to her and there was no covering letter?
A That is what she told me. I have just told you I was not there so I cannot dispute what she told me.

Q Do you want look at page 336 in volume 2 because you will have seen this because you have been through the notes before. Do you see that?
THE CHAIRMAN: It is not 336.

MISS O’ROURKE: Is it not? 336 in the bottom. I am looking at the sheet that says “Patient 6 Henshall CNEP group 5 patient no 198”.

THE CHAIRMAN: It looks like that.

MISS O’ROURKE: That is the one. What I am looking at, what it says is “Bonding sent” tick. Do you see it?
A Yes.

Q That the doctors will say is an indication that the bonding questionnaire was sent out?
A Yes.

Q Not taken out by the health visitor but sent out?
A Sent out by who?

Q Sent out with a covering letter?
A It does not say that, it says “Bonding sent” yes. It does not say it is sent by post, it does not say it was sent by carrier pigeon or whatever. It just says it has been sent.

Q All I am saying is that is the evidence that will be given including by Theresa Wright who is the nurse who wrote the letter.
A “Bonding sent” tick does not mean it was not sent with Sister Halfpenny, does it?

Q So that is your version then, that the covering letter never came with it?
A That is my version, yes.

Q Llin Golding, who was your MP. You involved her in the campaign for the public inquiry. Yes?
A We did, yes, as we were entitled to.

Q You were aware that she wrote to the Sentinel earlier this year regretting that she set in train the witch hunt, in other words that she had got involved and set in train a witch hunt and she apologises to Professor Southall and his colleagues?
A That is her opinion, it is her right to express that opinion.

Q You are aware that other parents have disagreed with you? They have voiced their disagreement on television programmes and they have also written letters to the paper disagreeing with you?
A As is their right.

MISS O’ROURKE: Sir, I wonder if it is a good moment to take a break so that I can check. I think I have finished but it may be there is two more questions I wish to ask but I need to take instructions on them if that is an appropriate moment?
THE CHAIRMAN: Had you said you had finished I would have then said to Mr Forde this will be a good time to take a break.

MISS O’ROURKE: Sir, why do we not take a break and if I want to ask the two questions I will, if I will not I will leave the floor to Mr Forde?

THE CHAIRMAN: Yes, that is fine. We will break now and come back at eleven o’clock.

(The Panel adjourned for a short time)

MISS O’ROURKE: Sir, just two questions. Firstly, Mr Henshall, I asked you about the study about bronchiolitis and apnoea. You may have or may not have seen it, it was a published article but can I give you the first page of it and the summary? (Same handed)

THE CHAIRMAN: That article comes from where?

MISS O’ROURKE: It comes from “Archives of disease in childhood.”

THE CHAIRMAN: The date?

MISS O’ROURKE: It was accepted on 9 March 2004 but it appears to have been published in 2005. We can make copies available because I anticipate in due course I am going to be putting it in full to Dr Stimmler and possibly to Dr Nicholson.

THE CHAIRMAN: Yes.

MISS O’ROURKE: Sir, and the same with the Lancet articles, it would be our intention in due course to actually make them available to the Panel because they are published articles in respected medical journals. Mr Henshall, you had sought to suggest to me that we were talking about tiny numbers. In fact, you will see it is 52 infants in the study. Do you see that in the summary?

A 52 infants, yes.

Q You will see the figures there that I quoted you that the rates of intubation went up to 17 which was 82% of referred cases and the median stay on the Paediatric Intensive Care Unit was 7.5 days where previously it had been two days?

A I will have to read this first, please. (The witness read) It does not give a percentage for what is referred to as the NPV, which I assume is the Negative Pressure Ventilation Centre, it says 8 of 31, it does not actually give a percentage. Then it went up to 14 out of 17, 82% of referred cases were intubated.

Q That is the reference to Stoke because Stoke’s figures after negative pressure ventilation was stopped suddenly they found that the rate was 82% and they suddenly found that the median stay was now 7.5 days instead of two and you will see the conclusions were that of use NPV was associated with a reduced rate of endotracheal intubation and shorter PICU stay. So what was being said is because they were not able to use it any more we suddenly found that we had more patients intubated and we had a longer stay in the Paediatric Intensive Care Unit neither of which would be a good thing?
A I think I would have to read the whole paper rather than just the quick summary because it says that in the two years after the NPV centre discontinued use of NPV 14 out of 17, 82%, of referred cases were intubated. So what do you mean by referred cases?

Q Referred to the Paediatric Intensive Care Unit.

A I would have to read the whole study before you ask me to comment on it because the summary is like a very quick snapshot and does not necessarily have all the meat in it.

C Q I am sure we can make it available to you. The point is this, your campaign to stop the use of negative pressure ventilation in Stoke appears, from the authors of this paper and from the study, to have had an adverse effect in terms number of patients needing intubating and an adverse effect in terms of length of stay on PICU?

A Median length of stay.

Q The median had been two days, the median goes to 7.5. That is not good?

A Without seeing all the data, I mean, you cannot really, you know, okay, the median has gone from two to seven days so…

Q These people had---

A …it shows a favour but the median on small numbers could probably be affected by a very small number needing a couple of days extra.

D Q The authors of this paper – and, of course, I can see it and the Panel will see it in due course too – are Dr Samuels and Dr Southall, but among seven authors; the authors of this paper think it has had a negative effect and that you were the cause of that because it was your letter to the Chief Executive that got negative pressure ventilation stopped.

THE LEGAL ASSESSOR: That is a statement. What is the question?

MISS O’ROURKE: That is what I am suggesting to him. (To the witness) This is the effect of what you have done. You have destroyed choices for paediatricians and you have destroyed choices for other parents?

A We have had an unproven treatment and no evidence base stopped because the choice was not being properly offered to the parents. They were not being told it was unproven and unvalidated.

F Q My final question is this, Mr Henshall. I am offering you now a final opportunity to come clean and tell the truth; to withdraw the perjury that you have already committed and tell the truth now about the consent forms, about the naming of Patient 6 and the final opportunity to retract your lies?

A Actually, I am glad you have asked me that because yesterday when we went through the nursing notes and you picked up one or two examples, obviously overnight I have had time to look through the nursing notes again. I have actually come up with one or two discrepancies in the nursing notes, so if I can just show you them now. I have managed to find them in this bundle, so it is still appeal bundle 2, behind tab 5. The first thing I need to point out, I think, is I am not sure if in here there is a copy of the consent form for Patient 6 but on page 22 behind tab 5 – has everybody got that? – where it says “Reviewed at 4 hours” and everything, “Randomised to CNEP”, then there is a signature which I am pretty sure matches the signature on that consent form which Claire Stanley
has said is hers. If you turn to page 27 the incident of 20/12 also seems to be signed by a C Stanley but it is a different signature to the one on page 22, and I think that needs looking at and perhaps explaining. It looks like it says “C Stanley” on page 27 but it looks a different signature to the one on 22.

Q Do not worry, she is going to come and we will ask her about both pages.
A That is fine. The other thing is in the nursing records on page 61, where Patient 6 is named on the 14th, I think it says it was a Val Lythgoe who has signed – the signature is a Val Lythgoe – and on page 125 there is Val Lythgoe, it is the same signature again, on the feeding and progress chart, has made some insertions. I think Miss O’Rourke drew us to the attention of the word “moaning” and how it was spelt, in particular the “g” looking like a number nine. There, this again, signed by Val Lythgoe, she has wrote “moaning” and the “g” is completely different to the “g” on page 61. In fact, the whole word looks to be in a different handwriting but signed by the same nurse as on page 61, so I think, again, that perhaps needs exploring.

Q What are you saying, that this is proof there has been forgery?
A All as I am saying is you have got there, particularly page 61 and 125, you have got a nurse writing records at the same time but with different handwriting.

Q So you are saying forgery?
A I am saying the same nurse is using different handwriting at the same time and that needs explaining. You made a great play about saying “Look how distinctive the ‘g’ is, it looks like a number nine”; well, sorry, on page 125 her handwriting does not look like a number nine.

Q I am asking you what you are saying, because my question to you was “Do you want to retract all the lies?” Do you want the final chance to now come clean, to let the press know you have whipped it all up for nothing and you have lied consistently about these doctors for years? Final opportunity, final question---
A No, I do not want to retract that.

Q You do not?
A I do not want to retract that.

Q Your response has been to refer to these pages. Are you saying that Claire Stanley’s signatures are forged? Let us know so that we can ask her.
A I am saying that the signatures do not look the same. There is two signatures that look different and supposedly both say “C Stanley” and the signatures look different. Again, there is different writing on two forms which are supposedly written at the same time by the same nurse. When you talk about we have made these wild allegations, there is no proof to back them, I think you are looking there at possibly some proof to back it up.

Q To back what, forgery?
A Possibly forgery, yes.

Q So that is my answer to your question “Do you want to retract your perjury?”
A I do not see it is perjury.
Q We say it is – you are lying on oath; we say it is perjury?
A I disagree.

Q And you are saying it is the truth?
A I am saying it is the truth.

B Q And you do not want to retract it?
A I do not want to retract it.

MISS O’ROURKE: I gave you the opportunity, there you go.

Cross-examined by MR FORDE

C Q Good morning, Mr Henshall. I have got a number of questions for you and I hope to be finished by lunchtime. I was interested in your last answer, when you said to Miss O’Rourke that certain matters need to be investigated. By whom?
A We thought the General Medical Council would look into this and it appears that they have not.

D Q What you were hoping for – can I just understand this – is a General Medical Council inquiry which would be wide-ranging, involve handwriting evidence perhaps?
A Perhaps, yes.

Q All the parents---
A Not necessarily in the hearing. I thought this might happen before the hearing.

E Q That all the parents that you have been linked to in your campaign would find themselves giving evidence perhaps?
A That would be their choice. You know, I would not force them to come and do it. If they wanted to come and give evidence I think they perhaps should be given the opportunity to.

Q And that all the allegations that you have made in the past, some of which are extremely serious, would form the subject matter of charges?
A I think the charges should have been right after a full investigation had been done, to be honest.

Q You must be, rather like Mr Nicholson, concerned that the charges that these doctors currently face are rather thin and do not reflect all the wrongdoing that you believe occurred in this case?
A I am disappointed that some things have perhaps been left out. It is difficult for me, from a lay perspective, to look at something in legalistic terms because I do not really understand all the implications of how things are worded and what it actually means – it is difficult for me. Although I might think I am a bit disappointed in the heads of charge, the heads of charge might actually reflect more than I think, they might actually reflect less than I think. It is quite difficult from a lay perspective.

Q The things that the heads of charge do not reflect that I suggest you might have
wanted them to are as follows. There is no head of charge which suggests that these

doctors have or might have been involved in forgery, is there?
A There is no head of charge, but obviously that has been well explored. Although
it is not a head of charge, it has been sort of aired.

Q You must have come here hoping that this Panel would be able to reach a decision
that one or all of these doctors had been involved in forgery?
A I was hoping we could come to the General Medical Council and get the right
answers. Again, it is the legal procedure, as I think I said to Miss O’Rourke, where you
have to name doctors – the same happened to us when we made a complaint to the
UKCC. You have to come up with names and then level charges at each name – which,
you know, is not always the easiest thing to do when you are looking for answers. I
think, as my wife said, this is one of the reasons why we would have liked a public
inquiry where the remit is just far more wider so all these issues could be raised like that.

Q I understand, and I will bring you to some of the letters you have written in a
moment. You must have wanted some sort of mechanism by which this Panel could
publicly proclaim that forgery had occurred?
A I would have liked to be able to have that evidence looked at.

Q And also presumably you would have liked some mechanism by which it could be
publicly proclaimed that CNEP had harmed children in the trial?
A I would like that looking at as well but I---

Q You would like a solid statement from somebody that CNEP harms children,
because that is your belief, is it not?
A Would I like that? To be honest, no, I would not like that because then if I had
said no all those years ago then my daughter would not be damaged now, so no, I would
not actually like that, if I am truthful.

Q We will explore your motivation and your feelings in a moment, but your belief, I
think – it certainly seemed to be the belief of your wife when I was questioning her – is
that CNEP caused the death of Patient 7 – and I do not mean to be impersonal by giving
her a number---
A No, that is fine.

Q …or underestimate your distress at the time, and has led to Patient 6’s current
disability?
A I think their involvement in the CNEP trial has had some bearing on the death of
Patient 7 and the disability of Patient 6.

Q What you and your wife have been searching for since the middle 1990s is some
way of making that connection?
A I think to some extent, yes. There have been answers really. Like I have just said,
you know, there is nothing I would hate more than for somebody to come and say “Your
daughter was damaged because of CNEP because then, you know, how guilty would that
make me feel, looking at her every day?

Q I will explore with you potential problems with guilt, because they have been
written about by certainly your wife. One of the reasons that we are here and one of the reasons that the press have shown such interest in you is because you have been quoted as making the link between CNEP and the trial and in particular Patient 6’s current disability?
A Yes.

Q When we were arguing abuse of process – I know you were not here – The Sentinel published yet another piece that said that you and your wife were hoping to establish the link between CNEP and the death of Patient 7 and the brain injury which Patient 6 suffers from?
A I do not think we actually said that to The Sentinel at that time.

Q But it is what the press keep doing, is it not?
A Yes, yes. I understand that the press are not the most reliable.

Q But that is the story they want, is it not?
A I daresay they would like that, yes. I think the press would like a story like that because they can make---

Q It sells papers?
A I suppose it sells papers, yes.

Q You must feel, as no doubt these doctors have felt, at times somewhat manipulated by the press?
A I do not so much see manipulated – let down at times. There has been attempts to manipulate us. There has been attempts to speak out on other areas which are not of our concern and we have made great play – we say we are just not going there at all.

Q You will recall when the Daily Mail article was put to you that they could not resist dealing with covert surveillance and other issues involving Professor Southall as he then was?
A Yes. I protested – obviously, I have protested for other people about that. There was one in particular, there was a BBC piece that we did and I made a strong complaint over the telephone because that was mentioned at the very end, about Dr Southall’s work in child abuse and covert video surveillance. I said “That’s unfair because you’re making a link between us---”

Q And that?
A And it’s not fair, there is no link.

Q You know, do you not, that doctors not guilty of serious professional misconduct is not going to sell papers? They are not interested in my cross-examination – they are not here?
A I brought that point up, speaking to the Press Association girl who was sat in here – and it is disappointing for me, for the press to be so narrow-minded as to just look at that.

Q What you said yesterday – and it is day 12, page 36 for everybody else’s note – was that you had made it clear to the press that Professor Southall was not involved with
your children, then Miss O’Rourke said they had ignored you and you said this:

“Yes, and they will carry on ignoring us. I think only yesterday we were told by a press officer that they will only cover this hearing as long as either my wife, myself or Dr Southall are giving evidence because that is all they are interested in. That is the press.”

That is what you have been told by the Press Association?
A That was the Press Association girl who has been dotting in and out of here, yes. It was in the lift going down one day. I think my wife just said to her “Are you covering the whole of this?” and she gave the comment then “We’re only covering it as long as you two or Dr Southall are giving evidence”.

Q Did you see The Sentinel report yesterday?
A Yes, only online.

Q The only real quote from the hearing was that you described the CNEP tank as looking horrific?
A I know, I did pick up on that. There was a lot more. I should imagine that today’s will be a totally different perspective – today’s report in The Sentinel will be from a totally different perspective, I would imagine.

Q We have not got anybody, as far as I can tell, who is going to cover this aspect of the hearing. Can I just ask you about some of the allegations that you have made in the past, and then I want to ask you some questions about memory and recollection? If you can have available to you for these purposes just the bundle that we have got of your correspondence involving yourself, the GMC, newspapers etcetera. We have not actually given it a number, I do not think.

THE LEGAL ASSESSOR: It is not an exhibit, and I do not have it.

MR FORDE: I thought you had it. (To the witness) We will deal with that in due course. First of all, I would like you to go, and the number is in the middle and the bottom of the page, to page 111. It is a letter dated 27 January 1998.
A I see that.

Q We have your distinctive header C and D M Henshall?
A Yes.

Q I assume that stands for Carl and Deborah Millicent.
A That is right.

Q Your address which I will not read out?
A Yes.

Q And Mrs Sudlow is the Chairperson of the Community Health Council based in Stoke-on-Trent?
A Yes, she was at the time.
A Q We also have your email address. Can we take it, as it is on headed notepaper that has both your names on, that you would accept this as a joint view, what is being expressed here?
A Perhaps not necessarily. Probably in general, yes.

Q Because, and I know Miss O'Rourke has been at pains to get you to retract matters, I was interested in what appeared to be a disassociation from the views expressed in the letter by you yesterday. If you go to the second page, the last paragraph talks about justice for their children and their families who suffered as a result of being subjected to medical experimentation without their knowledge. Doctors should not be allowed to lie. They ought to be able to be trusted, and you deal with the suspension of police officers. Then you say this:

"We have accused these doctors of murder, fraud, actual bodily harm, et cetera, and yet they are still free as we speak to carry on without worry of recompense. They know they can lie some more and get away with it as no one questions their conduct or credibility."

(Document not supplied to shorthand writer)

At the time you wrote the letter that was your view, was it?
A I think my wife said that she wrote this letter.

Q You told us yesterday, and I can turn up the reference if you want me to, that you wrote most, if not all, the letters?
A I wrote the majority of them. I would not have said I wrote them all as that would be untrue.

Q Are you suggesting that those serious allegations are allegations made by your wife that you do not associate yourself with, or do you?
A I associate myself with the majority of them. The word “murder” is the wrong word to use. It is just the wrong word to use because that has all sorts of connotations from a legalistic point of view which we would not understand. I think I told her that I thought murder was the wrong word to use. Whether she wanted to make a point of how strongly she felt, but I do think that murder was the wrong word to use there.

Q I am grateful for that at least. You do I think stand by allegations of fraud, potential financial gain and falsification of documents?
A Yes, I stand by most of the others, yes.

Q One of the things that I want to suggest may motivate your complaints is the fact that you are dealing, as you have carefully explained to the Panel, daily with Patient 6's disability, and that cannot be easy for you or your wife?
A Yes.

Q That cannot be easy?
A It is not easy, but at the same time it is very rewarding. As she has grown older and reached different milestones, we have been there with her for all those milestones. We have a lot of children and sometimes one day they are not doing something and the next day they are, and you do not really notice when they started doing it. With Patient 6
we have been there for a lot of it and helped her achieve her goals, and it is great to see despite all her difficulties what she is actually achieving. It is hard work but at the same time it is very rewarding.

Q Again, from your perspective, and I am concentrating on your perspective at the moment, to have experts and authors of papers talking of somebody you live with daily in terms of statistical significance must be bordering on the insulting. She is your daughter, not a statistic.

A It is difficult because as a parent you do not like your child referred to as a number. You made that point; I appreciate that. But at the same time I understand that you have to have these statistical analyses, in the same way I understand that you and Miss O'Rourke and Mr Foster are here are doing your job, so you are going to ask me difficult questions and try and prove me to be - you are doing your job, the statisticians are doing theirs. I can see that. You may not like the fact your daughter is referred to as a number or a statistic, but it is life; that is how things are done.

Q Do you accept that there are occasions, particularly with premature babies, where without fault on anybody's part these children may suffer disability or die?

A Definitely, yes. I would be stupid to sit here and suggest anything different. At times we have gone on record, I do not know if it has ever been published, that possibly if it had just been Patient 7, because they were premature, we may not have questioned anything unless anything cropped up later to cause us to, we may not have questioned anything. It is more to do with Patient 6 and what went on particularly in the first 12, 13, 18 months of her life and little snippets we found out that caused us to start questioning firstly her care and then later we found out her involvement in the trial. We are well aware.

Q I will come to that in a moment, but you raise an interesting point. You and your wife have clearly immersed yourself in everything you can read or find involving CNEP?

A Yes, it has been important to us.

Q It has been fullish time, other than the children obviously?

A On and off. There have been periods when we have not touched the file or done much at all. We are now eleven years since we first made a complaint to the GMC. We have not been eleven years full on just doing this, we do do other things. It is important to us and we have done a lot of work on it, yes.

Q Do you think that it is therefore, occasionally at least, difficult for you to discern what you can recollect about events in 1992 and that which you have read and assimilated since?

A I think there are two elements to that. There is the recollection of the consenting process, which there are things that stick out in your mind, the sort of things you are told and the sort of person telling you. Those sort of things stick in your mind, and things like when you first see your child in a tank or with a tube down their throat. Those sort of things stick in your mind. I do not think that those are in anyway coloured by what we have found out since. It is very easy to make slips. I think I did straightaway when I started speaking when I referred to it as CNEP being trialled, and what I meant was being used, because over the years we have got used to calling it the CNEP trial now rather than just the CNEP equipment. It is easy to make slips, but I do not think our memory of the
time on the unit has been coloured to any really great extent that it completely changes what happened.

Q But memories fade, would you accept that?
A Yes.

Q Could you accept at least the possibility that there may be occasions when information you have since acquired may to you seem to be contemporaneous with the events of 1992-93?
A It is difficult to say. We might get something that jars a memory. That is possible. But I still maintain that my recollection of being asked for Patient 7 to go into CNEP is, you know, as accurate as it could be. I am quite happy it is an accurate recollection. I do not think it has been coloured by anything said since.

Q What you said in answer to questions from Ms Sullivan, Day 12 page 4 letter F and onwards, about Patient 7 was this. I will come back to whether it was a nurse or a doctor if I may when we look at the notes together. You say:

"Bear in mind this was the first one of our children that had been ventilated, I was completely ignorant as to what the problems were."

I think Miss O'Rourke established - am I right in this - at the time Mrs Henshall then Davies had five children?
A Six.

Q And you were not the natural father of any?
A Of one.

Q So the sixth child was yours?
A Yes.

Q So when you commenced your relationship with her she was a mother of five?
A Yes.

Q Was child number six your first child?
A Yes.

Q And you celebrated your 40 birthday on 17 May, a Saturday?
A Yes.

Q Well timed. At this time you would have been 24 or thereabouts?
A Yes.

Q Without being impolite, I think your wife is a little older?
A She is four years older.

Q She was the experienced mother. Five previous children. Presumably you were not present for the birth of those but the sixth had not been ventilated, so you had no experience of ventilation at all?
A No.

Q You did, in fairness, correct this. You went on to say:

“She told me that what they were actually doing is they have a pipe down my daughter’s throat which in itself could cause damage to the windpipe.”

A Yes.

Q “Then they were blowing air into her lungs under pressure, which could have caused damage to her lungs and it could even over inflate and rupture the lungs.”

A Yes.

Q “She went on to say: ‘We have this new kind of gentler treatment that we are trialling’ - sorry, not trialling ‘that we are using on the unit. It works by just a negative pressure around your daughter and helps them breathe more naturally. Would you like your daughter to have this treatment?’ I mean, of course I said, ‘Yes, I do, yes’.”

That is what you said yesterday about that conversation.

A Yes.

Q If in that bundle you go to page 132, this is your wife describing her first sighting it would appear, of Patient 7. It is 164 at the top and 132 at the bottom. She says this:

“Then we got downstairs I was totally shocked. I could barely see Patient 7 for tubes and wires and worst of all her head was outside of the incubator inside a separate box. I visibly shook and burst out crying. The neonatal staff came to me and comforted me. They explained that the machine Patient 7 was in was a newer gentler type of ventilator that hopefully would mean that she would not need the tube down her throat for as along as it would assist her breathing by sucking up the chest wall using a negative pressure less than sub atmospheric pressure. They explained to me that they had explained the new ventilator to my husband and told him about the dangers of the old treatment. They said that the tube used to take oxygen into the lungs can cause problems by narrowing the windpipe so that the baby would need permanent supplementary oxygen.

She said that the positive pressure ventilation could cause scarring of the lungs and it could also cause a baby’s lungs to over inflate and rupture which can kill the baby. The new method would revolutionise the way we ventilate babies. It was a more natural method which came from America and was only newly available in this country and we were lucky to be offered the treatment. When I asked how come every baby was not in this machine if it were the best treatment, she explained that the tanks were very expensive and that there were only a few available at the moment, but that there would soon be only this type of incubator on all units in the country. At the end of her talk I felt privileged and happy for
my baby to receive the newest, best treatment”. *(Document not supplied to shorthand writer)*

That is very similar to the conversation you claim to have had with a nurse the night before, it would appear?
A Yes.

B Q Were you present, because she does in this letter say “We” going downstairs – top of the page – for the second similar explanation of the CNEP tank, do you think? She has got it down as under February 12th but I thought you had gone home, you see. This is why I am slightly confused. At the moment neither of you seem to be saying you both went to the neonatal unit together, saw Patient 7 in the tank and then I know you had to go and look after the other children?
A I think that is probably just a typing error on behalf of my wife because everywhere else she is just referring to “I”, “I”, “I” and that is the only place where she puts “we”, so I would just presume that is a typing error.

C Q What I am instructed is that the consenting process does not necessarily just stop with the forms and exchange of information. There continue to be explanations of what is happening with treatment. Do you recall other discussions with nursing staff about CNEP other than at the time that you signed the form?
A I do not recall many other conversations about CNEP. The main conversations I remember are about her kidneys, not passing of urine, that might be an indication there was something wrong with her kidneys.

Q I think again, in fairness to you, at the time of Patient 7’s death you and your wife were thinking only really in terms of the kidney problem being a cause?
A Kidney problem, infection was the two things.

E Q And her prematurity, obviously?
A Obviously her prematurity was a factor. I think we were thinking more along the lines of infection. I think actually my wife went to see the obstetrician a little later, she had an appointment to see the obstetrician and I think she discussed infection with him there but I cannot remember exactly what the outcome of the discussion was at this time.

F Q All right. I just want to ask you about another topic before we turn to the notes themselves, and briefly because you have traversed much of this ground with Miss O’Rourke. Forgery, in relation to Patient 6’s consent form. Is it correct to state that at one stage at least, whatever your evidence has been to this enquiry, you and your wife thought that Patient 6’s consent form had been forged?
A We have always thought it was a possibility.

G Q Right. If you go to page 330 in that bundle, this is a letter that you wrote to Paul Phillip – it starts at page 326 if you need to orientate yourself – at the General Medical Council in September 2002 and you list a number of issues. I think this is your letter because you have put on 326, “I” and the in brackets, “(Carl)” signed a consent form for [Patient 7] but you did not give properly informed consent and then you deal with other concerns which are not the subject of charges. Then on Page 330, although you said, “I (Carl)”, I am assuming this is actually your wife’s recollection?
A Yes.

Q Under the heading of “Consent” it says this:

“I do not believe I gave anything but verbal consent to a treatment I believed to be a standard therapy and that which the doctors were telling me was the best treatment for my baby.”

Do you see that?
A Yes.

Q “I was fooled twice.”

C That does not sit very easily, does it, with page 132 where your wife is saying that she was told about positive pressure ventilation causing scarring, that this was a new method from America, more natural and that she specifically queried why it was that not all the babies were in the same type of tank, does it?
A Why does that not sit with that

Q Because she is saying that as far as she was concerned it was standard therapy, whereas in the previous document she seemed to have an appreciation that it was new therapy and that you were lucky to be offered the treatment, the tanks were expensive and there were only a few available?
A Yes, I think from a lay person’s point of view, a new treatment does not necessarily mean it is unproven or on trial. It means it is a new treatment and to be honest the public perception from what I have found is that if you talk about it as “new”, then automatically you think it is better.
Q I see.
A So the word “new” needs to be taken in context like that, but the rest of it, verbal consent to a treatment she believed to be a standard therapy which I believe tallies with what she was being told there.

Q What she is making quite clear is that she only ever gave verbal consent. If you go down a couple of paragraphs she says this – or it is said in the letter:

“I believe my consent form was signed after the event by persons unknown.”

A Yes.

Q So that cannot be, therefore, an acceptance that it is her signature because “persons unknown” is not Deborah Millicent Henshall, is it?
A She is just saying “persons unknown.”

Q Yes, but “persons unknown” cannot be her because she is a known person?
A Because she is saying she has no recollection of signing it.

Q That is not quite what it says, is it, because it says, “I believe my consent form
was signed after the event by persons unknown”?
A With respect---

Q Shall I just read on?
A Can I just explain---

Q Perhaps you could just explain, if I just read on in fairness to you. I am going to miss out the next bit but if you think it is important then do mention it:

“This makes the form fraudulent, a serious accusation and a criminal offence especially as these children were indeed harmed as part of the study.”
A Yes.

Q So give me your answer now?
A You are arguing basically technical legal points with me. You are saying that from a legal point of view this has this meaning, these connotations, and I am trying to tell you, from a lay person’s point of view we are just writing down what we think. We are not thinking how is this going to be used against us in the future, or who is going to put what sort of meaning on this. To be honest, I think you are giving us far more credit than what we deserve, to be honest. We are just parents at the end of the day. I have got no formal legal training or medical training. I am just saying what I see.

Q Mr Henshall, I think you are being a little self-deprecating, if I may say so. You are clearly an intelligent man and I am just asking you to look at the words and interpret not a legal meaning, just their ordinary meaning. If you read that – forget this case – and somebody had written to you, “I believe my consent form was signed after the event by persons unknown”, you would, would you not, regard that as suggesting that it was not signed by your wife?
A Yes, I suppose in some respects she is suggesting that because she is saying she has got no recollection of signing it, so she is saying she cannot remember signing it so somebody else could have signed it or might have signed it or has signed it, you know, whatever.

Q All right. I am really not trying to trap you by asking these things.
A No, I appreciate that. At the end of the day it is one interpretation from one point of view, another interpretation from another point of view on what it actually means. I am not – obviously you are a highly trained barrister who looks at things from a legal point of view; I am a parent who does not necessarily look at it from that same point of view.

Q The other allegations you have made include a suggestion that mothers were subjected to Caesarean sections in order to provide neonates for the trial. Do you stand by that allegation?
A I think that allegation comes from another parent’s medico-legal case and there is a couple of other parents who have sort of suggested “I really do not know why I was delivered” and that is where that allegation has come from and again we were hoping that would be investigated.
Q From the point of view, just so I understand it, of your own children you are not making that allegation, I do not believe. Is that correct? Or are you? Are you saying Patient 6---
A We have got concerns about whether Patient 6 should have been born when she was, but we are not in a position ourselves to take that forward ourselves. We were hoping other people would come and look at that for us and help out in that respect.

Q What concerns those of us on this side of the room and I want to give you chance to deal with this, is that you seem to be quite free with your accusations?
A Possibly, yes.

Q You have complained about a lack of an evidence base for CNEP?
A Yes.

Q Would you concede that there may be a lack of an evidence base for many of the allegations you have made in the past?
A I think there is evidence to support it probably in some allegation made probably there is not enough for a Panel like this to support it, but I think it is again, looking at it from lay perspective, this is some of the discussions we have had over the years with lawyers and barristers. From a lay perspective it seems black and white but from a legal perspective it is anything but, so although we will put the allegation forward and say we think this has happened and this is why we think that happened, then barristers like yourself might look at it and say that is not right because of this, this and this, you need more evidence.

Q A final document I just want to ask you about in this bundle and then we can move to the notes. Could you go to page 459, which is a letter dated 16 May 1997 which is marked “For the attention of Peter Swain” at the Conduct Section and it has your header at the top and ends, “Yours sincerely, Deborah Henshall and Carl Henshall.” Do you think this is a letter that expresses a joint view?
A I will have to read it quickly.

Q Read it to yourself if you need to.

THE CHAIRMAN: While Mr Henshall is doing that, what was the date of that letter?

MR FORDE: It is 16 May 1997, sir.

THE CHAIRMAN: Can you recall the date of the earlier letter? It was a letter to the Chair of the Community Health Council. It was the first letter which you referred to?

MR FORDE: I can, sir. I think it was page 112. It starts on page 111, it is dated 27 January 1998 and the reference to murder is on page 112 and was disavowed by Mrs Henshall.

THE CHAIRMAN: Thank you very much.

MR FORDE: Have you had a chance to read that?
A Yes.
Q Right. I just was curious because you have obviously made serious allegations against this doctor but this is a letter written to Peter Swain and we know that Dr Simon Newell was somebody who produced a medico-legal report for you when you were investigating whether you could bring a claim on behalf of Patient 6, yes?
A That is right, yes.

Q So he was attempting to assist you in the claim but ultimately was unable to support a civil action? We have seen his letter of 8 December 1995?
A Yes.

Q We have got a copy of his report and you remember me asking your wife whether she scribbled on it before she got the notes?
A I do remember, yes.

Q I am not going to ask you about that because it is not your handwriting. I am just curious because it may be of interest to the Panel, what you say is this:

“We had a preliminary report done by Dr Simon J Newell of St James’s Hospital in Leeds but it was inconclusive due to the lack of data and Mr Newell was not entirely honest with us in his findings.”

What did you mean by that?
A I think after we had had his report and then we got the manual of neonatal intensive care by Dr Roberton and we had gone through what Mr Newell’s opinion was and compared it with what Dr Roberton was saying, we just found some discrepancies and I think actually subsequently – this will be when my wife went through the report, made notes on it – then we produced basically a report on his report which went to barristers for barristers’ opinion. I think actually the barristers suggested we get two more experts to look at it on the back of what we put about Dr Newell’s report. I think he was suggesting then a paediatric neurologist and – I cannot think but I am pretty sure there were two experts but that never happened, obviously, because we changed solicitors and everything started again from fresh.

Q What concerns me though, Mr Henshall, is this. What do you say about writing to Peter Swain and telling him in terms that Dr Simon J Newell has not been entirely honest with you, because he is on the Register; it is a serious allegation?
A Again, I understand from your point of view it is a serious allegation to write to the General Medical Council saying that a doctor has not been entirely honest with us, but, you know, if we really thought he had been dishonest in respect – we have been criticised for the number of doctors we have complained about. If we really thought he had been that dishonest as to mislead and everything, we would have obviously put a complaint in about him, so although I see it is written there and I understand where you are coming from about the serious allegation, we did not see it as that particularly serious.

We were just sort of thinking he is saying this but the book says this and I think we actually wrote to Dr Roberton asking if he could confirm that what was put in his book was still right and would he be willing to talk to us about it. Obviously the hospital Trust have already contacted him beforehand. So I understand where you are coming from by saying not entirely honest and it is going General Medical Council but, again, we do not
see them implications of those words unless it is actually pointed out by somebody like yourself.

Q  Did you think that he might be part of this NHS medical conspiracy or wall of silence that you think you have confronted?
A  Not particularly. Not Dr Newell because, again, I think we have put there that there was a lack of data and we still at this time had not got full sets of notes. So he had done a report on what he had got available to him at the time which probably might not have been enough. We were concerned that he had --- I am pretty sure it was around the blood gases. He is saying this and the book says this. Which one is right?

Q  Mr Henshall, I have to suggest that if you are prepared to make that type of comment in a letter to the General Medical Council about a clinician who has been instructed to assist you then it may be instructive when considering the validity of the claims that you make against these doctors. Do you understand the question?
A  Not at all, no.

Q  Here is a doctor who is trying to assist you. Yes?
A  Yes.

Q  You are prepared with your wife to accuse him of dishonesty?
A  Yes, okay, yes.

Q  You do not regard that as a particularly serious allegation, you told us?
A  No, I did not, no.

Q  Therefore, that may help us to understand how easy it is for you to make serious allegations against clinicians?
A  But I think I have just explained to you it was not just, oh, we think he has lied to us without some reason of why we think --- we could say that we do not think report is accurate. That would have probably been a better way to put it; we do not think this report is accurate because and then gone through the concerns, the differences between what was in the manual and what was his in report. We did go back to Dr Newell I think first with that saying it is saying this, it is saying this and he did not change his mind.

Q  So because he did not change his mind once you had queried his expertise using Cliff Robertson’s book you feel entitled to describe him as not entirely honest?
A  You are twisting slightly what was actually meant by it.

Q  Let us not labour the point. Let us have a look at the notes together now. If you could just take up our Panel bundle 2. I hope we can deal with this relatively swiftly. I would like you, first of all, to turn if you could with me to page 11 at the top?
A  Is that behind tab 4?

Q  Behind tab 4, sorry, Mr Henshall, you are right to ask. Do you have that?
A  I have, yes.

Q  You have maintained at times serious misgivings and concerns about accuracy of the nursing and clinical notes?
A

Some of them, yes. Some of them.

Q I just want to investigate and explore that with you. On this page we have a clerking in note dealing with your wife, describing her as Deborah Davies, her blood group, her rubella, her status, that she is not a smoker, she does not take alcohol, she has been treated with antibiotics and dexamethasone and then her obstetric history and then her past medical history, insulin dependent diabetes. “Husband’s family has asthma” Is that correct?

A Yes, asthma, like most people in North Staffordshire we have asthma, yes

Q And a previous matter which we do not need to go into in a public hearing. So reasonably accurate?

A Apart from I was not her husband at the time.

Q You can understand how you might have been described as such, do you not think? Common law husband at least?

A Possibly but...

Q This is the second child you are having together?

A Yes.

Q You have taken on at a relatively a young age the responsibility of a young woman with six children?

A It is probably an understandable assumption to make but it is still nevertheless incorrect.

Q Then we have got the note that I think you do query and that is all written - and I am happy for you to be shown the original --- actually we do not have the originals of Patient 7’s notes?

THE CHAIRMAN: Not yet.

MR FORDE: If anything arises I am sure we can ask you look at it. Take it from me that this is to be found in Patient 7’s notes and it has been identified by the GMC as a relevant note and it goes through the history, it is timed at twelve noon, the facts of the delivery, it is going to be an elective lower section Caesarean section, goes through the endotracheal tube size, the length of the tube that was used to intubate Patient 7, her APGAR scores. That she has gone off the Special Care Baby Unit for further management and then she is weighed, temperatures is taken, etcetera. She was electively intubated and was on a ventilator from the moment she was born?

A Yes.

Q That was an ordinary ventilator to start with. Do you recall that?

A Yes, I remember seeing that, yes.

Q That is accurate, is it?

A As far as I can see, yes.

Q As far as you can see?
A  

Q  Then the management and investigations section which I will not trouble you with. Then we have the asterisk “CNEP consent obtained from father.” You are not described as husband. There is an umbilical arterial catheter inserted and it is signed by Dr Arumugam who was at the relevant time a registrar?

A  Yes.

B  

Q  You seem to be suggesting you have no recollection of having a conversation with him about signing a consent form?

A  I did not have any conversation with any male doctor at that time so.

Q  I will return to that, if I may, in a moment. If we go over the page we have a different hand, 3.15, your daughter was born round about eleven o'clock if I am not mistaken. Randomised for CNEP trial at 3.05, that would be round about four hours following her delivery?

A  Yes.

Q  Then at 3.15 there is some values taken, the confirmation of CNEP and a head scan was done. You told us about this yesterday. If I can remind you very briefly of your evidence, if I can find my transcript, you said this, D12/5B:

"Q  You said you agreed to your daughter receiving this treatment?
A  I agreed to her receiving the treatment, yes.

Q  Were you asked to sign anything, Mr Henshall?
A  I was asked to sign - the nurse just said, “You just have to sign - there is a form saying that she can have this treatment”. She went away for a couple of seconds. She came back with the form, as I remember it, on a clipboard. She just said, “You need to sign your name - print your name and sign your name here”, which I did. I did not read the form because I did not think I needed to. She just told me what I was signing for, so I signed it. I mean, I was quite anxious at that time as well to get home, as you can imagine. There was lots of things going through my mind about the children at home, Deb up on the ward, Patient 7. So if you have just been given an explanation by, you know, a member of staff on a neonatal unit, you basically accept what they tell you.

Forget the gender of the person taking consent for the moment. You seem there to be suggesting you were in a bit of a rush?

A  I was on my way home, yes, yes.

Q  You also seem to be suggesting that you were an anxious to get back to the six children at home?

A  Yes.

Q  Did you have childcare in place for that evening?

A  We were lucky at that time because Deb’s mother lived about 100 yards down the
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road and she had got two teenage daughters, Deb’s sisters, who were quite willing to help out at a time like that.

Q There were aunts on hand?
A Their aunts were on hand but I did want to be back for when they got back from school because obviously the kids knew that mum was having the baby that day so they would be coming back from school wanting to know what had gone on. So I was quite---

Q You were hoping to be back by what sort of time, 3.30, 4 something like that?
A I think they finish school about 3.15, so I wanted to be back by about three o’clock at the latest.

Q How far was the hospital from your home?
A At that time I would say five or six miles, I would have thought.

Q We know there is an error or it has been suggested to you an untruth in that because you only, I think you accept, printed your name and signed your name?
A Yes.

Q Miss O’Rourke dealt with that with you, I do not need to go over it with you. If we turn on to the consent form itself, it is page 19 at the top. Do you accept that if you read the form you would be left in no doubt that it was a trial?
A If the top part of had been filled in, yes, I would probably have realised it was not just for treatment if I had read all the form, yes.

Q You would have seen a reference to information in the first typed paragraph?
A Yes.

Q I think as Miss O’Rourke suggested to you, I know you are sceptical of the Trust’s investigation, but the Trust found when they investigated that every single parent involved in the trial at Staffordshire had been consented using a form like this?
A Yes, sceptical because I think what they looked at was there was a signature on each form. I do not think they actually cross-referenced anything or made sure it was actually a parent’s signature or anything like that. They just went through the forms I said, yes, there was a signature on each form, as far as I understand.

Q You have been asked about Dr Arumugam’s signature but it does appear printed and signed by that doctor?
A Yes.

Q Whose note appears to have been made at page 13?
A Yes.

Q So, as has been suggested to you, here is a doctor confirming that he has explained the investigation and trial to you?
A He is signing to say he has done that, yes.

Q Your evidence is that he did not do that?
A No, he did not do that.
Q I have to suggest that you have simply forgotten that process of consenting because not only the length of time but because you were in a rush?
A I think it would be difficult for me to forget whether I was spoken to by a man or woman about it.

Q You may have been spoken to by a man and a woman. Do you countenance that as a possibility?
A I was not. I was not. It was one nurse.

Q The difficulty with your version of events is that the fact of the consenting having been done also finds its way, does it not, into the nursing note at page 20?
A It does actually, yes.

Q "Dad spoken to by Dr Aru and consent for CNEP trial given"?
A Yes, I mean I have a problem with the first sentence of that "Dad, brothers and sisters visited." This note is made, this is saying like 11.30 in the morning. So when it was made or not but basically what it is saying there is that while Deb was going down for a Caesarean section I had - 1992 - I would have had a ten month old daughter with me, a two-year old son and possibly a four-year old son with me on – basically on that ward where the theatre is, they would have had to be with me in the fathers’ room, which I do not think---

Q They might have been brought later?
A No, you cannot say that because this is "Dad, brothers and sisters visited”. What I am saying is I went up to the hospital, Deb went for surgery, I dotted between Deb and the neonatal unit then I went home to the children – you know…

Q You had some children of school age, did you not, and at least two that were below school age?
A That is what I say – there would be two, definitely a ten-month old daughter and a two-year old son would have been with me and possibly the four-year old son might have been with me, if that is to believed. That would have been totally irresponsible. Where would they have been? There is no way those brothers and sisters would have been allowed to stay with me while I am dotting between Deb---

Q I am just trying to understand that. You were not present at the Caesarean section, were you?
A No, I had to wait in the fathers’ room, but the fathers’ room is still on the actual ward – I think they call it a progress ward, labour ward.

Q This was an elective Caesarean section so you knew that your then partner/now wife was going in for a section?
A I knew the night before that she was going in for a section, so why would I have
taken the children with me? I cannot understand that note.

Q  Equally, why not? It was not rushing to the hospital. It was a planned procedure and there was going to be a baby at the end of it.
A  I would not have taken a ten-month old baby with me.

Q  Anyway, that is your evidence. As I understand it, half the reason you query this note – and we see the page continues in different hands with different signatures – is that you did not see it for a number of years after the birth of Patient 7?
A  Nursing records, is it not? I cannot remember if this was part of those nursing records or not or whether we had these and it is just the nursing records in relation to Patient 6 that appeared some time afterwards.

Q  You are suspicious of the nursing notes?
A  I am suspicious – the first sentence does not sit right with me. I know there is no way I would have taken children with me on that morning and, like I claim, it was not Dr Arumugam who spoke to me. I did come up with a perfectly plausible scenario of what had gone on and I was not particularly complaining about that scenario. If they needed me to sign a form, they got me to sign a form and Dr Arumugam, who might not have been available at the time, signed it afterwards because they knew I was in a rush to get home.

Q  There we are. Miss O’Rourke has suggested that – I am suggesting your recollection is at least faulty; it has also been suggested to you that you are telling untruths about that. You do understand the purpose of these notes is to allow people to look back and refresh, if they need to, their memory. They are supposed to be better than recollection?
A  The point that was brought up with Miss O’Rourke was that is timed at 11.30, so obviously that note could not have been written at 11.30 otherwise I would have been asked for consent 20 minutes after my daughter was born.

Q  I cannot remember what time she was born – let us just check---
A  Ten-past eleven, I think it was.

Q  11.10?
A  Yes, ten-past eleven. Basically, sir, we are saying if that note was written at 11.30 then I was being asked to consent for my daughter to take part in a CNEP trial 20 minutes after her birth – that is ridiculous. The suggestion Miss O’Rourke made is actually that note had been written some time afterwards, this had all happened from 11.30 onwards and it could have been written at any time up to about ten-to ten at night, because that is the next note. It might be that when the nurse is writing that up she is writing it up some time afterwards and just forgets the thing about the brothers and sisters.

Q  The 11.30 could, of course, be a reference to her admission to the neonatal unit?
A  Yes, but there is only one signature. That is only one handwriting.

Q  I quite understand that but this is one of the difficulties of dealing with a case so long after the case in question. You would like to interpret the note as suggesting that paragraphs 1 to 5 were all written at 11.30 and therefore inaccurate, and of course on this
side we would like to interpret the note as 11.30 being attributed to the first three lines and the other matters being written later. That is the difference between us. We are never going to resolve it, are we?

A No.

Q The important matter that I am dealing with you is that there is a nurse who has noted that you were spoken to by Dr Aru – and we have got his signature – and you gave consent for a CNEP trial; that is what it says in black and white?

A If she is writing up these notes retrospectively she might have just gone and looked whose name was on the consent form and put that there.

Q You are aware, are you not – and if you are not, do say – that it is not uncommon in situations such as these, stressful, for parents in your position to forget major elements of the consenting process. There are lots of papers on the subject, have you read them?

A I have seen a couple of them, yes. I have seen reference to others, yes.

Q So it is not an uncommon situation?

A I do not know how common it is. There has been several studies done on it.

Q Initially, you did not think you had signed a form at all, did you?

A Yes, as soon as Dr Newell mentioned about we would have to sign a form, I said “I did sign a form for Patient 7”.

Q That may be quite important. You first, is this correct, began to consider the signing of the form during your meeting in early 1996 with Dr Newell?

A I first considered?

Q Yes, you first had reason to reflect upon it?

A Possibly, yes. Possibly.

Q Which is about four years or so after the events in question?

A Yes.

Q The children were in a trial and you are telling this Panel “That’s when I said I remember signing a form”?

A Yes.

Q There was no reason for you and your wife, presumably, if your evidence is to be accepted on this point, to discuss the signing of any forms or consents prior to your meeting with Dr Newell?

A No, she was not aware I had signed that form. No.

Q In fact, we know from correspondence she seems quite irritated that she was not told you had consented to a, we say trial you say procedure or treatment, and you signed it and she never knew?

A Yes.

Q For four years?

A Yes.
Q Do you think that your recollection could have faded in the four-year period between the signing of your form and your consideration of that matter?
A I would accept it is a possibility but I do not think it did because my recollection is quite clear. Straight away, as soon as Dr Newell said “You would have had to sign a form” I said “I did sign a form for Patient 7, I can remember doing that”.

B Q Can I just ask you now a few questions about Patient 6, which is behind tab 5?
A Yes.

Q I cannot deal with the consent form in great detail with you because it appears to have your wife’s signature on it?
A Yes.

C Q Would you agree it appears to have your wife’s signature on it?
A It appears to have her signature on it.

Q Do you agree with her and maintain your stance that you are somewhat mystified as to how it happens to be there?
A As I said, I was not there at the time so I cannot cast any opinion. I have no reason to doubt my wife’s recollection or not of events.

D Q Do you accept that if she read the consent form that it ought to have been apparent that Patient 6 was being entered into the trial? It is the same as the one we looked at previously.
A You have asked me was it a trial and I said I probably would – I cannot speak for my wife at that time. I cannot answer that question.

E Q I just want to ask you a little bit about this delivery, if I can. It is day 12, page 13 that you deal with it in the transcript. I just want to understand from you whether I have got the correct impression about the sequence of events, and I will read you the relevant parts. You were asked, I think in chief by Ms Sullivan, this question, just below letter C:

“Could you see much of Patient 6 when she was born? How did she look?”
A Yeah, I saw them pull her out. Yeah, I saw them pull her out. I think she - they clamped her, cut the cord and there was a paediatrician in the theatre who whipped over to the side of the theatre. I could not see what he was doing.”

Do you recall explaining that?
A Yes.

Q Then:

“Q Was sterilisation discussed at that stage?
A Yes, we discussed this with the consultant obstetrician. Deb said previously that she wanted this to be the last one. Contraception, nothing had worked. She did not want to be in this
position in 12 months’ time. He was reluctant to make any specific note for contraception. He said because you have lost a premature baby before, you might change your mind after you have given birth. Deb was adamant on the table. She wanted to be sterilised. I think it was the registrar who had done the caesarean. He asked two or three times, ‘Are you sure?’ ‘Are you sure?’ He fetched a form which Deb signed and then he asked how Deb wanted it done.”

Then we have got the question at letter G:

“Q  How was your wife at that stage, when signing that form?
A  When she signed that form she made her point clear that she wanted to be sterilised and she was okay. It was afterwards. I do not know whether it was because she had had an anaesthetic and it was a spinal anaesthetic, but she started to talk about feeling sick.”

The impression I have got from that sequence of answers is that Patient 6 was born, your wife had a discussion about sterilisation and then signed a consent form---

A  For sterilisation.

Q  …for sterilisation. So that is when she is open, on the table, having had the Caesarean section, there is this discussion and the signing of the forms – that is as you recollect things?
A  Yes.

Q  We have got some documents which we would like handed to you and the Panel dealing with the issue of consent, D8. (Same handed)

MS SULLIVAN: Can I see them?

MR FORDE: Of course. (To the witness) So there is no mystery, what Dr Spencer has done is he has gone through your wife’s maternity notes, which we have got as part of the unused material in the case. Perhaps I could just remind you of one other thing, not only that which your wife said but in her affidavit in support of this complaint at paragraph 18 she said in relation to the form:

“At no time during our conversation did the doctor ask me to sign a form or give me any written information on CNEP”

- and you know there is an issue there.

“I do not believe I would have been able to sign it anyway as I was still high from the morphine painkilling injections I was on. I could barely raise my head, let alone write.”

Okay?
A  Yes.

Q  It would appear, according to the evidence you gave yesterday, that your wife was
capable of conversing about the issue of sterilisation following the caesarean?
A She definitely was, but I am not sure if she was on actual morphine then because she was still on the anaesthesia.

Q Was it at this stage that you were having a discussion about the name?
A About the name?

B Q Yes, the Alison/Zoë discussion?
A Was beforehand, before I first came in.

Q Before the Caesarean section?
A Yes, I think it was. Yes.

C Q Again, it is difficult to remember. It is not a trick question, I just wanted to know. We have looked at the drug chart but I will put this to Dr Stimmler. There is an anti-emetic, something that stops you being sick, called Stemetil?
A That is it, yes.

Q Which your wife was written up for but it was never given?
A Never given?

D Q No, according to the chart?
A I saw him give it.

Q Anyway, looking at this, this is what we think happened and I just want to see whether you would accept that your memory is faulty in this regard. On 18 November 1992 your then partner/now wife gave consent for a tubal occlusion – that is a type of sterilisation. So that is before, about a month before, Patient 6 was born?
A They did not know she was going to be born in a month’s time, did they?

E Q No, but they had obviously had a discussion with her, presumably when she is on the bed rest for six weeks, and she was making it clear then that she wanted to be sterilised?
A She did tell the consultant she wanted to be sterilised but I do not think it is practice to sign consent forms that far in front, is it?

F Q We say it certainly is not practice to try and get consent for sterilisation post-Caesarean section with a mother who has an open wound and then go to ligation – that would just be most improper; it would not be a valid consent?
A Equally, it is improper to do it a month before, so she would be 28 weeks pregnant.

G Q But she was expressing a strong view, as you appeared to be indicating in your evidence yesterday, that contraception was not working and she did not want any more children?
A That is right, but it still would not be policy to take consent.

H Q I suggest that it was an appropriate way of doing things?
A Certainly, she had a tooth out that day in hospital while she was on bed rest.
A

Q  You think somebody has written tubal occlusion when they mean dental extraction?
A  I just point out that she had a tooth out that day.

Q  What is the point you are making?
A  That she had a tooth out that day.

Q  You recall now, do you, that your wife had a tooth extracted on 18 November 1992?
A  No, she recalled it.

Q  You --
A  A long time ago.

Q  Over the page, 14 December, we suggest prior to the Caesarean section, consent for a section, plus sterilisation, aware irreversible. That would all have been done before, and it is signed by your wife on 14/12/92, bottom of the page, she had the Caesarean section. That is how it should be done?
A  That is not how it was done.

Q  Do you think that your recollection could be faulty? Do you think that you could have got it wrong when you are thinking back and saying that this was all done on the operating table?
A  I would not say it was all done. The Caesarean section could well have been consented for before, but the sterilisation bit was actually done. With having a premature baby they did not want for her to be sterilised. They would have preferred her to come back in I think six months' time to have the sterilisation.

Q  I have to suggest one of two things. Either your recollection is entirely faulty or you are not telling us the truth about that?
A  I am telling you it as I remember it.

Q  That could be because your recollection is faulty?
A  Why?

Q  Just for completeness - it is a slightly separate topic - you and your wife have been maintaining for some time that she has a particular problem with anaesthesia. She appears to have raised this with a Dr Depares, consultant obstetrician and gynaecologist. That is the next page. He is asking for a thorough search - this is 25 May 2005 - of the notes dealing with the Caesarean sections on 10 April 1991, 12 April 1992 and 14 December 1992?
A  Yes.

Q  He writes:

“I understand that she had significant anaesthetic complications post-operatively and as we are planning to operate on her very soon, I would be grateful for any assistance you may give us.”

D13/53
What Dr Readman did, over the page, is to go through the notes, and we will put this to Dr Stimmler if he is appropriately qualified, and Dr Spenser has done the same. There is nothing in the notes recorded to suggest that your wife has problems with her conscious level or lucidity following a general anaesthetic?

A I think some medical records were produced at the end of my wife giving evidence where it showed how her temperature dropped and her blood pressure dropped.

Q Her temperature dropped, and again we can put this to Dr Stimmler. Perhaps you will take this from me, her blood pressure recording there is normal for her?

A It is normal for her? We have not had the privilege of looking through the obstetric records. I can see what he is saying.

Q Can you see at the end of that letter that he says that the spinal anaesthetic, 14 December 1992, whilst under my care.

“This operation was apparently performed under a spinal anaesthetic and I can find no evidence of any problem in the notes whatsoever.”

A Yes.

Q So there is no possibility, I have to suggest to you, of your wife signing that form and being unaware of it, is there?

A Why is not there? I have seen her under anaesthetic and morphine. I have seen it.

Q Barely raise her head, let alone write, but it is her signature, is it not?

A Where are you looking at now?

Q I am looking at her affidavit. I read it out to you earlier, paragraph 18. I am sure you can have a copy if you want, but when she made her complaint in November 2000 that is what she said.

“At no time during our conversation did the doctor ask me to sign a form or give me any written information on CNEP. I do not believe I would have been able to sign it anyway as I was still high from the morphine pain killing injections I was on.” (Document not given to shorthand writer).

A That is a different time. That is after all the operations. You are talking about during the operation when she would not necessarily have been on morphine because she was still under anaesthetic.

Q Your story has fluctuated. At times it is the morphine that causes the problems with recollection and lucidity, and at other times it is the anaesthesia?

A No, we are saying we do not know which one it is. That is what has been stated. We do not know which one it is. She was under the spinal anaesthesia for Patient 6. Therefore, as far as I am aware she probably would not have needed any such painkiller then. The painkillers come in for as the anaesthetic wears off.

Q We know that these were small 10mls therapeutic doses with no record in the nursing notes of an adverse reaction?
A  Adverse reaction such as?

Q  To the morphine. A loss of conscious level. Intramuscular morphine given and
the nurses you would expect to observe a loss of conscious level?
A  You would do, yes.

B  But there is nothing in the nursing notes to suggest that occurred.
A  I observed the loss of conscious level. I was there. I observed it. Because the
nurses have not made a note of it...

Q  There is another dereliction in duty. When they are not making the notes up they
are failing to record vital signs?
A  I can only tell you what I saw at the times. Just because that does not tally with
what is in the notes, I cannot speak for other people what other people do or do not do,
what they are supposed to or not supposed to do. I can only tell you what I see at the
time.

C  You were not there, in fairness to you, at the time when consent for CNEP was
obtained?
A  In regard to Patient 6, no.

D  Where were you?
A  I was probably at home.

Q  When you visited your daughter, Patient 6, it was immediately apparent to you,
was it not, that she was in a CNEP tank?
A  Yes.

E  Do you recall the symbols on the incubators of those children not in the trial
making a reference to CNEP and a trial?
A  No.

Q  You do not recall the teddy bear we showed your wife?
A  No, as Dr Southall stated those not on the CNEP tanks ---

F  Dr Southall was not working at Staffordshire at the time. So anything he has
written about the signs at that time must pertain to Queen Charlottes?
A  To be fair, he was there for about the last 12 months of the trial. I think he came
in 1992 and this finished in 1993.

G  He certainly was not there at the time?
A  And he never visited the neonatal unit to have a look at the CNEP tanks.

Q  He had no clinical dealing with patients in CNEP, as I understand it.
A  Did he visit the unit and have a look at the CNEP tanks?

A  I am not saying, you were saying that he was not working at the hospital at the
time. Actually he was for the end part of the trial. Did he visit the neonatal unit at that
time and have a look at CNAP?

Q So, Mr Henshall, the fact that he has written about experience that could be at North Staffs or Queen Charlottes, you are happy to grab that and say it has to be a reference to North Staffs?
A No, I did not say that. The statement Dr Southall makes is that after the first four or five months, I think it is, one of these posters was on every CNEP tank or incubator of every child in the trial.

Q Dr Spencer was there, and he instructs me that the teddy bear sign was on the incubators of those children who were not in the CNEP tank?
A They were not on the CNEP tanks or they were on the CNEP tanks.

Q They were not. “I am receiving standard treatment within the CNEP trial” was the sign on the incubators of those children that were not in the CNEP tank?
A I would not dispute that. As I said, they were not on the CNEP tanks. Whether the were on the standard ventilator I do not know because we were not encouraged to go around and look at other babies, you had to basically stay with your own baby. You were not allowed to go around to the other children.

Q It was quite clear, was it not, to anybody who went into that neonatal ward that there were standard incubators and standard ventilators and there were CNEP tanks?
A I would imagine that people would see the difference, yes.

Q You could?
A Yes.

Q And everybody was discussing, nursing staff, doctors and possibly other parents, the fact that this was a trial?
A Really.

Q Because it was unusual?
A I do not recall anybody mentioning it was a trial, certainly not to us.

Q I know your version of events is that you did not know until the Newell meeting? 
A That is right.

Q Did you provide a witness statement for Dr Newell to look at, or was it only your wife?
A I think it was just my wife. I think that the action was taken in her name. As I remember with Mr Evans, I dropped Deb off at his offices and she would do all the necessary paperwork and things like that and I would pick her up later.

Q When did you call Evans to try to find a copy of the statement?
A Was it Tuesday? I think I was asked to do it over the weekend but never got around to do it, or forgot about it. I think it was Tuesday while we were here.

Q You were asked to do that by Miss Morris?
A Yes, I was. It might have been last week when Deb was giving evidence.
Q Who did you speak to about the file?
A I think it was a girl called Emma who was his secretary or receptionist.

Q So you did not speak to Mr Evans himself?
A No. I got our case number and was very explicit what Miss Morris and you needed.

Q A letter of instruction?
A There was a letter of instruction, something to do with the legal aid application, which I cannot exactly remember the exact words, and the statement I think.

Q As a non-legally qualified person you felt competent to undertake that task, did you?
A I was just regurgitating information. I think Miss Morris probably just thought it would be quicker because James Evans had dealt with us, so basically it was our case.

Q I have one further topic to ask you about to do with your meetings with Dr Morgan. If you go behind tab five to page 35 at the bottom, you will find 36 at the bottom right and it is the page before. The top consultation for everybody’s note, we all agree should be 22/9/1993. The date is missing. That is what he records as being the case?
A Yes.

Q Then there is a consultation on 19/1/1994?
A Yes.

Q Where there is concern about a convergent squint?
A Yes.

Q If you go two pages back to the 2 March 1993 that is a consultation we think with a Dr Doherty where she lists a number of things - prematurity, respiratory distress syndrome, two days of IPPV, five days of CNEP. Apnoea recurrent, post-haemorrhagic ventricular dilatation. That is a reference to the scan - “(mild)” jaundice at prematurity. Your daughter had to go under the light?
A Phototherapy, yes.

Q She wrote about that. If you go through the bundle to page 193, on 2 March she lists the same five matters. Do you see that? J Doherty, registrar to Dr Spencer?
A Yes.

Q Then if you go over two page to 195 this is Dr Morgan's letter to Dr Bradbury your GP?
A Yes.

Q Convergent squint?
A Yes.

Q If you go over to page 200 he is referring to the clinic we have just looked at on
19 January. If people want to cross-reference that, that is page 35. It says:

“Prematurity born at 32 weeks. Right convergent squint. Developmental delay”?

A Yes.

Q Nowhere in the clinical notes or in those letters is there any suggestion of a conversation about a brain damaging brain bleed?
A Sorry where?

Q Neither ---
A 1994?

Q Neither in the clinical notes nor in the letters written by the registrars Doherty and Morgan to your GP is there any reference to any conversation about a brain damaging brain bleed, particularly with Dr Morgan because the evidence you and your wife have given is it is Dr Morgan who alights on the fact that your daughter’s condition may be because to the brain damaging bleed and you had no idea it had occurred?
A When else do we hear of the bleed then?

Q I am just asking you whether your recollection is correct that he was linking the bleed to your daughter’s cerebral palsy. That is what you have told this Panel and that is what you wish them to believe?
A The letter on page 200 is written to Dr Heycock. So by that time we had already been referred to – this was like a referral letter to the consultant paediatrician.

Q That is a letter to Dr Heycock dealing with her developmental delay and he is asking for a detailed developmental assessment. If he had thought that the developmental delay was causatively linked to the ultrasound scan or the mild bleed, as it is described by Dr Doherty, he would have said so. It is an important piece of information for him to communicate to Dr Heycock.
A It is actually important. I do not understand why he has not done it because obviously Dr Doherty thought it was worth making a note of so I do not understand why Dr Morgan has not.

Q Again, she is noting five things that are correctly noted about your daughter’s previous history but she does not appear to be linking the mild ventricular dilatation to your daughter’s condition does she?
A No, not linking it to it, no, and to be fair the final meeting with Dr Morgan where that issue was raised, I was not present at that. It was one that my wife went to and I think he questioned her on that.

Q In fairness to you and to the Panel we have already looked at what Dr Spencer had to say – it is pages 212 and 213. There is a letter from Dr Heycock at 218 which deals with the ultrasound scan:

“Soon after birth showed some post haemorrhagic ventricular dilatation. Please could you organise for her to have a CT scan under sedation in order to elucidate the cause of the current findings.”

D13/58
A

A  Yes.

Q  So she then organised that scan?
A  Yes.

B

Q  Is that the scan that you say Dr Newell had or did not have access to when you saw him in 1996?
A  Dr Newell?

Q  Yes.
A  I thought it was – Dr Newell, it took some time to get the scans to him and then Dr Newton saw all the scans.

C

Q  We know – and I am not going to take you to it because I explored with your wife the fact that Dr Newton was suggesting injury between 25 and 35 weeks’ gestation?
A  Yes.

Q  Were you present at any meeting where he was expressing a different view?
A  I had the same view as my wife. I thought he was basically saying it was post birth rather than previous.

D

Q  Certainly you and your wife have written letters saying it occurred between 32 and 35 weeks, have you not?
A  That will be after birth, yes. We were saying it happened some time after birth, yes.

E

Q  The reason you have written that, really to end where I started, is because you believe that the brain damaging event occurred after Patient 6 was born?
A  Yes, I do, yes.

Q  You have just struggled to find medical support sufficient to bring an action based upon that belief?
A  So you believe it was---

F

Q  As you told us yesterday, I think.
A  So you believe she was born with this? Is that the belief?

Q  I am not really here to express a view, Mr Henshall but I just want to explore your motivation, if you like, in terms of this complaint?
A  One thing I would just point out, if she was born with this damage, a congenital neurological abnormality, that is actually an exclusion criteria for the CNEP trial.

Q  It may have been but it would not have been one known until the ultrasound was done?
A  They should have done the ultrasound – if that was an exclusion criteria, they should be doing brain scans before those children go into the tanks to exclude that.

H

Q  I know, and I see your wife nodding vigorously, that is your view. You have
since gone into the protocols but at the time, real time, real world, back in 1992, none of
this was known to you was it?
A    What is your point on that? Because we were ignorant it was OK?

Q    No, I am not suggesting that.
A    Now we know we are lying?

B    I am not suggesting that. We are not here facing a charge of failing to scan
Patient 6 prior to entering her into the CNEP trial. No doubt you think we should be.
A    I think – one of the heads of charge, I am quite sure, is still regarding the trial
protocol, so if you are standing there and suggesting that child 6’s damage was
congenital, then that should exclude her from the trial.

C    That may or may not be. We are going to be debating the protocol. You know
that the protocol was approved by the Ethics Committee?
A    Yes.

Q    One of your other complaints is that the adverse event in Queen Charlotte’s, the
neck injury, was not notified to you?
A    It was not notified to us, was not notified to the parent, was not notified to the
Ethics Committee or the Coroner.

D    You know that there are those, a respectable body of medical opinion, who first of
all do not regard that as an adverse event, do you not?
A    That is their opinion.

Q    You know that one of them is Dr Stimmler who is being called by the GMC, who
says in terms, “I do not think this was an adverse event that needed to be notified to the
Ethics Committee at North Staffs”?
A    But the Medical Ethicist thinks it should have been.

Q    Be that as it may, the Medical Ethicist has never run a trial.
A    Neither have the people on the Ethics Committee. You have just made great play
of saying this approved this trial.

F    You know, do you not, that the adverse event occurred at Queen Charlotte’s, not
at North Staffs?
A    That one occurred at Queen Charlotte’s. There was another one occurred at
Queen Charlotte’s.

G    You also know that there is no suggestion of such an injury occurring at North
Staffs?
A    Not as I have heard of, no, but there were other adverse events. Temperature
control was one.

Q    Yes, but again not the subject---
A    At North Staffs.

Q    Not the subject of a charge?
A It is subject of a charge because that is all a part of the consenting process and I think we should have been told about it.

Q Can I just ask you this? Why have you not complained about those doctors that were on the Ethics Committee that approved this trial, because you believe that the CNEP trial should never have been approved of?
A We have written letters of complaint to the old Health Authority, who – it is difficult to know who to complain to about the Ethics Committee because they are sort of an independent committee and my lay understanding, they are sort of immune from that sort of complaint because---

Q No, if they are registered doctors on the Ethics Committee – and I am instructed they would have been – they should be here as well, should they not?
A Why should they?

Q Because your view is that CNEP should never have been approved of. There was no evidence base for it, you tell us?
A I do not think we have ever said that the CNEP trial should never have been approved. What we are saying is there was flaws in the design that should have been picked up.

Q By the Ethics Committee?
A They are partly charged with that, yes.

Q That is what they are there to do, is it not, to pick up flaws in design? Doctors come up with a trial and seek approval. If it has been approved in your view wrongly, then the doctors on that Ethics Committee should be standing next to me?
A I think you will find that Ethics Committee members are immune from that sort of action by being on the Ethics – I think, I may be corrected but I think there is legal immunity. When you sit on an Ethics Committee you give these decisions and you are then not responsible if that decision turns out – you can genuinely approve a study in all good intentions and that study goes on to be proved actually it is causing damage. I do not think the actual Ethics Committee can be charged with anything over that.

Q I am not sure where you have got that view from. We do not need to explore it now. Can I just ask you about some of the GMC witnesses? How do you feel about the fact that Dr Brookfield, who you maintained for some time complaints about, is not the subject of this enquiry but is, in fact, a General Medical Council witness?
A I think with Dr Brookfield, when we first got---

Q He was in charge of Patient 7’s care, was he not?
A That is the crux of it because we sort of disagree with that because it seemed to be that Dr Spencer was making the majority of the clinical decisions about Patient 7, so our understanding seems to be that – and not just ours, this is something we have picked up since although at the time--

Q Let us just see if we can get a “Yes” or “No” answer.
A Let me just explain to you – I understand I am rambling a bit and I apologise for that but the point I am trying to make is that at the time on the unit we were aware that Dr
Spencer seemed to be making most of the clinical decisions with regard to Patient 7. Dr Brookfield was down as Patient 7’s consultant but from talking to other parents and we feel the same, when children were on CNEP Dr Brookfield seemed to take a back step and let Dr Spencer make those decisions, which is my understanding of why the complaint against Dr Brookfield was dropped, because we were not saying that he was taking responsibility for these children at CNEP, he was taking a back step and letting Dr Spencer, so it was untenable to maintain that complaint against Dr Brookfield.

If that is the case, if Dr Brookfield was taking a back step, perhaps he does not wholeheartedly agree with using CNEP, so I have no problem with him being a witness for us. It will be interesting to see what he says.

Q Dr Brookfield made a number of decisions in relation to Patient 6. His name appears in Patient 6’s notes long before Dr Spencer’s. You knew that, did you not?
A I have seen his name there, yes.

Q Shall we look at it together, because I just want to understand the logic of your position. You know Dr Spencer was not on duty at 10.30 at night when Patient 6 was born, do you not? I am sorry, six minutes to seven when Patient 6 was born. You know that, do you not?
A I did not know that, no. I do not see as it is relevant to be honest.

Q He was not any part of the consenting process involving your wife, was he?
A I never said he was.

Q He was not part of any of the consenting process involving you with Patient 7?
A No.

Q Did you ever consider making a complaint against Dr Aru?
A I have made a complaint to the local Trust.

Q Have you made a complaint to the General Medical Council…
A No because---

Q …suggesting he has forged the consent form?
A No.

Q Why not?
A I did not say he had forged the consent form. My complaint there was that I had the procedure explained to me by a nurse but then Dr Arumugam has countersigned the form as though he has explained it to me. I have made that complaint to the local hospital Trust. The hospital Trust said they could not find Dr Arumugam, so then hat is the point of me making a complaint to the General Medical Council then, because they probably will not be able to find him. He may well have left the country.

Q We start the story with the notes on page 21 – it is slightly obscured in the photocopying. Born 1850, it says top right, behind tab 5.
A Yes.
Q We do not know the first signature on page 22 but it is not ours. The next one, we know is Stanley, although you query the way she signs her name. We will ask her about that. You complained about her, did you not?
A We complained about her?

Q Yes?
A No.

Q No. Palmer, Kate Palmer you have accused of forgery in the NIRS trial?
A Yes.

Q Do you maintain that complaint?
A It is obviously not, we cannot maintain it, can we. It has been thrown out.

Q You might still have a view that she is guilty of forgery?
A Actually again that is something you would have needed to ask my wife because I was not there at the time. That was ongoing.

Q The first signature we see that we can identify, apart from Stanley, on 15 December, which is long after the consenting process and when your daughter is already in CNEP, that is the distinctive signature, I am told, of Dr Brookfield, about a third of the way down the page, just above the second 15.12.92. The next note is not Dr Spencer, it is an RA – I do not think we can identify that signature. It goes on over to page 24. Day 3 we have on page 25. Day 4 also, 18.12.92. Then the first note we can find on page 26, which is Day 4, is seen by Dr Spencer, “out of CNEP tank.” Are you telling me you have a recollection of Dr Spencer making the relevant clinical decisions for the first four days of Patient 6’s life, or is that surmise on your part?
A Surmise? No. Dr Spencer was her named consultant.

Q Yes, I know, but Dr Brookfield was patient 7’s named consultant but you are prepared to absolve him because you say Dr Spencer was making the clinical decisions. Dr Spencer spoke to you and your wife towards the end of her tragically short life about whether or not her life could be sustained. That was why you recall him and Patient 7?
A I did not speak to Dr Spencer.

Q The notes recall, do they not, that Dr Spencer had spoken to you and the nursing notes recall that Dr Aru had also spoken to you and your wife about the fact that your daughter, patient &, was not doing well. It is page 17 behind tab 4?
A I did not speak to – I think I made that clear I did not speak to Dr Spencer.

Q It says,

“Dr Spencer has spoken to parents, explained how seriously ill Patient 7 was, also discussed concerns regarding renal and brain perfusion. He explained to the parents that because of poor perfusion the kidneys are in failure.”

H That is all made up, is it? Parents, plural? You never spoke to Dr Spencer?
A I never spoke to Dr Spencer, no.

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D13/63
Q: So that is made up as well?
A: Probably just written wrongly because I think it was actually written again afterwards, was it not? I thought there was some problem with the timing.

Q: It has got 14.12.92 and I know you see suspicion in everything but it looks to me as if the six has been altered from a twelve hour clock to 18.00, 24 hour clock?
A: Possibly, yes.

Q: Neither of us are forensic examiners and we do not have the originals of these notes but I gather they are on their way?
A: I did not speak to Dr Spencer. I think as I said remember coming in and speaking to a large Asian doctor who was brought to me by Deb because she was talking to him at the time. I think there is a note there.

Q: Do you remember speaking to a Dr Jugnu?
A: I would not know what the doctor’s name was. As I described, I came on to the unit and there was lots of people around Patient 7’s tank at the time and Deb was obviously crying and she came across to me followed by a large Asian doctor who then made some explanation about Patient 7’s poor condition and possibility of things like CNEP.

Q: Dr Aru I am told is a slightly built gentleman but if we look at the page, in the nursing notes behind tab 4, 22, it is probably easier to see 23, the next page, then go back. 22 is obscured by a line. There is an entry “16.15 mum and dad spoken to by Dr Aru re poor prognosis despite all measures taken so far.” Are you seriously suggesting that if you have had a conversation with a doctor about your daughter’s poor prognosis at quarter past four that you would have left the ward by six o’clock and left your wife to cope with that on her own?
A: I must have done because I did not speak to Dr Spencer.

Q: Did you speak to Dr Aru at quarter past four?
A: I do not know if it was Dr Aru I spoke to. I spoke to a doctor as I have described.

Q: Do you accept that you were on the ward at quarter past four on that day?
A: Actually we cannot say it was quarter past four, can we, because the timings on these are not reliable. These could have been written---

Q: There is a 17.00 so I am prepared to look at that and say that it is likely to have been accurate because all that has been written it is a rather important conversation at 16.15 is that you are having a conversation about poor prognosis?
A: Not necessarily 16.15. That has already been established.

Q: Were you on the ward at approximately 4 p.m. on that day or not?
A: No idea.

Q: You cannot remember?
A: I cannot remember what time it would be on the ward.
Q  But you can remember everything else that suits your version of events, can you not?
A  I have never claimed to remember exact times of things. I can remember events that happened.

Q  Let us try the afternoon then?
A  Possibly in the afternoon, yes. That could be any time from one o'clock when the previous record was logged.

Q  I will attempt to be as delicate as I can about this because it was clearly a very, very upsetting day but the nursing note seems to suggest that you were there for the rest of the day but more importantly do you recall being on the ward throughout the afternoon and the evening until your baby was, as we see on the next page, 23, certified as having passed away?
A  I doubt whether I will have been there all afternoon and all evening because, like I have already said, we did have other children to consider.

Q  I know you did but you had been told that this child was gravely ill. Are you telling the Panel that you would have gone home to look after the other children?
A  I may have had to nip home to do something, yes. The scenario would have probably been I was going up the hospital thinking everything was okay---

Q  Your wife has explained that.
A  When I get to the hospital thinking I am only going to be up there for an hour or so, so telling whoever was looking after the kids I am only going to be an hour or so, to be then told, well, I think you need to be here. This is in the days before the mobile phone and things like that.

Q  I am not---
A  You are trying to cast aspersions on me---

THE CHAIRMAN:  You are talking over each other again. It is difficult for us and certainly difficult for the shorthand-writer.
A  You are trying to cast aspersion on me by saying you were told you have a sick daughter and you went home. I may have had to go home, I had other things to do.

Q  I am not in any way, shape or form seeking to criticise you---
A  I think you are.

Q  ---but this case, as you know, depends on recollection?
A  Yes.

Q  I am simply suggesting to you to you that if ever there was an afternoon that a young father would remember it would have been this afternoon and you ought to have a clear recollection of whether or not you stayed with your wife at that tragic time or whether, as you put it, you nipped home?
A  I probably had to nip home. I cannot---

Q  You cannot remember, can you?
A
I cannot remember exact timings, no, I cannot. I do not think anybody could.

Q
Mr Henshall, I am not asking you for timings. When we are asked to look back at events a long time ago most of us who are parents remember birthdays, Christmas, sports days, life events?
A
Yes.

B
Q
This is a life event, the loss of your child, is it not?
A
Yes.

Q
I am just intrigued as to why it is you cannot now tell us whether you spent from the time you arrived at the hospital, the rest of the time with your wife or not. You do not have a clear recollection?
A
Not an absolute clear recollection, no, because then, you know, it has been said I have got to state the truth, the whole truth and nothing but the truth and that is as I remember it. What I can tell is the things that happened on day. I cannot tell you exactly what time those things happened or even to something that, you know, I know I was home, hospital, home, hospital throughout that day, I cannot tell you what times they were or whether I was given that conversation and then went home, or I was given that conversation and stopped there but, you know, I did spend most of that day up there but I did have other things to consider. I have got young children at home, a ten month old baby at home still who I could not just leave at home and hope somebody would look after her, I had to make sure she was going to be looked after as well.

Q
I am not criticising you, I am simply seeking through you to make the point that it is difficult for you to remember now?
A
It is difficult for me remember exact timings.

E
Q
I was actually only asking you about afternoon and evening. I was not asking for quarter past four or five o’clock?
A
I think I did say I would have had to nip home at sometime between the afternoon and the evening for the benefit of the other children at home.

MR FORDE: Mr Henshall, that is all I ask unless you think I have cut that last answer short. Thank you.
A
No.

THE CHAIRMAN: Mr Forde, can I be clear so that I do not leave myself confused. So far as the teddy-bear poster is concerned as I understand the position, and I think we saw it, the purpose of this was to identify those babies who were in the CNEP trial but who had been randomised out of the CNEP tank.

G
MR FORDE: Yes, absolutely right, sir.

THE CHAIRMAN: Presumably you have got ordinary incubators in the neonatal unit some of which will be babies in trial, some of which will be babies out of trial and the poster with the teddy-bear on it is to identify those in trial?

H
MR FORDE: Yes, and the reason for that, sir, it is obvious, as I think we all agree, when
you are in the tank but it is not obvious when you are in the ordinary incubator as to whether you are part of the randomisation process or not. So it was thought only necessary to have the sign on the incubators which indicated I am in the trial but I am receiving standard treatment.

THE CHAIRMAN: Thank you. I was a bit confused as to whether there might have been more than one but there was just this one.

MR FORDE: No, and we will get it copied for you.

THE CHAIRMAN: Thank you. This looks like a good moment to break for lunch. Mr Foster, have you got any questions?

MR FOSTER: I will have no questions.

THE CHAIRMAN: Ms Sullivan, when we come back after lunch if you have any re-examination I will call on you to do so then. Thank you very much. Five past two everybody.

(The Panel adjourned for lunch)

THE CHAIRMAN: Welcome back, everybody. Ms Sullivan?

MISS O’ROURKE: Sir, I think Ms Sullivan had agreed I could ask one matter. Sir, I came upon the Staffordshire Police letter to the Chief Executive. You will remember I asked Mr Henshall about it and I quoted him paragraphs from it that I had had copied out from the briefing notes. He contended that, in fact, it said rather more than that and could he not see it, sir. We now have it and unless there is any objection I think the Panel has should have a copy of it. It is a letter from the Staffordshire police from a Detective Chief Superintendent to the Chief Executive in October 2002. I feel it is only right Mr Henshall should have an opportunity to see it so that he can retract that which he said about it yesterday that it said a lot more that, in fact, I had contended to him it did say. That is a copy for Ms Sullivan. Sir, there are copies for the Panel. (Same handed)

THE CHAIRMAN: Perhaps Mr Henshall could have an opportunity to look at it?

MISS O’ROURKE: If he can have a look at it and then I can put to him what he said yesterday about it.

THE CHAIRMAN: That will be D9, Miss O’Rourke.

MISS O’ROURKE: Yes, sir. (The witness read)

Further cross-examined by MISS O’ROURKE

Q Okay?
A Yes.

Q Have you had a chance to read that?
A  Yes.

Q  Let me now read to you from the evidence yesterday, D12/41, starting just below letter C. Question from me:

“The Staffordshire Police kicked it out?”

Answer from you:

“They said that forging a medical consent form is not criminal fraud.”

I think we will see that they do not say that forging a medical consent form is not criminal fraud, they say that they have looked at the evidence put forward, they have had senior specialist Queen’s Counsel look at it and he has reviewed everything and he has concluded that there is an insufficiency of evidence and there is nothing in the public interest to prosecute. I then replied to you:

“Q  No, they did not. The Staffordshire Police said, and I will read you the bit from their statement. The Staffordshire Police said that they had leading counsel, that means top Queen’s Counsel, to look at it and there was not evidence to sustain your allegations and it fitted with what they had always said?

A  Could you point me to that letter because I think that it says a lot more than that. Could you tell me where in the bundle it is?

Q  It is not in the bundle.

A  It needs showing because it says more than that. It talks about does not constitute fraud in the criminal sense of the word, or something like that. That is what it says. What they were telling us was this needs to go to the GMC not the police. They talk about you need monetary gain to be criminal fraud. What we were being told was that criminal fraud needs some sort of monetary gain. They could not see where the monetary gain in forging a consent form for a medical trial. That was the sort of explanation we had.”

You will agree, there is nothing in the letter about monetary gain, there is nothing in the letter about monetary gain to be a criminal fraud, there is nothing in the letter about monetary letter/forging a consent form – yes?

A  No, there is nothing in the letter about that. No. Perhaps you misunderstood when I was saying what they have explained to us, because we did actually have telephone conversations to actually try and clarify some matters. At the top of the second page it does say “As far as the specific criminal of ‘forgery’ (as defined by statute not the dictionary)”, so they are talking about criminal forgery there but if you look at the second-to-last paragraph:

“I am aware that I asked the Trust to ensure the security of the original consent forms in this matter which Mr Fillingham assured me was in place. I would assume that you would still retain their
security in view of the matters that are still ongoing and in particular the investigation by the General Medical Council.”

So they are inferring there is still matters there for the General Medical Council to look at but it is not an actual criminal offence. I think that is going along the lines of what I.... Again, I am not legally trained so that is my lay understanding of it.

Q The Panel has the letter now; they have also got what you said in evidence and they can form their own views about it. I was giving you the opportunity to retract the evidence you gave yesterday but obviously you do not wish to do that?
A No.

MISS O’ROURKE: Thank you.

Re-examined by MS SULLIVAN

Q Just a few matters, Mr Henshall. Do you remember a little while ago now you were asked about the statement that you made for the purpose of these proceedings?
A Yes.

Q So the statement since Ms Morris has become instructed in this matter?
A Yes, I think I have got it here. I have found it. I have got it here now actually. Okay.

Q I just wanted to ask you because it was suggested that you wrote this yourself; I just wanted to establish who took the statement from you?
A It was Ms Morris who took the statement from us and she drafted them, gave them to us to check for accuracy as best we could and then I think she re-wrote them and sent the copies to us.

Q How does that explain your e-mail address – it was suggested or certainly there is your name on the bottom of the statement?
A It just says “12 December 2007 Carl Henshall” – I should imagine that is Ms Morris’s file note. I would imagine.

Q Next I would like you to have in front of you, please, because we now have them, the original consent forms for first of all Patient 7 and then Patient 6, so they will be handed to you.
A Okay. (Same handed)

Q Those are the original forms that we have been supplied with, Mr Henshall. Can you identify first of all, please, is there anything on the reverse of either form?
A There is not, no.

Q Is it completely blank or---
A Completely blank.

Q Looking at each of those forms, is there any staple mark at all in either of those forms that you can see?
A  No, there is not.
Q  Or any indentation of the type made by a paper clip?
A  No, there is not.

Q  Thank you. If you would like to give those back so that we keep those separate, please. (Same handed) Could I ask you then, please, just to take up file 2 a moment and to go behind tab 5, and perhaps just go first to page 33? This obviously relates to Patient 6, Mr Henshall?
A  Yes.

Q  These are the various appointments that took place after her discharge from hospital?
A  Yes.

Q  We have the first appearing at page 33 on 2 March 1993?
A  Yes.

Q  Do you recall who took your daughter on that occasion?
A  The first appointment was my wife took her.

Q  It would seem that it was a Dr Docherty who saw her on that occasion?
A  Yes.

Q  Then thereafter if we turn on to page 34 it looks as if there were appointments arranged for 25 May, do you see that on the next page?
A  I do, yes.

Q  Then 29 June?
A  Yes.

Q  Then 11 August 1993 with a new appointment being sent, I think, for 1 September?
A  Yes.

Q  I think a health visitor to call as well?
A  Yes.

Q  Have you any recollection of a health visitor calling for the purposes of these appointments?
A  Not for missed appointments. I remember health visitors calling; I cannot remember them saying about missed appointments.

Q  Then 1 September 1993, again there is no appearance at that appointment. Do you have any recollection of needing to change any appointment for any reason?
A  Yes, we do have to change appointments. Obviously, we had a very busy household so I cannot remember specific reasons why we had to, but I do remember we would phone up and change appointments – we still do to this day.
A  Q  So if we turn the page to the next page, page 35, we see then I think the date is cut off but we know it is 22 September 1993?
   A  Yes.

   Q  We know that from page 195, if you would just like to turn that up at the same time?
   A  Yes.

   Q  This is a reference to an appointment with Dr Morgan?
   A  Yes.

   Q  Who saw your daughter on that date. Can you recall who attended that appointment?
   A  On 22 September, that would have been me.

   Q  Then I think the next appointment after that was 19 January 1994, which we can see from page 35 still in the notes and also a letter written in relation to that at page 200?
   A  Yes.

   Q  Again, can you indicate who would have taken your daughter on this occasion to your recollection?
   A  That would have been Mum on that last one, yes.

   Q  Then at page 203, if you would just turn on?
   A  Page what, sorry?

   Q  Page 203?
   A  Yes.

   Q  I think that is the appointment in March 1994 with Dr Mali?
   A  Yes.

   Q  What is your recollection of Dr Morgan’s appointments?
   A  I took Patient 6 to two outpatient appointments with Dr Morgan, obviously there is only two outpatient appointments here and Mum took her to the last one. It actually says in the notes there “Mum says about six months in relation to 19/1/94”. There was some discussions because I remember, I think it said it was 22 September where they are talking about having a convergent squint. I remember that conversation with Dr Morgan, but I also remember a conversation about Dr Morgan about whether the other children running around were threatening Patient 6 and stopping her development because she was not attempting to do anything, she just seemed content to sit in the middle of the settee, in the corner of the settee.

   Q  You have said, Mr Henshall, that your motivation in relation to these matters is your daughter?
   A  Absolutely, yes.

   Q  How important is it for you to understand what happened to both your daughters in fact?
A It is extremely important. We need to know and she needs to know as well. I think we all need to know what went on there and what happened. We all need the answers.

Q Do you consider you have ever had answers to that?
A No. Not really, no.

MS SULLIVAN: If you wait there, there may be some more questions.

MR FORDE: Just before there are Panel questions, can I just enquire of Ms Sullivan if, in relation to the last series of questions, it is the General Medical Council’s position that these parents will receive answers to those questions in the course of this hearing? I thought that was directed to causation, but if I have got it wrong I would like to be corrected.

MS SULLIVAN: I am enquiring as to the parents’ beliefs as to the position.

THE CHAIRMAN: My recollection, Mr Forde, of what Ms Sullivan said there was that she was asking Mr Henshall about the belief, but this is an issue that has been raised on a number of occasions, and I think that the last time to which Ms Sullivan responded she indicated that that was a matter she felt she should best address once Mr Henshall had given evidence. Presumably that is something Miss Sullivan which you will now give thought to.

MS SULLIVAN: Of course, Sir.

MR FORDE: We wait with baited breath, Sir.

THE CHAIRMAN: Mr Henshall, that completes the questions from the lawyers on both sides of the room. The opportunity now arises for the Panel to ask questions if they have any. What I am proposing to do is that which we did when your wife gave evidence and just take a short time to consider among ourselves whether there are matters of clarification which we would wish to ask you about. So if I could ask the Panel to stay here and everyone else to leave. We will let you now when we are in a position to carry on.

(The Panel adjourned for a short time)

THE CHAIRMAN: Yes.

MR FORDE: I am sorry, I have just had to speak to the office about an IOP hearing, but I will mention that once you have finished with this witness.

THE CHAIRMAN: Thank you all very much. Mr Henshall, as you heard when your wife was giving evidence that when it gets to the opportunity for Panel members to ask questions, the purpose of any questions will be by way of clarification of anything that you have given by way of evidence. We have taken the opportunity to talk among ourselves to see whether there are any aspects of the evidence you have given on which we would like clarification. There are none. So there are no questions which any
Member of the Panel would like to ask you. Thank you for your assistance. You are now free to leave that chair and to return to the back of the room.

THE WITNESS: Thank you.

(The witness withdrew)

THE CHAIRMAN: Mr Forde, was there something you wished to mention that was independent of these proceedings?

MR FORDE: There is. I do not know whether it is best mentioned now or later. I will mention it now. I think that I may have appraised you of the following situation. I cannot recall if it was you I had the conversation with or Mr Forrest. There is an IOP hearing which I am scheduled to conduct if I can get it moved from London to Manchester, which I have just achieved, on Monday. It will be listed first. It should be a very quick review. One new document has come to light. Would you give me permission as I have acted for this doctor before to deal with that at 9.30? There are two ways we can deal with the matter, and I needed to consult my client. One is that you can continue in my absence because I am confident that Mr Foster and Miss O’Rourke would be able to keep an eye on things for me. We do not at the moment know which witnesses are going to be called on Monday. Or, if you felt happier, you could perhaps allow me to say my piece very shortly in the IOP. I would hope that I would have finished by about ten, and we might have to start a little later.

Mr Foster, while I am on my fee, was keen to advance a proposal that we start tomorrow at nine so can finish a little earlier on a Friday. I do not know whether that is something you wish to consider as a Panel, if not now, at a later stage. Most of us are here by about nine o’clock in the building in any event. I think that the travel arrangements certainly back to London are very complicated over the weekend. I think that Virgin trains may not be operating at all until August, so we need to look at that, or as I did, come via Leeds on Monday, although I am sure it is cheaper to fly. Those are the matters I wanted to mention.

THE CHAIRMAN: Thank you very much, Mr Forde. We will consider what we do about tomorrow. I think that the idea of trying to end earlier a bit earlier generally on a Friday is a good one. Once I have had the opportunity of talking to the Panel, we are happy to start at nine o’clock tomorrow morning. Is there anyone against starting at nine o’clock tomorrow?

MS SULLIVAN: I am not against starting at 9.00, it is just that we have witnesses scheduled for Friday but Mr Forde indicated that he is not going to be in a position to cross-examine the witnesses we have scheduled. Therefore, I am not sure we are going to have that many witnesses tomorrow.

MR FORDE: I do not think it is just me. We received on 18 April, with the notice of inquiry, a proposed order of witnesses. I understand that trial management is difficult. The proposal was that we had all the parents first, then the North Staffordshire Hospital staff, then I think Dr Raine, query some Ethics Committee evidence not being produced, unfortunately by members of the Benefits Committee but by those who purport to
produce the documentation, and then the expert evidence at the end. That is the order that we thought in general would be followed so we would not have to deal with the medical witnesses or the nursing witnesses until after we had seen the pattern of the evidence of the parents.

All three of us would like to have made available to us - and we are told it has been but certainly Miss O'Rourke and I have not seen it - the notes that relates to the children of the parents being called. I have seen some clinical notes, I am not seen I have seen nursing notes, and I am not suggesting that they have not been supplied. That could be a deficiency on our part as I know that Miss Morris has been very efficient in getting to us the unusual material. That is probably something I can deal with overnight, if need be. What we will be looking for will come as no surprise to you is any reference to consenting in the nursing notes, as we claim to have found with the Henshalls. That is the only hiatus. We do not, as I understand it at the moment, have a proposed order of witnesses after this afternoon. I do not know if Ms Sullivan can enlighten us on that now.

MS SULLIVAN: We gave a list of witnesses earlier this week. That is the order in which it was hoped we would call the witnesses, the order which Mr Forde has just outlined. That has gone by the board because we have lost time. Therefore, the witnesses are not all available in the ideal order. So we gave a renewed order of witnesses earlier this week. It had been proposed that we would call tomorrow John Alcock, Dr Ayra, Dr Newell and Janet Wakefield, but I am told that Mr Forde will not be in a position to cross-examine those witnesses. We are in some difficulties. We tried very hard to accommodate what we have been told, but we have only two witnesses so far tomorrow, two parents who are able to come. I think that this week is half term. That causes problems in asking people to reschedule at the last moment. Of course with doctors as well it is difficult because of their professional commitments to change dates at the last moment.

MISS O'ROURKE: Could I indicate our position. We, as Mr Forde, were given an order of witnesses on 18 April which said parents first, doctors and staff second, Jo Raine, who was at Queen Charlotte’s third and then the Ethics Committee and then the experts. That is obviously a logical order to hear it.

I indicated to Miss Sullivan at the outset that I thought the Henshalls might take longer than had been anticipated. Of course there was also the problem of the abuse arguments which effectively lost us six or seven days. I indicated that I was not averse to an interposition of witnesses and I accepted, particularly as someone who represents doctors, that they have commitments and have to be switched in and out, that I wanted 24 to 48 hours’ notice if a doctor witness was going to be called, because that was a witness for whom I would have to do additional preparation. I was less concerned about the parents.

We were given a revised list earlier this week, I think on Tuesday, handwritten by Miss Morris. I took it that was going to be the order it was. It said Wednesday, Thursday Friday, and, yes, it did have Dr Ayra and Dr Newell, but it had them as witnesses number eight and nine after the Henshalls. In other words we were going to hear from people called the Hammonds time two, Alcock, Shufflebotham times two, Janet Wakefield and somebody else before we got to Dr Ayra or Dr Newell. I was not therefore expecting, until 1 o'clock today, when I specifically asked who was coming tomorrow, to be told that
those two witnesses were coming tomorrow.

Dr Newell I consider to be very important. I am sure you will too. You have heard her name mentioned repeatedly. She was Dr Stanley. She signed the consent form that is, query or not, alleged to be forged by the Henshalls. I would have a problem about her coming tomorrow now in the light of effectively being told only today that that would be the position, that she would not be maintaining her position on Miss Morris’s handwritten list from earlier in the week.

As far as Janet Wakefield is concerned, I had not immediately recognised the name in the wealth of all the paper. I thought she was a parent but I now understand that she is in fact a staff midwife. I think I would be in a position to cross-examine her tomorrow, given I could do some work on it tonight. I possibly, maybe probably, could deal with Dr Ayra tomorrow. My problem would be dealing with Dr Newell Stanley. I think that it is inappropriate for her to be called tomorrow, when I understood she was going to be witness number nine after the Henshalls and not witness number three.

As far as this afternoon is concerned, I understand there are two other witnesses here. They are both parents. I do not have their notes to hand, but in part that is probably my fault. My instructing solicitor has received the notes for parents. Although I do not know the totality of them, I had indicated that until we had a firm batting order then I did not need to be troubled by them. I suspect that I can probably cross-examine either or both of them this afternoon if that is where we get to.

My only comment is that I do not want Dr Newell tomorrow, but I can probably deal with the others. What I would like from hereafter, now that we have got over the witnesses that were going to be lengthy, I would now like to see a plan for the next two to three weeks so that I have notice in advance of the order of witnesses so we do not hit the situation again.

MR FOSTER: On Dr Samuels’ part I am not expecting to have a great deal to put to these witnesses, so this is not a debate that greatly concerns me.

THE CHAIRMAN: Ms Sullivan, the concern from Miss O’Rourke - and Mr Forde are you in the same position so far as Dr Newell is concerned?

MR FORDE: Yes. I would prefer to deal with her after we have dealt with the parents if possible. I understand that she has clinical commitments. Certainly I could deal with a little more notice of her attendance than this afternoon, although, in fairness to the GMC’s legal team, I was given a handwritten list that included Drs Ayra and Newell to be called on Friday. It also suggested other witnesses on Wednesday and Thursday. Once we had got to Thursday I assumed we would maintain the order; in other words, would have the Wednesday witnesses the Thursday and the Thursday the Friday. As far as the parents are concerned, I am not sure whether the notes we have been supplied with are just the clinical notes or include the nursing notes. I do not know if Miss Morris can help us. But it is likely to involve two or three pages at most, so I do not see it as being a serious impediment if there are copies available here. I certainly do not have them with me, although I understand that they were sent at some point in May as unused material. It is just somewhat unfortunate that we have all wrongly assumed that we would keep the
basic order that we were informed of back in April. We understand that things have overrun, although I apprehend that we will speed up greatly now. I do not know whether the nursing notes for the next two witnesses are available?

MS SULLIVAN: The nursing notes are there. They have not been copied because they have already been supplied.

MR FORDE: I quite understand. As I have said, I am not criticising anybody on the opposing team. I am happy to sit and look at them or give them to my client to look at while the evidence is given in chief.

MS SULLIVAN: In fact, the list of witnesses was given last Friday I am told by my instructing solicitor, so the list has been in existence for this week for some time. Rather than getting involved in any argument about that, which will not advance matters, perhaps we could adopt a list for tomorrow of Mr Alcock, Mrs Shufflebotham, Dr Ayra and Janet Wakefield. Therefore I am not calling Dr Newell but otherwise calling the witnesses we intended to call with the addition of Mrs Shufflebotham. I just would like confirmation that my learned friends will be in a position to deal with those witnesses tomorrow.

MISS O'ROURKE: I will be.

MR FORDE: Yes, we can cope with those witnesses tomorrow. I am just looking at the previous list and wondering whether we were going to get Mr and Mrs Shufflebotham or was it suggested we would only get mister.

MS SULLIVAN: There is it not a mister.

MR FORDE: All right. With the Alcocks, both parents or one?

MS SULLIVAN: There is only one parent coming tomorrow because they cannot come on the same day. It will be mister tomorrow because he is available tomorrow. Mrs Alcock will come at a later stage. It will not be possible to maintain the hoped for order of parents followed by medical staff, given the availability now of witnesses.

MR FORDE: I was just wondering if there was any prospect of a proposed line up for Monday be given as well.

MS SULLIVAN: That will be given to you, but we needed to sort this out first. That will be given to you.

THE CHAIRMAN: You have two witnesses here?

MS SULLIVAN: I have two now to call. My instructing solicitor has quite rightly raised an issue about whether these parents want anonymity, which we have not been giving them in the course of these discussions. We have given numbers to their children, just as we have done with Mr and Mrs Henshall, but we should double-check the position with them. It will not take a minute. Then I will be calling Mrs Hammond first. Once my instructing solicitor has asked she can come in and start her evidence.
THE CHAIRMAN: Then the proposal would be for four witnesses tomorrow, two parents?

MS SULLIVAN: Yes, two parents tomorrow, a doctor and a nurse. That would be all. I think that we had rather thought that that would be how we would try to arrange witnesses, to have four in the course of the day. It is a little difficult to tell because I am not sure how much cross-examination there will be. I do not know if my learned friends can assist as to whether that is a proper scheduling of witnesses tomorrow, being conscious obviously of the travel difficulties, I do not want to overload the day with witnesses.

MISS O'ROURKE: Of the two parents very little, for Dr Ayra and Janet Wakefield a little bit more, in particular Janet Wakefield because she is the staff midwife who talks about whether nurses are entitled to take consent. You can appreciate from the evidence you have already heard the importance of that and exploring that with her.

THE CHAIRMAN: Linking the two ideas, maybe a 9 o'clock start tomorrow morning would be a good idea.

MS SULLIVAN: I think that is probably right now, Sir.

THE CHAIRMAN: If you are a position to let Miss O’Rourke, Mr Forde and Mr Foster to know the witness line up for Monday as soon as you are able and then before we part company tomorrow we can then take a view on Mr Forde’s position with his IOP hearing on Monday as to whether he wishes to firm up one way or the other. The Panel would be anxious to get on, so really it is a matter for you to indicate whether you feel that, given the witnesses that are being called, and you would be content for them to carry on in your absence or whether you would want to invite us to start a little later on Monday.

MR FORDE: I suspect if they are parents I would not be over anxious about missing a little bit of the morning. If they are doctors it may be more problematic.

Can I just check, as we have purloined these notes from Miss Morris's desk, there are no confidentiality issues around the notes, are there, as far as you are aware?

MS SULLIVAN: No, there is consent for disclosure of the notes. All we are proposing to do, as is apparent from the bundles, is to give the baby in question a number. She is patient 3, you will find.

MR FORDE: Are we calling the parents by initials?

MS SULLIVAN: No, they are happy to be named, which makes it easier for us, so Mrs Hammond is the next witness, sir.

THE CHAIRMAN: Very well, we will have Mrs Hammond in, then.

JANINE TERESA HAMMOND Sworn
Examined by MS SULLIVAN

D13/77
Mrs Hammond, I am going to ask that you be handed a piece of paper just to remind you of the number by which we are referring to your daughter, because I know it is not natural to refer to your child in that way. Just have that by your side to remind you.

(Same handed) Would you mind beginning with your full names, please?

A Janine Teresa Hammond.

Mrs Hammond, I think you gave birth to your daughter, whom we are referring to as Patient 3, in May of 1993. Is that right?

A That is correct.

What exactly is her date of birth?

A 8 May 1993.

Thank you. Before her birth, Mrs Hammond, did you suffer from high blood pressure?

A Yes.

As a result of that were you in and out of hospital?

A Yes.

For a number of weeks before she was born?

A Yes.

You were in and out of hospital in Stafford. Is that right?

A Yes, that is correct.

Then shortly before the birth of your daughter, patient 3, were you transferred to North Staffordshire hospital?

A Yes.

Did they monitor your blood pressure?

A Yes.

Was a decision made very shortly for you to have an emergency Caesarean section?

A Yes.

I think that that was done under general anaesthetic. Is that right?

A Yes.

Your husband was obviously called to the hospital?

A Yes.

He arrived just as your daughter was born and on her way from the operating theatre to the neonatal ward?

A Yes.

Did you know anything at that time, Mrs Hammond, about CNEP?
Q: In fact I think your daughter was born just after midnight. Is that right?
A: Yes.

Q: When did you feel recovered from the general anaesthetic that you had had?
A: I think I came round properly round about mid morning the following day.

Q: At some point did your husband tell you about CNEP?
A: Yes.

Q: Do you remember when that was? Was it that day that you came round from the anaesthetic or was it later? If you cannot remember just say so?
A: I think it probably was that day but I could not say for definite that it was that day, but I think it probably was.

Q: What ward did you go to? Do you remember?
A: After I was moved I went to the post natal ward.

Q: Did you stay there for any length of time?
A: I was there for a couple of days, I think, maybe a bit longer, and then I moved. Brian and I had the flat in the special care baby unit for a few more days where I was actually still in hospital as such, had not been discharged at that point, but moved.

Q: How well were you in terms of your blood pressure following the birth of your daughter?
A: It stayed quite high for some days afterwards. I felt quite well in myself with regard to the blood pressure but it still stayed quite high and the nurses were taking it for me every day and were going to ask a doctor to come and have a look because it did not seem to be going down but eventually it did and was all right.

Q: Can you remember when it was you saw your daughter for the first time?
A: Yes, when I was on my way to the post natal ward I was wheeled in my bed and they took me through the special care baby unit and I saw her from still lying in the bed. That is the first time I saw her.

Q: Was she in an incubator at that stage?
A: Yes.

Q: What type of incubator?
A: A CNEP one.

Q: How was she being ventilated? Do you remember?
A: I think she had a ventilator thing in her mouth.

Q: Did she have any tubes…
A: She did, yes.

Q: …as well as being on the ventilator?
A Yes, I am sure she did
Q How was she at that stage when you first saw her?
A As far as I am aware she was as well as could be expected for a baby born that early.

B Q How early had she been born?
A She was born at 28 weeks.

Q How was she thereafter?
A She was doing all right most of the time. There were times when she had high temperature and when her heart rate dropped during the next few days but she seemed to be – there did not appear to be any cause for any of the medical staff to panic over her. She was doing as well as – as far as I am concerned she was doing as well as one might expect until she had the episodes of bradycardia.

Q When approximately was that? Do you know? Do not worry, we have got her notes if necessary?
A I cannot really remember, to be honest, the time scale. It was a day when I went up to visit her and her heart rate kept dropping and the monitor thing that she was on kept pinging all the time and seemed to be giving some cause for concern. That went on until into the evening when Brian joined me to stay with her and that was the day that she came out of the CNEP incubator.

Q For how long was she in the CNEP incubator? Do you know? Do you remember? If you do not, do not worry?
A No, I do not really. I cannot remember exactly at all. It seemed to be a long time to me but probably it was not.

C Q I just want to ask you a little about CNEP. From whom did you receive any information about it?
A From my husband initially, who had given consent, and I suppose really just from the nurses who were looking after Patient 3.

D Q Did a doctor ever speak to you about it, or explain what it was?
A Not to me that I remember, no.

Q What did your husband tell you about it?
A He said that it had been explained to him by the doctor who had asked him for his consent to be possibly a gentler, more effective means of ventilating babies and that was really all I remember, to be honest. He said it was a negative pressure thing.

E Q When you understood it was a gentler method of ventilating babies, what was your understanding about whether your daughter would receive that gentler method or not?
A I assumed from what Brian told me that Patient 3 was going to receive that form of ventilation. I thought - when he told me I thought that was what was going to happen.

F Q I want to ask you please, I think you have been shown various leaflets in relation

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to CNEP and I wonder if you could just be handed file 1, please. If we could take up file 1. If you could turn to page 336 in the top right-hand corner behind tab 3. Mrs Hammond, you will see at page 336 a page entitled “Parents’ leaflet”?
A Yes.

Q There is another one overleaf and then if I could just ask you to turn on a few pages to page 341. It is rather blurred there but what it says is “Negative Pressure Trial information booklet for patients”?
A Yes.

Q Prior to being shown those items when you gave your statement, have you any recollection of seeing any of these leaflets before?
A No.

Q Were you given a copy of anything about CNEP?
A Not that I remember.

Q You have told us that your main contact was with the nursing staff. What, if anything, did they say to you about CNEP? Did they explain it to you or what were they helping you with?
A They explained how I could still touch Patient 3 and look after her. They explained about why her head was out of it. I do remember a nurse explaining how the conventional ventilation worked and really that is all I remember.

Q Yes. You say you did not have any discussions with doctors. Do you remember seeing Dr Spencer at all whilst you were on the unit?
A I remember actually seeing him once when he was going round with children there. That is really the only time I remember seeing him.

Q But did he speak to you at all on this occasion?
A Not that I remember, no.

Q You have told us about your daughter having episodes of bradycardia, in fact, of her heart rate dropping. We know she was in CNEP for a few weeks before she was gradually weaned on to a different type of ventilation?
A Yes.

Q Do you recall that?
A Yes, I cannot really remember the timescale. I remember the day when she was having these episodes and I do remember the nurse who was looking after her saying by the time it got to the late evening that she was going to take Patient 3 out of the CNEP tank and she said that sometimes the neck seal pressed on a nerve.

Q I am sorry, I did not quite catch that?
A I am sure she said to me that sometimes the neck seal of the CNEP incubator pressed on a nerve which depressed the baby’s heart rate so she was going to take her out and put her in a normal incubator.

Q So she was taken out and put into a normal incubator, is that right?
Q Having been put into a normal incubator did she stay then in a normal incubator?
A Yes, yes.

Q She was finally discharged from hospital when?
A She was transferred from the North Staffordshire to a Special Care Baby Unit at Stafford once she did not need ventilation any more and she was finally discharged mid-July, about a week before she should have been born.

Q I think much later on somebody had a look to see how she was developing?
A Yes, that was when she was about ten.

Q In terms of her development was she all right?
A Yes, fortunately. She was below average in one area according to the test that they did but other than that she was either average or above average.

Q In what area was she below average?
A Cognitive I think, I cannot remember off hand.

Q I think there is no debate, it was sensory?
A Sensory, that is it, yes.

Q Would you mind looking again in the bundle just a little further forward to page 387 and 388 to 9. I think we can see from the name at the top of page 387 that this is a bonding questionnaire that relates to your daughter?
A Yes.

Q Did you complete that, Mrs Hammond?
A Yes, yes.

Q Do your answers there reflect how you felt about the treatment that your daughter received?
A Yes.

Q Then finally this, I want to ask you do you know Mr and Mrs Henshall?
A No.

Q Have you read anything about a family in the Stoke area and their children being involved in CNEP?
A Yes, and that was probably about five or six years ago before I was contacted to ask if Patient 3 would have these tests done. It was sort of something on the television, something in the local paper.

Q But do you know much about their involvement?
A No, not really, no. I did not really know anything much.

Q Can you just help us as to this. We have just looked at that bonding questionnaire. Can you help as to how you received it? How you came to receive it, Mrs Hammond?
A A doctor who turned out was the wife of one of the GPs at the practice that I go to worked there and brought it to me and asked me if I would mind filling it in at the North Staffordshire Special Care Baby Unit.

MS SULLIVAN: Thank you very much. If you wait there there may be some more questions.

B MISS O’ROURKE: Sir, I am going first simply because Mr Forde popped out of the room and missed a few minutes of this witness’s examination and so it seems more sensible for me to go first to cover one or two things said while he was out.

Cross-examined by MISS O’ROURKE

C Q Mrs Hammond, it is a long time ago, it is presumably quite difficult for you to remember all the details?
A Yes.

Q 15 years last week or effectively this week as well?
A Yes.

Q So you are trying your best in terms of your recollection but it may be that you simply do not remember certain documents that you may have seen or things that you were told?
A It is possible, yes.

Q Just asking you about what you said there about the bonding questionnaire. You said it was given to you by a doctor who is the wife of one of your GPs. You live in Stafford rather than Stoke or you did at the time?
A Yes.

Q The doctor’s name, could I suggest to you it was a Dr Kate Palmer?
A I cannot remember.

Q Whose husband is a GP in a practice in Stafford?
A I was just in conversation when she came into the Special Care Baby Unit.

Q Can you remember the name of the GP that was in the practice that you say was married to her and then we can establish---
Q Dr Hannigan.

Q I think that is Dr Kate Palmer’s husband. Dr Kate Palmer is going to be a witness so we can then ask her about handing out the bonding questionnaires. Do you remember whether when she gave it to you there was a letter with it?
A I do not remember.

Q You said that Patient 3 was followed up about ten years later. Can I suggest that was by a study that was being done by the University of Nottingham?
A Yes.
Q It was being led by a woman called Katherine Telford?
A Yes.

Q I think she herself may have actually have come to see Patient 3?
A Yes.

Q So you were part of what was the follow up study of CNEP?
A Yes.

Q Patient 3 I think was above average in some areas and the only one she was below average was sensory motor which was looking at hand eye coordination and fine motor control?
A Yes.

Q But otherwise Patient 3 is doing very well?
A Yes.

Q She was found to be above average in terms of things like memory and intellectual level?
A Yes.

Q I think in the witness statement that you prepared for this case you said the following, let me read it to you see if you agree with it:

"[Patient 3] is still alive and doing very well at school. I am very grateful to the doctors at the North Staffordshire Hospital"?

A Yes.

Q Does that remain your position?
A Yes.

Q Do you know why you are here?
A Yes.

Q Why are you here as you understand it?
A As I understand it, it is a fitness to practise hearing against the three doctors mentioned before with regards to the CNEP trial and I am here because my daughter was part of that trial.

Q Do you have any personal complaint against any of these three doctors?
A No.

Q Dr Southall, who I represent, who sits to my right, have you ever met him before?
A No.

Q Do you have any reason to believe that he was in any way involved in Patient 3’s care?
A No, I did not think he was actually.
You did not think he was?
A No.

You have no complaint against him?
A No.

Again, looking at your witness statement you make reference in paragraphs 5 and 9 to Brian, who is your husband:

“…telling me about the CNEP trial and I have been asked if I can recollect my understanding of how the CNEP trial worked.”

You at all times understood it was a trial?
A Yes.

In addition you say in your witness statement:

“I think I understood that selection for the scheme was on a random basis”?

A Yes.

So you knew that in the trial you got randomised into one part or the other?
A Yes.

I will follow that up because you did say something to Ms Sullivan and you said, well, I understood that Patient 3 was going to have a CNEP because she was suitable or something to that effect?
A Yes.

The time you had this conversation with Brian your husband presumably was mid-morning?
A Yes.

Because you answered Ms Sullivan’s question by saying I had a general anaesthetic and the first time came round and would have been with it would have been mid-morning?
A Yes.

Patient 3 was born some time around midnight, I think?
A Yes.

By the time you came round and your husband talked to you she already had been randomised into CNEP? In other word, he had given his consent many hours ago?
A Yes.

The cards were then drawn and she was randomised into CNEP?
A Yes.
Q So by the time you first had the conversation she was already in CNEP?
A Yes, I believe so, yes.

Q You say that you know these are fitness to practise proceedings but you have no complaint yourself about the way in which the trial or study was done or the randomisation process?
A No, I have not got a complaint.

Q Did anybody show you the heads of charge against these doctors before inviting you to become a witness?
A No, not that I remember, no.

Q So you are here giving evidence against heads of charge you have never seen. Do you understand you are part of what is called the prosecution case? In other words, you are being called to give evidence against the doctors; not in support of them?
A Yes.

Q Do you have evidence to give against any of these three doctors?
A No, well, no --- I do not know.

Q You were asked about the Henshalls. You are presumably someone who has lived in the area, read a lot of what they might have said in the newspapers and seen some stuff on TV and heard some stuff on radio?
A Not a lot, no.

Q Some?
A But I have seen some, yes.

Q Have you seen anything positive about any of these doctors or the trial or has it all been negative?
A No, I have not seen anything positive. I would not say what I had seen was necessarily negative, just that these people were sort of taking further their action. Nothing sort of detrimental to anybody particularly that I have seen.

Q Were they not making serious allegations against each of these three doctors, including things like forgery and---
A I have never seen that.

MISS O’ROURKE: Thank you. I have no further questions.

Cross-examined by MR FORDE

Q Mrs Hammond, I am acting for Dr Spencer and I just wanted to ask you a very few questions about your time at North Staffordshire. I have got a copy of your witness statement. Your daughter would have been 15 a couple of weeks ago, is that correct?
A Yes.

Q You have explained to my learned friend Miss O’Rourke that understandably you
have some difficulties in recollecting after all this time the fine detail?
A Yes.

Q You were quite ill, were you not, when Patient 3 was born?
A Yes.

Q You were yourself being looked after and you tell us that you were not aware of any of the conversations that took place between your husband and the medical staff until the following morning?
A Yes.

Q My understanding is he was able to explain to you the conversations he had had with doctors about your daughter going to CNEP?
A Yes.

Q You have explained that your understanding has always been that it was a trial?
A Yes.

Q We have got some documentation which suggests that [Patient 3] was in CNEP for about 20 days. Does that seem about right to you – three weeks or so?
A Yes.

Q I have also been looking at the nursing note and it is quite right that you did pretty much live at the hospital; when you were not visiting you were staying?
A Yes.

Q Because she was only 28 weeks, was she not?
A Yes.

Q You told us about the conversation with a nurse taking [Patient 3] out of CNEP. The nursing note on 27 May 1993 – and we can have this copied for others – says this:

(Copy not provided to the shorthand writer)

"Patient 3 was very distressed evening until 2 a.m. Taken down and checked. Settled at 2 a.m. CNEP -4. CPAC"

(that is the positive pressure)

"3 cm. Then [Patient 3] was rested but had consistent bradycardic episodes"

- so in other words her heart was slowing.

"Frequent physio and suction yielding thick secretions"

- this was all being done by the nursing staff.

"Her temperature was a little unstable so she had the suction and she
was removed from CNEP. Doctor aware.”

That seems to suggest that the nursing staff made the doctors aware that [Patient 3] was going to be taken out of CNEP. Do you have any recollection of that at all?

A I do have a recollection of all that happening. I do not remember seeing the doctor but that does not mean that the nurse did not make a doctor aware.

Q Can I just ask you a little bit about staffing? This is a neonatal unit. Is it fair to describe it as being an area which is very much, in terms of observations and the testing, nurse driven – in other words, lots of nursing staff that are there observing these young babies very closely?

A Yes.

Q Occasionally, particularly if there was a crisis, you might see a doctor there?

A Yes.

Q The patient that everybody is concerned about, once you got better, is the baby?

A Yes.

Q Not the parent?

A Yes.

Q You tell us in your witness statement that you think you met Dr Spencer on one occasion and that is your recollection. We have been through the notes and it would appear from looking at the notes that he saw your daughter on at least six occasions and a Dr Brookfield, according to the notes, saw her on four occasions. Do you recall Dr Brookfield?

A No, I do not. I do recall seeing one or two other doctors around but I do not really know their names.

Q You recall Dr Palmer though, do you?

A Yes.

Q Because you were a patient of her husband’s practice, did you discuss your daughter’s progress with her?

A I cannot remember that. I am sure we must have just had a general sort of chat about how Patient 3 was doing.

Q You have been asked about the bonding questionnaire – let me see if there is anything else I need to ask you. You certainly were of the opinion and impression, you said commendably in your witness statement (which is quite recent), that you have a recollection of there being a random element to this trial?

A Yes, though may I…?

Q Yes, carry on?

A I have since, when I had a look at the papers that the solicitors sent me, the Patient Parent booklet and that, how I understood it at the time was that as the babies were born and sent to the Special Care Baby Unit it was at that point that somebody would say “All right, this baby is, say, number 5 that is suitable for CNEP and we’ll ask the parents for
their consent”. I did not realise that everybody was asked for their consent and then it was a random allocation. That is not how I understood it.

Q I understand that and we will have to see whether your husband has a recollection because he would possibly have been part of that process?
A Yes.

Q The note suggests that your daughter was allocated by 5.30 a.m. and she was born at about 20-to one?
A Yes.

Q When you were still recovering, I think?
A Yes.

Q Did you feel that if you had any questions or concerns that the nursing staff seemed quite happy to deal with those concerns whilst your daughter was in the neonatal unit?
A Yes.

Q Did they appear to be competent?
A Yes.

Q And concerned?
A Yes.

MR FORDE: Mrs Hammond, thank you very much.

MR FOSTER: There is nothing from me, thank you, sir.

MS SULLIVAN: No re-examination, thank you, sir.

THE CHAIRMAN: Mrs Hammond that completes the questions which the respective barristers have for you and, as I indicated earlier, this is now an opportunity if any member of the Panel has anything they would like to ask you it is their opportunity to do so. (Pause)

It seems we do not have anything which we want to ask you, so that completes your evidence this afternoon. Thank you very much indeed for coming and the assistance that you have given us. You are now free to leave the chair. Just before you go, I was just about to say we will have a five-minute break but Mrs Khan has asked whether we can have a slightly longer one than we might ordinarily have now to sort something else out. We will take 20 minutes and come back at quarter-past four. Sorry to hold you up, Mrs Hammond. Now we are having a break and therefore there will be a gap before, as I anticipate, your husband comes in to give evidence, can you please not speak to him during the 20 minutes that we are breaking?
A Okay.

THE CHAIRMAN: Thank you very much indeed. We will come back at quarter-past four.
THE PANEL adjourned for a short time


MS SULLIVAN: Sir, the next witness is Mr Hammond.

BRIAN JOHN HAMMOND, sworn
Examined by MS SULLIVAN

Q I am going to ask you, please, to start with your full names?
A Brian John Hammond.

Q What is your occupation, Mr Hammond?
A I am Audit Director for Virgin Trains.

Q Mr Hammond, I am going to ask you some questions about your daughter, Patient 3. We have just heard from your wife that prior to your daughter’s birth she suffered from high blood pressure. We know that she was transferred to North Staffordshire Hospital because of that. I think it is right that you received an emergency call in the middle of the night to go to the hospital?
A That is correct, on the Friday evening, the 7 May. I visited Janine in the afternoon in the North Staffs. I had come home and gone to bed. It was probably about 11 o’clock, 11.30, I received firstly a call from the Staffordshire police to come back up to the North Staffordshire Hospital. After I had put down the phone on that call I had a call from a doctor at the North Staffs to say, similarly, come up to the North Staffs Hospital because they were going to give my wife a Caesarean section to deliver the baby.

Q Were you able to get a taxi to the hospital?
A Yes, fortunately I managed to get a taxi reasonably promptly and got up to the North Staffs about 12.30.

Q So we are now into the 8th, the day your daughter was born. In fact just after midnight she was born?
A Yes.

Q As you arrived at the hospital did you see your daughter being taken from the delivery room in a mobile incubator?
A Yes, I was met at the front door and went to the special care baby unit. Virtually as I got there my daughter was being brought in from the delivery suite.

Q We know that she was very premature; she was born at 28 weeks?
A Yes.

Q I think she was very tiny at that stage?
A Yes, very small. She was one pound fifteen ounces and about 13 inches long, so to me she seemed incredibly small.

Q After you had arrived at the hospital, did any doctor approach you about your daughter and her inclusion in a trial?
A Yes, who I assumed to be the duty doctor on that evening approached me.

Q Male or female?
A A young male doctor.

Q What qualifies as young?
A I would have said about 30ish.

Q Where were you when he approached you?
A I was in the special care baby unit. My daughter had just arrived. She was being “sorted out” for want of a better term. The doctor who was present at the present time approached me and mentioned about the CNEP trial.

Q I want to ask you about your state of mind at that time. What sort of state of mind were you in as far as decision making was concerned?
A I was in a very shocked situation. As I said, my wife had been transferred to the North Staffs earlier that day. We both recognised that the baby was going to come sooner rather than later, that it would not go full term, but neither of us was expecting her to be delivered within a matter of hours. In my mind I was thinking a few days, maybe the end of the week. We were given no indication that she would need to be born that quickly. Therefore I was woken out of a sound sleep. I had been working hard. I was a chief accountant and we had been doing annual accounts so I was absolutely shattered. Then to be woken out of a sound sleep, and under those circumstances and being told to rush up to North Staffs where my wife had had a serious operation, my baby had been delivered, it was the middle of the night, you know, I did not really know whether I was on my head or my heels.

Q Were you able to take on board what the doctor said to you?
A I could understand what he was saying, and I appreciated that, but I do not think that I was particularly capable of any form of rational thought. My mind was blown at that time. My thoughts were with the baby and my wife, and the general situation I was in.

Q Did the doctor give you anything to look at about CNEP?
A Yes, I believe he gave me a summary of what the CNEP trial was about. I recall it being a small folded document that I could look through.

Q What sort of size paper was it on, do you remember?
A My recollection was that it was what I would call an A5 size. How I remember it is that it would be, say, four sheets of A5 folded together.

Q Did he give you anything that you could keep yourself thereafter?
A Not that I appreciated that I could do. My recollection was that I had the document to have a look at, which I did do, and that was it. In fact, to be given a bit of paper and have to wander around with it or find somewhere to put it would not have been particularly convenient anyway.

Q So, did you retain any piece of paper?
A No.
Q Were you able to focus on what may have been in those pieces of paper?
A Not particularly. Certainly, the technical detail in there would have been over my head really. Under that situation, any form of rational thought I would not have been capable of. I could really just pick out the headlines from what the document was telling me.

Q What did you understand you were being asked for consent for?
A I understood that I was being asked that Patient 3 could enter this trial. How I interpreted it from what the doctor said to me and from the bit of paper was that the trial itself would be of no more disadvantage to the baby than the normal method of ventilation and incubation, but that it would possibly be of benefit because it was a more gentle way of achieving that.

Q How long were you given to consider whether you would give your consent to that?
A It is difficult to say that. I was given a bit of paper soon after Patient 3 came to the social care baby unit. I would say probably about 30 minutes after that. Quite how long I had to make my decision I do not know. I did not feel pressured into making that decision.

Q Did you feel you were thinking clearly in the time that you had?
A In headline terms only.

Q What was your understanding about what treatment your child would receive if you were to agree to her entering a trial?
A As I understood it, it was no more disadvantageous than the conventional treatment, but it would be a kinder, gentler method of ventilation. On that basis it seemed a sound and sensible thing to go for.

Q Were you aware at the time, Mr Hammond, of there being any element of randomisation in relation to your daughter?
A No, how I interpreted it was that Patient 3’s number had come up as being given the opportunity of going on to the trial and me giving my consent would be that she would actually go on to the trial.

Q Go on to the trial to receive which form of treatment?
A The CNEP treatment. If I said yes that is what she would get.

Q Did CNEP mean anything to you prior to this?
A No, not at all.

Q Did you have any idea at the time how incubators work?
A No.

Q Had you any experience of them before this time?
A No.

Q Were you asked to sign a consent form?
Yes, I was.

I will ask that you look at the original. If we could take up file one, we will look at a copy of it. It is page 386 behind tab three. Is that the form you were asked to sign?

Yes, I am sure it is. It is certainly my writing at the bottom and my signature.

It is your signature. Did you write the name beside it, Brian John Hammond?

Yes, and “father” is my writing.

And date, 8 May 1993?

Yes, that is all my writing.

Is it countersigned by anyone?

No.

Did you write any of the writing at the top of the page?

No.

For completeness sake there follows a bonding questionnaire which I asked your wife about. Do you have any knowledge about that, Mr Hammond?

No.

I am going to ask you to look at some documentation in the file. Perhaps we could go to page 336, the first page behind tab 3. You will see there, Mr Hammond, a parents’ leaflet?

Yes.

If you turn on to page 341 you will see what is described as “Negative Pressure Trial Information Booklet for Parents”, which goes through to page 364. So there are a number of pages about negative pressure. Can I ask you about that latter document. Have you any recollection, or did you see that particular document, which is at pages 341 through to 364?

No, I am sure I did not.

Can I ask you about page 336? Did you see that at all?

That is not as I recall it. I recall the leaflet I was given as being, as I have said, an small A5-document, probably of four pages. That was my recollection. This appears to be a single page. Certainly, I did not see the full booklet either.

Can you give us any indication of how long the doctor spoke to you about CNEP, the young doctor who asked for your consent?

A minute, maybe two, something like that.

Thereafter did you have any discussions with doctors about CNEP once your daughter was in the CNEP tank?

No, no.

So, who was involved with her care once she was in the tank? Was it doctors or nurses?
A Primarily our interface was with nursing staff or maybe junior doctors. Certainly, after the first week I was only there in the evenings. I was going back to work so I was only actually there in the evenings when it tended to be the nursing staff anyway. Through the first week, again it seemed to be nursing staff that we were mainly liaising with.

B Q What was your impression of the tank that your daughter was in? Can you help us with that?
A When you say my impression...

Q When you first saw your daughter in a CNEP tank, what did it look like?
A A perspex box with her head protruding from one end of it and obviously wires and tubes in all directions.

C Q We know we have got your daughter’s notes and heard from your wife about the length of time that she was in the tank and the fact that she did have some problems with her heart rate dropping. Do you recall that? Were you there for that?
A Yes, I recall that very vividly. I was over there for my evening visit and when I arrived there Janine explained to me there had been problems through the day with the baby’s heart rate and it was quite alarming because while I was there obviously she was monitored all the time for her heart rate and I believe it was set at 100 and it continually kept dropping down and setting the alarm off, so we were told to give her a little shake to push her heart rate back up and all evening we seemed to be sat there and her heart rate, we could see it drop from 120, 115, flicker up and bit and down and set the alarm off and you had to give her a shake to get her rate back up, so it was a very distressing evening.

Q Yes, and did she stay in the tank when she had those problems?
A No, obviously the alarm going off all the time, nurses were coming to attend to her and one senior nurse there indicated that she thought the problem might be with the neck seal of the tank actually causing problems with her heart rate somehow causing that to be a problem, so she took her out of the tank and it was the first time that Janine had held her properly and from then on it seemed to stop the heart rate problem and she picked up from then onwards.

Q Yes, and from then on was she in the CNEP tank or out of it?
A No, she went into a conventional incubator and then quite soon after that into a cot.

Q Finally this. Do you know Mr and Mrs Henshall?
A No. I know their names, Mr and Mrs Henshall, but I do not know them personally at all.

MS SULLIVAN: Thank you. If you wait there, there will be some more questions.

Cross-examined by MR FORDE

Q Good afternoon, Mr Hammond. I act for and represent Dr Spencer and I have a very few questions to ask you. Your wife in her witness statement says that when Patient 3 was born, and you have indicated just how tiny she was, that she had doubts as to
whether or not she would survive. Did you have similar doubts?
A  I think one has, to have no real prior knowledge of a baby born at 28 weeks I was certainly shocked by her size but one is always hopeful and one never believes that the worst is going to happen.

Q  Apparently she is now a robust 15 year old doing well at school. Is that correct?
A  Yes, that is correct.

Q  Your wife when she gave her evidence was expressing gratitude to the staff at the North Staffordshire Hospital. Do you feel a similar degree of gratitude?
A  Yes, both North Staffs and Stafford, where she was transferred to. Yes, I do feel gratitude to the medical and nursing teams at both locations.

Q  Just to deal with your involvement with the CNEP trial, first of all you were left, following your conversation with the young male doctor, in no doubt but that this was a trial?
A  Yes.

Q  So you knew that there was some sort of investigation into the best form of ventilation for premature babies?
A  Yes.

Q  We believe – and I do not know whether this is a name that you recognise – that the doctor that you spoke to – and I appreciate it is 15 years ago – was a Dr Morgan. Is that a name that rings any bells with you?
A  It does not ring a bell at all, no.

Q  It is likely, is it not, that he would have introduced himself to you?
A  He could well have done.

Q  Could well have done, all right.
A  I am not very good with names and faces at the best of times and under those circumstances…

Q  No, that is very fair of you. You say in your statement you were offered tea or coffee and you were so concerned, no doubt, about your wife and your child you could not even make a decision about that?
A  Yes, I was. That is correct.

Q  So a stressful time for you. I think you understood, though, and appreciated that a decision needed to be made about the entry of your daughter into the trial within a few hours of her birth?
A  Yes, I could appreciate that from a medical point of view, yes.

Q  You were asked about the length of time you had to consider the material you were given – and I will come back to the material in a moment. In your witness statement you say this:

   “The impression I got was that the decision had to be taken reasonably
quickly and Janine”

- your wife –

“would not be capable of making a decision for many hours”

- because she was being cared for herself, was she not.

A Yes, she was still unconscious.

Q She was still unconscious:

“I do not know for sure how much time I had. I think I had a couple of hours to consider.”

Do you think that is about the right period of time?

A I would say so, yes.

Q Because we know that Patient 3 was born at 20-to one?

A Yes.

Q And the notes we have seen suggest that she was randomised into the trial at about half-past five in the morning but you think you were given some time, possibly a couple of hours, to think about the decision as to whether or not she entered the trial?

A Yes, I think I was given the piece of paper probably half-past one-ish and then given a reasonable period, as I saw it, to consider it.

Q You have said in your witness statement that you did not feel pressured to make a decision one way or the other?

A No, I did not feel anyone was hovering over me to make a decision.

Q I will come back to the question of randomisation in a moment but have you still got page 336 open? The parents’ leaflet?

A Yes.

Q You have told us and it is a long time ago, that you neither recall getting a single sheet, such as this, nor the information booklet which we have got, if you go on, starting at page 342?

A Yes.

Q Is that right?

A That is right. I recall it as being a folded document.

Q Do you think after this time that your recollection might be faulty as to what you were given?

A It could be. I was not particularly concerned about the shape or format of the document I was given.

Q What you do say in your statement is that you were aware of a booklet - and I will
just remind you of what you say:

“The doctor outlines CNEP and he gave me four sides of paper to read which was an outline of what the CNEP trial was about. I do not think the document was an A4 document. I thought it consisted of four sides of folded paper which I flicked through. My recollection could be wrong though. It did not mean much to me at the time. I was not focused enough to study it in detail. I think the doctor took it back and kept the booklet.”

Then you say normally you would have taken several days to mull over the pros and cons – accountant’s caution, no doubt?
A Yes.

Q You knew that sort of time was not available to you?
A Yes.

Q In terms of this decision?
A Yes.

Q We have not been able to identify a four sided folded document…
A No

Q …of the sort you describe and you fairly say you may be wrong about that. Can I ask you this – do you think, looking at page 336, that the sort of information that is given there was the sort of information you were given 15 years ago? I just want to highlight a few things.
A Yes, I believe it was. I remember it in a different type of format.

Q In a different format?
A Yes.

Q OK.
A But that sort of information.

Q Can we just check – and this is a lawyer’s pedantry now – the suggestion that it is a new technique to deal with breathing problems in premature birth – is that something you think you were made aware of at the time?
A Yes.

Q That it involved a negative pressure and a rubber seal with the baby’s head coming out through the rubber seal? I know you saw that – it may be that you cannot distinguish between what you saw and what you read but do you think you were aware of…
A I think I read it. As I would not know what a conventional incubator looked like I would not know whether that was different or normal.

Q Do you think you saw in this form or in booklet form, any drawing or diagram of how the CNEP incubator would look? If you go on to page 341, it is not very difficult to
see, it is Negative Pressure Trial Information Booklet. Do you think you saw a diagram a bit like that at any stage?
A It is possible. I do not remember it.

Q You do not remember. All right. Then if we go back to 336:

“Although the technique has been shown to be safe and effective, we now need to find out whether it is better than the usual treatment which involves blowing air into the baby’s lungs through a small tube placed in the windpipe, positive pressure ventilation.”

Do you think you were aware of the contrast between the two types, or you read something along those lines?
A I think I probably read it – whether I appreciate the significance and the difference…

Q OK. Then there is a section which deals with consent to being entered into the study:

“We will use a method of random allocation to decide whether your baby receives negative pressure ventilation. A number of babies receiving negative pressure ventilation will need positive pressure ventilation as well and this will be given when needed.”

Your wife told us that she was aware of the process of randomisation and we know she was being cared for and unconscious at the time that you were reading whatever you read. You have told us very helpfully in your witness statement that you told her when she was well enough to appreciate the fact of the trial about the trial. What I am discerning from that is that if she recalls random allocation she must only have got that information from you. Do you think it is possible that---

MS SULLIVAN: I was just going to say, she had a particular understanding of random allocation.

MR FORDE: OK. The word “random” is good enough for my purposes at the moment. Do you think that she may have a recollection of “random” or “randomisation” which you have forgotten?
A No, I am sure she has not. She was not involved in the consent for the CNEP trial or not. I did that myself.

Q We know she was unconscious.
A Yes.

Q I am just curious as to how it is she seems to have an appreciation of a random element – I hope that does not offend Ms Sullivan – and you do not have that recollection. Can you help us as to how that might have occurred?
A Yes, I think we are tripping over the randomness of the selection. My understanding was, and it still is my understanding, that say baby 3’s number came up as being offered the chance to go on the trial and that was the randomness of the selection.
Q I see.
A Having that number coming up I then said “Yes” and she was on the trial. That is how I see the randomness, not that subsequent to her number coming up and me saying “Yes” there was then a degree of randomness.

Q All right, that is your recollection now. Do you recall seeing a teddy bear sign on some of the incubators indicating that some babies were receiving standard treatment within the trial?
A I could not say.

Q Did you appreciate that some babies were in the trial but not getting CNEP?
A No.

Q Did you, looking at this form, whether form this leaflet or some other source, understand and appreciate there was not an element of compulsion about entering the trial? In other words it says:

“Should you decide you do not wish your baby to be studied, it is perfectly all right and your baby will receive the usual form of treatment for his or her condition”?

A Yes, I was perfectly clear that it was a consensual issue.

Q Thank you. I just wanted to ask you a couple of questions about Patient 3 coming out of the CNEP tank. We have got some medical notes which I will not burden you with but looking at something which we will put to others, which is the Intensive High Dependency Care chart that is filled in by nurses, it looks as if on the 21st day, about three weeks, your daughter was in CNEP; at some point between 5.00 and 6.00 in the evening she was taken out of the CNEP tank. Does the approximate time of day, never mind the date, seem about right to you?
A I would say it was slightly later than that.

Q All right, because you were travelling after work?
A Yes, I had done a day’s work in Birmingham and then travelled up to Stoke on the train. I would have put it nearer seven o’clock – seven o’clock, 7.30.

Q What we have got is another note which again we can put to others, a decision in the clinical records timed at 5.45 which says this:

“Nurses are concerned very large number of bradycardic attacks”

- that is when the heart beat slows –

“Majority are not associated with desaturation”

- so that is when the oxygen level in the blood falls. They give various drug therapy, there has been a chest X-ray and then there is a plan to take Patient 3 out of CNEP but if there is no improvement in her condition, to put her back into CNEP. Were you aware of
that being discussed with the medical staff, the doctors?
A No. As far as I was aware while I was there I cannot recall a doctor coming to see baby 3 in the CNEP tank. Our liaison was with the nurse and she would disappear out of the room and then come back.

Q If the time is right, 5.45, you might not have been there by then, is that right?
A If that time is right that is a possibility, yes.

Q Would it be fair to suggest to you that this was very much within in the neonatal unit a lot of nursing activity? It seemed to be quite a nurse driven facility? Lots of nurses caring for babies, looking after babies, encouraging mothers to care for their own children and doctors appearing less frequently?
A Yes, that is correct.

Q I think you had trust and confidence in the ability of the nursing staff?
A Oh, yes, 100%.

Q What you also said in your witness statement was that whilst you were considering whether or not to allow your daughter into the CNEP trial you asked some questions and I just wondered whether you now have a recollection of that? You say in paragraph 10:

“I asked whether the outcome with CNEP would be less favourable than the normal level of resuscitation. I was told it was a kinder, gentler method for the baby. Looking back I can see that was right”?

A Yes.

Q Can you recall who you asked about that?
A It would have been the doctor that I signed the form with.

Q The male doctor?
A Yes, that is correct.

MR FORDE: Thank you very much, Mr Hammond.

Cross-examined by MISS O’ROURKE

Q Mr Hammond, I ask questions on behalf of Dr Southall. Just following up that last question that Mr Forde asked you about reading from your statement, paragraph 10: “Looking back I can see that was right.” Presumably what you are saying about it being right is the kinder, gentler treatment is that Patient 3 did not have a tube down her throat and because she was in the Negative Pressure Ventilation?
A Yes, what I read subsequently it is easier on the baby.

Q It is easier on the baby and on the baby’s windpipe?
A Yes.
Q Do I take it from what you said in your statement, paragraph 7, you say they were not geared up for Patient 3 to be born when she was and you then said it was like crash, bang, wallop, here you are, you are now a father. Was this your first child?
A Yes.

Q At the time that you were talking to the doctor - we also think it is Dr Morgan but you have said that you cannot remember but Dr Morgan is coming and it may well be he will identify his note - that at the time you were dealing with surprise arrival of a child you were not expecting; this was your first experience of fatherhood; it was the middle of the night and you were tired but you were appreciated the importance of the decision within a period of time if Patient 3 was going into the trial?
A Yes.

Q So you have no complaints as such about the way in which the consent process was carried out because you appreciate for the study and in order to take advantage of the study you had to make a decision within a timeframe?
A Yes, I understood that I did not have days to make a decision. It had to be reasonably prompt.

Q Although you do not remember the format of the information you accept you were given an information leaflet of some sort?
A Yes.

Q That it contained quite a bit of information about what the differences in the two forms of treatment were?
A I believe it outlined on the lines of that.

Q It also did make reference to randomisation?
A In terms of the random method of the initial selection, yes, that was my understanding.

Q Could it be that you have now 15 years after event mis-remembered, or, indeed, at the time misunderstood the randomisation process?
A It could have been but I was clear at the time and my recollection is clear now that if I said yes to going into the trial she was into the trial. There was no subsequent randomisation after that.

Q I understand that. I am saying to you could it be that because it was the middle of the night, you were tired, you were making a decision, you had just become a new father, you had a wife who was unconscious that you, in fact, may have misunderstood it?
A Yes, if that is what was written there, yes.

Q If it was written there or, indeed, if your doctor told you because I think you now understand that what happens, or you may have been told that once consent is given a phone call is then made. Yes?
A No, I did not know.

Q You do not know that now?
A No.
A

Q You have not read subsequently?
A No.

Q Let me just appraise you. We have got a record that shows the time a phone call was made, by whom it was made and who received the phone call in order to randomise Patient 3 into the trial.
A Right.

Q All of that it is recorded including the time that that happened. That is why Mr Forde put to you about 4.30 in the morning. We know that Dr Colin Morgan made the phone call hence we are thinking it is more likely than not at the time of night it was him who spoke to you because he would have been a young doctor in his thirties or thereabouts. We know who answered the phone call and we know the decision to randomise Patient 3. That is why I am asking you, taking into account what actually happened is it possible that you could be wrong?
A My recollection could be wrong or I did not read the document that carefully at the time.

Q I represent Dr Southall. I do not think you ever met Dr Southall in the course of Patient 3’s care at the hospital or thereafter?
A No.

Q You are not in any way suggesting or, indeed, have no awareness that he was in any way involved in Patient 3’s care?
A No.

Q You have no allegations or complaints to make against Dr Southall?
A No.

Q Whether it is about Patient 3 being in the trial or the way in which consent was taken from you or the information that you were given about the trial?
A No.

Q Indeed, you have got complaints at all about him as far as I am aware?
A No.

Q Or, indeed, any of these doctors?
A No.

Q Again, as you said in answer to a question from Mr Forde you are very grateful to the doctors and nursing staff on the paediatric unit at North Staffordshire Hospital?
A Yes, I am.

Q Do you know why you are here?
A Really to try and shed some light on events around the CNEP trial as being a parent of a baby that was involved in the trial; to actually assist the understanding of the Panel as to the events that went on.
Q You said you had heard of the Henshalls?
A Yes.

Q But never met them?
A No.

Q Had you read some of what they had written or were reported to have said in various newspapers?
A I think I have come across it in the press, yes.

Q So that is what? In the national press or in the local press?
A I think that is predominantly in the local press.

Q That is the Sentinel, is it?
A I live in Stafford so it would be the Stafford press.

Q Have you seen them on the television or heard them on the radio?
A I have probably seen them on the television if they have been interviewed, yes.

Q Have you seen anything positive written about or said by them about CNEP or these doctors?
A I cannot recall either way.

Q So you cannot recall whether it is disparaging or positive?
A No, I realise that they have raised concerns about the CNEP trial.

MISS O'ROURKE: Thank you. I have no further questions.

MR FOSTER: No questions, sir.

Re-examined by MS SULLIVAN

Q A couple of matters, Mr Hammond. You have told us that the doctor told you it was a kinder, gentler treatment?
A Yes.

Q Were any down sides explained to you?
A No. My understanding was that it was as good as the conventional treatment but possibly with the benefit of being a kinder and gentler treatment.

MR FOSTER: I will let Ms Sullivan finish with this witness but an important point of clarification arises out of that line of questioning.

MS SULLIVAN: As far as the information that you saw was concerned, Mr Hammond, you have described what you thought you saw as sort of A5 size?
A Yes.

Q Was that something that you were given to keep or what happened to it after you had looked at it?
A I have got no idea what happened to it.
MS SULLIVAN: I have no further questions.

DR OKITIKPI: Mr Hammond, good afternoon. Just one question, it relates to page 386 which is the consent form that you signed?
A Yes.

Q Could you remember whether the script at the top it “CNEP Spencer and [Patient 3]” whether they were on the form when you signed it or from your recollection did you sign a blank form?
A I cannot recall. I would have expected to sign a form that had already been partly completed. I would not normally sign a blank form without having the patient’s name on the top or whatever. I am not in the habit of signing blank forms.

DR OKITIKPI: Thank you.

THE CHAIRMAN: Anything arising out of that question?

MS SULLIVAN: No, thank you.

MR FORDE: No, sir.

MISS O’ROURKE: No, sir.

THE CHAIRMAN: Mr Hammond, thank you very much for coming and the assistance that you have been able to give the Panel. That completes your evidence so you are now released and free to go. Thank you very much indeed. (The witness withdrew)

MR FOSTER: Sir, can I make this point. Ms Sullivan asked this witness about warnings in relation to the down sides of CNEP. Two observations. One, there is no head of charge which relates to verbal warnings about the down sides of CNEP. Secondly, if this is to be an appropriate line of questioning to be repeated on further witnesses could the GMC please identify exactly what it is said are the down sides of CNEP because none has been identified so far?

MISS O’ROURKE: Sir, I would echo that. I would like to know what warnings it is said should have even given because although I agree with Mr Foster that there is no charge about warning there is, of course, a charge as far as Professor Southall is concerned, head of charge 11, which relates to informed parental consent and in respect of that the only one that I can think it could possibly fit into it is (c) “You misrepresented within the leaflet the technique had been shown to be safe” but that is the leaflet. So otherwise it could only be (b) “You failed to provide adequate training to those taking consent for the trial.” So whether in the training something should have been said to them as to what was to be said as to warnings. It is difficult to see how it does fit into that but if it is being said to be that then I would like to know what some expert is going to be saying should have been said to be the down sides because unless my recollection is failing me I have not read it in the expert evidence adduced by the GMC and I did make a point about the...
particularisation of these heads of charge at the outset and, indeed, as to why we were not saying anything in respect of head of charge 11.

MR FORDE: Sir, can I very briefly associate myself with those observations. In my submission, it can only be 11(c) which is specific to the leaflet. I know that the Henshalls believe that the neck trauma was an adverse event, that is in our charge 6(a). We do not accept it was an adverse event that needed to be notified, hence our denial of the charge to the Ethics Committee at any time and you are aware that no such trauma was sustained by any child within North Staffordshire. If the GMC are expanding their case to allege that the Queen Charlotte neck trauma experience should have been a down side notified verbally then I await the addition of charge 11(e).

THE CHAIRMAN: Ms Sullivan, can you help on this?

MS SULLIVAN: Perhaps I could consider that, sir, given the time and come back to you in relation to that?

THE CHAIRMAN: Yes, very well. I think that completes matters so far as today is concerned. Ms Sullivan, you will take away that point which has been raised?

MS SULLIVAN: I shall.

THE CHAIRMAN: Thank you very much indeed. We are agreed that we will start at nine o'clock tomorrow morning. We will adjourn now and meet again tomorrow morning at nine. Thank you very much.

(The Panel adjourned until 9 a.m. on Friday, 30 May 2008)
GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council’s Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988)

On:
Friday, 30 May 2008

Held at:
St James’s Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

STEPHEN ANDREW SPENCER BM BS 1976 University of Nottingham
Registration No: 2305893

DAVID PATRICK SOUTHALL MRCS 1971 Royal College of Surgeons of England
Registration No: 1491739

MARTIN PHILIP SAMUELS MB BS 1981 University of London
Registration No: 2732178
(Day Fourteen)

Panel Members:
Mr D Kyle (Chairman)
Mrs V Brickley
Mrs S Hollingworth
Dr T Okitikpi
Dr M Sheldon
Mr A Forrest (Legal Assessor)

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MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hempsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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THE CHAIRMAN: I think we are all here. Good morning, everybody. We continue with the case of Dr Spencer, Dr Southall and Dr Samuels. I am sorry, I missed the fact that Dr Southall is not sitting next to you, Miss O’Rourke.

MISS O’ROURKE: Sir, can I apologise for his absence? There has been a family problem and he got called away to Wales last night. His wife phoned and he felt it was important that he go there rather than be here. He means no disrespect to the Panel.

THE CHAIRMAN: No, of course.

MISS O’ROURKE: He is happy for me to continue today in his absence. The witnesses that are being called today are not witnesses where he feels he would be compromised by not being present. He simply wanted me to apologise to the Panel in the circumstances.

THE CHAIRMAN: Thank you very much.

MISS O’ROURKE: Sir, while I am on my feet, can I just mention another matter which I raised with Ms Sullivan? I have downloaded from Casetrack the judgment of the judicial review permission application in the case involving Dr Prowse. I have copies for everybody, including the Panel. It is a two-page document. I do not know whether you want it now or handed in at some later stage.

THE CHAIRMAN: We might as well take it now since you are carrying it in your hand. It will be D10. (Same handed to the Panel) Ms Sullivan.

MS SULLIVAN: Sir, thank you. Before I call the first witness this morning, could I just deal with a matter raised by Mr Foster and I think adopted by others last night? That was the question of whether any down sides have been pointed out to parents when doctors were consenting.

Sir, what I would say in relation to that is this: of course, you have in head 6 of the charge - and I am using Dr Spencer’s charge just by way of example for a moment - you have there an allegation that the adverse event, the neck trauma, should have been reported to the Ethics Committee. Then going forward to head 11 of the charge there are two allegations there: first of all that the doctors failed to provide adequate training to those taking consent, or rather failed to ensure appropriate procedures were in place, and, secondly, that there was a misrepresentation within the parental information leaflet that the technique had been shown to be safe. You will recall that when I opened the case I indicated that one of the reasons why that was a misrepresentation, it was said, was because there had been the neck trauma which had occurred in Queen Charlotte’s in February of 1990.

Sir, therefore, in considering those heads of charge, you will need to consider the whole of the consent-taking process and its adequacy. You therefore need to know from those involved what that process was and you will be hearing evidence from a variety of witnesses. For example, one witness did explain that there had been problems with the neck seal to patients - for the benefit of my learned friends, that is Dr Palmer at paragraph 40. Others would not have done so. Likewise, in respect of expert evidence, Dr Nicholson - and this is paragraph 47 of his report - indicates that it would no longer
have been accurate to say that the CNEP technique was safe following that neck injury, and the fact that an injury might well have left a survivor with permanent scarring was something that any responsible parent would wish to know. There is obviously a different approach taken by different witnesses to this, but it is relevant to those particular heads of charge, in particular head 11 to which I have just made reference.

Sir, that is the purpose in eliciting it. You need to know the factual background against which you will have to assess in due course whether or not there had been any failures.

THE CHAIRMAN: I think the point which Mr Foster was making when he raised the point was obviously the - from the point of view of not asking a leading question but to ask about a down side is obviously an appropriate way to ask the question, but I think he was entitled to ask whether and, if so, what down side might be in prospect.

MS SULLIVAN: Yes.

THE CHAIRMAN: I think, as I understand you saying, it is around this matter of the neck trauma.

MS SULLIVAN: That is right.

THE CHAIRMAN: So that is the way the GMC puts its case.

MS SULLIVAN: That is right. It is flagged up within those reports.

MR FOSTER: My question was a very specific one: were there any adverse consequences of CNEP which the GMC says should have been communicated to parents? It appears to be Ms Sullivan’s suggestion now that the neck trauma - which is the subject of paragraph 6 of the charges against Drs Spencer and Southall - was such an adverse consequence. If that is the case, then I invite her to point us to the passages in the evidence of her own experts which support the suggestion that it should have been communicated to the parents.

It is one thing Dr Nicholson saying that it was something which should have been factored into the general assessment of safety; it is quite another thing to say that it was something specific which should have been notified to parents. Dr Stimmler - who is the real expert, the paediatrician - specifically says that it was not something which should be communicated to the parents.

So far as the attempt to bring it within head of charge 11 is concerned, I was specifically referring to verbal assurances. All that my learned friend could point to was the parental information leaflet. I am still none the wiser as to how the case is being put.

MISS O’ROURKE: Sir, I do not understand which head of charge it applies to as far as Dr Southall is concerned because, yes, 6 deals with the adverse event, but that is a different issue as to whether you go back to the Ethics Committee about it.

If you look at it in the context of asking parents questions, then the only potential relevance of the parent’s evidence can be head of charge 11. Head of charge 11, it cannot
be (a) which is delegating the task “to too many different medical” staff. That cannot be relevant to questioning of the parents. It cannot be (c) because that is the leaflet and she is talking about the consenting process. It cannot be (d) because that relates to the leaflet. The only thing that it can be is (b):

“You failed to provide adequate training to those taking consent for the trial.”

If it is being said that those who were taking consent for the trial should have been instructed to tell parents when taking consent about the adverse event, and specifically the neck trauma, then I want to see who is saying that. I do not think Richard Nicholson is saying it. I agree with Mr Foster; the real expert, if any, is Dr Stimmler and I do not read him as saying it. The objection arose in the context of asking a parent a question. Well, it can only possibly be relevant to 11(b).

MR FORDE: Sir, I am disappointed that an effort is being made to get that part of the evidence that was elicited into the charges at this late stage. If the GMC are suggesting that an adverse event - in other words the neck trauma which, as you know, we do not accept was an adverse event that should have been reported to any Ethics Committee - that occurred in one child in a different hospital should either have found its way into the patient information sheet provided to parents at the North Staffordshire Hospital, or should have been part of the verbal consent process; there is a risk that your child will suffer life-long neck scarring, then it should be specified in the charges. I wait to be pointed to the part of the opening on the part of the GMC which made that clear to us, that that was the charge we were facing.

It is also somewhat disappointing that you have not had confirmed to you what we believe to be the fact which is that Dr Stimmler does not believe that the neck trauma (a) should have been reported to the Ethics Committee - which is important because there is no expert support for it, we would say, which is valid - and one then assumes (b), which should not have been reported to the Ethics Committee, did not to form any part of the consenting process either.

We really do need this matter clarified because it will impact upon the cross-examination of all the parents if they are going to be asked, “Were you told about the neck trauma event in another hospital”, and may also impact upon cross-examination of the doctors as to whether, by the standards of the time, the neck trauma occurring in a single patient in a different hospital was of sufficient concern to be part of the verbal consenting process at North Staffordshire. We say not.

I would also like Ms Sullivan to confirm there was no instance of neck trauma of the sort that occurred in Queen Charlotte’s Hospital at the North Staffordshire Hospital. Again, you may feel that the doctors at North Staffordshire would not have been warning of an event which had never occurred in the context of their own practice. We do need to have this clarified.

THE CHAIRMAN: Ms Sullivan, the Panel, in a sense, is sort of half way informed about this because we do not know yet what the expert evidence is, but we can see what the charges are. It is clear, again, by reference to Dr Spencer, that charge ---
MS SULLIVAN: 6 relates to the Ethics Committee.

THE CHAIRMAN: Relates to the Ethics Committee and the neck trauma, so that is a clearly specified charge.

MS SULLIVAN: Absolutely.

THE CHAIRMAN: When one looks at 11, as both Miss O’Rourke and Mr Forde pointed out, the specific charge about misrepresenting within the leaflet that the technique had been shown to be safe, well, if the suggestion - irrespective of what the expert evidence actually is and we do not yet know that - when we are shown the parenting information leaflet and taken through it with the expert evidence, we will be able to see to what extent the leaflet deals with things. This seems to be about whether the parents should have been told about that irrespective of what it said in the leaflet.

MS SULLIVAN: Yes.

THE CHAIRMAN: In which of the heads of charges, if we take 11 as an example, would you say that that allegation is dealt with in the charges?

MS SULLIVAN: Yes, I agree with Miss O’Rourke; it really is a matter for 11(b) when you are considering the adequacy of the training because you obviously will have to consider whether those taking consent were adequately trained. That will involve knowing what it was that they said to the patients(sic) in order to obtain informed consent.

THE CHAIRMAN: Which then brings us back to the point which Mr Forde has specifically pointed out, that they are anxious - and of course we are not in a position at the moment to enter into this debate - which aspects of the expert evidence you are intending to call you would rely on in order ...

MS SULLIVAN: Yes.

THE CHAIRMAN: ... to suggest that that is something which should have been part of the training and should have been communicated to the parents.

MS SULLIVAN: Well, yes, as I indicated to you, sir, when I set out the factual background of it, a number of the doctors would not have pointed out that neck injury when taking consent, but Dr Palmer, for example, would have pointed it out. There are obviously differences in approach between the doctors in relation to that particular injury.

There is also a division of opinion, as I indicated to you when I opened the case, there are a number of divisions of expert opinion in this case which you will have to consider in due course. Dr Nicholson’s view is that that was something that he would have expected the parents would want to know before reaching a decision about consent. Dr Stimmler, it is quite right to say, has a different view of it. Again, sir, it is a matter for you, the Panel, to hear the evidence about it and for you consider in due course whose opinions you prefer in relation to particular aspects of the case.
THE CHAIRMAN: The position you are adopting, however, is that insofar as there may have been differences of practice amongst the doctors who were going through the consenting process, your position, as I understand it from what you are saying, is that there should not have been such a difference in practice; there should have been consistency.

MS SULLIVAN: Yes, exactly. It goes to the adequacy of the training. If there were any inconsistencies in approach, one or other approach may be the correct one, but you do need to know how each of them was approaching consent in its totality in order to be able to assess whether proper training had taken place, because of course there should be a consistent approach in relation to obtaining consent.

THE CHAIRMAN: In answer to the question to identify the source of the evidence on which that proposition would be based, your answer to that is Dr Nicholson, although Dr Stimmler takes a contrary view.

MS SULLIVAN: Takes a contrary view. That is right. Also, within the factual evidence, Dr Palmer did explain it; others did not, I accept that entirely, but she says that she did. Again, there is that difference.

Sir, in a case where you are considering consent, it seems to me you do need to know exactly what process was gone through by each of the doctors in order to be able, at the end of the day, to assess whether that was a proper process or not.

THE CHAIRMAN: I can understand that. Of course, the specific here is whether it is appropriate to ask a patient(sic) whether they were communicated any down side to the CNEP treatment. That question has to be founded on evidence that they should have been so asked. First of all that the GMC says there is a down side - and we seem to be talking about neck trauma - and, secondly, that there is evidence which the GMC intends to call, and on which it relies, that the neck trauma is a down side which should have been communicated to the patients. That is the point.

MS SULLIVAN: Yes. In relation to that, sir, as I said, it is Dr Palmer on the factual side and Dr Nicholson, paragraph 47 in his report. Of course, there is another side of the coin. That is the case in relation to a number of matters that are before you, but there is a basis for it is what I am saying.

MISS O’ROURKE: Sir, I am sorry, it is not good enough. The position is this: we have the strange situation where we are having parents called in respect of whether or not they were giving informed consent. It would not be an unusual situation in a Fitness to Practise Panel to have that situation where the respondent practitioners were the people who had taken the consent and therefore you were calling the parents to say, well, he failed in this duty, he did not tell me what he should have told me. Of course, you know that none of these three doctors took consent from any of these patients (sic), so that of course cannot be the charge. The charge, instead, has to be he failed to provide adequate training, because they were not involved in the consent-taking process, or, therefore they were not involved with the parents, so the question of what the parents were told, whether they were given the downsides, it cold be due to a defect or a deficit in the individual consent-taking doctor. That cannot be the responsibility of these doctors, unless it is said...
they did not properly train them.

The problem that Ms Sullivan then has, and it is why it smacks to me, for one, of this being now decided on the hoof as to how you fit it in. All of the doctors who took the consents are being called as her witnesses, not ours, so she cannot cross-examine them. She has to take their evidence as it is in their statements. Well, I am sorry, yes, Dr Kate Palmer does make reference to whether she would have mentioned neck trauma. None of the others say anything about it and none of them in any way criticise their training. So how are we going to get this evidence elicited when we deal with, for example, Dr Arya, who is coming today? There is nothing in her statement relating to it. How is Ms Sullivan going to introduce that evidence, and if she now wants to introduce it from Dr Arya and others, then I, for one, want to see a supplemental statement.

MR FORDE: Again, for the record, I am looking at the opening, and I can see absolutely no mention of the evidence of Dr Kate Palmer being germane to this issue, either charge 6 or charge 11. We are now, I think, on day 14 of the hearing that we have heard of this. It should not be difficult for the supplementary statement to be taken, because, to my consternation, as I walked past the General Medical Council witness room this morning, there was a solicitor, I believe employed by Eversheds, in the GMC witness waiting room with, I think, three of the four witnesses it is proposing to call today.

THE LEGAL ASSESSOR: I do not there would be anything unusual in that.

MS SULLIVAN: There is nothing unusual in that.

THE LEGAL ASSESSOR: At least to familiarise the witnesses with what is happening, as opposed to coaching them. If there were any question of that, you would have a very legitimate complaint and you are entitled to ask ---

MR FORDE: I shall be asking them what they were discussing in relation to this hearing when I cross-examine.

THE LEGAL ASSESSOR: And you are certainly entitled to do that.

MR FORDE: If there is any issue that has been discussed which forms part of the charges, then I want the Panel to know.

THE LEGAL ASSESSOR: I am slightly concerned about this, sir. I do not know which part of the opening Mr Forde is looking at. I am looking at page D8/45D-F. Ms Sullivan opened the case on the basis that:

“Further study is warranted to determine the value and safety of CNEP in reducing”

- that is what the report says. Therefore, she went on to comment:

“...It is hardly justifiable, therefore, to claim and to continue to claim in the patient information leaflet that CNEP was safe even before the trial had started...”
Certainly I understood the misrepresentation in the leaflet to be not that CNEP was safe whereas it was in fact unsafe, but simply that it had not been shown to be safe. In other words, the position was neutral on that, no-one knew whether it was safe or unsafe. That is how I understood that ---

MS SULLIVAN: Can I refer you to C above, the third line of that paragraph:

“You may recall that if [it] was in the information leaflet that we looked at in file 1, tab 1, page 5, that CNEP was described as a technique that is shown to be safe.”

I think it must be “it was,” not “if” and:

“You will be hearing from Dr Nicholson in relation to this. He accepts that earlier studies had shown that CNEP was capable in many infants of reducing their oxygen requirements and, whilst to that extent effective in respiratory failure, however, it is said that safety is a different matter; and, of course, there were potentially serious problems - for example, the neck seal that caused the neck problems at Queen Charlotte’s Hospital.”

THE LEGAL ASSESSOR: The reality is one is not going to stop the parents saying what they were told. The specific objection arose in the context of you prompting them in re-examination, I might add, as to whether they had been told the downside. It seems to me they should not be asked that, they should simply be asked in chief...

MS SULLIVAN: What they were told.

THE LEGAL ASSESSOR: ...what they were told.

MS SULLIVAN: I can see the validity of that.

THE LEGAL ASSESSOR: That actually seems preferable to me, rather than they go and be reproved and their attention drawn to a specific point. If nothing is said, nothing is said, and that is the end of the story.

MS SULLIVAN: Yes. Really, I think the objection is more to the way in which the question was asked rather than what was said, but what I am anxious to elicit from all the parents and, indeed, from all the doctors as well is what was involved in the consenting process, without attaching any particular criticism at this stage to it, but so that there is a factual basis upon which the experts and, indeed, the Panel, in due course, can consider whether or not the charges are potentially made out. I am quite happy to ask the question differently, but I am anxious to elicit all the information.

THE LEGAL ASSESSOR: On a pragmatic basis, are there any objections to that course?

MISS O’ROURKE: Sir, I think what I would say this: I will be making a half-time submission it is irrelevant to the charge, but that is obviously another matter. I am more
concerned now - given Ms Sullivan answered it was 11(b), as I had suggested, it could be relevant in terms of the oral discussions as opposed to the leaflet - what she is going to elicit from the doctors who are being called because, other than Kate Palmer, I do not think any of the rest of them mention it, so I am more concerned that if she is now going to take that up with them, then I want advance warning what they are going to say.

MR FOSTER: Questions clearly should not be asked which are designed to elicit irrelevant evidence. I take it from the concession which is now being made by Ms Sullivan that she acknowledges that verbal mention by the doctors of any specific complications associated with CNEP were not necessary. I would just be grateful for that clarification. If it is continued to be said there should have been a mention of disadvantages, for example, associated with neck trauma, then we need to know that now.

MR FORDE: Sir, can I just make the following point: we, as you know from abuse of process delay submissions at the beginning of this case, are now 16, 17 years on from the events in question, and we are still waiting for a report from Dr Stimmler which indicates which aspects of which charges he continues to support, and it is regrettable acting for a doctor in these circumstances, but the General Medical Council’s case seems to be shifting and expanding almost daily. I would also like to record my consternation publicly and ask that that report, dealing with matters charged by charge is furnished to us as soon as possible.

THE LEGAL ASSESSOR: Dr Stimmler was going to be back on the 23rd.

MR FORDE: Of May, yes.

MS SULLIVAN: And indeed has been devoting attention to it. It is imminent.

THE LEGAL ASSESSOR: Some would say so is the end of the world.

MS SULLIVAN: I hope it is more imminent than that. I am not making the concession that Mr Foster indicated, but what I am indicating is that I will seek to elicit, obviously in a non-leading form, what the parents were told, and I do not propose to go outside what is in the statements that have been served on the other side, in which they have had an opportunity to see, so that they can see exactly what the doctors are saying.

MR FOSTER: I really do not want to be difficult about this, but I am still completely unclear. My learned friend says that she will not seek to elicit from the parents evidence about disadvantages of CNEP, which were told to them by other doctors. If she is not seeking to elicit that information, then it must follow that she is not saying that there should have been any specific mention of CNEP.

THE CHAIRMAN: Any specific mention of ---

MR FOSTER: CNEP complications.

THE CHAIRMAN: What I understand Ms Sullivan to be saying is that - I mean, I think it would be common ground there has to be a consenting process. There cannot be any doubt about that: there needs to be a consenting process. The form of that consenting
process is in issue in the case because of charge 11, which we have been looking at. The consenting process, in very broad terms, it might consist of and is suggested it should have consisted of giving them a leaflet with information in it, and it is suggested in the charge that aspects of that leaflet were misleading.

MR FOSTER: Yes.

THE CHAIRMAN: Also within the consenting process, of course, is going to be how the procedure is introduced to the parents and how it is explained to them, which will include a verbal indication. The issue which we are considering at the moment, it seems to me, is the matter of what the witness - we are dealing with parents at the moment, but there will be doctors as well - should be asked about anything which transpired at the consenting process. What Ms Sullivan is saying is she is intending simply to ask, if it is a parent: were you given any written information? Were you told anything and, if so, what; to leave it neutral like that and to hear what they say.

MR FOSTER: If it is Ms Sullivan’s case that there should have been specific mention by these doctors of the downsides of CNEP, then we need to know that now. If it is not her case there should have been specific mention, we need to know that now. If it is not her case there should have been mention of specific downsides of CNEP, then the concession about the ways the questioning will go, which Ms Sullivan has made, is a proper one. If she still intends to suggest to you that there should have been mention of specific downsides of CNEP, then it seems to me she is bound, on the GMC’s behalf, to probe that with the parents in the way that she has just assured you that she will not do.

THE LEGAL ASSESSOR: As I understand the GMC case at the moment - and Miss O’Rourke makes what may not be a valid point as to what will be the submission at half-time - it is said that the next trauma, which after all has been talked about in cross-examination of the Henshalls, at some length, was a downside, which should have been communicated to the parents and that failure to communicate that indicates - sorry, should have been communicated to the parents so that the persons taking the consent should have been trained to communicate it to the parents and that therefore founds the charge of the head of charge that there was insufficient training. Is that the way it is put? Unfortunately my tone of voice will not be heard in the transcript.

MS SULLIVAN: Yes. I have indicated that there will be a conflict of evidence on that point. It is evidence that I want to put before the Panel so that the Panel can assess it.

THE LEGAL ASSESSOR: You do say positively that the neck trauma was a downside which should have been communicated to each parent?

MS SULLIVAN: That is the view of Dr Nicholson and Dr Palmer did explain it. It is right to say Dr Stimmler’s view is different, and others from whom you will be hearing, other doctors, would not, or did not communicate it. They deal with it in their evidence.

MISS O’ROURKE: Sir, then she needs to pin her colours to her past. She has got two witnesses in conflict with each other. She is presenting the case on behalf of the GMC and the Henshalls. She has to say which one she is running with because we need to know when we cross-examine these witnesses. Our case, I think all three of us, quite
clearly is: (a) it is not an adverse event that should have been reported to the Ethics Committee; and (b) therefore it did not need to be included in the training of these doctors for consent; and (c) it would have been positively wrong, certainly as far as my client is concerned, to tell any parent about it, because it would have been disproportionately worrying to them when in fact there was no justification for it given, the actual facts of the one particular case in which there was some neck trauma found.

I want Ms Sullivan to say - it is not good enough to say Dr Stimmler says this and Dr Nicholson says that. She is presenting the case, she is prosecuting it. Which horse is she backing? Is she saying it should have been said and therefore she is going with Dr Nicholson? We are entitled to know before we cross-examine any of these doctors, so then when Dr Nicholson comes in to give evidence, we know that if we effect his evidence in a way that demonstrates lacks credibility, independence and everything else, then that is the end of that head of charge. It is not good enough, in my view, to say one says this and one says that. She is running the case. Is she going with Dr Nicholson and saying that is what should have been done so that we can cross-examine these doctors on whether they think that is what should have been done.

THE CHAIRMAN: I rather understood, Ms Sullivan, that is precisely what you were saying, and just picking on the exchange you had with Mr Forrest, it is your case that the neck trauma was a downside which should have been communicated to the parents via the training which was given to those consenting, and that you rely on Dr Nicholson in support of that.

MS SULLIVAN: I do rely on Dr Nicholson in support of it. It is quite right to say that other evidence will be called which will not support that. That is not necessarily uncommon for there to be a conflict of evidence, which obviously you will have to take into account in due course. That is the opinion of Dr Nicholson, as is apparent from paragraph 47 in his report.

THE CHAIRMAN: If this is the position, it would seem to follow from that that whilst, of course, there is a question about the best way to elicit the information from the witnesses, it is appropriate to seek to elicit evidence from them about what they were told in relation to - as part of the consenting process.

MISS O’ROURKE: Sir, I do not think we have any objections to that. From the perspective of what my client would say, we would be very surprised if any of the doctors did tell them, because they should not have, because there was need to, because it was not an adverse event, and they were not trained to tell them.

THE CHAIRMAN: Yes, of course, and that represents the case on the one hand and the case on the other.

MISS O’ROURKE: It presents the mainstream paediatric view, we would say.

THE CHAIRMAN: That, of course, becomes a matter of evidence for the Panel to consider in due course. We do, at least, I think, seem to have resolved the matter so far as to what is appropriate to invite the witnesses who are called about the consent process to be asked. Thank you. Ms Sullivan.
MS SULLIVAN: Sir, the first witness will be John Alcock, who is a parent.

THE CHAIRMAN: I understand, Ms Sullivan, that Mr Alcock has no difficulty with his own identity being referred to?

MS SULLIVAN: That is right. We are going to anonymise the child.

THE CHAIRMAN: Is that a boy or a girl?

MS SULLIVAN: It is a boy, sir, Patient 42.

JOHN MICHAEL ALCOCK, sworn
Examined by MS SULLIVAN

Q Good morning, Mr Alcock.
A Good morning.

Q Would you mind beginning by telling us your full names, please?
A John Michael Alcock.

Q As the Chairman mentioned to you we want to ask you about your son whom we are calling Patient 42. Was he born on 27 November 1992?
A Yes.

Q Was he the first child that you and your wife had had together?
A We lost one about twelve months before that at seven months but we did not have actually any children together. We have got children from different relationships.

Q But that as you indicated you lost a baby in the previous year who was stillborn, is that right?
A Yes.

Q So when your wife became pregnant again was she monitored?
A Yes.

Q At the hospital on a daily basis?
A Yes. Later on in the pregnancy more so.

Q Then there came a stage, I think, when she rang you and let you know that she was going to have an emergency Caesarean?
A Yes.

Q Did you as a result go off to North Staffordshire Maternity Hospital and go down with your wife to the theatre?
A Yes.

Q Do you remember what sort of anaesthetic your wife had?
A Spinal tap thing.
Q Were you present at the birth?
A Yes.

Q After your son was born on 27 November of 1992 did he have difficulties breathing, Mr Alcock?
A Yes, they measured him but they did not weigh him --- sorry, they weighed him but they did not measure him, they said he has got breathing difficulties so we will have to whip him off.

Q Did they take him off also almost straightaway to the neonatal unit?
A Straightaway, yes.

Q Did you stay initially with your wife?
A Yes.

Q Did you then go to the neonatal unit?
A Yes.

Q Was your son in an incubator?
A Yes.

Q What sort of incubator was it?
A A clear one with the holes in the sides, you could actually put your hands in if you needed to.

Q Did any medical staff speak to you on the neonatal unit?
A Only the nurses. I only spoke to nurses.

Q Did you at any stage speak to a doctor?
A Not until later.

Q So initially you spoke to nurses?
A Yes.

Q Approximately how long was it after your son was born that you spoke to a doctor?
A It would have to be a rough guess, it has got to be at least two hours I would imagine, something like that. I am not really sure. I know it was a while after.

Q Who approached who?
A I was approached by a nurse and the doctor and I think nurse introduced whoever it was.

Q Can you remember whether it was a male or a female doctor?
A It was a male doctor.

Q I do not suppose you can remember the doctor’s name?
A No. He did give me his name at the time but no.
A

Q When the doctor approached you were you still on the neonatal unit or were you anywhere else?
A I cannot remember actually whether I was actually on the neonatal when I was waiting for the wife to come down because she had not actually seen him then because she was put in a side ward when she had her operation and then taken to a proper ward after and that is when they bring him down to see her, it was at least two or three hours later I would imagine.

Q What did the doctor say to you when you had this conversation?
A It was about joining the --- if I was prepared to put him into this new technique for doing something like CNEP. Pressurised unit.

B

Q I wonder if you could just sit forward a bit because it is quite a large room?
A Sorry. If I would be prepared to let Patient 42 go in to the experimental thing with a pressurised tank.

Q Do you know what that was called?
A I could not remember it at the time, I know it is CNEP now but I could not remember at the time. At the time your mind is elsewhere.

C

Q What did the doctor say to you about this particular type of tank?
A I think basically it was an experimental thing that they were doing at the time. I cannot remember too much about it, to be honest. I know it was experimental.

Q Can you remember what you were told apart from it being experimental?
A That it was on a trial basis really.

D

Q How long was the conversation approximately with the doctor?
A I would say from the time I met him to - my wife was not with me at the time actually, I said at the time it is not a decision I would make on my own. I said I would have to discuss it with the wife but more or less at the same time the wife actually came in, they just walked her down in the wheelchair to where we were. Basically she was out of it really but I should say less than five minutes. Five minutes at the most. It was a very brief meeting.

Q Then you have indicated that it was decision that you did not want to take on your own?
A Correct.

Q So did you discuss it with your wife?
A Very basically, yes. As much as I could from what I knew of it.

Q Was the doctor there when you were discussing it with your wife?
A Yes.

Q Can you remember anything that you were told about it then?
A I think I said to the wife it is an experimental thing that they are doing possibly to give him a better chance to help him breathing. I know it is on a trial basis but they have
asked if we would consent to go into it but I think at the time you do not know what is
going to happen to the child because he is struggling for breathing so you try and give
them the best chance. If it needs to be that is his only chance then, yes, but I would not
sign it either, I let the wife sign the consent form.

Q  How was your wife at the time that she signed the consent form?
A  Very much out of it. She had just had an operation. I do not know whether it was
morphine she was on but basically my view was like she was either doped up or a drunk.
I have seen both. They are not in this world anyway really. Everything is very hazy to
her.

Q  I am just going to ask you, please, to look at the consent form. Perhaps you could
be given the original consent form and if we could look in file one, tab 3, page 104. Is
that the form that relates to your son, Mr Alcock?
A  Yes.

Q  Do you recognise the signature there?
A  Yes, more than anything, I assume it is Lynn’s signature but I would say, yes,
I would say that was Lynn’s but bear in mind she had been slightly awkward(?) because
as I say she was not quite with herself, if you know what I mean.

Q  We will ask her about that in due course. Prior to your wife’s signing that form
can you just help as to this, Mr Alcock, were you given any information leaflet about this
treatment?
A  I could not remember at the time. I have seen --- since then I have seen a picture
of the tank. Then I remember I have seen it which basically it is the diagram, the picture,
the print on it was the actual tank and I said, yes, I remember seeing one of them. So that
triggered, yes, I did see it but even if I had read it I cannot remember reading it because at
the time my head would not have been --- my focus would not have been on it. I would
not have been concentrating, I might have looked at it but it would have gone straight out.

Q  Can we look a moment - perhaps you could be given file 1, please. If you could
just look behind tab 3 at page 336, the numbers are in the top right-hand corner.
A  I cannot remember seeing that. I have seen a copy of it since but I cannot
remember seeing it at the time.

Q  Yes. I think you were shown a copy of it when you made your statement?
A  Yes. Up to then I could not remember seeing it.

Q  If I could ask you just to turn on a few pages, please, to page 341 you will see
there a document which goes on through to page 364 which is called an “Information
booklet for parents”. Do you recall having been shown anything of that type at the time
when you were being asked for consent?
A  No. I could not remember at the time but, same as I say, the tank dud trigger
something when I saw it again, the diagram of the tank.

Q  Which one triggered something?
A  Something like that one.
Q Can you give us the page number at the top?
A 349. No, it is not, sorry, it is 351 because it is the full one.

Q 351?
A That is what triggered me to say, yes, I have seen it but that was later.

Q Triggered you to say you had seen what?
A Something of this. This. I never saw it at the time and I could not remember seeing it at the time but when I saw it when I was doing my statements that triggered, yes, I have seen that because I remember seeing it in the hospital as well.

Q So what had you seen in the hospital?
A I just seen one of these in the ward.

Q When you say you have seen one of these?
A The tank, the pressure tank.

Q The tank you had seen in the ward?
A Yes, so I remembered then, I remembered, yes, I might have seen it but I cannot remember the context. That is about the only thing I remember of it. That picture.

Q I am just trying to be clear as to whether you are saying, Mr Alcock, that you had seen the tank or a picture of the tank?
A I had seen a picture of the tank.

Q Whereabouts had you seen it?
A I can only say I must have seen it when I was given this but I cannot remember being given it at the time. It is a long time ago. Same as I say, at the time your mind is not actually on things like that because it is on your son and on your wife. Do not forget we are talking within two or three hours, he is struggling for his breath, the wife is not too good at all so recollections are not generally forthcoming as if you have got a clear mind about things.

Q We understand that.
A I did actually see one of these tanks on the baby unit, I think.

Q You saw one of the tanks on the baby unit?
A I am assuming it was that tank on the unit purely on the basis that the child’s head is out of the tank.

Q So, again, are you saying you saw the tank or a picture of the tank?
A I have seen both but I remember the tank in the baby unit but it was only actually when I saw it when I was shown this when I was making my statement that it triggered, yes, to have seen that triggered it because I had seen the tank as well, that triggered, yes, I must have had this information otherwise I would not have remembered seeing it in print form.

Q Can I ask you how long were you given to make the decision about whether to be part of this experimental treatment?
A Everything was done, I would say, within five minutes of meeting the doctor and
A Lynn coming, within five or ten minutes of Lynn coming and seeing the doctor, me seeing the doctor, Lynn coming at that time and signing.

Q That is what I was trying to ascertain as to how long it was before your wife signed the form?
A To have read that or had that I might have been given that at the time but I certainly would not have read it in until after. I would not have been able to sit down and read this. It was such a short time.

Q What was your understanding of what treatment your son was going to receive if you consented to be part of this experiment?
A I would have assumed if he went into the tank it would have been a pressurised tank to take the pressure off his chest to help him breathe more freely. That is about as much as I can recollect.

Q So you have seen and identified a picture of the tank?
A Since.

Q The CNEP tank. Yes. You have described before an ordinary incubator?
A Yes.

Q Which of those did you understand your son would go into?
A At the time we were discussing it I had not actually seen the tank. All I know is when I went to him on the ward he was in an incubator with his oxygen pipe round his nose, or whatever, and you could get your hands into. My understanding was from my point of view, as I remember it, to me if you say it is a pressurised tank then it would be a sealed unit with perhaps just his head or his hands and his arms out. That would be my perception of it.

Q When you were being asked for consent by the doctor to your son being part of this experiment what did you understand was going to be the treatment your son would receive?
A That he would go into one of these tanks if needed be.

Q Which sort of tank?
A The pressurised tank, not the ordinary one. We have got the incubator and then the pressured tank, if needed to.

Q If he needed to. What, in fact, happened with you son? Did he go into it?
A No.

Q I think he was ventilated, your son, for a little while?
A Yes.

Q Then he made good progress?
A Yes.

Q And in due course was released from hospital?
A Yes, well, not for a while after because it was when they put the oxygen they
discovered he had got a cleft pallet. It was some time after that.

Q  I think as far as any bonding questionnaire is concerned, I think you have been shown it, but that is something you did not complete yourself.
A   That is right.

MS SULLIVAN: If you wait there, there will be some more questions.

Cross-examined by MR FORDE

Q  Good morning, Mr Alcock. My name Martin Forde and I am acting for Dr Spencer. I want to ask you a few questions about the events you have been giving evidence in relation to. Your son, Patient 42 we are calling him, was born on 27 November 1992. Is that correct?
A   Correct.

Q  You are now being asked to record events that occurred about 15 and a half years ago?
A   Yes.

Q  Would it be fair to say that you are finding that a little difficult?
A   Very fair.

Q  I want to see if I can prompt your recollection in a few respects, but it is perfectly acceptable for you to say “I do not know” or “I do not remember.” Nobody will criticise you for trying to do your best.
A   Yes.

Q  We have some documentation that shows that your son was born in the late afternoon around about four o’clock. Does that ring a bell with you?
A   Yes.

Q  You were there before your son was born?
A   Yes.

Q  Your wife had something that is known as a spinal anaesthetic?
A   Yes.

Q  Can you recall whether she was able to converse with you when she was going through the labour?
A   Yes, we were talking during the operation.

Q  Did she appear to be making sense to you when you were talking to her during the operation?
A   Yes, she did not seem too bad. She only had a spinal tap.

Q  For instance, she new she had given birth to a son rather than a daughter?
A   Yes.

Q  Did you choose a name straightaway or had you come with a name in mind?
A   No.
Did you name your son shortly after he was born or at a later stage?
A  I cannot remember whether it was later on that same day or not, to be honest.

We have another document that suggests that a doctor called somebody to see whether your son would go into the CNEP tank about nine o’clock in the evening, so about five hours after he was born?
A  Yes, I remember that.

Can you help us whether or not the discussions you were having with doctors about what you have told us was an experiment and a trial may have been some few hours later?
A  I would have it down as a couple.

Two hours?
A  Thereabouts, or perhaps a bit longer.

Was it later still that your wife was brought down in the wheelchair?
A  No.

What I am understanding - tell me if I am right - you appear to have had a discussion with a doctor?
A  No.

Then your wife was brought down?
A  I was actually having a discussion with the doctor. I said it is not a decision I would make without discussing it with the wife. It might perhaps have been for a couple of minutes, but then she brought the wife down in a wheelchair, so everyone was there. It was coincidental, but as we were having the discussion, she was wheeled in at the time.

Was she being brought down to see your son?
A  Yes. She had not seen him at the time.

You were somewhere within the hospital having a discussion with somebody about the - you have described it as an experimental pressurised tank?
A  A doctor.

Was it a nurse who brought your wife down in the wheelchair?
A  Yes.

Again, it may not be something you can recall, but we have seen and you have been given the original of the consent form. The doctor who witnessed the consent form is a Dr C Stanley. We know that that was a female doctor?
A  I do not know.

You seem to be suggesting you were talking to a man?
A  I thought it was a man. I am sure it was a man. I cannot remember talking to a women doctor. The woman doctor - it was a woman doctor who performed the Caesarean. I am sure I was talking to a man. I think the wife will tell you the same: it was a man.
Q We will ask her. Again, you were asked to look at some other documents and you seem to have some sort of recollection, you said, prompted by a photograph on our page 351. It is a photograph of a child in a CNEP tank?
A Yes.

Q What I want to ask you, and if you cannot remember please say, do you think you saw a photograph like that when you were having a discussion with a doctor?
A No, I would have seen that after the discussion. As I say, the conversation did not last long. Basically the forms were signed. We were left with that, and that would have been for later browsing, not at the time.

Q You think you were left with the booklet?
A Yes.

Q If you go to page 342, back a few pages. Page 351 is a picture within a booklet. It says “Information booklet” and if you flick through the next five or six pages, can you now recall whether you saw the picture at page 351 as part of a booklet?
A All I can remember, basically, is information sheets. The only thing I can remember about it is the tank. That is the only thing that triggers anything for me.

Q You remember information sheets of some sort. Can I again ask, without going through matters in laborious detail, did you understand you could, if you wanted to, say no to the trial?
A I would have assumed at any time I could say no.

Q Did you understand that a decision was going to be made as whether or not your son went into the tank or whether he had ordinary treatment, because we know he ultimately had the standard treatment?
A We assumed at the time that he was on oxygen with the pipe. We assumed if he deteriorated - that is an assumption, not a recollection - and that was his best chance, then he would go in one. That is an assumption not a recollection.

Q I want to ask you a little about your wife’s state. This is two hours after a spinal anaesthetic you are telling us?
A Or maybe a bit longer.

Q She is brought down in a wheelchair?
A Yes.

Q You said you would not make the decision on your own. Do you remember being able to discuss with her whether she was happy to agree to the possibility of your son going into the special tank?
A We discussed it on the ward when they brought her down. Everything was done within minutes.

Q I understand what you are saying about timescale. You told the Panel that it was not a decision you would make on your own. We know it is your wife’s signature on the form, and I am asking you if you can recollect saying to your wife something along the lines of “They have asked me about the trial. I am not happy to make a decision”?
A On my own.

Q “Let us discuss it”?
A That is right.

Q Did you have a conversation along those lines, do you think?
A Basically it would go something like, “It is only to help his breathing. It is an experimental thing to help his breathing, a pressurised tank.” I may or may not have said it, and, basically, “If he needs to and is having bigger problems, he might need to go into it.” Basically, we both decided, the best as I could remember or not so much as how she was. I remember how she was. As we have said, that is when she signed it, to give him every chance.

Q You were, in the course of that discussion, satisfied in your own mind that she could understand the decisions that the two of you were going to make?
A No, I was a little bit selfish, really. If there was going to be a signature, she would be the one signing it. I would not necessarily be happy with her decision or whether she could do it. All I know is I was not going to put my name on that paper. It is a bit of a selfish attitude I know, but...

Q You wanted her to take the responsibility?
A Yes. I suppose so.

Q When you were explaining to her what you understood: you were satisfied in your own mind that you were having a conversation that she could think about?
A No, I do not think she really could.

Q Two hours after spinal anaesthetic?
A Do not forget, after the spinal anaesthetic, the pain would be coming through and she would be on drugs.

Q We can look at the drug charts and the doses. She knew you were her husband?
A Yes.

Q She knew she had given birth to a baby?
A Yes.

Q She knew she was in hospital?
A Yes.

Q And that she had a son?
A Yes.

Q You were quite satisfied that she appreciated all those things?
A In as much as she had a son and she was all right and he was struggling, but she did not seem her normal self.

Q I understand she had just given birth.
A Probably the correct way to say she was not her normal self.

MR FORDE: Mr Alcock, that has been very helpful. Thank you.
Cross-examined by MISS O’ROURKE

Q Mr Alcock, I am going also to ask you some questions. I ask them on behalf of Dr Southall, who is one of the respondents in this case. You have said it is very fair to say that your recollection may not be all it should be because it is 15 and a half years since the events in question. Could I assist you with your recollection based on notes because we have your son’s medical notes?

A Yes.

Q As you probably know, nurses and doctors tend to write things down and often they tend to time their notes. They write down things that they do. The notes I have available to me suggest that the consent that was given, and we know that is by your wife, not you, is some time after 6.15 and before nine o’clock. Your son, from the records, was born at ten-past four. It is at least two hours after, and it looks more likely that it may have been some time around eight o’clock, so three, three and a half hours after. Would you accept that as possible?

A Yes.

Q The notes we have make it very clear that the doctor who took the consent was a female doctor called Claire Stanley. Could you be wrong in your recollection that it was a male doctor?

A I could be, but I am sure it was a man.

Q Can you describe him?

A No, I cannot. To my mind, it was a man. I could be wrong.

Q The notes make it clear that it was a female doctor. She will be giving evidence and we will be able to ask her about her consent form and indeed her notes and the notes that are in the records.

A I will go with a doctor.

Q The nursing notes say that you were given some photographs and some unit leaflets in respect of this trial. It is actually recorded in the notes.

A Yes.

Q Would you accept that that may well be correct and that you could now be mistaken?

A Yes.

Q In terms of what you saw?

A Yes.

Q The notes reflect that a telephone call was made to decide which part of the trial your son would go into around about nine o’clock, and the nurses write that up in their notes, written sometime between eight o’clock and ten o’clock. So again that suggests that the consent was given and the decision was made to make the phone call and find which tank he should go into?

A I do not know about a phone call. I do not recollect any phone call.

Q What I am saying is that our records appear to suggest, therefore, it was probably
around about eight o’clock that the decision was made to consent?
A It could be.

Q The position was that your wife had had a spinal anaesthetic and had given birth at four o’clock, ten-past four?
A Yes.

B Q And so by eight o’clock in the evening, unless she had been given some opiate-type pain-killing medication, there would be no reason why she was not able to carry out conversation and understand what is being said to her?
A You could have a conversation with her, but she did not seem her normal self to me.

Q You presumably would not have allowed her to sign an important document if you thought - and you know her well - she was not fit to sign it, would you?
A If that was the case, it would not have got signed at all. I would not have signed it.

Q The fact that this got signed with both you present indicates it was a joint decision. You felt she was up to the making the decision, because I think, you fairly told us, that you told the doctor, “It is not a decision I would make alone.” You waited for your wife to come and you must have formed the judgment that she was in a fit state to make a decision in order for the decision to be made and the form to be signed, because there are two of you there. Sounds right, does it?
A All I say is I know she signed it, but in my opinion she was not what she would normally be.

Q You would have stopped her signing it. You would have said, “Lynn you are not up to it, love, we will think about it later.”
A Not necessarily. At the end of the day, if he needed to go into that tank quicker than that, would they have done it anyway? Without that signature it would not have happened.

Q He did not in fact go into the tank?
A Yes, I know he did not. We did not know that at the time.

B Q Indeed, that is because it was explained to you that it was a randomisation process. He was in a study and he could go into the tank or not go into the tank.
A I cannot remember.

Q Somebody else was going to make the decision. The doctor would make the decision. That is what you understood.
A As I understood it, basically as soon as we signed that form somebody else would make the decision, not us.

Q You understood - I think you used the word experimental - this was a study or a trial?
A Yes, I would say so.

MISS O’ROURKE: Thank you. I have no further questions.
MR FOSTER: No, thank you, sir.

Re-examined by MS SULLIVAN

Q Mr Alcock, apart from the picture of the tank that you pointed out to us, do you recollect receiving any other information?
A No, it does not mean they did not. I just cannot remember.

Q You have referred to your wife and how she was after the anaesthetic. Had she been given any other medication following the spinal anaesthetic?
A I think she had.

Q Do you know what that was?
A I do not know whether it was morphine or something like that for the pain, but I thought she had had something.

Q What was your understanding about what would happen to your son if his condition deteriorated?
A Then the doctor would make a decision to put him in a tank. They would have then made the decision whether he went into the test or whatever it was. They would have made the decision and would have done it.

MS SULLIVAN: I have no further questions.

Questioned by THE PANEL

DR SHELDON: Good morning, sir. I appreciate that it is a long time ago. Like the others, I will say the same. If you cannot remember, please say so. First of all, how early was your baby?
A I think it was eight weeks.

Q When he was taken up into the neonatal unit, he was put into an incubator?
A He was put in one when I got up there. I did not go up straightaway.

Q How long stay did he stay the incubator?
A Best part of a week, might be longer.

Q Did you notice anything attached to that incubator, any notice of any sort?
A No, only his notes. The only things that was attached to him was his pipes and bleepers.

DR OKITIKPI: Good morning. I wanted to check, when you spoke to the doctor about the study and then you said your wife came in a wheelchair, then you explained to your wife about the study so you could make a decision, was the doctor standing next to you during that period?
A That is a good question. I do not know. I cannot remember whether he spoke to her or not. I know that he was with us.

Q You cannot remember whether the doctor gave your wife information about the study, or was it just you who spoke to your wife?
A I am not wrong. While I have been sitting here, I am not wrong. I did speak to a
male doctor. Whether the doctor signed a consent form or not, or whoever signed it or not, I do not know, but I know I spoke to a male doctor. Whether that doctor spoke to the wife or whether I relayed the information - I think actually I spoke to the wife rather than the doctor.

DR OKITIKPI: Thank you.

THE CHAIRMAN: I have one thing I would appreciate your assistance on, if you can remember. Again, along with everyone else, I appreciate that it was a long time ago. When Miss O’Rourke was asking you questions, you indicated you understood that once the consent form had been signed that the decision whether your son went into the CNEP tank was going to be taken by somebody else.

A I would assume that, yes, I would say yes. Once that signature is given it would have been out of our hands as to when he needed to go in it or if he needed to go in it.

Q Right. That is what I wanted to ask you about. So far as the decision which you understood was going to be made by someone else, what was your understanding as to the basis on which that decision would be made?

A I would - I cannot remember, what I would do is assume that his condition and his breathing had deteriorated, that is when the decision would be made.

Q So looking back over this length of time, your assumption is ...

A This is an assumption.

Q ... a decision would be made based on your son’s condition?

A Yes.

THE CHAIRMAN: Thank you very much indeed. Any questions arising?

Further cross-examined by MISS O’ROURKE

Q Sir, two. Firstly, on that last one you say you assumed. No one told you that that would be the situation. I am going to suggest that what you were told - and it may be you do not remember - what you were told is that once you consented to the trial, there were two parts to it and somebody else would be making a decision which part your son went into.

A I cannot remember that bit.

Q But it was not told to you that it depended on his condition deteriorating. You have used the word in answer ---

A I cannot remember actually anybody saying to me, “This is when we will make the decision”.

Q Secondly, in answer to the question as to - you said, “I know I definitely spoke to a male doctor”, and then you think you may have relayed the information to your wife. Can you just confirm were you present when your wife signed the form?

A Yes.

Q Right. Then I am going to suggest to you, if you were present when she signed the form, it was a female doctor who was standing with her with the form and who also
signed the form, and it was a female doctor who gave her an explanation before she did sign.
A  No.

Q  That is what ---
A  I distinctly remember - there might have been a female doctor there but I distinctly remember the explanations came from the male doctor, not the female doctor.

Q  Could it be that you had explanations from a male doctor and then a female doctor explained it to your wife and witnessed your wife’s signature and signed the form herself?
A  She might have been there to see her sign, but I do not remember any doctor talking to the wife. I know I said, “It is an experimental thing. This is what they want you to do”.

Q  We are going to hear from the female doctor and if she says that she would have, before signing that form, spoken to your wife and explained it, otherwise she would not have signed the form, would you accept that and say your recollection may well be faulty?
A  Yes.

MISS O’ROURKE: Thank you.
A  I still say it was a male doctor I spoke to.

THE CHAIRMAN: Ms Sullivan?

MS SULLIVAN: No, thank you.

THE CHAIRMAN: Mr Alcock, thank you very much indeed for coming this morning and for the assistance you have given the Panel. That completes your evidence this morning. You are now free to leave the chair. You can stay in the room if you wish to or you are free to go.

THE WITNESS: Thank you.

(The witness withdrew)

MR FORDE: Sir, just before the next witness is called, arising out of Dr Sheldon’s questioning, the information we have suggests that the last witness’s son was born at a gestation of 32 weeks. He weighed 1,730g. He was ventilated for two days and was on oxygen for four days and he was discharged on 16 December 1992.

MISS O’ROURKE: Sir, just to further my point, the notes are available. You have not been provided with them. You will know that I had them when I asked this witness questions. There are nursing notes that confirmed the timings of CNEP being taken, the timing of the randomisation call and, indeed, there is a nursing note to the effect of photos and leaflets given to parents.
Sir, I think it may be material that you have copies, at the very least, of those pages. Indeed, sir, it may well be, I do not know, whether Dr Sheldon or some other member wants to look at the full notes because I think for each of these patients the notes are available. They have not been given to you to overburden the bundle. It may well be that the Panel wants to have one copy of them just to have somebody look through because there is material in it.

Sir, can I just add this: we understand Mrs Alcock is coming, but probably some time next week. There seems to have been some suggestion she was given some drug that may have put her out of it. If that is going to be part of her evidence, I, for one, would like to see her notes. We have had the child’s notes provided to us, but we have not had her notes. Because it would not be our understanding - and I am sure it will not be Claire Stanley’s evidence - this woman was drugged and out of it, and so we need to see the notes, as we had with Mrs Henshall where we were able to establish a very small therapeutic dose of morphine and the timing of it.

If Ms Sullivan is going to have Mrs Alcock called next week, can we please have Mrs Alcock’s maternity notes before she is?

THE CHAIRMAN: Ms Sullivan, a few requests there. There is the suggestion that - I mean, obviously at the moment we have heard what Mr Alcock had to say and his impression of how his wife was, but I think the request which is made there is a reasonable one.

MS SULLIVAN: Yes.

THE CHAIRMAN: I suppose that particularly where there may be issues of recollection - which clearly there are in Mr Alcock’s case - of who he was speaking to, that having the notes for the children available I think probably would be helpful. It probably would, as Miss O’Rourke suggests, be sensible if the Panel did have a copy of them so that we could refer to them.

MS SULLIVAN: Yes, sir. We did not want to overburden you, as you have heard.

THE CHAIRMAN: I appreciate that.

MS SULLIVAN: But if the Panel would like one copy or would you like to have more than one copy?

THE CHAIRMAN: The suggestion at the moment is a copy. I think in some ways this is largely dictated by what happens when the relevant medical staff are giving evidence because if it becomes necessary to have great reliance on the notes to the point where it becomes difficult to follow through explanation as to what they are talking about, then at that point I think it becomes helpful for the Panel to have access to the notes. It may be a judgment which you make in terms of organising a copy. We certainly would be quite happy for us all to have a copy of these notes as a separate bundle.

MS SULLIVAN: Yes, perhaps I might discuss that with my learned friends. I was
wondering, sir, in the light of the request that had been made, it is probably best that they are put in train sooner rather than later. I wonder whether it might be appropriate to have a break at this point so that I could deal with that. Certainly we have one more parent to call today, but I think she was not scheduled to be here until eleven. I have other witnesses here if you want me to go on and call other witnesses now; it is not a problem.

MISS O’ROURKE: Sir, I would rather that we called the parent before one of the other witnesses because the next parent, the consent is taken by one of the doctors who is going to come after, so I want Dr Arya to come after Mrs Shufflebotham. I certainly do not want Dr Arya next because Mrs Shufflebotham, I anticipate, is going to say, “I do not remember the consent” and whatever. We are going to actually then hear from the doctor who took and signed the form. It is important we have them that way around so that we know exactly what is said. The only other witness that I would think Ms Sullivan could call now ahead of the parent would be Janet Wakefield, if she was here.

MS SULLIVAN: Yes, I can see the logic in that.

THE CHAIRMAN: Yes, I think that is both a matter of logic and reason that the witnesses should be called in that order. The other witness you are proposing to call is?

MS SULLIVAN: It is Janet Wakefield.

THE CHAIRMAN: How long do you anticipate she would take?

MS SULLIVAN: I do not really know how long cross-examination is going to be. That is my problem.

MISS O’ROURKE: I can say this: if Ms Sullivan elicits from that witness everything that is in her evidence in-chief, I will not need to ask her any questions; she will have answered everything I need. If it is not all asked, then I will have to ask it to bring it out.

MR FORDE: Five to ten minutes for me, sir.

MR FOSTER: I am happy for the statement to be read, sir.

MISS O’ROURKE: Indeed, sir, I would be happy for the statement to be read as well. That is why I say if everything she says in the statement comes out I do not need to ask her any questions.

THE CHAIRMAN: I will leave that to your judgment, Ms Sullivan.

MS SULLIVAN: It would have been nice to have known that before.

THE CHAIRMAN: I thought you might say that, but I was not going to make any comment. I am just relating this to the conversation we had yesterday about finishing time today, that it might be I think sensible to call Nurse Wakefield now.

MS SULLIVAN: Yes.
THE CHAIRMAN: Then we will have a break. That will probably coincide with the time when your next witness, Ms Shufflebotham, is here.

MS SULLIVAN: Yes.

THE CHAIRMAN: We would ordinarily be looking to have a break about eleven o’clock anyway.

MS SULLIVAN: Certainly. I will call Janet Wakefield.

JANET WAKEFIELD, sworn
Examined by MS SULLIVAN

Q Good morning. Is it Miss or Mrs Wakefield?
A Missus.

Q Mrs Wakefield, would you mind just starting with your full names, please?
A Janet Wakefield.

Q Mrs Wakefield, I think you qualified as a midwife in 1978. Is that right?
A That is right, yes.

Q Was that at North Staffordshire Hospital?
A Yes.

Q Have you worked there since that time?
A Yes. I became a sister on the neonatal unit I think it was 1987. Then I was a clinical teacher, and then in 1991 I became clinical nurse specialist.

Q When you became clinical nurse specialist, was that on the neonatal unit?
A Yes.

Q For how long did you remain in that position?
A About three years until I became senior nurse manager.

Q So in the early 1990s, you were a clinical nurse specialist?
A Yes.

Q I want to ask you, as I think you know, about the CNEP trial. Do you remember that?
A Yes.

Q Were you involved with it in a nursing capacity throughout the time it was in operation at North Staffordshire or not?
A I would have been involved until early 1994 when I became senior nurse manager and then moved away from the unit.

Q I want you to cast your mind back, if you would not mind, to just before the start
of the trial on the neonatal unit. Did you meet Dr Southall at all prior to the commencement of the trial?
A Yes, he came to the unit regularly.

Q When you say regularly, can you give us some idea of how much he came?
A No, I cannot remember. I cannot remember how often.

Q What about Dr Samuels? Did he come to the unit?
A Yes, he did.

Q How often did he come? How would you describe that?
A I do not know specifically how often. I am just - I can recall that they did come to the unit.

Q Yes. Was he there as much as Dr Southall or not?
A I really could not say.

Q When they did come to the unit, what were they coming to do?
A I do recall that we had sessions in the seminar room on the neonatal unit. Groups of staff were invited to talk about the trial, express any concerns that they had. That is one thing that I do vividly remember.

Q So you were able to ask questions about the trial, by the sounds of it?
A Yeah.

Q As far as the nurses were concerned, was anyone appointed to assist specifically with the trial?
A Yes, a research nurse was appointed, called Theresa Wright.

Q So were you involved in training the nurses for the trial in any way?
A No.

Q Did you receive any training from anyone about the trial?
A Yes. I do recall that there was a tank that was set up in the seminar room with a doll in it, and that was used to teach the nurses how to prepare the baby, if the baby needed to go into the CNEP tank.

Q Apart from that, do you recall any other training?
A I remember attending a session in the large classroom at the maternity hospital, and that was given by Theresa.

Q Yes. Was there any material in the unit itself to assist with the CNEP tanks?
A I recall that there was a manual available on the unit.

Q Was that a manual for staff or for others?
A For staff.

Q Now, we have talked about Dr Southall and Dr Samuels. You obviously know Dr Spencer as well, Mrs Wakefield. To what extent was he involved in setting up the
trial that you were aware of?
A Well, Dr Spencer was based on the unit. I do recall that he did work closely with Theresa.

Q Now, I would like to just ask you a little about the consenting process. Were you, as a nurse, involved in taking consents from patients at all?
A No.

Q Were any of the nurses involved in the consenting process?
A Not that I am aware.

Q What about Theresa Wright?
A Theresa, I do not think, was involved in the consenting process.

Q Your understanding was that consent was taken by whom?
A By doctors.

Q When you say doctors, was it doctors of any particular seniority or what was the position?
A I cannot recall that level of detail.

Q Do not worry. If you cannot remember at any stage, just say so, Mrs Wakefield. You have told us that you were not involved in the consenting process, but do you recall what happened if a baby was going to be considered for the trial, what the process was?
A The baby had to meet a certain criteria at a certain age. If that happened, the parents would be spoken to by a doctor to ask for consent for the trial.

Q Once consent had been obtained, what was the next stage in the process?
A Once consent had been obtained, then randomisation would take place.

Q Were you ever involved in making a call in order to set about the randomisation process?
A My statement shows that I was.

Q Yes. I think if we just have a look, you will be handed file 1, tab 3, page 369. Just turning it on its side there, Mrs Wakefield, I think you have seen this before, been shown it before?
A Yes, I have.

Q If we look at the dates on the left-hand column, 14 February 1991, which is the bottom of the second box of the dates there, do we see a reference to your name as the caller, “Janet Wakefield” there?
A Yes.

Q It seems that you made a call at about quarter-past seven in the evening and that this particular baby was randomised to standard treatment.
A Yes, that is right.

Q I think I am right in saying that that is the only occasion that we see your name

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there, Mrs Wakefield.
A  Yes, on that page.

Q  Just on that page?
A  Yes.

Q  So it seems on that occasion you would have made a call. To whom would you have made your call?
A  It was Martin Samuels.

Q  So we can see that again from the column “Answered by”?
A  Yes.

Q  As far as your understanding of the process was concerned, obviously you spoke to Dr Samuels. How many doctors were involved in the process of randomising the children?
A  I really could not say.

Q  We will find that out from others. I think we see on that page two sets of initials, on the page that we are looking at there for calls, “Answered by,” and we see the initials “MPS,” who you said are Dr Samuels’ on a number of occasions. I think there is probably no dispute.

MISS O’ROURKE: Sir, there is no dispute. There were only two doctors involved in the randomisation process, either Dr Southall or Dr Samuels. You see the initials are either DPS or MPS.

MS SULLIVAN: Yes, thank you very much.

Q  There we are, there is no dispute about that, Mrs Wakefield, it was either Dr Southall or Dr Samuels. Can you recall what the process would have been when you made such a call to Dr Samuels? What sort of discussion would there have been?
A  He would have asked about the baby’s condition, would have asked questions like what level of oxygen, apart from that, I cannot remember.

Q  Cannot remember how the process worked?
A  No. I mean, it is 17 years ago.

Q  As I said, if you cannot remember, just say so. Now, we know that babies were either randomised to standard or CNEP treatment. Had you been involved with CNEP tanks before this trial began?
A  Yes. The tanks had been used on the unit before.

Q  As far as the CNEP tanks were concerned, were there any practical difficulties in nursing with CNEP tanks as opposed to standard incubators?
A  The tanks had cuffs around the portholes. Sometimes, initially, it would be difficult to manoeuvre inside the tank in terms of caring for the baby, but, with experience, that obviously improved.
Q Was there any more work involved with the CNEP tank rather than a normal incubator?
A In terms of preparation of the baby, the babies wore like a stocking net vest and a neck protection, and that was put on before the babies went into the tank.

Q Yes. Do you remember when they became requirements for the CNEP tank, the use of the vests?
A It was from the beginning.

Q What about the baby’s neck? Was there any protection for the baby’s neck?
A A gel-like substance called Spenco was used.

Q Can you remember when that started being used?
A My recollection is that it was always used, certainly with the babies that I cared for.

Q Yes. You obviously cared for a number of babies on the unit. How many members of staff were there on the unit? Perhaps give an indication of its size?
A There were three rooms. The first room was the - I cannot remember now - I think it was the high dependency room, and the middle room was the intensive care room and there was a smaller room at the end with just six cots and that was for babies who were just feeding and growing.

Q Where were the babies who were part of the trial?
A Usually in room 2.

Q Room 2 being?
A The intensive care.

Q So they would be in there. How many incubators would there be in there?
A Between six and eight.

Q How many nurses would there be covering those six to eight?
A Well, if a baby was receiving intensive care, it would be one to one.

Q Would the baby have a named nurse?
A Yes, for the whole of the shift.

Q Now, you were involved in the care of the babies Mrs Wakefield, but as far as the trial was concerned, did you complete any paperwork in relation to the trial?
A Only in terms of regular observations of the babies.

Q Yes, which would go into the normal nursing notes, presumably?
A Yes, but no trial information.

Q So no trial information was entered by you on any particular forms relating to the trial?
A No, no.
Q Can you remember who had that job?
A Theresa had that job.

Q I think you indicated earlier that as far as training was concerned, you were not involved in any training?
A I was not involved in delivering the training, no.

Q Did anyone else come to assist at any stage with the trial, in terms of nursing?
A There was a nurse, Kate Lockyer, who was involved, but as I have said previously in my statement, I cannot remember at what point she became involved or what her specific role.

Q Or why she came. Can you remember that?
A No.

Q Now, as far as the tanks themselves are concerned, you have described how there was work involved prior to the baby being placed in the tank. Once the baby was in the tank, were there any particular problems with the tanks that you can recall?
A I recall that at some point there was a problem with temperature control.

Q Yes. And ---
A And this was modified and improved.

MR FOSTER: I just wonder, rhetorically, to what head of charge all this goes?

MS SULLIVAN: I thought I had been told earlier I could read this statement so I did not think for a minute there was going to be any objection.

MR FOSTER: It is taking up a good deal more time now than just reading it out would do.

MS SULLIVAN: I am not asking anything that is not in it, as my learned friends can see.

THE LEGAL ASSESSOR: I think that is right, I think Mr Foster is merely indicating perhaps that more of it could be led by leading questions.

MR FORDE: I am not sure that he necessarily is. I am concerned that an impression may be sort to be created of general difficulties unspecific with CNEP tanks. I do not think it is fair that these doctors should be facing allegations outside of those that are charged. Like Mr Foster I do not see any charge relating to problems with temperature control.

THE CHAIRMAN: I suppose the difficulty is that Miss O’Rourke’s position was that she was wanting --- her position providing --- we do not know what was in the statement---

MR FORDE: That may have been her position but as you will be aware, sir, we are quite content for relevant evidence to be led in relation to the charges. Anything else is extraneous and we would say irrelevant.
MISS O’ROURKE: Sir, I had no problem with it being read because, of course, it is a bit more full than the answers that are given verbally. I had indicated that if everything that was in the statement was elicited I would not need to ask any questions. Unfortunately it is not all being elicited. It may be that Ms Sullivan is asking the right questions but it is not coming out as fully in part because she is not leading, she is asking it in more general terms. That is why I indicated I would prefer it to effectively be read. Yes, this witness does deal with how there were things that needed to be looked at but she also deals with how they were all overcome and it was sorted. I do not have any problem with it being elicited provided it is elicited in full because it then makes clear this was a trial where they were working to solve anything that needed to be done as you would expect to be done in medicine and they were considering, they were thinking about it and it was, therefore, a very well run trial. It is not coming that way in part because of the way the questions are asked. That is why I go back to what I say; I would be entirely happy for it to be read, (a), it would be quicker, and, (b), we would have the totality. At the moment I am now going to have to ask four or five questions which are likely to involve me reading to the witness parts of her statement because it has not come out.

MS SULLIVAN: All it needs is for someone to indicate to us beforehand whether statements can be read and whether there is any objection to anything within them and then we can consider the position.

MISS O’ROURKE: Mr Foster and I both said before this witness got in the witness box that we would be happy for it to be read.

MS SULLIVAN: Just as the she came into the room.

THE CHAIRMAN: We are in a position where the witness is in the witness box. I think probably this is an invitation, if I can put it that way, from those representing the doctors is that, unless Mr Forde takes a different view, that you can effectively lead this witness very quickly through effectively what she has said in her statement.

MR FOSTER: Absolutely, sir, lead it all but all means all, please.

MISS O’ROURKE: All means all.

MS SULLIVAN: I am going to lead all that is admissible.

MS SULLIVAN: I am sorry, Mrs Wakefield.

A That is fine.

Q We were I think just mentioning temperature. I think you have recalled that there was a problem with the temperature in the tank but you are of the view that keeping very tiny babies warm is always a problem?

A Yes.

Q You were also asked if you remembered how the babies were nursed and whether they had to have a towel or nappy between their legs to keep their heads towards the head of the tank?
A: Yes, I do, I do remember that the babies did wear sort of, well, nappies at first but then Theresa made some harnesses for the babies.

Q: You described how one of the difficulties with the tanks was that the pressure would be lost as soon as the port holes were opened?
A: Yes, and I also said that with experience this improved.

B: Q: Yes, there was a cuff, you say, to maintain the seal where you put your arms?
A: Yes.

Q: Your view, I think, was that you soon became used to it?
A: Yes.

C: Q: But it was difficult to manoeuvre within the tank at first?
A: At first.

Q: You were also asked if you remembered any problems with the babies’ necks?
A: I do not recall any problems specifically at Stoke.

Q: That is right but you seem to remember something about an incident of neck trauma at Queen Charlotte’s Hospital?
A: Yes, but I do not recall the detail.

D: Q: That is right. You say that the babies had to have a jelly like protection around their necks, you have already mentioned Spenco gel?
A: Yes, yes.

E: Q: But you did not think that was due to any particular problems with the neck?
A: No, not at Stoke. It was to protect the neck.

Q: It was to protect the neck?
A: Yes.

Q: You have been asked as well how the babies received phototherapy when they were wearing a vest but you could not recall how that was achieved?
A: No, but since then I remember that the units were just pushed over the tank so that the light was above the tank.

Q: I think you were shown a copy of a parental leaflet?
A: Yes.

G: Q: Which we have got in our bundles. I am not going to ask you to look at it now but you believed that that was the leaflet that the doctors used when taking consent?
A: Yes.

Q: I think you, in fact, indicated you were not present when consent was taken, was that right?
A: I was not involved but I was aware that discussions were taking place between parents and doctors on the unit and in the room.
Q You were recall Theresa Wright making up packs for each baby with the charts and other documentation for the purposes of the trial?
A Yes.

Q And that that leaflet would be included, you say, in that?
A Yes.

Q You also looked at an information booklet for parents and you recall that document?
A Yes. I seem to remember an album with photographs in as well.

Q Do you know when those came into existence?
A I cannot recall specifically.

Q Where they were kept?

MR FORDE: I am happy for you to lead paragraph 14.

MISS O’ROURKE: Yes, lead it all.

MS SULLIVAN: You cannot remember?
A I cannot remember specifically, I know that they were there.

Q There was also a manual, I think, for staff on the ward, is that right?
A Yes.

Q You have, I think, is that right, no recollection of Mr and Mrs Henshall?
A No.

Q Or their second baby?
A No.

MS SULLIVAN: If you wait there, there may be some more questions.

Cross-examined by MR FORDE

Q Mrs Wakefield, I act for Dr Spencer and I will ask questions on his behalf, if I may. I want to ask about the unit in general. You and your nursing colleagues were responsible for some of the sickest children in the hospital?
A Yes.

Q Is that fair?
A Yes.

Q You were all highly skilled, well trained and conscientious so far as your duties were concerned, is that correct?
A Yes.
Q Among your duties would be the constant monitoring of these neonates?
A Yes.

Q You all knew that to be your responsibility?
A Yes.

Q We have got examples in the nursing notes, which I will not take you to, but as an experienced nurse, you tell us you qualified in 1978?
A Yes.

Q You knew, as did the rest of the nursing team, that you had to monitor vital signs?
A Yes.

Q So blood pressure?
A Yes.

Q Saturation levels?
A Yes.

Q Fluid balance?
A Yes.

Q Haematology, if need be?
A Yes.

Q The umbilical arterial catheter once appropriately sited would that give regular readings of blood pressure?
A Yes, it would give continuous reading of blood pressure and percentage of oxygen in the baby’s blood as well.

Q And in an ideal world those readings would be recorded at fairly regular intervals?
A I think it was hourly.

Q What about blood gases? How often were the nurses supposed to record those in the notes?
A I cannot remember how often the blood gases had to be done but the results obviously would need to be recorded in the notes.

Q But, again, would you agree with me that the actual recording in the notes was primarily a nursing responsibility; it was something that nurses would do?
A The recording of the blood gas?
A Yes.
A It could be either.

Q Nurses or doctors?
A Yes.

Q I think what Dr Spencer is saying to me and I want to see if you agree with this,
the nurses would write them on the chart and the doctors would put them in the notes?
A    Yes, yes, that is right.

Q    Is that the proper division of labour?
A    Yes.

Q    As far as the CNEP trial was concerned you say in your witness statement that prior to the commencement Dr Southall and Dr Samuels spent a lot of time introducing the trial to the unit?
A    Yes.

Q    Before you even started, as I understand it, you had meetings in the seminar room involving all the nursing staff?
A    Those that could be there. Those that were on duty.

Q    Then the junior doctors, would they attend as well?
A    Yes.

Q    You say in your statement that the seminars enabled staff to ask questions and clarify any points that arose?
A    Yes, they did.

Q    Again, when you work in a neonatal unit you has a nurse have to be satisfied that you can deal with parental concerns. Is that fair?
A    Yes.

Q    You had to deal with extremely concerned parents who are worried about the life of their child?
A    Yes.

Q    You regarded it, do you not, as part of your professional duty to be in a position to answer questions and queries from parents?
A    Yes.

Q    So far as you can recall, is this correct, the nursing staff would have familiarised themselves with the training manuals?
A    Yes.

Q    The patient information sheets and have been in a position to explain in simple terms, not necessarily medical terms, to parents how CNEP was working?
A    Yes.

Q    Do you recall this being placed upon cots?
A    Yes, I do.

Q    It is a diagram of a teddy-bear and it says “I am in the CNEP trial receiving standard therapy”?
A    Yes, I remember that.
That would be on the incubators where people were getting IPPV?
A Yes.

You under understood the difference, did you, between IPPV and CNEP?
A Yes.

You were in a position to explain that to parents if they wanted an explanation?
A Yes.

Was it correct that sometimes patients received both? They would get a bit of IPPV, a bit of CNEP as you monitored the condition?
A Let me just think about that.

If you cannot remember do say.
A I just cannot remember that specifically.

That is fine. “Trial” writ large on the cot. Everybody knew, did they not, within the unit that involvement with CNEP was a trial?
A Yes.

Everybody new that they had to phone Dr Southall or Dr Samuels for randomisation? You all knew that?
A Yes.

Would you agree with me, it is inconceivable that any parent would not realise that you were running a trial? Just the appearance of what was there to be seen with the tank and the notices and the information?
A Yes, yes.

Would you agree with that? You tell us that the photographs were available. I wanted ask you a little bit about that. I think there was, according to your witness statement, an A4 folder is what you say with photographs of the tanks?
A I am not sure that it was an A4 folder but there was a folder or an album with photographs in.

Was that something that you were accustomed to showing to parents if they wanted to see how things worked?
A I do not recall specifically myself showing it to parents.

I will read what you say.
A You say:

(Document not available to shorthand writers)

“I have been shown a document entitled Negative Pressure Trial Information booklet for parents.”

And we are all familiar with it now.
“I do recall this document, although I cannot remember now whether it was within an A-4 ring binder on the unit or if there were copies available to be given to the parents. There was also a photo album that would be taken to the labour unit to show parents what their children would look like if they were entered into a CNEP tank.”

A   Yes.

B   Q   So that would be prior to randomisation, you could say this is what the appearance will be?

A   Yes.

Q   Then you say this:

   “I have been shown a further document which I believe is the instruction manual prepared by Teresa Wright for staff.”

C   You do not recall the flow chart specifically, and we can circulate it later, but there were decisions to be made at certain points, two hours and four hours and telephone calls. That was all set out in a flow chart so people knew what they had to do.

A   Yes.

D   Q   You knew about the existence of the bonding questionnaire. The parents were asked how things had worked out?

A   Yes.

Q   Is it right that the surfactant was given to all children at a certain time, whether they were in or outwith the trial?

A   I think it actually came in part way through the trial.

E   Q   Absolutely right. Your memory is excellent as far as that is concerned. You described Teresa Wright in this way:

   “Teresa was always meticulous in her record-keeping and organisation”.

F   Do you stand by that view?

A   Yes, I shared an office with her.

Q   “She prepared a folder for each patient in the study.”

G   Is that right?

A   Yes, she did.

Q   Did the folder contain the information sheet and the single booklet?

A   Can you read that again?

Q   You say this, and you can be shown your statement if needs be:

   “I would also agree with Dr Southall’s response to the comments on nursing

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expertise. He describes the dedicated folder produced by Teresa for each patient in the study that I have referred to in paragraph 13 above."

We go back to that. What you exhibit is a parents leaflet which you describe as,

“...the parental information leaflet that the doctors would use when taking consents from parents. Teresa made up packs for each baby with the charts and other documentation”.

This leaflet would be included?
A That is right, yes.

Q You are quite certain of that, are you?
A Yes.

Q It would have the consent form in it as well? Signed by the parent. Do you recall that?
A The signed one?

Q No, a blank one in the pack?
A Yes.

Q And then there would be a signed one later?
A I remember there being the blank ones. I cannot say for certain where the signed ones would be.

Q The pack would comprise the information booklet and a blank consent form. That is what you would expect to be given to parents?
A Yes.

Q Do you recall that some parents did not agree to go into the trial, so they were given an option?
A I know that parents were given an option, and I am aware that certainly one set of parents withdrew.

Q They could withdraw part way through if they wanted to?
A Yes.

Q I am going to ask you a little about the neck because you gave some evidence that the entirety of your witness statement was not put to you. You say this:

“The main difference between CNEP and conventional treatment was that the baby had to be prepared before being placed in a CNEP tank. We would have to put a special vest on the baby and protection around the baby’s neck prior to the baby being placed in the CNEP tank. As far as I remember the vest and neck protection were requirements from the outset of the trial. The instruction booklet prepared by Teresa included details of how to prepare the baby. She also provided us with training on this prior to commencement of the trial.”
A

Is that correct?
A Yes. And, as I said before, there was also a tank set up with a doll so that nurses could ...

Q So you could practise, as it were?
A Yes.

B

Q You have exhibited some documents dealing with a stockinet vest, sizing of latex, thin latex for CNEP only and you have also helpfully told us about the special gel you put around the neck to prevent any difficulty with the neck seal?
A Yes.

Q That was something I suggest as nursing staff you were very keen to monitor, to ensure there was no damage to the neck. Is that fair?
A Yes, in fact I think that one of the sets of observations that were done regularly included inspection of the neck.

Q In addition to vital signs and more conventional observations, with CNEP babies you think there was a specific task in relation to observation of the neck?
A Yes.

Q We are not aware of any problems with the neck at North Staffordshire. Can you recall there being any difficulties?
A No, I do not recall.

MR FORDE: Mrs Wakefield, that is very helpful. Thank you.

Cross-examined by MISS O’ROURKE

Q Mrs Wakefield, I ask questions on behalf of Dr Southall. I only have a few extra questions because Mr Forde has obviously asked you many of the important ones. Firstly, you indicated that Dr Southall came regularly to the unit before the trial commenced. I am going to suggest that that was for the purpose of familiarising the staff and people on the unit with the concept of the trial, with how it would work, with various processes, and he was available to give advice, training, answer questions, et cetera.
A Yes.

Q When you say he came regularly, he made sure before the trial started that all the staff were fully appraised, fully trained and fully informed. And if they needed to know anything else they could ask?
A Yes.

Q He was also available at the end of the phone line because of course he was one of the people phoned for randomisation purposes?
A Yes.

Q Did you, as a consequence when you started working with babies in the trial, feel you were well trained, well informed and well supported?
A Yes.
Q: And did you feel that throughout the trial - that you were informed, trained and supported? In other words, you were not getting into any difficulty?

A: No.

Q: I think that you effectively say so in our statement because there were issues about whether nurses were trained and had sufficient knowledge. You say in paragraph 16:

“I always felt comfortable that I had sufficient knowledge of the CNEP tanks to care for the babies in them.”

A: If not, Teresa was always available for advice.

Q: Would you say that the other nurses you worked with and who were nursing babies in CNEP felt the same?

A: My recollection is that they did.

Q: You then mentioned Teresa, and you said she was appointed as research nurse. In your statement you say in paragraph 3:

“She provided ongoing training sessions”?

A: Yes.

Q: So it was not just at the outset; you trained as you went along?

A: No, it was on an ongoing basis. Obviously you have new staff coming in.

Q: You also said in the same paragraph:

“There were guides on how to prepare the equipment and the baby”.

A: Yes.

Q: So the staff had not just Teresa available to answer questions and provide training but they had documentary material to which they could refer.

A: Yes.

Q: Although there were new staff coming, there would always be staff there who had already worked with it?

A: Yes.

Q: Could I ask you about the randomisation process? You indicated that a telephone was made. Can I remind you of what you said in your statement and see if you agree with it.

“Once the call was made either Dr Southall or Dr Samuels would have a box of cards in sealed envelopes. They would open one of the envelopes when they received a call and then they would determine which treatment the baby would receive based on what was on the card”.

D14/43
A  Yes.

Q  So it was a randomisation process where it was not them deciding themselves, this will go into one and this into another. They were drawing lots effectively?
A  That was something that we went through in sessions.

B  So you were made aware of how that worked?
A  Yes.

Q  In terms of the randomisation, if there was any suggestion that parents when they were consented were told which side of the trial they would go into, what would you say about that?
A  Could you repeat the question?

C  If there was a suggestion that the parents were told at the time of consent “Your child will definitely receive CNEP”, would that be right or was the consent always obtained prior to calling and the randomisation went after?
A  Consent was always obtained. Otherwise there would be no point in randomisation.

D  So it just did not happen that parents were told, you are definitely getting CNEP, before consent?
A  Not to my knowledge, no.

Q  CNEP had been used in North Staffordshire prior to this trial, had it?
A  Yes, it had.

E  It was not a new technique even to this hospital?
A  No.

Q  And the staff on this neonatal unit had nursed babies in CNEP tanks before and they were not new devices as far as the staff were concerned?
A  I think they were slightly improved on the first ones we used, but they had used them before.

F  And it might have been slightly younger babies as well?
A  I think it was slightly older.

Q  No, older babies had used them before, and now you were using them for younger ones. That is what was different?
A  Yes.

G  Can I ask you this briefly about the neck seal? You indicated something about a problem at Queen Charlottes. Did you ever see that tank?
A  No.

H  Do you know if it was in fact even the same neck seal or the same tank?
A  No.
MISS O’ROURKE: Thank you.

Cross-examined by MR FOSTER

Q I have one question about the randomisation. You ring up, you speak to Dr Southall or Dr Samuels. You have mentioned that sometimes they would ask you questions. Those questions were directed solely to determining whether or not the child in question met the exclusion criteria, or, to put it another way, the trial criteria?
A Yes.

Q There was never any clinical advice given over the phone by those two doctors?
A No.

MR FOSTER: Thank you.

MS SULLIVAN: I have no re-examination.

Questioned by THE PANEL

DR SHELDON: Good morning.
A Hello.

Q I am a GP, and it must be 40 years since I was in a neonatal unit. I would like your help to paint a bit of a picture. You have told us there were the three rooms. The nursing station presumably was in the middle?
A It was outside the rooms, on the corridor.

Q Was there a doctors’ room?
A There was a sitting room that the doctors used.

Q Were the medical records all kept at the nursing station?
A Yes. You mean the medical notes?

Q Did you have a trolley with the notes?
A There was a notes trolley.

Q And the nursing record was always kept separately, was it, from the notes?
A Yes, because it was needed by the bedside regularly to record observations and results.

Q So throughout the stay in the unit, were the nursing notes always separate from the medical notes?
A Yes.

Q On the incubator there would be another clipboard or somewhere where the actual observations were made?
A Yes.
Q So the notes were in three different places while the baby was on the ward?
A No, sorry. The medical notes would be in the medical notes trolley. The clipboard and the nursing notes were in the same place on the incubator.

Q So if a nurse wanted to write in the nursing record she would go to the incubator, take down the chart and write on that board.
A Yes.

Q And things like blood pressures and temperature charts were all kept on the clipboard?
A Yes.

Q Though throughout the stay in the unit?
A Yes.

Q Then what happened at the end when the child moved on somewhere else?
A If the child was in the unit for, say, eight weeks, it might be that at some point some of the charts would get put into the notes because obviously you would end up with a big bundle on the clipboard.

Q Whose job was it to do that, to put all the notes together either when the child moved on...?
A At the end of the stay?
Q Yes.
A There was a ward clerk on the unit.

Q So his job was to look after all the records and the notes?
A Yes, but for the purpose of the trial Teresa had that role.

Q In the CNEP babies Teresa acted like the ward clerk and put all the records together?
A I think she did at the end before the babies actually went.

Q And checked that everything was there?
A Yes.

Q That was her responsibility?
A Yes.

Q I am right that in December 1992 you were on the ward during that time period?
A Yes.

Q So you are aware of exactly what was happening in that time period?
A In December 1992?
Q Yes?
A I do not remember specifically what was happening.
Q It was just you said you had been a sister, and then you became...?

Q Yes. Then you were on the ward as a clinical nurse specialist?
A Yes.

Q So, around that time - I am not saying you were there in December - you were working on the ward at that time?
A Yes.

Q So you were aware of the exact procedures that were going on at that particular time?
A Yes.

Q Can I ask about the doctors? What sort of medical cover was there for the unit?
A I cannot recall specifically the level of medical cover.

Q Let us start at the top. Dr Spencer was responsible for the whole unit, was he?
A There were two consultants at that time: Dr Spencer and Dr Brookfield.

Q So they share? They would take half and half, would they?
A Yes.

Q So on-call, was one on-call ---
A They did on-call. There were registrars on-call. There were junior doctors actually available on the unit.

Q That is what I was trying to get at. There was a junior doctor always on the unit or responsible for the unit?
A I just cannot remember the specific details. All I can recall is that there was never any problem getting medical input and there were doctors around. As to the specifics, levels and numbers, I do not remember that.

Q The chances are that most of these medical firms would have a senior type of registrar?
A Yes.

Q And a junior doctor at least ...
A Yes.

Q ... available all the time?
A Yes, definitely.

Q The nursing staff, if there was any worry, would be able to call the doctor?
A Yes.

Q That doctor would be able to call his senior?
A Yes.
DR SHELDON: I think that is all. Thank you very much.

MRS BRICKLEY: Apart from the extra observation of perhaps the neck in the CNEP trial, were generally the babies, the CNEP babies, and standard babies observed the same way? By that I mean blood pressure, gases and that sort of thing.
A Yes, they all had - babies in the trial all had the same set of observations at the same intervals.

Q So the nurses were all very capable and experienced of doing standard observations on all the babies?
A Yes.

Q If a nurse observes that a baby’s observations are not quite right, what is the process then? By that I mean if one specific observation does not appear to be right, what does a nurse do?
A She would need to inform the doctor or a more senior nurse.

Q Are the nurses experienced enough to know that a collection of observations might lead them to think of something serious?
A Could you repeat that, please?

Q Yes. If one observation looks slightly abnormal but actually does not alert you to anything, but a collection of observations does alert you to something. Do you understand what I am saying?
A Well, I mean it depends what the particular observation is because if it was that the baby’s blood gas level had lowered, then that in itself would be cause for concern.

Q Okay. Let me put it this way: if a blood pressure was slightly abnormal and that does not raise a concern but along with another symptom would cause concern, a nurse would be sufficiently experienced and skilled to know?
A Yes. I just need to clarify something. The nurses who looked after these babies had to have a specialist qualification called the ENB 405 course to be able to look after these babies requiring intensive care, so they were experienced and qualified staff.

Q That is an observational type of qualification, is it, or an intensive care qualification?
A Neonatal intensive care qualification.

MRS BRICKLEY: That is all I wanted to ask you. Thank you very much.
A Okay.

THE CHAIRMAN: Any questions arising?

Further cross-examined by MR FORDE

Q Can we, without possibly blowing your own trumpet, would you agree with this: the neonatal nurses are among the most highly trained nurses within the hospital setting?
A They are highly trained nurses.
Q But would you agree they are among the most? I am not saying they are necessarily *the* most, but among the most.
A Among? I thought you said *the* most. Among the most.

Q Would you agree with that?
A Yes.

Q Just in terms of medical cover, Dr Sheldon was asking you a question. Dr Brookfield was the other consultant on the ward. Is that correct?
A Yes.

Q He was senior to Dr Spencer at least in terms of qualification and age. Is that right?
A I do not know about qualification but age, yes.

Q He is an older man?
A Yes.

Q An older more experienced man?
A Yes.

MR FORDE: Thank you very much.

THE CHAIRMAN: Anything else arising?

MS SULLIVAN: No, thank you.

THE CHAIRMAN: Mrs Wakefield, that completes your evidence to the Panel. Thank you very much for coming and for the assistance that you have been able to give to us. You are now free to leave that chair and to indeed leave the building if you wish.

THE WITNESS: Okay, thank you.

(The witness withdrew)

THE CHAIRMAN: Now that probably is an appropriate moment to take a break. We will break for quarter of an hour and come back at 20-to twelve. In saying that, Ms Sullivan, I assume that your next witness is now here?

MS SULLIVAN: Yes, she is, sir.

THE CHAIRMAN: In that case we will come back at 20-to twelve.

(The Panel adjourned for a short time)


MS SULLIVAN: Sir, before I call the next witness, it might just help everyone to see the schedule we have prepared of the witnesses who will be attending. I have a copy for
everyone so that you can see what is hoped for certainly. (Same handed to the Panel)

MR FOSTER: Before the witness comes in, I wonder if I could make the daily request - which is usually made by Mr Forde - for the promised clarification of the GMC’s case about whether or not CNEP did any damage or not.

MS SULLIVAN: Sir, I will deal with that but I am going to deal with that on Monday, not now.

THE CHAIRMAN: We now have a schedule which indicates that the expectation is that the GMC witnesses will all be completed by - the last witness will be here on 18 June?

MS SULLIVAN: Yes. Certainly, sir, we would hope that it would not be necessary to have Dr Nicholson giving evidence for quite as long as that, but that is for how long he is available.

I think I just heard someone mention Dr Raine and the order in which he is there. That is because he is away, as I understand it.

MISS O’ROURKE: Sir, I would want Dr Raine called before Professor Hutton at the very least and possibly before Dr Stimmler, but it depends on what Dr Stimmler says in the report which is imminent. We will probably have to reserve our position on that. Dr Raine is someone who was involved with the writing up of this trial and indeed the Queen Charlotte’s end of it. If Professor Hutton is going to talk about statistics and scores and scores including death, then Dr Raine should be giving evidence before her.

THE CHAIRMAN: Is that a matter which you could discuss with Ms Sullivan and see where you get to on that, rather than now?

MS SULLIVAN: Yes, I do not think it is going to achieve anything discussing it in here, sir, as you say. There are difficulties with Dr Raine’s availability.

MR FOSTER: Sir, can I also say with regard to timetabling that I will be submitting that Dr Nicholson’s evidence is inadmissible, so some time will have to be factored in for the determination.

THE CHAIRMAN: Yes, I think that had been heralded at an early stage.

MS SULLIVAN: Perhaps that can be slotted in at an appropriate stage.

THE CHAIRMAN: Yes.

MS SULLIVAN: Mrs Shufflebotham is the next witness.

THE CHAIRMAN: She is happy to be named?

MS SULLIVAN: She is. She had a son, sir.

THE CHAIRMAN: He is going to be referred to as?
MS SULLIVAN: He is going to be referred to as Patient 69.

DONNA MARIE SHUFFLEBOTHAM, sworn
Examined by MS SULLIVAN

Q Mrs Shufflebotham, I am going to ask you questions first of all. Would you mind telling us your full names, please?
A My full name is Donna Marie Shufflebotham.

Q Mrs Shufflebotham, I want to ask you about the birth of your son, patient number 69. I think it is right that on 13 January of 1993 whilst you were pregnant with your son your waters broke unexpectedly?
A That is correct.

Q Approximately how far in advance was that of your expected date of delivery?
A It was about eight/nine weeks early, so it was about 30 weeks, something like that.

Q Were you then admitted to hospital and monitored?
A Yes, I was.

Q Having been admitted to hospital, I think you were given some medication to strengthen the baby’s lungs. Is that right?
A Yes, I was given steroids.

Q I think the baby was in the breech position. Is that right?
A Yes. I did not know that at that actual time until later on with a scan.

Q You were told that you would need to have an emergency Caesarean?
A Correct.

Q Were you given the option of either a general anaesthetic or an epidural?
A I think I would have been given the option, but it was too late for an epidural, anyway, but I would not have chosen an epidural, so that was fine.

Q So you had a general anaesthetic?
A I did.

Q Your son was born, I think, on 14 January of 1993 at 12.30 p.m.?
A Yes. Correct.

Q How long did it take you to come around from the anaesthetic?
A I was not sure about the timing at all. I could not say. I cannot remember looking at my watch or anything like that. I can only sort of go by things that happened during that day and an estimated time.

Q Was it the same day that he was born?
A Yes, it was the same day, and it was still early in the day. It was not evening. It was earlier than that.
Q Describe how you were feeling?
A When I actually came around?

Q Yes.
A The first memory I have got when I actually came around was asking about my son, you know, was he okay, where was he, and I can remember my husband being by my side. My husband had already seen my son before, obviously, I did come around and obviously I asked him if everything was okay, what did he look like, and I was really anxious to see him. They did not want me to leave the bed, obviously, because I had only just come around. I was still under the anaesthetic, and obviously a belly full of stitches as well, but not long after that, I can remember that I wanted to go to the toilet. I have never been one for wanting to use a bed pan. I have only been hospitalised once before; when I was about 14 I had my tonsils out, and I was adamant then I would not use a bed pan. I just could not. So I insisted I went to the toilet. They did not really want me to do that, but I insisted and I persisted and I got to go to the toilet, via wheelchair, very carefully to the toilet and back again. Well, you know, then after that, I wanted to go and see him.

Q See your baby?
A Yes.

Q Did they let you go and see your baby?
A Initially not. They did not advise it, you know, still, to stay in bed a little longer. I did insist. I said that I had been to the toilet. I had managed that, so I was wheeled down in a wheelchair.

Q You were wheeled down in a wheelchair. Was your husband with you?
A Yes, he was with me.

Q How alert were you feeling at this stage?
A Very alert. I just could not wait to see him and that is what I wanted to do, and that is what I got to do. I was very excited and a bit emotional at the same time, because I did not know quite what to expect, but I was told things were looking okay.

Q Could you actually touch or hold him at that stage?
A No, not when I actually got there, because he was in an incubator. I could just look at him.

Q When you went to look at your son in the unit, did any doctor speak to you?
A I can remember speaking to a doctor. I do not think I was approached. I think it was a case of it was quite busy at the time. It was a lady that pushed me down in the wheelchair and obviously directed me to my son. Then following that, I think the doctor did approach, come along, and I asked him questions.

Q The lady who took you down, was that a nurse?
A I would think so.

Q You say that you spoke to a doctor once you were down on the unit?
A I did, yes.

Q Can you remember, was that doctor male or female?
A I think he was a male doctor. Yes, I am pretty sure he was a male.

Q What did he say to you about your son at that stage?
A I think it was me doing most of the questions, because that is the sort of type of person that I am. I am quite inquisitive. You know, I obviously asked him if he was all right, and asking him questions about the machinery. He was quite accommodating, because he answered the questions for me, you know, and just reassured me that things looked okay for my son. He explained to me the wires and things.

Q What sort of incubator was your son in?
A He was just in a normal incubator. I did not realise there were different sorts of incubators.

Q How was he breathing at that stage? Did he need any assistance?
A No, not at that time. He had got the oxygen in there, but he was not on a ventilator at that point of time, for that day.

Q For how long did you speak to a doctor on this occasion?
A Not long. Probably just two, three minutes. Just enough, really, to answer questions, because they were quite busy there, you know.

Q Did the nurses assist you with your son?
A I cannot remember a lot from that little part at first, sort of thing. I just remember the doctor at that stage, but, yes. I mean, there was a lot of support from the nurses, because I tried to breastfeed and had to express the milk and one thing and another, so there was a lot of support from the nurses there, yes.

Q The following day, did your son have any problems?
A I think it was the second day that he was put on the ventilator. They actually came to me. I was upstairs with a bit of news, and I thought - you think the worst, type of thing, because they just wait a second until they have taken you somewhere a little more quieter, if you like, and then they informed he had been put - he could not breathe for himself, so he had been put on a ventilator.

Q Did you go and see him then?
A I did, yeah. I saw him every day, anyway, and obviously whilst I was in hospital I saw him every second available, really.

Q You stayed there for a few days, I think.
A Three or four days.

Q And your son was there a little longer?
A Yes, he was. That was hard, going home and leaving him.

Q Were you at any stage, Mrs Shufflebotham, told anything about your son being included in a trial?
Six years later when I had a letter informing me that my son had been included in a trial.

Prior to that, had there been any mention to you, by anyone, either doctors or nurses, about a trial?

No, not about a trial. I did - when Patient 69 was two months old, I received a letter from - I cannot remember where the letter was from, North Staffordshire University.

Yes. I do not think we need to worry about ---

Not that one at all, but I did get confused, thinking that that might have been what was being referred to, because that was the only thing that I could remember about anything to do with any study or research or anything, so I did get confused, thinking that that was it. That was the one ---

Subsequently, he was involved in something, but, at the time of his birth...

It was not connected to this.

...that is what this Panel is concerned with - was anything said to you about a trial?

No, not until six years later.

You say six years later. Six years later, did you in fact receive a letter from the chief executive of the North Staffordshire Hospital?

Yes, I did.

I think indicating that a review was being carried out of consenting.

Yes.

And asking for you, whether you would give access to your son’s notes?

Correct.

Did you sign a consent form, saying that you would allow access to the notes?

Yes, I did.

Then did you later receive a copy of a consent form?

I did, yes.

I am going to ask you, please, to look at the original, if you could be handed that, and if the rest of us, please, could go to tab 3, page 412. You have the original there, Mrs Shufflebotham. We have a copy of it. I am going to ask you, the name of your son, I think, appears at the top there as the name of the patient, do you see?

Yes.

There is reference to a CNEP trial of RDS and then the name of a clinician, Arya. Is any of that in your handwriting?

No, definitely not.

Then looking below, can you help us as to what, if anything, is in your handwriting on that form?
A I have not seen the form before, so I was astonished, as in the signature looks familiar, although the signature is very - as if I was drunk, perhaps, if that is my signature. It does not quite look as neat as my signature usually is. None of the other handwriting on the form is mine. I am 100 per cent positive of that.

Q Have you any recollection at all, Mrs Shufflebotham, of seeing that form at the time?
A No, not at all.

Q Or of signing it?
A No, not at all.

Q You indicated to us earlier that you first saw a copy of that form some six years later...
A Yes.

Q ...once your records were released?
A Yes.

Q So that was in 1999.
A It was.

Q Then, I think, subsequently, Mrs Shufflebotham, your son was seen by Professor Marlow. Is that right, at a much later stage, in 2003?
A Yes.

Q He checked your son to see whether he was all right after you had...
A His development, yes.

Q ...you had given your consent in relation to it?
A Yes. Correct.

Q The results of the test showed he scored just below average with his memory and language skills, but in all other aspects, he was normal or above average?
A Yes.

Q And you were pleased with the results?
A Yes.

Q Just going back a minute, you told us about the consent form. Perhaps you could just be given file 1, a moment, behind tab 3, at page 336, first of all. Mrs Shufflebotham, had you seen that document at all before it was shown to you when you made your statement for these proceedings?
A No, absolutely not. The first time I have seen this document was this year during the meeting with...

Q With Ms Morris?
A ...yourselves, yes.
Q Had you been given a leaflet such as that in hospital, would you have been able to read it?
A Definitely not, and I would struggle with my glasses on to read this, if it was as bad a print as this is. I certainly would not be able to read anything like this without my glasses on. I have not got my glasses now.

Q Yes. Obviously we are a few years on now.
A Sorry.

Q Would that have applied to your eyesight in 1993?
A Yes, and now. I think it is even worse.

Q Just going on a little, if you would not mind, at page 341. There is big print here, do you see?
A Yes, I can see that.

Q An information booklet and it goes right through to page 364?
A Yes.

Q Again, had you had sight of that document prior to being shown it by Ms Morris?
A No, not at all.

Q In fact, you have described the sort of incubator that your son was in. Until you were shown this booklet, had you any knowledge what a CNEP tank looked like?
A No, not at all. I had not, no.

Q Have you any recollection of any baby on the neonatal unit being in a tank anything like the one, for example, that is shown?
A Once I had seen the picture of a CNEP tank, which was only this year, I do recollect seeing a tank that looked such as this that was on the neonatal unit at the same time as my son, and there was an older child in it, possibly nine, ten months old. He has got his head - I think it was a little boy - protruding out of it, but that was my recollection, through this picture.

Q Yes. So if we just go through to page 346, how does that compare with the incubator your son was in?
A That was the type of incubator that my son was in, yes.

Q I want you just, please, if you will, to turn further on in that bundle to page 413. This is a bonding questionnaire. Is that your writing on the top where your son’s name appears?
A No, definitely not.

Q Have you any recollection of completing this questionnaire? We notice there are a number of ticks. There is nothing else written here.
A I could not remember signing this questionnaire, however, since giving my statement and thinking about it and obviously things go through your mind, you try and go back in time to see what you can remember, I mean, it was 15 years ago, I get a slight
recall of possibly having this questionnaire the day that I was coming out of the hospital when I was taking my son home and at that time ready almost to go and leave and I think I recollect now being given a questionnaire and I did it in a hurry, I am not absolutely positive but that is just what has come to mind when you are sleeping and you are going over because you want to make sure you have told everything the way it is, that I have just got a slight memory coming back of this questionnaire perhaps and it was rushed through because I wanted to go obviously after being in there for two and a half weeks I needed to get my son home.

Q Had you seen anything whilst you were in the hospital to indicate that your son was in a trial?
A No.

MS SULLIVAN: If you wait there, there will be some more questions.

Cross-examined by MR FORDE

Q Good afternoon, Mrs Shufflebotham. I represent Dr Spencer, he is the gentleman that sits next to me. Do you recall seeing him at any time 15 years ago?
A No, I cannot remember.

Q You have been sitting in a room waiting to come into this hearing, I believe?
A I have.

Q Did you reacquaint yourself with Dr Arya, a female doctor?
A Since coming here?

Q Yes.
A Not to my knowledge.

Q You did not see---
A Unless that was a doctor that was in the room with us.

Q Did you see a female doctor in the room?
A I do not know whether she was a doctor but there was a female in the room.

Q Sri Lankan appearance or Asian appearance?
A Yes.

Q But you did not recognise her either?
A No.

Q The reason I ask is because the consent form you have been taken to, I do not know whether the original is available?
A I have got that.

Q Is counter-signed by the doctor who has just been sitting in the room who is the next witness.
A Is this her name then on here?
Q: This is her name, yes.
A: No, I have never seen her before. I cannot recollect seeing her.

Q: She has signed a declaration: "I confirm that I have explained nature of the above investigation to the above named relative/legal guardian". So on 14 January 1993 this doctor has signed a form purporting to have explained to you the aims and procedures of the clinical investigation or trial known as the CNEP trial of RDS. Do you see that at the top?
A: Yes.

Q: Her name as clinician R Arya. The name of your son whom we are referring to as patient 69. She has then put her name into the second line of the first paragraph. Do you see that?
A: Yes.

Q: "I have read and understood the information set out overleaf" and that is the patient information form that you have been taken to by Ms Sullivan. "I understand that participation in the study is voluntary and that he/she may withdraw at any time of his/her own accord" etcetera. Now there are two possibilities. Either 15 years on - and I note that your witness statement is dated 19 February 2008?
A: Yes.

Q: You have forgotten your interaction with this doctor, before you shake your head because this doctor is giving evidence next on oath, or this doctor has fabricated this form. What do you say about that?
A: I say I do not know the doctor, I am sure she is a very good doctor in what she practises in, I do not know, but I have never seen her before and I have never seen this form before, not to my recollection.

Q: So she has put her name to a false declaration?
A: Yes.

Q: From your perspective?
A: From my perspective.

Q: Do you countenance even the possibility of having failure of recollection of your encounter with this doctor?
A: No, but there could be another explanation, it could be maybe that that is my signature because I cannot verify that that is not my signature and it could be that I was just not in this world at the time anything was said to me and I have signed that and that will probably be why I do not recall anything. So there is that.

Q: A third possibility is that so affected were you by the anaesthetic given for your Caesarean section, we know it was a general anaesthetic, that you were not sufficiently *compos mentis* to appreciate what was being explained to you?
A: Yes, that is a possibility.

Q: That, of course, then means that the doctor who took your consent failed to
recognise that she was consenting a patient who was incapable of understanding what was being explained to her?
A  That is the way it is.

Q  What confuses me about that possibility is this, your son was born at 11.51 and we have some nursing notes---
A  Was he not born at half twelve?

Q  11.51 according to the notes.
A  I have always had half past twelve.

Q  Maybe that is something we need to explore but according to the clinical notes I have got, in fact, it was not 11.51 it was 11.45. 11.51 a.m. transferred from maternity theatre at five minutes of age. That would seem to suggest that he was born about 11.46, 31 to 32 weeks gestation, which I think is what you thought. Is that right?
A  Yes.

Q  Then the nursing notes that we have indicate that your son was randomised into the CNEP trial at 15.51 and was to receive standard therapy and we also have a note which we can put to Dr Arya signed by Dr Arya at 4.15 which says “For arterial gas UAC”, umbilical arterial catheter, “randomisation into CNEP trial consent.” So she has written that into her clinical notes as well but you have no recollection of meeting her or discussing this with her?
A  No.

Q  The reason I was expressing some mystification is that you had a fairly vigorous conversation with staff about seeing your newborn son, did you not?
A  I did.

Q  You insisted on using the lavatory facilities rather than the bed pan?
A  I did.

Q  You described yourself, this is prior to you seeing your son, as being very alert, that is what you said this morning?
A  Yes, I do feel that once I knew where I was and I felt that was my first memory of being alert, yes.

Q  So very alert when you are insisting on going down to see your son because I think the nursing staff were telling you you had to stay in bed?
A  Yes.

Q  Your husband had already seen your son and you say in your statement he described him as gorgeous and you were very anxious understandably to see him yourself?
A  Yes, correct.

Q  So all of that you remember, do you?
A  Yes.
Q: But you have no recollection of signing the consent form?
A: No.

MR FORDE: Thank you, that is all I ask.

Cross-examined by MISS O’ROURKE

Q: Mr Shufflebotham, do you want to think carefully about Dr Arya?
A: Sorry, I was looking round and I could not see you.

Q: Sorry, I should have introduced myself. I represent Dr Southall who is not here today but I am asking questions on his behalf. I want to ask you about Dr Arya, the doctor that you have been sitting with in the waiting room.
A: Okay.

Q: You say as far as your recollection is concerned you have never seen that doctor before?
A: No.

Q: Your son, I think, remained in hospital for about 18 days?
A: Yes.

Q: I am still in the middle of my count but there are at least six or seven notes on here on different days signed by Dr Arya. While your son remained in hospital did you remain with him?
A: For three, four days I was in hospital for.

Q: Did you thereafter come in every day to see him?
A: I did.

Q: You would have talked to or seen the doctors who were involved in his care, particularly if there were any decisions to be made?
A: Yes.

Q: According to the clinical notes Dr Arya saw your son at 4.15 and possibly slightly before that, she makes the note at 4.15 on the day he was born. He was born, as we know, at some time like 11.45, there is a note that he first comes to the neonatal ward at 11.51. Yes?
A: Yes.

Q: You, of course, for 15 years it appears thought it was 12.30?
A: 12.30, yes.

Q: The note that Dr Arya makes by that time you say that once you came round you wanted to get to see your son after you had been to the toilet. Presumably you arrived and stayed with him for a little while?
A: Yes.

Q: Couple of hours?
A  Yes, I would imagine so.

Q  So in which case if Dr Arya was seeing your son around 4.15 and writing a fairly
detailed clinical note of him and his observations you would more likely than not have
been there?
A  Can you repeat that again for me, please?

B  Q  Dr Arya appears to have seen your son some time before 4.15 and to then write a
note at 4.15. She writes notes about various observations made of your son, how he is
doing, that a chest x-ray should be taken, that other investigations should be undertaken
and that he should randomised into the standard side of the trial. What I am suggesting to
you is if you have come down to see him after you had come round and after you had
been to the toilet, you presumably have not just seen him for five minutes, you have
stayed with him for a period of an hour or two or something of that sort?
A  Yes.

Q  If that is correct then on the timings it appears that you would have been present
with your son when Dr Arya is carrying out observations of your son some time around
about four o’clock?
A  I cannot remember that.

D  Q  I am going to suggest to you that is, in fact, coincident with the time that Dr Arya
was getting your consent on that consent form?
A  Absolutely not. I have not seen any of that evidence. I have not seen that form,
so if I signed that form absolutely not, absolutely not. Not at that time.

Q  You do not think that you could have forgotten?
A  No.

E  Q  In everything else that was going on that day?
A  No.

Q  In the same way you have forgotten what time your son was born?
A  I do not think I forgot. I have always thought that 12.30. Always. At the end of
the day I was not awake when my son was born. I had an emergency Caesarean and I
cannot tell you what time I saw my son but I do know that my husband went home to pick
up by daughter from nursery and came back again in the evening. So I was not there long
on my own with my son without my husband by my side. My husband cannot recollect
anything about this either so how would you explain that?

F  Q  Because memories fail you 15 years later and you do not remember---
A  I would remember if I had seen that information.

Q  Can I understand then what you are saying---
A  I would remember if I had known whether that was a CNEP tank or not.

Q  Can I understand this then so that I know how to ask the next witness questions.
Are you saying that she forged your signature on that form?
A  I cannot remember signing that so -- I cannot say that. I have got nothing against
the doctors. My son is absolutely fine. I just get this information asking me, letting me
know that he has been in a trial that I did not know about. I am just telling it from my
end. I do not know - I am impartial, I have got nothing to gain, I have got nothing to lose.
That is my story.

Q Let us look at the two possibilities. One is that she forged it, she forged your
signature and she wrote her own signature below it with a false statement saying she had
explained it to you. Second – and I am going to suggest to you much more likely – the
possibility is that it is your signature, she did explain it and sign the form with you but
that you have forgotten?
A Or thirdly it was signed much earlier than what is stated and that was signed while
I was still under the anaesthetic.

Q If you were under the anaesthetic you would not be able to sign at all?
A It is a shaky signature. It does not really look like my signature, it is similar but it
is not as neat as mine, it looks as if it is done under the influence of alcohol or
anaesthetic.

Q Let me put to you so you have the opportunity of considering it. Dr Arya’s has
got notes for 4.15 the day your son is born; she has got a note for day five when she again
saw your son and was making an assessment of him; she has got another note for day 16
and that one includes the following words “Mum wishes to breastfeed”, which suggests
that she has possibly had some sort of discussion with you and she then has another note
for the 31st, in fact she appears to have done the discharge for your son. Were you
present when a doctor discharged him?
A Yes.

Q She did the discharge note.
A It was 15 years ago, so remembering somebody’s face - and I did not really look
at her closely in the waiting room as I did not know who she was. You are not supposed
to look or talk to anybody.

Q According to the notes, and we will put them to her when she comes in, she did
the discharge. What I am going to suggest to you is that you have forgotten her, and, with
that, you have also forgotten discussing the form with her and signing the form?
A I simply would not have forgotten those pictures. I certainly would not have
forgotten that he was part of the trial and I certainly would have remember for six years
later.

Q But he did not go into the CNEP trial, he went into the standard side of the trial?
A There is that. That is another reason why later on it is quite important because he
could have been in the other half of the trial. I am not even saying that that would have
cased him any harm. All I know is what I have been asked. What I have been giving is
the truth.

MISS O’ROURKE: Thank you. I have no further questions.

MR FOSTER: No, thank you, Sir.
MS SULLIVAN: I have no questions.

Questioned by THE PANEL

MRS HOLLINGSWORTH: Mrs Shufflebotham, hello. You have just had major surgery and you have said you had only been in hospital once before when you were much younger. Is that right?
A Yes, when I was about 14 I had my tonsils out.

Q You have just had major surgery and, very bravely, insisted on going to use the lavatory?
A Yes.

Q Were you in any pain?
A Yes, lots of pain.

Q Do you remember being given any medication to relieve the pain?
A Yes, I did have some medication.

Q Can you remember what sort of medication?
A Not really.

Q Was it an injection?
A I cannot remember.

Q Can you remember how soon after the operation you had some medication? Was it before you went to the lavatory?
A I think it was regular doses, probably every four hours or something.

Q I am interested that you said you felt alert?
A I was alert in my brain. My body might not have been, I do not know. I had terrible problems as well with wind. I know that sounds awful.

Q I understand that these things are quite normal. What I am interested to explore is whether you had any medication?
A Yes, I did. I did have regular doses of, I am not very good with the drugs I am not a doctor, I do not know

Q You still felt wide awake. You do not thing that your senses were dulled in any way by pain relief?
A I do not think so. I think I was on cloud nine so you are slightly like that. I was on cloud nine. I was worried. I was excited. But I just know that I was alert enough to have remembered this, had I been shown this. Neither would I have been able to read it. I was rushed in anyway. I had not my glasses with me, so I did not see any of this. I just did not.

MRS HOLLINGWORTH: Thank you, very much.

DR SHELDON: Good morning. I am interested in this period of time when your son
was first admitted into the neonatal ward. You say that your husband was there at the time?
A Yes, he was.

Q Was he still there when you came down to see your son?
A Yes, he came with me. I do not know what time. I do not know what time it was, but he went down with me. I did not look at my watch. I know that he had to get back to pick up my daughter from nursery around 3 o’clock and he came back again in the evening. My friend looked after my older daughter and he came back.

Q It was before 3 o’clock when you were brought down in the chair?
A Yes, before three, because my husband had left. I was left down there; he left me down there.

Q I think you said a male doctor came to talk to you?
A Yes.

Q Do you remember him?
A Now I get to think about the lady’s face I have just seen in the witness room and I think I can perhaps remember her face, but that is only because I am trying to think of her floating around the neonatal unit. There were lovely doctors there, and I had a lot of connection with one or two of the women there because I was trying to breast feed. Perhaps that was the lovely lady. But I did not have any of this shown to me, and I cannot remember seeing and certainly not signing this consent form.

Q I understand that, it is just that sometimes, for me, I cannot always tell the difference between a doctor and a nurse in this sort of situation. Were they dressed similarly or were the doctors always in a clean white coat that was different from the nurses?
A Just my visual perception of a doctor - white coat. I cannot remember. I just wanted to see my son and ask some questions. I remember it was a male doctor. It might have been a women doctor. It was 15 years ago, but I think it was a male doctor. I asked questions. I found out what I needed to know and then I just zoomed in on what I was there for.

DR SHELDON: Thank you.

DR OKITIKPI: Mrs Shufflebotham, I want to find out from you about breast feeding; did anybody speak to you about it?
A Yes, and it might have been that lady. One or two of the nurses I spoke to.

Q You think it might have been her?
A It could have been.

Q You are not sure?
A No, it is 15 years ago.

DR OKITIKPI: Thank you.
THE CHAIRMAN: Mrs Shufflebotham, did you say - I may have misheard - that you did not have your glasses with you at the time?
A No, I did not.

Q Is your sight not good without glasses?
A Not for reading, definitely not.

Q How about if you find yourself writing without glasses?
A No, not very good either, better than the reading. My sight is not that poor. It is just a case of small writing. I could read a line or two and then get blurred vision without the glasses.

Q You were talking about the signature we have been looking at on the consent form as being not your normal signature and as if you were drunk?
A I do not think that glasses would affect my signature. I think that you have your hand/eye coordination and you could do your signature with your eyes closed really, can you not?

Q Second point, you told us about how your son was in what you describe as an ordinary incubator?
A Yes.

Q We know that you were visiting him regularly while in that incubator. Was there anybody attached to the incubator in the form of a piece of paper?
A What do you mean “attached”, like medical notes?

Q Did you see anything with writing on it?
A I did not read any medical notes, no.

Q I was referring to something other than medical notes.
A I do not know what you mean.

Q Any picture of a teddy bear on it?
A It got a teddy bear inside the incubator.

Q I wondered if there was anything drawn on a piece of paper?
A I did not see anything?

THE CHAIRMAN: Thank you very much, indeed. Any questions arising?

MISS O’ROURKE: No, Sir.

MS SULLIVAN: No, Sir.

THE CHAIRMAN: Mrs Shufflebotham, that completes your evidence. Thank you very much for coming and for the assistance you have been able to give us. You are now free to go.

MRS SHUFFLEBOTHAM: Thank you very much.
MR FORDE: Miss O’Rourke has made a suggestion to me. I do not know if it commends itself to the Panel. We might consider having lunch now. We should have copied for the Panel the extract of the notes relating to the last witness’s son, so that you can have available to you the notes that we believe she made contemporaneously at the time. We will also need at some point, but not today, in the light of the Panel questions that have been asked, again the maternal notes. I suspect, certainly when Dr Stimmler gives evidence, that we may need to ask him whether he thinks that the degree of anaesthetic plus any pain relief will have any effect on conscious level. I put that marker down.

THE CHAIRMAN: We will break for lunch and come back at half one.

MISS O’ROURKE: I indicate that I do not know if you will need them all. That (indicating) is the totality of the notes. I am very keen that Dr Arya sees the six notes that I think she has made, and that the Panel see those too. I do not know whether it is too much of an undertaking to copy everything. I think it is probably unnecessary, but there are those six notes that I can find plus the nursing notes.

THE CHAIRMAN: It would be helpful if you are able to agree among yourselves what notes are going to be referred to and then copy those for us.

MISS O’ROURKE: Thank you, Sir.

(The Panel adjourned for lunch)

MR FORDE: The reason I am on my feet is that I am addressing consternation about the possible contamination of GMC witnesses because they all sit in the same room and may have a natural inclination to discuss evidence, that I may have given the impression that I was in some way impugning the professionalism of the solicitors acting for the GMC. I did not intend to do that. If it is thought that I did, I withdraw any comment that could be interpreted that way.

THE CHAIRMAN: Thank you. Miss O’Rourke, having mentioned the copies of the notes, are you going to put them in at the appropriate time or are they coming in now?

MISS O’ROURKE: I was presuming that they had been copied by the GMC solicitor rather than me. I identified the six pages I required. I think Mr Forde identified one or two other pages, so I think it is only eight or ten pages. I am hoping that it has been done.

MS SULLIVAN: It has been and they are being collected now.

RENU ARYA, affirmed
Examined by MS SULLIVAN
Good afternoon, Dr Arya.
Hello.

Could you start by giving us your full names?
It is Renu Arya.

What are your qualifications?
MB CHB MRCP FRCPH DCH MA.

You qualified when?
In 1987.

Now I think you are a consultant paediatrician?
Yes.

Whereabouts are you a paediatrician?
In Swindon.

I think you moved to Swindon in 2004?
Yes.

Prior to that had you been a consultant paediatrician in Manchester?
Yes.

Prior to that I think you were a senior registrar in Manchester.
Yes.

Before that were you a registrar for two years in Stoke?
Yes.

Were you in Stoke between 1992 and 1994?
Yes.

I do not think that I need to take you back further than that with your various appointments. As you know, I want to ask you about your time in Stoke when you were working there as a registrar. Perhaps I should ask you this. Was that your first registrar appointment or had you had others before?
No, I had been a senior SHO, which is the registrar equivalent, in Weston for a year. Then I have been a registrar in Luton for nine months.

When you go to Stoke you work in which particular units?
I worked on the neonatal for about nine months, general paediatrics for about six months and community for six months.

So how much time did you spend on the neonatal unit overall?
During the two-year period I did nine months continuous daytime work on the neonatal unit, and then on-call for the whole two years.

How frequently would you have been on-call for the neonatal unit?
A I was trying to remember. I think it was one in five or maybe one in six.

Q While you were working on the neonatal unit, was the CNEP trial, as we have come to know it, being conducted?
A Yes.

Q When you started, was it already in operation?
A Yes.

Q Before you went to Stoke had you any experience with CNEP at all?
A No.

Q Were you aware of what it was even?
A No, not really.

Q Who introduced you to it once you arrived in Stoke? Can you remember?
A I am not clear as to who introduced me. I think it was the other registrars. I cannot be sure.

Q Do you remember which registrars you were working with in your time in the neonatal?
A Not all of them. A few I remember because I had more contact with them.

Q Do you remember their names?
A Kate Palmer, Sarah Watkins, Colin Morgan, who were based on the neonatal unit with me doing research. There was John Hewitson, Tina Marinarki, Hans somebody or the other. There was Ann. I have forgotten her maiden name, but her full name was Ann Herriot when she got married.

Q That will probably do. How many registrars were there at any one time?
A I think there were five or six of us plus the research registrars.

Q And the research registrars you have identified as Dr Palmer and Sarah Watkins?
A Yes.

Q Were any of the others involved in research?
A John Hewitson and Tina Marinarki. Then there was Kate as well. She started later.

Q And Colin Morgan. Was he involved in research?
A Yes.

Q The consultants on the unit, we know, were Drs Spencer and Brookfield?
A Yes.

Q How able were you to approach the consultants?
A If I needed them I could call them at any time, but they did regular ward rounds.

Q We have also heard reference to an American doctor being there at the time?
A  Yes.

Q  Do you remember him?
A  Yes, Carl Bose.

Q  Tell us a little about the size of the neonatal unit when you were there.
A  It was a large unit. Again, struggling to remember exactly how many cots, I think there was six. I could be mistaken. I know there was about 5,000 deliveries a year.

Q  What was your role as registrar?
A  The day-to-day supervision and running of the unit. Making sure the babies were looked after. Supervising the SHOs. Going to resuscitations. What else? Teaching as necessary.

Q  Carrying out ward rounds as well, I expect?
A  Yes.

Q  I think you also did some research but not linked to CNEP. Is that right?
A  Yes.

Q  You say you cannot recall who introduced you to CNEP, but are you able to say whether it was doctors or nurses just in general terms or not?
A  I think it was a mixture of both but I could not say for definite who.

Q  Do you remember any formal training sessions for it?
A  No.

Q  How did you find handling the babies within the CNEP tanks?

MR FOSTER: The relevance of that, please?

MS SULLIVAN: I have not had any objection to any of this.

MR FOSTER: I am making the objection. I would just like the relevance of this passage which you are proposing to adduce to be explained.

MS SULLIVAN: We have heard evidence from everyone else about this, so I am not quite sure what the problem is now. I think it is important that everyone understands how the trial worked and how the tanks operated because there are obviously issues in the heads of charge.

MR FOSTER: Perhaps it could simply be explained by reference to the numbers of the heads of charge to what head of charge paragraph 10 goes. A very simple question.

THE LEGAL ASSESSOR: I think it is probably background rather than anything else.

MS SULLIVAN: It probably is.

THE LEGAL ASSESSOR: Perhaps unusually the objection does not seem to have been
 echoed by the other two counsel. One of the problems is whether they sometimes want evidence in that the others do not. I wonder if they would care to make their position clear.

MR FORDE: Yes, sir. I can see why Ms Sullivan might want to adduce this evidence but I, like Mr Foster, do not at the moment see it as being related to any of the charges. I would have thought that we could probably move in the statement to paragraph 12.

MR FOSTER: Just to make it clear, this evidence does not relate to any of the charges against Dr Samuels. It is not harmful in any way to Dr Samuels. I am just concerned generally that the way that the questioning is going is in a very unfocused way. It is going to take us a lot longer than is necessary to go through all these witnesses if there is going to be this amorphous approach. I am trying to spare everybody time.

THE LEGAL ASSESSOR: I am going to suggest that we have a case management meeting of all the lawyers to try and see the way forward, because it is rather unedifying that all these arguments are taking place in public when they could, with greater convenience to the witnesses, be dealt with in advance.

Having put down that marker, do you object to the line of questioning being continued at least with this witness?

MR FOSTER: There is nothing sinister in what is proposed to be adduced. It is just irrelevant and time wasting. If it is repeated - as I presume it is going to be repeated - time and again with every witness, we are going to be sitting here for hours and hours and hours listening to irrelevant evidence.

MS SULLIVAN: This evidence would have been finished if there had not been an interruption. It is only a matter of a couple of questions. If anybody wants to object to the evidence that I propose to adduce, everyone has had the statements for some considerable time. I am very happy if someone would care to communicate with me in advance if they have any objections and I will consider it.

THE LEGAL ASSESSOR: Meanwhile it seems to me that you should be able to ask those few questions as background.

MS SULLIVAN: Thank you. (To the witness) Sorry, Dr Arya. I am sorry you had to be interrupted in that way. I was asking you about how you found the CNEP tanks and the handling of the babies. Would you just help us with that?

A It was not as easy to get access to the babies in the CNEP tanks as it was in the normal incubators because you had to put your hands through the seals. I am quite short so I had to stand on a box and reach as far as I could.

Q As you say, you were there for nine months also and no doubt in due course you got used to the tanks?

A Yes.

Q I want to ask you about the consenting process in relation to the CNEP trial. You, as a registrar, were you involved in consenting for the trial?
A Yes.

Q Do you remember whether you received any specific instructions about how to go about consenting for a trial such as this?
A I really do not remember, it is such a long time ago.

B

Q Had you consented for trials prior to this time or not? Do you remember?
A Yes.

Q At what stage would you seek consent for the CNEP trial?
A Again, not easy to remember, but I think - I used to go and speak to parents if there was time. If they knew they were going to have a premature baby I would go and talk to them before delivery to tell them what to expect when their baby was born, sort of general information about what would happen on the unit and what they could expect would happen to their baby. I think at the same time I would talk to them about the CNEP trial.

Q Yes, so that is obviously if you were able to do that?
A Yes.

Q Just dealing with that process for a moment, when you spoke to parents at that sort of stage before delivery, would you have any written information to give them?
A I remember taking a pack of photographs to show them how the CNEP worked and what the tank looked like with a seal. I am sure I would have given them a parent information leaflet. I do not remember what other information I took with me.

Q No. Would that information have been for them to look at and keep or would you take back that packet from them at some point?
A I would take the photographs back.

Q What about the leaflet?
A That was theirs.

Q So that is the procedure that you would follow if somebody was being consented beforehand. Just help us a little more as to what you would have said about the nature of CNEP itself. Can you remember?
A Again, not easy to remember what I said in those situations. I can remember saying it was a trial because we did not know whether CNEP was better than the normal conventional ventilation. We presumed it would be better for the babies because they did not need as much pressure, but we did not know that. I remember telling them that they could - they did not have to consent and that they could withdraw at any time and that it would not affect the care the baby got, and also that I could not tell them, if they consented, which arm the baby would go into, whether or not they would receive CNEP or whether they would get conventional ventilation.

Q Would you speak to one or both parents?
A Usually there were two parents but I do not know, I cannot remember if on occasions there was only one.
Q: Would you speak to them after the baby was delivered as well or would you just consent prior to delivery?
A: I think there might have been some babies that we consented after delivery if they met the criteria.

Q: Yes, you say there may have been some consented after delivery. How would that arise?
A: If there was not enough time to go and speak to the parents before delivery, then if the babies - again, I cannot remember exactly what the criteria were, but if the babies born fulfilled the criteria for the trial then I would go and speak to the parents and introduce myself and the trial and then obviously give them an update on their baby.

Q: Yes. So can you recall as to when it was after the birth of a baby that you would approach the parents if you had not spoken to them beforehand?
A: It would certainly be after the baby was stable. Again, I cannot remember the exact details of the trial. I think there may have been a period of time to see if the baby fulfilled the criteria, so I do not know.

Q: Yes, we ... A: I cannot remember.

Q: ... have seen that from the information that we have about the trial. Can I ask you this: if a mother had had a Caesarean and had had a general anaesthetic, what would be your approach to taking consent from such a mother when she obviously had had a general anaesthetic?
A: Again, really difficult to remember what I did, but I think if I had not spoken to her before, then once the baby was stable after birth, and hopefully she was awake and able to speak to me, then I could go to speak to her then or at least speak to the father.

Q: Yes, would there be occasions when you would just speak to the father?
A: I may have done but I do not really remember.

Q: In terms of individual cases, we have seen your name on ...
A: Quite a few.

Q: ... a couple of consent forms. Have you any individual recollection of the process?
A: No. I mean I think I tried to speak to both parents but I really do not remember individually.

Q: I wonder if I might just show you the two forms a moment, just to ask you whether there is any recollection that you have. I am just going to give you a piece of paper a moment, Dr Arya, on which you can have the numbers. Just look at this first one a moment and we will just check the number of the second. (Same handed) You can see which baby we are referring to as 69?
A: Yes.

Q: Can you just indicate whether that is your ---
A: That is my signature.
Q That is your signature on that particular form.

THE CHAIRMAN: Patient number 121.

MS SULLIVAN: Thank you. I am grateful for that.

Q The other consent form that you have there we think is for 121, if you just look at that. Again ---
A Yes, it is my signature.

Q Apart from seeing it is your signature, do you have any recollection, Dr Arya, of those particular patients?
A No.

Q Now, you were telling us what you would say to the patients. Would the parents whom you were consenting know, from what you said to them, that it was a trial that their babies were to be involved? Would you have used that expression?
A I think I would have done. Like I said, I cannot remember the exact terms I used, but I am clear in my own mind that I would have said it was a trial or a study, because I can never tell the parents what form of treatment the baby is going to receive.

Q So a trial or a study, I think you have just said. Did you go into any further explanation with them as to what that was?
A I would tell them that I - I would tell them the details of how the CNEP worked and how it differed from conventional ventilation, and then tell them that once they consented, I would have to go and speak to the two consultants and then I would let them know which ventilation the baby is going to get.

Q How did you describe the different types of ventilation to the parents?
A I think I said that we would put a tube down - the usual form of ventilation is to put a tube down into the baby’s lungs and then put oxygen into the lungs using pressure, and that we knew that using pressure could sometimes damage the lungs, so this is a different form of ventilation. It was like the old iron lungs, and this - again, I cannot remember the exact terminology, but talked about using pressure outside to help expand the lungs and hopefully use less pressure and therefore it would cause less damage.

Q Did you give any indication to the parents as to how the two types of ventilation compared as far as the baby was concerned?
A Well, we would talk about the CNEP tank.

Q Yes.
A So obviously that was the difference.

Q And in terms of the equipment that was needed to be used and the effect on the baby?
A Once I used CNEP for a while, I could see the bigger babies seemed to be more settled in it. I do not really remember saying much more. I mean, if they had questions, obviously I would answer those.
Q Yes. Then once you had consent - sorry, I should have asked you this: in terms of whether the babies fitted the exclusion criteria, was that something that you assessed?
A Yes.

Q At what stage would that assessment have been done?
A I think it was done after the baby was born.

Q You cannot recall after this stage?
A No.

Q So the assessment was done after the baby was born. If any consenting needed to be done after the baby was born, at what stage was the consent process started?
A It depended on whether I had spoken to them in the beginning - before the baby was born.

Q Let us assume you had not spoken to them.
A It would be always after the baby - I sorted the baby out first and then went to speak to parents. I cannot remember. I think there was a time period in which the baby either met the criteria or did not and, if it did, then I would go and speak to parents after that.

Q Yes. We are talking four hours, just to help you with that?
A Okay.

Q Does that give you an indication of when you would have started the consenting process post-delivery?
A It would take me at least an hour just to get the baby stable, so it would have to be after that.

Q How much time were the parents then given to consider whether to consent or not?
A That, I do not remember. I cannot remember how quickly they had to be into the CNEP tank.

Q In terms of when you spoke to - we know it was either Dr Samuels or Dr Southall, you would have phoned them in London. When, in relation to consent ---
A No, sorry, they were in Stoke.

Q They were in Stoke when you were there?
A Yes.

Q We will be corrected if we are wrong about that.
A Okay.

Q They may well have been for part of the time, if not all of the time, but you would have telephoned them, wherever they were, would you?
A Yes.
A
Q To obtain their instructions about which the baby was to go into?
A Yes.

Q My question, really, to you was this: when in relation to the consenting process did you telephone doctors Samuel or Southall?
A Once I got consent.

B
Q Were head scans done for the babies, do you recall?
A I know they were done. I do not remember who did them or when they were done.

Q I think it was the nurses who got the babies into the tank. Is that right, prepared them?
A Yes.

C
Q We know there was a seal around the neck. Were there any problems at all with the neck seals whilst you were on the unit?
A No major problems. Sometimes the necks would be a little bit red or flaky, but and occasionally the seal would fail, but that would always be corrected.

D
Q I think when you made your statement, you were shown a picture of a baby from Queen Charlotte’s?
A Yes.

Q Did you ever see anything like that at Stoke?
A No.

E
Q You have indicated that sometimes a baby’s neck would get a bit sore?
A Yes.

Q Was any mention made of that to any of the parents prior to the consent process being done?
A I think I did talk about the neck seal, because that was so different to the conventional ventilation. I think I might have said if there were problems, we can take the baby out of the CNEP. But, again, my recollection of it is so poor.

F
Q Do you recall any problems with the seals? I am not talking about the babies’ necks now, but the seals themselves, were there any problems with those?
A No.

G
Q Once the consent form had been signed, what would you do with it? To whom would you give it, or where would it go in the unit?
A I am not sure. I cannot remember if there was a separate folder or if it went into the baby’s notes. Sorry, cannot remember.

Q When you took consent from parents - you have seen two forms that you have signed - would it be the case that you signed the forms yourself if you had consented the parents or would anyone else ever sign?
A I think it was - if I had spoken to the parents then it was usually me that signed the
consent form.

Q I think it is right that you had nothing to do with the scoring itself?
A No.

Q By whom was that done?
A I think by Dr Samuels or Dr Southall.

Q I think you have also had a look at the notes for Patient 6. I am going to ask that that be written down for you now. I am sorry. In the meantime, if you could take up file 2? It is tab 5, page 23. Dr Arya, these are the notes for a baby who was born on 14 December 1992.
A Yes.

Q Now, on this particular page, page 23, we see a note here on 15 December 1992 at 12.30 p.m. Do you recognise that note?
A It is my writing.

Q Indeed, is it your writing over the page as well to page 24, Dr Arya, where we see a note for 16 December?
A Yes.

Q Which goes over, I think, just to the top of page 25?
A Yes.

Q Can you just help by reference to that note what it was that you were recording had happened to this baby on 15 December 1992 at 12.30 p.m.?
A It looks like the baby’s heart rate has slowed down and the baby had stopped breathing, so was needing oxygen through a bagging mask. The baby was already on CNEP and I decided to intubate, put a tube down into his lungs to provide positive ventilation.

Q The baby, I think, received surfactant as well. Is that right?
A Yes.

Q Once she was positively - it is a she, this baby, once she was positively ventilated.
A I had also put a line into the belly button to monitor gases.

Q What was her progress thereafter?
A The following day she had actually improved and we could take her off the ventilator and we actually managed to take the tube out of her lungs as well.

Q I think you looked through these notes before, Dr Arya.
A Yes.

Q Apart from the discharge summary, is there any other entry by you in the notes in relation to this baby?
A No.
A
Q Can you just help us to this: we know that this baby was in CNEP. What was the position as far as taking blood pressure was concerned, do you know?
A Most babies would have had a line into the umbilical artery, and the blood pressure would be monitored through that.

B
Q What is that called? It is a?
A A UAC.

C
Q A UAC, and if the baby did have a UAC in that way, where would we find the blood pressure recorded?
A Sorry, I am not sure ---

Q Would a note be made of the blood pressure of the baby?
A It should - it would be on the nursing records.

Q Should be on the nursing records.
A Yes.

Q That is if there was a UAC in place or not?
A Yes.

D
Q If there was not a UAC in place, was it easy to measure blood pressure for a baby in a CNEP tank?
A If we could not get an umbilical line, then we would try for a radial line, a different place to put a catheter into an artery. If that did not work, then they would do manual blood pressures on an arm or a leg. I do not think it was always easy to do it in a CNEP tank.

E
Q Were blood pressures taken, therefore, of babies in CNEP tanks, do you remember, or not?
A I am sure they would have been done.

F
Q I am just going to ask you to look at some documents. If you put that file to one side a moment and just take up file 1 behind tab 3. I am going to ask you to look at some documents starting with the first one behind tab 3. This is a parental information leaflet. You made reference to them earlier on and I wonder whether you have any recollection of this document at all Dr Arya?
A Not really but I may have only looked at it once and then not referred to it again.

G
Q In terms of whether there was anything hanging on any of the tanks or incubators in the unit do you remember seeing anything hanging on those in relation to CNEP?
A I really, again, do not remember. There may have been but I could not say for certain.

Q Again, if you could just turn on, please, to page 341 through to 364. This is described as a parental information booklet. Have you any recollection of this?
A I recognise the pictures.
A  Q  You described having some pictures when you told us earlier about what you had when you would speak to parents but do you remember written information like this being available for parents?
A  I really do not remember.

Q  In terms of your own use of the CNEP tanks were there guidelines and some information about it for you, the doctors, to use?
A  Yes.

Q  You no doubt would have been aware at the time of the protocol?
A  Yes.

Q  For the trial?
A  Yes.

Q  If you would not mind just looking at page 340. We see there some information about the inclusion and exclusion criteria. Was that a document that was prepared for you, a doctor, or what was the position?
A  I am not sure. I do not know.

Q  Do you recognise it?
A  Only vaguely. I remember the criteria but I do not think it is that document I saw.

MS SULLIVAN: If you wait there, there will be some more questions.

Cross-examined by MR FORDE

Q  Good afternoon, Dr Arya. I represent Dr Spencer. I want to ask you a few questions about CNEP. You have told the Panel a little about your previous jobs, I would like to explore that if I may very briefly. I think you trained in Liverpool in 1987. Is that right?
A  Yes.

Q  You tell us you that you had house jobs at the Royal Liverpool Hospital. Then you decide to specialise in paediatrics. Was that when you became a house officer that you decided to do that or was it as a junior registrar?
A  My first SHO post, senior house officer job was in Warrington in paediatrics.

Q  You have remained in paediatrics or neonatology ever since, is that correct?
A  Yes.

Q  Which year did you commence your first paediatric post, do you recall? Was it about 1989?
A  No, in 1988.

Q  So by the time we are talking of you would be specialising in paediatrics for 13 or 14 years because we are in 1992/93 --- sorry, four years?
A  Yes.
Q You went to Alder Hey and then you did nine months as a registrar in Luton and then you tell us that you also worked in Great Ormond Street which is a specialist paediatric centre?
A Yes.

Q Of international repute, do you agree?
A Yes.

Q You were a registrar. Was this a senior registrar at Stoke?
A No, just a registrar.

Q Between 1992 and 1994. Presumably from your first day on the wards, even as a house officer, you were acquainted with the appropriate taking of consent from patients?
A I am not quite sure what you mean.

Q Is it not the case that something as basic as the taking of consent is drummed into you from the moment that you find yourself training on the wards? It is a basic skill that a doctor has to have?
A Yes, if I did surgery I would take consent from patients.

Q By the time that we are now talking about, which is late 1992, you had consented hundreds of patients?
A For various procedures, yes.

Q What other trials had you I been involved in prior to arriving at Stoke because you suggested to my learned friend that you had been involved in trials before? Can tell us briefly what other trials you had been involved in and when?
A In Luton there was a Curosurf trial, it is a factant. That was the main one before I came to Stoke.
Q Was that a randomised trial as well?
A Yes.

Q It was?
A I think it was but I think it was it was looking at two different doses of Curosurf.

Q How do we spell that drug just in case?
A C-U-R-O-S-U-R-F.

Q You had be involved in the taking of consents for that trial?
A I think so.

Q Moving to this hospital that we are concerned about, Stoke, you arrive as a registrar and I think by the time you arrived the CNEP trial was already in progress?
A Yes.

Q Do you recall a research nurse called Theresa Wright?
A I think so.

Q She was the lady who was very hands on as far as the trial was concerned,
gathering up the notes after discharge, looking at outcome scores and that sort of matter. Does that ring any bells with you?

A Unless I knew her face I do not think I would be able to remember.

Q The staff team that you joined had been involved in CNEP for some time and did you form the impression that they were competent and confident in terms of their management of the trial?

A Yes.

Q Nursing staff included?

A Yes.

Q Do you now recall whether you attended any formal seminars in relation to CNEP?

A I do not think I did but I cannot be sure.

Q Do you recall, as we have seen told by Janet Wakefield, a CNEP tank in a seminar room with a doll in it so that people could familiarise themselves with the equipment? Do you think that might have been available to you?

A I cannot recall anything like that.

Q In any event Dr Spencer tells me, I wonder whether you can confirm this, a lot of the documentation has gone missing, but there were staff handbooks and protocols dealing with CNEP, photographs of babies in tanks, a lot of educational materials available to you if you sought to consult them?

A Yes.

Q Were you confident in your own mind that you had the relevant experience and training to explain to patients what CNEP involved?

A I would say yes.

Q You see, we have some consent forms, and they have been shown to you, dealing with consent for the CNEP trial. You were shown one which pertains to Patient 121, first of all, I would like you to look at that and I would also like you to look at the one relating to Patient 69.

THE CHAIRMAN: We have one and not the other.

MR FORDE: Almost identical in form, sir. You have confirmed that it is your signature, I think, in respect of both consent forms. Is that correct?

A Yes.

Q What you have written under study title is “CNEP trial for RDS”, so that is respiratory distress syndrome, is it?

A Yes.

MS SULLIVAN: File 1, tab 3.

MR FORDE: I am very grateful. Then it has got name of clinician and you have put
A

your first name initial and then your surname. Do you see that?
A Yes.

Q Name of the patient or volunteer. Then certainly in relation to Patient 69 you have put your name into the second line of the text?
A Yes.

B

Q If we work our way through this form it begins dealing with aims and procedures of the clinical investigation. Are you satisfied in your own mind you would have explained to the relevant parents that this was a trial?
A Yes.

Q Then it says:

“I have had the opportunity to ask questions and to consider the answers given.”

Would you encourage parents to question you about the trial if they had any queries?
A Yes.

D

Q Did you emphasise that participation in the study was voluntary and that they could withdraw at any stage?
A Yes.

Q As far as you were concerned did you place parents in a position where they were giving fully informed consent?
A I felt I did.

E

Q You underneath the parents’ signature in both instances have signed your name and the following declaration occurs:

“I confirm that I have explained the nature of the above investigation to the above named relative/legal guardian”?

A Yes.

F

Q Can you satisfy this Panel that you would not have put your name to that declaration unless you were quite satisfied that you had given a proper explanation?
A If I had taken consent then I felt I had done a good job then I would sign it.

G

Q But you are not going to sign a form such as this unless you feel you have explained things adequately, are you?
A No.

Q Any suggestion by any parent, as we had this morning, Patient 69, that either you did not consent them, although your signature appears, you would refute presumably?
A Yes.

H

Q Similarly in terms of your clinical skills, do you think you would seek informed
consent from a patient who following a general anaesthetic or pain relief was obviously to 
your eye unable to understand the process? 
A No. 

Q Can I then ask you a few questions about Patient 6 having dealt with those few 
general matters. You were taken by my learned friend to the notes of Patient 6. I do not 
know if you have still got them open at the relevant page. You confirmed that our pages 
23, 24 and the top of 25 are in your handwriting? 
A Yes. 

Q Can we just look at what you were recording. I think the signature above your 
entry is that of Dr Brookfield. Do you recognise that? 
A Yes. 

Q He was the senior consultant on the ward? 
A Yes. 

Q And was also involved in the trial? 
A Yes. 

Q This child at 12.30 you have noted suffered a prolonged bradycardia and apnoea 
and had to be bagged and masked. You put down an endotracheal tube, you have noted 
the size of the tube and you are giving 60% inspired oxygen? 
A Yes. 

Q The nursing staff were sufficiently well trained, were they not, to alert you to 
bradycardia and apnoea attacks? 
A Yes. 

Q These children were closely monitored not only by observation but via 
technology? 
A Yes. 

Q When you inserted the umbilical arterial catheter, which we see on the first page, 
you knew that that would automatically monitor blood pressure? 
A Yes. 

Q And blood gases? 
A Yes. 

Q Would be fixed to a machine, the saturation levels as a percentage would be on a 
visual display. Is that correct? Or was it on a print out? Sorry, saturations from the clip 
on the finger, I apologise. Would that go to a visual display? 
A Yes. 

Q Were the machines set to alarm if the saturations became dangerously low? 
A Yes. 

Q In relation to blood pressure, that was monitored again I suggest at the digital 
display by the umbilical arterial catheter?
A Yes.

Q Anybody walking past any child in an incubator would have seen it when the UAC is in, can glance across and see what the blood pressure is?
A Yes.

B Q You would expect, would you not, competent nursing staff to recognise prolonged periods of hypoxia?
A Yes.

Q They fill in some complicated charts. I would like you to look at an example in the bundle. Could you turn in that bundle for example to page 87, just by way of example, and confirm for us that that is the sort of chart that the nursing staff were expected to fill in when monitoring a child who finds himself in the neonatal intensive care unit?
A Yes.

Q What we have there if we look down the left-hand column is you see head box O2 CNEP. Do you see that?
A Yes.

Q And the negative pressures are all recorded?
A Yes.

Q They appear hourly?
A Yes.

Q Then you have peak pressures, respiratory rate, the percentage of inspired oxygen, the time of the inspiration, the temperature of the child, the temperature of the inspired gases, and the oxygen saturations. Would you agree with me that if the saturation seems to be fluctuating between 95 and 99 it is unlikely that such a child is hypoxic?
A Yes.

Q You then have, on the right-hand side, some more temperature information. Then what do you take the graph to denote?
A Looking on the right-hand side?

Q The top right. What is being recorded there?
A Temperature, you have respiratory rate and heart rate.

Q Then if we go down the page, can you see BP mean?
A Yes.

Q That is supposed to be where the blood pressure is recorded by the nursing staff?
A Yes.

Q It appears on this occasion that that has not been filled in by the nursing staff.
A Yes.
A  Would you agree that, from a doctor’s perspective, it was a nursing responsibility to record the blood pressure there?
   A  Yes.

Q  Could I ask you to turn back to page 61 of these notes. These are nursing notes. We have seen your clinical note, which is lengthy, between pages 23 and 25 where you have recorded a great deal of information. Is it right that the nurses also record information in the nursing notes such as we see on page 61?
   A  Yes.

Q  Would you expect, subject to normal human error, the nurses to record clinical signs and activity accurately?
   A  Yes.

Q  Did you have any reason to think that any of the nurses working on that unit were in the business of fabricating notes?
   A  No.

Q  So if we look at what was happening at 2230 on page 330 there is a record of the father visiting and explanations being given. There is a recording in relation to the head box and the percentage of oxygen. Then we see at 0635 that somebody has recorded that the baby has been randomised into CNEP?
   A  Yes.

Q  Would you, from your experience, expect that to be an accurate record of what actually happened?
   A  Yes.

Q  As far as randomisation is concerned, did you explain to parents as best you could, that consenting to CNEP did not necessarily mean their child would ultimately be entered into CNEP and into the tank?
   A  Yes.

Q  You did explain that?
   A  Yes.

Q  I have just thought of one matter I should have asked you about in your witness statement. I will explore the nature of the scan finally with other witnesses. I was interested in the fact that you said this about head scans.

   (Document not available to shorthand writer)

"It was common for head scans to be taken without the parents’ knowledge."

This is back in 1992 and 1993. Is that your experience in the hospitals you worked in?
   A  What I meant by that was that you would do the head scan without telling parents you were going to do it at that particular moment in time.

Q  At some stage you would communicate the fact it had been done?
A

A Yes.

Q Then you say this:

“If there are minor abnormalities of no consequence, then we do not tell the parents. This would still be the case now”.

B

A Yes.

Q So if an abnormality - it would be a matter for others as to whether the abnormality here was minor or not - was regarded clinically as a minor abnormality, in the early 1990s and even in 2008, you take the decision as a doctor not to worry parents by telling them about minor abnormalities?

A Yes.

C

Q Is that fair?

A If it is not going to cause any harm to the baby or the results then we often do not worry parents unnecessarily.

Q Is that still your practice as a consultant paediatrician now of many years’ experience?

A Yes.

MR FORDE: Thank you very much, doctor.

Cross-examined by MISS O’ROURKE

Q I ask questions on behalf of Dr Southall who is not here today. I have just a couple of questions and want to do just a quick run through as to when you are taking consent. Can I confirm with you that the following would have been explained in taking consent when you took it. Firstly, it was a trial or a study?

A Yes.

Q You would have used one or other of those words and possibly both?

A Yes.

Q Secondly, that there was a randomisation process so you could not explain to the parent which limb of the trial they go into?

A Yes.

Q Thirdly, that they were going to need to sign a consent form.

A Yes.

Q Fourthly, that they should read that consent form before signing it.

A I think I might have actually read out a lot of it.

Q You would read it out to them, but you would make sure that they just did not sign on the dotted line without having a chance to look at the words?

A Yes.
A

Q And otherwise you would read it to them?
A Yes.

Q If they said “I have not my glasses” or “My eyesight is not so good”, what would you have done?
A I do not remember anyone saying that.

B

Q If someone had said that?
A I would read it out.

Q We had a witness before lunch - it is Patient 69, you have the form there - she was telling the Panel that without her glasses she would have difficulty reading in a closely typed form. If that was the case, would you have read it to her?
A Yes.

Q Can I confirm that for every patient from whom you took a consent, you would have ensured either they had been given a patient information leaflet or had access to one?
A Yes.

D

Q You also say in your statement that the nurses had laminated cards with photographs on them of how babies looked in the tank?
A Yes.

Q You would have shown those photographs?
A Yes.

E

Q As a doctor you would be able to appreciate whether someone is following what you are saying?
A Yes.

Q So, if somebody appeared not to be *compos mentis* or to be out of it you presumably would stop the process?
A Yes or go back later.

F

Q Presumably, when you were taking consent you would offer the parent the opportunity to ask you questions?
A Yes.

G

Q Or say to you “I do not understand”, or “Can you explain it again”?
A Yes.

Q If they say that they do not understand and could you explain it again, what do you do?
A I change the language so they would understand.

H

Q The randomisation process - you were phoning either Dr Southall or Samuels?
A Yes.
Q Sometimes that happened in the middle of the night?
A Yes.

Q Indeed often it was in the middle of the night?
A Yes.

Q You were calling them to give them information to show that these children met the criteria for the trial, would you agree?
A Yes.

Q You were going through the exclusion criteria?
A If a baby was excluded then I did not ring them.

Q They were checking with you that the child should be in the trial and asking questions about oxygen saturations and birth weights and gestations. Do you remember that?
A I think that they would trust me if I was ringing them that the baby met the criteria. I do not think that they needed to go through it again with me.

Q Might there be occasions when they asked?
A Yes might be. I cannot remember.

Q In terms of signing consent forms, the mother who gave evidence before lunch - you might have seen her in the waiting room - the mother of Patient 69 says that she has no recollection whatsoever of signing that form and no recollection of you. When I asked her was she saying that you had forged her signature or made it up or whatever, she seemed to be saying one of two things, either yes her signature was not hers, she could not be sure it was hers, or, alternatively that she was so out of it as a result of having had a general anaesthetic a number of hours earlier she would not have been able to sign it. What would you say in response to your putting your name on that form?
A There is absolutely no way that is a forgery, so she has signed it. I hope that I would not have taken consent from somebody who was under an anaesthetic and could not remember.

Q Would there have been any incentive for you to forge a signature?
A No.

Q I think you say in your witness statement, there is certainly no incentive for anyone to forge a signature. It was actually easier if the parent refused consent as the conventional incubators were easier to use. That means easier for you, the doctor, and the nurses to use?
A For the nursing staff, yes.

Q So CNEP involved a bit more work?
A Yes.

Q I want to ask you about that particular mother. We have copies of her notes. I think you will be handed pages from her notes. (Same handed)
THE CHAIRMAN: These will be D11.

MISS O'ROURKE: It is the child who is male rather than the mother's notes. *(To the witness)* I think that these notes are not in chronological order; I think they are almost in reverse order? Would you look at page five? Can you identify the note that starts 4.15 and the signature at the bottom of the page, is that your handwriting?

A Yes.

Q So that is your note?
A Yes.

Q You have written in the middle of the note “randomisation to CNEP trial”, tick consent. Is that your writing, six lines down?
A Yes.

Q When would you have written that note, or why would you have written that note? Was that as a result of you taking the consent?
A Yes.

Q Would you therefore have had to see the mother to write that note?
A Yes.

Q And you would have had presumably to see the child to write the rest of the notes?
A Yes.

Q And as far as you would recall, would the mother be with the child at the time?
A That I cannot say from what I have written. I do not know if I went to mother or she was on the unit.

Q I want you to ask you to look next at page 2. I think it is the next one chronologically. On the second page you see at the top of the page 18/1/93 Day 5. Is that your writing?
A Yes.

Q Over on the far side is that your signature?
A Yes.

Q That suggests that you at the very least saw the baby at that time?
A Yes, it was on a ward round with Dr Spencer.

Q Would the mother have been there when it says, “starting oral feeds” or not?
A Not necessarily, no.

Q If you then look at page 3, is that your handwriting down the bottom where it says “31/1/93”?
A Yes.
Q And “For home” - diagnosis for home I think that ---
A It says “[therefore] for home soon”.

Q That is your handwriting again?
A Yes.

Q Then the next page, page 4, is a neonatal discharge stamp. It says “Well ... stable, home today”, and that is your signature again?
A Yes.

Q If that is the discharge, would you expect the matter to have been present at that point in time?
A Again, not necessarily. The baby might have been examined on a ward round and then allowed to go home later.

Q So those are all your signatures in the notes, so it appears that you were involved with this baby?
A Yes.

Q It is likely, therefore, that you would have been involved with its mother?
A Yes.

Q Just finally in respect of CNEP trial, as you know I represent Dr Southall. Dr Southall was available should any of the doctors have had questions about the trial or questions about the consenting process. Is that right?
A I presume so, yes.

Q You could have called him because you had a phone number obviously to call him for randomisation?
A Yes.

Q But, in fact, this was a well run trial with good research nurses, nurses who knew what they were doing and people available to give advice if it was needed?
A As far as I know.

Q As far as you were concerned, you did not have any worries about your role in it?
A No.

Q Your role in taking consent?
A No.

Q You did not feel that you lacked any training for taking of consent?
A No.

Q You did not feel you lacked any information for taking of consent?
A No.

Q You did not feel you lacked any information to actually do the work on the trial to nurse the babies?

D14/89
MISS O’ROURKE: Thank you. I have no further questions.

Cross-examined by MR FOSTER

Q Would you contradict me if I said that Dr Samuels was at Stoke from June 1992?
A I cannot.

MR FOSTER: Thank you.

Re-examined by MS SULLIVAN

Q Dr Arya, do you still have the consent forms in front of you there?
A Yes.

Q The originals? You indicated that you might read out something to patients ...
A Yes.

Q ... on occasion. We see on those consent forms that there is reference to “information overleaf”. Do you see?
A No - okay, yes.

Q Got it?
A Yes.

Q Is there in fact any information on the reverse of either of those forms?
A No.

Q Do you recall what the position was in relation to information?
A It was those laminated pictures and parent information and obviously what I told them. I do not know if there was other information.

Q You have also spoken and been asked about a patient who had a general anaesthetic. We know that the patients needed to be randomised within the trial within four hours?
A Mmm.

Q What was the process of assessing whether someone, having had a general anaesthetic for example, was able to consent within that time?
A I really do not remember very much, but if the patient was still on labour ward,
the midwives would be able to tell you whether or not the patient was awake and capable
of talking to you. If she was still out then you could not - there was no point in talking to
her.

Q No, obviously not. Apart from whether she was out or not, was anything further
done to assess ---
A Maybe her response to me; if I felt she was not capable of understanding or
talking to me then I would not persist.

Q You were asked as well about the recording of blood pressures in relation to
Patient 6 and you looked I think at page 87 in the notes as one of the examples of the
recording of various information about the patient, including blood pressure. We saw that
that was blank?
A Yes.

Q Can I just ask you this: were these charts to which the doctors had access as well
as the nurses?
A Yes.

Q So when doctors were going to see particular patients would they look at these
charts?
A Yes.

MS SULLIVAN: Thank you.

THE CHAIRMAN: Thank you very much, Dr Arya. That completes the questioning by
the lawyers. As I indicated at the outset, there is now an opportunity for members of the
Panel to ask questions, if any member of the Panel has anything they would like to ask
you.

Questioned by THE PANEL

DR SHELDON: I particularly want to talk about Patient 6 and your entry in the notes on
page 23. Do you have that in front of you? It is tab 5, page 23.
A Yes.

Q It is unreasonable for me to ask you to remember much about that morning at this
distance, but presumably if you were there in the middle of the day you had not been
there that night. You would have come on duty at what time, do you know?
A No, that does not always follow. Even now actually. When I started duty -
I would normally start duty at nine o’clock. If I was on-call I would continue overnight
and then I would finally finish at five o’clock the following day, so it would be a 32 hour
shift.

Q So the chances are that you came on at nine o’clock in the morning?
A I cannot tell from here whether I had been on-call the night before or whether
I started at nine o’clock that morning.

Q There is a note by Dr Brookfield just above yours. Do you remember anything -
A talking with Dr Brookfield or doing a round?
A I really do not know.

Q You sat down to write this note and put “15/12/92”. Underneath, do you look at your watch and say, “It is now 12.30”?
A That note will probably have been written after 12.30 because it would have been 12.30 when everything kicked off.

Q That is what I wanted to know. You started therefore doing these activities, like putting in the cannula, at 12.30?
A Yes.

Q So this note might have been written at 2.30 or three o’clock?
A Yes.

Q So at 12.30 you were asked to start doing some things for this child?
A Yes.

Q How long does it take to put in an umbilical catheter?
A It can vary; anything from 15 minutes to an hour, even longer. It depends on a lot of factors.

Q So you were working all over the lunch hour doing these various things?
A (No audible reply)

Q You cannot remember at all whether there had been a fuss, whether someone had said, “We must do something quickly”, or anything like that?
A No.

DR SHELDON: Thank you.

DR OKITIKPI: Dr Arya, it relates to the consent form of patient I think 69.
A Okay.

Q To the left-hand side of the signature is the name of the mother written out.
A Yes.

Q Is that your writing?
A That is mine.

Q Is that the normal pattern with consent forms, that you fill that section out and the parents sign it, or is it generally the parents sign and write on both sides?
A I think I used to write the names out so that I knew who was giving consent, but I do not know, there may be other forms where the parents have written those things out.

Q I just want to check whether there is any particular circumstance when you write that name as opposed to the parents writing the name?
A It was not done with any thought, I do not think.
Q The other question is to do with the study itself. You said in the very beginning that you had no training at all.
A Yes.

Q Aside from just the collection of the consent form, you have to have some knowledge and understanding of the nature of the study?
A Yes.

Q So how did you get that?
A Again, I do not really remember the exact details, but you see it in action, people tell you about it. You get used to using it, I suppose, and obviously read what other information was available.

Q I guess you want to find out whether all the doctors in the unit were involved in the study or whether some of the doctors were involved in the study, and if you were one of the doctors who were involved in the study was there a session that you had to explain what the study is about so that when you are informing parents you will have some understanding of what the study is about?
A I really cannot remember, but if you were on the neonatal rota then you were involved in the study.

DR OKITIKPI: Thank you.

THE CHAIRMAN: I wonder if you could just help me with a bit of clarification, please. When Ms Sullivan was asking you about the consenting process, you told us that if it was you who had spoken to the parents it was usually you who signed the consent form.
A Yes.

Q Can you help me as to what you meant by the word “usually” in that answer?
A I do not know and I cannot remember, but I think it was always me but there may have been somebody else who took - sorry, somebody else who explained the trial to the parent and then I went and got the signature.

Q If that happened, assuming that could happen, would that be a situation where the explanation was given when you were not present?
A Yes.

Q If you were signing the form in that situation, what would you have done to satisfy yourself that the explanation had been given?
A When you go and speak to the parents - again, I really do not remember and I do not remember on that occasion if that situation actually happened, but I would then go and ask them if they were happy to go ahead and sign the form. So I presume they had been given enough information that they needed.

Q So without being able to remember any specifics, you can envisage a situation in which an explanation about the trial might have been given by someone else and you would deal with the signing of the consent form and sign it yourself?
A Yes.
Q Being satisfied in some way that an explanation had been given, even though not by you?
A Yes.

Q Can you remember - again recognising you cannot remember any specifics - but if that process was undertaken, namely explanation by someone else dealing with the consent form and signing by you, was that in accordance with the training that you had received about the taking of consent?
A That is hard to - I do not know.

Q You do not know?
A No.

THE CHAIRMAN: We appreciate it is a long time ago. Thank you very much indeed. Any questions arising?

Further cross-examined by MR FORDE

Q Yes, sir, particularly in the light of the last few questions. Could I just establish with you these basic propositions? At the time in the ‘90s - and we now have our 360 degree appraisals et cetera in 2008 - on-the-job training was absolutely standard, was it not?
A Yes.

Q It was actually somewhat remarkable that this study had involved - if not involving you because you cannot remember - research nurses who were able to give seminars. That was not the usual scenario, was it, in the early ‘90s for trials?
A I had only been involved in one before that so I could not really comment.

Q Okay. You felt, as you told my learned friend, Miss O’Rourke, competent and confident in your understanding of what was involved in this trial?
A Yes.

Q You have been asked some questions by the Chair, based upon a hypothesis, and you will understand the difficulty for us is that this all happened so long ago. I do not think you were suggesting you could remember a single instance where, in fact, you had signed the declaration that risks and information had been explained to parents, but that had actually been done by somebody else?
A No, I cannot remember an incident.

Q You were simply being asked to speculate about the possibility of that happening?
A Yes.

MR FORDE: Thank you very much.

Further cross-examined by MISS O’ROURKE

Q Can I just follow up on that? It would indeed be highly unlikely that that would happen, because, as you said in your witness statement, a lot of these consents are taken
in the middle of the night, and that is why you thought you had taken a number of them; you would be on call. You would be the only Registrar on call, would you not?

A For the neonatal unit.

Q And nurses were not allowed to take consents for this trial?

A No.

Q It would be highly unlikely there would have been anyone else around to explain it?

A Yes.

Q It would be very, very unusual for you to allow somebody else to give an explanation and then you come along? There would be no need.

A The only time I can think that that possibly happened is if I was so busy dealing with a baby somebody else went to talk to parents, but then they should have got the consent.

Q Indeed, if they were qualified to take the consent.

A Yes.

Q You would have wanted to have been satisfied - when the Chair asked you about would you need to satisfy yourself before you signed that form - that if anybody else had given the explanation, it was the correct, appropriate explanation and one with which you agreed?

A Yes, but I do not remember any instances of that.

Q You do not remember it ever happening? And it would have been highly unlikely?

A Yes.

MISS O’ROURKE: Thank you.

THE CHAIRMAN: Anything else arising?

MS SULLIVAN: No, thank you.

THE CHAIRMAN: Dr Arya, thank you very much for coming this afternoon and for the evidence you have given the Panel. That completes your evidence. You are now able to go.

(The witness withdrew)

THE CHAIRMAN: Ms Sullivan, that completes the evidence you have available for us today?

MS SULLIVAN: It does, sir, yes.

THE CHAIRMAN: We will be adjourning now until Monday morning?
MS SULLIVAN: We will.

THE CHAIRMAN: Are there issues arising as to when we want to start on Monday morning?

MR FORDE: Sir, I am not sure this needs to be transcribed.

(Discussion re timetable and witnesses)

THE CHAIRMAN: There seem to be a number of pragmatic reasons why we should start at 10.30 on Monday morning, whether we get through the witnesses it is intended to call on Monday. We will rise now and come back at 10.30 on Monday morning.

(The Panel adjourned until 10.30 a.m. on Monday, 2 June 2008)
GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council’s Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988)

On:
Monday, 2 June 2008

Held at:
St James’s Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

STEPHEN ANDREW SPENCER BM BS 1976 University of Nottingham
Registration No: 2305893

DAVID PATRICK SOUTHALL MRCS 1971 Royal College of Surgeons of England
Registration No: 1491739

MARTIN PHILIP SAMUELS MB BS 1981 University of London
Registration No: 2732178

(Day Fifteen)

Panel Members:
Mr D Kyle (Chairman)
Mrs V Brickley
Mrs S Hollingworth
Dr T Okitikpi
Dr M Sheldon
Mr A Forrest (Legal Assessor)

MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hempsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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THE CHAIRMAN: Good morning. We will continue now with the case of Dr Spencer, Dr Southall and Dr Samuels. Miss O’Rourke, is Dr Southall still temporarily away?

MISS O’ROURKE: I am afraid he is not able to be here because of family difficulties. It is anticipated he will be able to be here by Wednesday. He is happy for the proceedings to go out on without him here and that I am well enough briefed to know what questions to put on his behalf.

THE CHAIRMAN: Thank you very much. Ms Sullivan?

MS SULLIVAN: Sir, the first witness I am going to call is Nicholas Duncalf who is the father of Patient 24, who is a son.

Nicholas John DUNCALF, affirmed
Examined by MS SULLIVAN

Q Mr Duncalf, just to help you, you will find a note of that patient number just to your right-hand side so that you can remember it in the course of your evidence. Would you mind telling us your full names, please?
A It is Nicholas John Duncalf.

Q What is your occupation, Mr Duncalf?
A I am an accountant.

Q As you know we want to ask you about the time of the birth of your son, Patient 24, who was born, we know, on 29 August of 1992. Is that right?
A That is correct.

Q I think it is right that your wife was bleeding very heavily and had to be rushed into hospital?
A Correct.

Q Did you go with her?
A I followed shortly afterwards. An ambulance took my wife to the hospital and I followed shortly after.

Q That is to North Staffordshire Hospital?
A Correct.

Q Did your wife thereafter have an emergency Caesarean section?
A Not immediately. She was taken into a receiving area where they sort of monitored her. She was bleeding which was why she was taken to hospital in the first place. Things seemed to calm down for a while and I think they indicated that if she could stop bleeding then they would keep her in hospital possibly up until the normal birth process but then unfortunately she started bleeding again and then she was taken to have the emergency Caesarean.

Q So they were unable to control the bleeding?
A Correct.
Q Do you recall how many weeks pregnant she was at this stage?
A 31 weeks.

Q They took her to have an emergency Caesarean section and were you present for the birth Mr Duncalf?
A No, I was not allowed.

Q You, I think, were in a waiting room nearby?
A Correct.

Q About 15 or 20 minutes later did you see an incubator going past the waiting room?
A Yes, I was told would I like follow and I was led along to another receiving area.

Q I think you went along to the neonatal unit where your son was being taken?
A Correct.

Q How small was your son? Do you remember what he weighed?
A Four pounds three ounces.

Q Once you got in to the neonatal unit with him was there any discussion with you about your son?
A Yes, I met a doctor who sort of took some details from me and then explained obviously that he was quite poorly and at that stage we talked about that he would potentially go into a trial process given the fact he was two months premature.

Q You say that there was talk about him going in to a trial process. Can you help us as to how soon that discussion took place? Was that as soon as you got into the neonatal unit or later?
A As I recall, please bear in mind this was nearly 16 years ago, that I had a discussion with a young doctor and I am fairly certain that at that point he gave me a form to actually complete to actually agree to take part in this test, this trial.

Q Can you remember, was the doctor male or female?
A Male.

Q Can you describe the doctor in any way?
A Without wanting to sound racist I can just remember he was a coloured gentleman. At the time I was about 36, I would say he was possibly slightly younger than me.

Q Help us, please, as to what he told you about the trial?
A Again it is 16 years ago. I cannot remember a lot of detail. Just the fact that my son was obviously very poorly being two months premature. I think tests were being conducted for children that were born at his early stage and this test or this trial would potentially help him.

Q You say that you were asked for consent. Were you asked to sign something?
A I am fairly certain, yes.

Q We will look at that in due course but let me ask you this, how much time were you given before you were asked to sign your consent?
A I am sure it was not a long deliberation. I would say I have subsequently been shown the form that I signed. It is definitely my signature on that form. The date is the date of his birth. I do not recall having a long discussion or seeing a lot of information but obviously I was somewhat shocked at the time.

Q I wonder whether you might just look at the original and perhaps we could look at a copy of your form. It is at file 1, tab 3, page 400. So, Mr Duncalf, we can see a reference at the top there to “RDS CNEP trial”, and name of clinician I think says doctor and then name of patient and it refers to “Baby Duncalf”. First of all, had you named your child at that stage?
A No, with it being two months early we were still in discussions in terms of names so we had not come to a name but by the same token I was being encouraged to give a name just in case there was any complications.

Q Is any of the writing at the top of that page yours, Mr Duncalf?
A No.

Q Right at the bottom we see the name of a doctor to whom we have had reference made before. You do not remember names, obviously, at this stage?
A No.

Q But is the writing at the bottom not yours either?
A The only writing that is mine at the bottom is my signature.

Q So did you write the date then underneath your signature?
A Looking at those numbers I would say not.

Q Likewise, did you write your own name to the left of your signature?
A No, I did not.

Q Or write the relationship “father” underneath?
A No.

Q That signature that we see there which you have told us is yours, Mr Duncalf, how does that compare with your normal signature?
A It is as bad as usual.

Q Have you any specific recollection of signing the form?
A Not specific but this is definitely my signature.

Q If you look at the body of the form it does refer to there being information set out overleaf in that first paragraph. That is the original of your form. Is there anything on the back of that form?
A No.
Q Do you recall seeing any information about the trial prior to signing the form?
A I do not recall.

Q Just help us a little as to your state of mind at the time when you were being asked to give your consent to this trial?
A Obviously in a state of shock sort of from my wife having a very normal, what appeared to be a very normal pregnancy to a short space of time going to potentially believing that I might lose either my child and/or my wife. So I was probably not very --- very shocked really and sort of my actually signing this document my belief was, I was told that it was something that could help my child so on that basis, I am an accountant, I am not a doctor, I tend to have a view that sort of professional people if they give advice that, you know, you should take it.

Q What treatment did you understand your son would receive if you were to consent to his participation in the trial?
A I understood that it was a form of incubator that would actually help him. I think I recall having a conversation where they were talking about negative pressure which would actually help a child that has had breathing difficulties. Anything that, sort of, could help him I was more than happy to comply with.

Q So did you have any understanding that your son may or may not receive that treatment? In other words, that it was a random process?
A I was not aware that it was random process in the sense of a statistically random process. I understood that it was a random process in the sense that he may or may not require it.

Q But if he required it what was your understanding about whether he would receive it?
A If he required it my understanding was that he would receive it.

Q We know it was you who signed the consent form. Was your wife involved in the consenting process or did you take it on yourself?
A I sort of got the impression that, sort of, time was not really something that one could afford to waste and so given my wife had just had a Caesarean operation I was not aware as to quite how lucid she would be, or even able to make those sort of decisions so I actually felt that there was a certain amount of time pressure to actually make this decision.

Q Did you discuss it with her afterwards?
A Yes.

Q What did you tell her about what you had consented to?
A I told her that that I had been asked to agree to Number 24 going into this trial and I said that I had actually agreed to it on the basis that it could help him.

Q I asked you whether you recalled receiving any written information. Did you have anything given to you to keep at all, Mr Duncalf?
A I cannot recall.
Q I wonder if you would mind just looking as well at the same bundle that we are looking at, so file 1, tab 3, page 336. I think when made your statement you were shown this particular document entitled “Information for parents”. Do you have any recollection of having seen it before?
A From the statement I made I could recall seeing some, not in depth, I recall seeing some information which actually I think originally thought might have been on the reverse of this document I had actually signed. I did not recall seeing quite more in depth detail, which I do not recall having seen that. Whether that was shown to my wife I am not sure but I do not recall.

Q We have that leaflet there at page 336 and then at page 341 to 364 there is what is described as a “Negative Pressure information booklet for parents”. Have you any recollection of that?
A I do not recall seeing that, no.

Q I think you were also shown, I will not ask you to turn to it, a bonding questionnaire?
A Yes.

Q But I think that was something that was for your wife to deal with rather than you?
A That was mainly for my wife, yes.

Q Apart from this discussion that you had shortly after your son’s birth in relation to him going into a trial, did you have any further discussion with doctors or nurses about his participation in it at any time thereafter?
A I do not recall any in depth conversations with any specific doctors. There were obviously doctors on the neonatal unit. We probably saw more of the nurses on the neonatal unit. The help and support on the unit was first rate. If we wanted any information then we could have it.

MS SULLIVAN: Thank you. If you wait there, there may be some more questions.

Cross-examined by MR FORDE

Q Good afternoon, just.
A Good afternoon.

Q I am asking questions on behalf of Dr Spencer who is the gentleman to my right. Do you have any recollection of ever meeting him before?
A No.

Q It does not come as a surprise. Your son, now nearly 16?
A Correct.

Q Some difficulties of recollection on your part?
A Yes.

Q You are, as you have been at pains to tell us, an accountant and the cliché
response to that is naturally cautious by nature. Would that describe you?
A  Correct.

Q   Are you also a man with a reasonable eye for detail, do you think?
A   Yes, but it may be diminished in time.

Q   You may be relieved to hear there is not much between us, Mr Duncalf. Your wife’s witness statement suggested it was about nine o’clock in the evening that she had her Caesarean section. Does that accord with your recollection?
A   Yes.

Q   Have you got fixed in your own mind a time when your son was born?
A   Not exactly.

Q   Is it around about that time?
A   Around about that time, which I think was corroborated in my statement.

Q   We have not got the notes, I am afraid. You signed a witness statement - I have not seen it. On 1 February 2008, you signed your witness statement for the General Medical Council. Was that the first time you were asked to recall these matters in detail?
A   No.

Q   How long ago do you think you were first asked to recall these matters in detail?
A   Probably eight years prior to that.

Q   In what circumstances?
A   I think similar circumstances.

Q   So you were contacted by General Medical Council solicitors?
A   I cannot recall.

Q   Could that have been not to produce a witness statement, because we know there was a survey done by the previous solicitors, but to confirm that it was your signature on the form?
A   It could be, yes.

Q   If you have produced a witness statement to the General Medical Council in 2000 or ‘99, I would be very interested to see it. Do you think you may have produced a witness statement that time ago, or simply confirmed that it was your signature on the form?
A   It may have simply been to confirm my signature. It was certainly not in the depth that ---

Q   Perhaps it is better to phrase my question with greater precision. Is it right that around about 1 February 2008 was the first time you were asked to give details, consideration to the events in question. Is that fair?
A   Yes.

Q   What you tell us in your witness statement is you recall it was a bank holiday
weekend...
A  Yes.

Q  And you arrived on the 28th. You say, “I think” - I will say your son, because I have momentarily forgotten his number - “was born around 9 p.m. on 29 August 1992, but then I stayed in the hospital until 11 or 11.30 p.m.”?
A  Yes.

B  “Beyond a certain point, there was not much that I could do.” You are unable to time - is this fair - exactly when between 9 p.m. and 11 or 11.30 you were asked about the potential for the CNEP trial?
A  I think it was very soon after his birth. I think it was literally as I was asked to follow the incubator down the corridor, went into the - it was like a receiving area in the neonatal unit, and the gentleman talked to me then, I think, about the trial, about considering giving a name to number 24, so I am fairly certain that was very soon after going in.

C  We have got a log of various telephone calls which I am sure you would not have seen which indicates he was randomised for the trial at about ten-past one in the morning, so that would have been the following morning. We can deal with that with others. I just want to ask you about your recollection in relation to the doctor in question. You remember him being non-Caucasian, is probably the PC word to use. Is that correct?
A  Yes.

D  It would appear from his name that he may have been of Sri Lankan origin.
A  That would be reasonable.

E  Does that seem to reflect his hue appropriately?
A  Yes.

F  If we look at our page 400, which is your signature, you tell us, on the consent form, what you said about your understanding of CNEP, and we look at the top of the page, it says, “Consent by proxy to conduct of a research investigation. Study title: RDS - CNEP Trial.” You were in no doubt that this was a trial, as I understand your evidence. Is that correct?
A  Yes.

G  You said very early in your evidence to my learned friend, “He could potentially go into a trial process.” Was that your understanding of the position?
A  Yes.

H  Now, the only difference between us, as far as that is concerned is this, and I just want you to consider whether you may have a failing recollection - your impression today, in 2008, is that if it was of benefit, he would be placed into CNEP. That is what you have told the Panel so far?
A  Yes.

Q  There is a subtle difference between us, and it is this: our system, as it was supposed to operate, was that you would be told he - consent was needed from you for
him to go into the trial, but he might also receive standard treatment, but that the standard treatment was also part of the trial. Do you understand?
A  Yes.

Q  You have got comparative scenarios.
A  A statistical trial.

B  Q  Do you think that you might have been told that and you have forgotten?
A  Given my state of mind, I might have misinterpreted what he was saying. I did not realise certainly until probably reading my own evidence and some of the things that have been sent through to me that it was actually a statistical trial, that these had actually been used for many years, it would appear, and they are simply for the means of trying to identify statistically whether it was better than a previous method of treatment. So, no, my understanding was that based on his particular health, on his particular requirements in terms of his difficulties in terms of his breathing, that would determine whether he went into it or not. That was my understanding.

C  Q  All right.
A  If it is a misunderstanding then I have misunderstood.

D  Q  Well, there are two possibilities: either you misunderstood, and we will deal with your state of mind in a moment, or you failed to recollect that subtle difference. Do you countenance both being possibilities?
A  It is a possibility, yes.

E  Q  In your witness statement you say: *(Document not provided)*

“I do not remember the participation in CNEP being proposed on a random basis; ie that if we agreed to be involved in the trial [Patient 24] may or may not have been put on to CNEP. I understood he would be placed in a CNEP tank once we consented to be included in the trial.”

I think you have very fairly conceded the two possibilities. Is that fair?
A  Yes, but as I said, my overriding impression was - I sort of got the impression this possibly would be better for a child who had particular breathing problems.

F  Q  You understood, because I am not sure this is dealt with in your witness statement, but you have told us today that you realised some matters about the possible use of CNEP. You understood it was associated with premature babies who might have breathing problems. Is that correct?
A  Correct.

G  Q  So you understood prematurity was a factor; breathing problems were a factor. It would also appear from your evidence you had some understanding from somewhere it might involve negative pressure?
A  Yes.

H  Q  That is not in your witness statement. That is what you have told us today, so I
am assuming some explanation was given to you as to how it worked?
A Yes.

Q Does that seem possible?
A Yes.

Q And although you do not recollect - if you go to our page 336, if we just go through some of the things in there together and see if this helps to jog your memory a little. First line is an evaluation of a new technique:

“...for the treatment of babies who develop breathing problems associated with premature birth.”

Not quite how you have expressed it, but, in general terms, you understood that. Did you understand there was any newness about it at the time?
A Well, as I said, I had surmised that it was a new treatment.

Q Okay. Then there is a description in the second paragraph of the chamber, negative pressure, and it helping to move the chest wall. Again, you described something along those lines when you were dealing with negative pressure with my learned friend. Did you have that understanding, that somehow the negative pressure was helping the baby ventilate?
A Yes.

Q Then do you recall, and if you do not, do say, any discussion about the negative pressure option, which was CNEP, as against conventional treatment, which involved blowing air, under pressure, into the lungs? Do you recall having any discussion ---
A I do not.

Q You do not. Might it have happened?
A Might have happened.

Q Then this is the paragraph that deals with randomisation, which, again, you have fairly said you may or may not have appreciated at the time:

“Should you give [your] consent to your baby being entered into the study then we will use a method of random allocation to decide whether your baby receives negative pressure ventilation. A number of babies receiving negative pressure ventilation will need positive pressure ventilation as well, and this will be given when needed.”

Then there is information about oxygen and blood pressure. Were you under the clear understanding that your son would be given the appropriate treatment? In other words, he would not be put into CNEP if it was inappropriate, and they would not persist with it if they thought it was not working?
A Yes.

Q Do you recall being told that you had the option not to agree to go into the trial?
A Probably not in the way you are saying, but by actually having been asked to sign
something, I am almost by virtue saying, well, yes, I am agreeing to that process, so, yes.

Q It is just that you say in your witness statement, and this is what interested me, this:

“The consent form”

“says that there is information overleaf. I am an accountant by profession and to be fair I do not normally sign something without reading the small print. If I sign to say I have read something overleaf then I will have read it. So I think I probably did read the information overleaf on the form, however, I have no specific recollection of doing this.”

Now, there is a problem with the form, which we have identified with others: the reverse is blank, but my instructions are that the system was supposed to involve having the parents’ leaflet we have just been looking at attached to the form. Would I be right in surmising that if you had turned that form over and found it blank, you would have said, “There is nothing overleaf,” or you would have been comforted by the fact that there was something more to read?

A As my statement says and as you rightly started out by saying, I am an accountant. I tend to be fairly sort of - one of the things I have to do quite regularly is read small print, contracts and things like that. So, in normal circumstances, I would not sign something that I had not read.

Q And if it was not there, would you tend to ask for it, do you think?

A I would tend to. The only sort of thing I would say against that is what I have said before, given my state of shock that I was in, whether my normal behaviour stopped me from doing what I would normally do, I cannot recall. As I say, I do not think I would actually do something that I felt would cause risk to my child’s life by signing something without knowing anything about it.

Q Yes. That is what I was going to explore with you. I quite appreciate - I do not know whether this is your first child or not.

A He was, yes.

Q First child, premature, surprisingly, late in the night, your wife recovering from a Caesarean section, and you are being asked to consider this trial, so it was a far more stressful situation than working in the office. We appreciate that. I just suggest to you, as a creature of habit, you would have wanted to feel, as this form says, that you were giving informed consent. In other words, you had sufficient information to satisfy yourself that your son, if appropriate, was going to receive appropriate treatment. As you have said, you would not just sign willy-nilly. Is that fair?

A That is fair.

Q Is it also fair to say a detailed recollection of any conversation or explanation is
impossible at this distance in time?
A Yes.

MR FORDE: Thank you very much, Mr Duncalf.

Cross-examined by MISS O’ROURKE

Q Mr Duncalf, I ask questions on behalf of Dr Southall, who is not here. I am only going to ask you a few questions because Mr Forde has already asked you the main points. Can I just confirm this: Dr Southall was never involved in the treatment of your son, Patient 24, as far as you know?
A Not that I am aware, no.

Q And you never met him?
A No.

Q You have no complaint to make against him?
A No.

Q As far as I am aware, you in fact have no complaint to make against CNEP?
A No.

Q You were perfectly satisfied with the way that your son was treated in hospital, the use of the CNEP tank and explanations in relation to it?
A Yes.

Q You are here because somebody contacted you to ask you about the consenting process?
A Correct.

Q Not as part of any complaint against not only Dr Southall but any of these doctors? A No.

Q Then just very briefly in respect of what you have signed, I am going to suggest to you this: you are, as you have said to Mr Forde, an accountant and therefore someone who would be careful about signing documents and looking at the detail. Is it possible that what you saw first was a consent form which did have something on the back of it, or attached to it? In other words, part of an information pack that had the one-page parents’ information leaflet, and then you were handed a separate form which had the same writing on it in order to sign?
A This is a possibility.

Q We have heard from a nurse that there was a pack prepared and it had the information sheet and a blank consent form on it, and that then it may well be the doctor handed a separate consent form to sign, so you did have an opportunity to read the patient information leaflet in some sort of pack. That is possible?
A That is a possibility.

MISS O’ROURKE: Thank you, I have no further questions.

D15/11
MR FOSTER: No, thank you, sir.

Re-examined by MS SULLIVAN

Q Just a couple of we questions, Mr Duncalf. Just looking at page 336, do you have it there in front of you?
A Yes.

Q You have obviously had an opportunity to see that today and also previously when you made your statement. Looking at it, how does that compare with the information that you recall being given at the time?
A In terms of verbally after the process, or how do you mean?

Q Before the process. Before you consented?
A I have a recollection of having a conversation with - this is presumably Dr Arumugam (sic). As, I say, I do not remember it being prolonged, but I do remember him talking about it. I do remember this negative pressure aspect, which was obviously brought out in this, so I feel as confident as I can be that I had sufficient information to make a decision. I would say that at no point did I ever feel that by signing something that I was actually increasing the risk of my son. I did not feel I was actually putting him into a process that could actually worsen his chances of life.

Q Yes.
A And that it could only be something that could actually improve his chances.

Q Yes. I think we all understand that. I wonder if you could just look at the consent form again. We have got it at page 400. You probably still have the original there, have you?
A This one.

Q You have told us, as an accountant, you are normally careful if there is reference to something overleaf, for example, to look at it. We see on the form that there are a number of blanks there.
A Yes.

Q Do you see in the second sentence the doctor’s name is left blank?
A Yes.

Q Also, there appears to be a blank space in the penultimate paragraph?
A Yes.

Q Were those matters that you would have noticed at the time, in the normal course of events?
A I suppose so, yes. Whether I felt that he would actually complete those after I had actually signed them, how actually relevant or important those aspects were - I mean, the bit at the start, “is to take part have been explained to me by Dr” is left blank. I thought, well, that could be filled in by the person after I had signed the form, anyway. In terms of “medical records may be disclosed to,” again, I did not see any problem in actually
having his medical records being shown to anybody. I do not think those actually - I probably would have looked to those and thought, well, I am not concerned about those. They are not really relevant or that important to me signing that document.

Q Those would not have worried you?
A No.

MS SULLIVAN: I have no further questions.

THE CHAIRMAN: Mr Duncalf, that completes the questions which the lawyers have to ask of you. As I indicated at the outset, it is an opportunity now for members of the Panel if they have questions. It seems that we do not have any questions by way of clarification, Mr Duncalf. It remains to me to thank you very much for coming this morning for the assistance you have been able to give us. You are now free to leave.

(The witness withdrew)

MS SULLIVAN: Sir, the next witness is Henrietta Duncalf.

HENRIETTA CHRISTINA PAO CHAI DUNCALF affirmed
Examined by MS SULLIVAN

Q Hello, Mrs Duncalf. Would you give us your full names please?
A It is Henrietta Christina Pao Chai Duncalf.

Q What is your occupation?
A I am an accountant.

Q Mrs Duncalf, as you know I want to ask you about the birth of your son on 29 August 1992. Was he your first child?
A Yes.

Q We know, because we have already heard from your husband, that you were losing blood and you were rushed into hospital?
A Yes.

Q I think at that stage you were how many weeks pregnant?
A I think it was just over 31 weeks.

Q You were taken by ambulance to North Staffordshire Hospital?
A Yes.

Q There they tried, we heard, to stop the bleeding so that the pregnancy could continue?
A Yes.

Q But that they were unable to do that?
A That is right.
Q We know that, I think it was at about nine o’clock at night on 29 August 1992 you had an emergency Caesarean section?
A Yes.

Q Is it right that you had a general anaesthetic, Mrs Duncalf?
A Yes, I did.

Q When you came round in the recovery area, had your son been taken away by that stage?
A From what I have been told, as soon as my son had been born he was taken away in an incubator and then I was in the theatre for about another 45 minutes being stitched up.

Q Did they give you any indication as to how your son was at that stage?
A Not until I was in the recovery room, because I was under general anaesthetic and it was only when they roused me by shouting my name that the nurse told me that I had had a baby boy and he was very poorly.

Q Were they asking what you were going to name him?
A Yes, but even though I had just woken up and I had not had any painkillers, I did have a bit of an argument over his name because I refused to name him until I actually saw the baby.

Q Did you then insist on seeing the baby?
A Yes.

Q Did they give you anything to ease the pain?
A Only when I asked for it because I told them I was in terrible pain and they said, “We had to wait for you to wake up and actually ask for the pain killers” and then they gave me some morphine.

Q At this stage when they had given you the morphine, had you seen your son at that point?
A No, I did not see my son until about 3.00 pm the next afternoon.

Q In the meantime obviously your husband had seen your son?
A Yes.

Q Did he come and tell you what sort of treatment he was receiving?
A When I woke up in the recovery room, Nick was there and after the nurses had tried to get me to name my son, Nick came forward and told me that the baby was very poorly and he told me that he had gone into a special incubator and it was a trial and I can always remember him saying it was a trial and I said, “That is OK”. I think I was trying to hurry him along because I wanted some pain killers.

Q All right. What did you understand about the trial at that stage? Anything more than you have told us?
A Not really. Nick said it was a trial and basically it would help the baby to live.
Q So what treatment did you understand your baby was going to have?
A At that time? I did not really think about the treatment. I knew he would be in an incubator but because nothing else was said to me, because there were other things on my mind like the pain and then once they gave me the morphine and I was probably tired and in shock, I just thought to myself I have had a baby and I did not really think anything more that night.

Q You say you finally saw your son the next day?
A Yes.

Q When you saw your son, what sort of incubator was he in?
A He was in a CNEP machine.

Q Did you spend some time with him there?
A Yes, I think I probably spent about 45 minutes to an hour, because when I went down, because I was four floors above in the building, a nurse had to be with me and I was in a wheelchair so they thought that that was probably long enough and then I went back up.

Q Did you have any explanation from anybody then about how the CNEP tank worked?
A Not that I remember but I think because it was the first time I had met my baby that I think they were more concerned – I think they wanted to take me down earlier and they were quite concerned about the bonding process but I do not know why but I did not go down until three o’clock and I think they were more concerned for me to touch my baby’s head and to feel them than to explain anything and I just assumed that they would have spoken to Nick, my husband.

Q We know that he signed a consent form in relation to your son going into the trial?
A Yes.

Q Did you ever sign anything at all?
A No.

Q As far as your baby was concerned, apart from needing to be in the CNEP tank, was he ventilated in any other way as well?
A I do know that he was ventilated in the normal way. He had got something over his face.

Q Yes and after I think needing oxygen for a few weeks was he then moved into a normal incubator?
A Yes, he was.

Q In due course you were discharged from hospital?
A Yes.

Q Can I just ask you to look at a few documents, if you would not mind? There is a file just to your left-hand side there. I wonder if you would turn to page 336. The numbers are in the top right-hand corner. It is behind tab 3.
A Yes, I have got that.

Q Do you recognise the leaflet that is shown at page 336? Have you any recollection of having seen it before, apart from when you were asked about it when you made your statement?
A No, I have not seen this before.

B Q Again, page 341, which is described as an information booklet for parents for the Negative Pressure Trial. It goes through to page 364. Again, apart from when you made your statement have you any recollection of seeing that document, Mrs Duncalf?
A No. No, I have not.

Q Have you any recollection of receiving any written information about the trial and your son’s inclusion in it?
A I think when we were at the hospital for a month with the baby before he was released and we did have some paperwork but I did not read it all because I think with just looking after the baby and trying to look after myself and also I returned to work a week after having the operation, that it may have been in the paperwork but I never read anything.

D Q You never read anything? I wonder if you could just finally turn to page 401 through to 403 in that same bundle? It is a bonding questionnaire? Is that your writing at the top of it with your son’s name?
A No.

Q Have you any recollection of completing this form?
A I do not have any recollection but I think I have said in my statement that if somebody had asked me these questions if I had been sitting there with the baby In the unit, these are the answers I would have given and it makes me think – this is not my writing and where it says about the 22 days breast feeding, that is not how I write a number, but it was 22 days I breastfed for.

MS SULLIVAN: Thank you very much. If you would wait there, there will be some more questions for you.

Cross-examined by MR FORDE

Q Mrs Duncalf, I ask a few questions on behalf of Dr Spencer. Do you recognise this gentleman at all?
A No.

G Q It is nearly 16 years ago?
A Yes, that is right.

Q Just dealing with your answer, 401 to 403, does it amount to this, that the information or the answers given are answers you think you would have given in relation to your experience of CNEP?
A Yes.
Q We believe from the records that your son was in a CNEP tank for four days and then after that he was placed into an ordinary incubator…
A Yes.

Q …with positive pressure. Does that seem about right to you?
A Yes, I know that he was only in the CNEP machine for probably under a week.

B Q You have told us that the nurses were very keen to have you bond with your son. Presumably it was the obvious area, the easiest area for you to touch when he was in the tank when you went down at three o’clock that afternoon, would have been his head?
A Yes.

Q You have a reason to remember the date you entered hospital because it was your birthday, the 28th?
A Yes.

Q Correct? Other than that, would it be fair to say that a detailed recollection is quite difficult for you after this distance in time?
A I think I remember the details up to the birth and the trauma because it was my birthday and I was planning to go out and all the detail there, but after the general anaesthetic and having the baby nine weeks early, it is more hazy then and after that it was just getting on with things.

C Q Yes, you have told us you went back to work after a week?
A Yes.

Q Do you recall generally the nursing staff being very keen to encourage a relationship between you and your baby?
A Yes.

E Q If you had questions, as I suggest you are bound to have had about CNEP – you might not remember what they were – do you have a general impression that they were happy to answer any questions or queries that you had about your son’s treatment?
A Yes. The nurses were very, very helpful and I think most of the questions were about breast feeding and how to wash the baby and change nappies.

F Q The care, yes.
A I did not really think much more about the CNEP machine because all I knew, I knew it was a trial and it was going to help the baby.

G Q All right. Again, just in terms of what was available to you, you were asked about the patient information booklet at our page 341. Can you recall - will not ask you about the booklet just at the moment – photographs being around of babies in CNEP tanks or being shown any – you said you thought there might have been some literature but you cannot remember in any detail what it was?
A No.

H Q Can you cast your mind back and think in general terms what it may have been that you were shown?
A  I cannot remember any pictures up on the walls but I would not have noticed them because my baby was actually in one of the machines anyway.

Q  Right, but what you do recall is some discussion about it involving negative pressure, at least?
A  Yes.

B  Q  Do you recall how that worked in relation to conventional ventilation?
A  I think a nurse explained it to me, it was like an iron lung.

MR FORDE:  OK, thank you very much.

Cross-examined by MISS O’ROURKE:

C  Q  Mrs Duncalf, I ask questions on behalf of Dr Southall, who is not in fact here today, but can I ask you this – did you ever have any dealings with Dr Southall when you were in the hospital?
A  No.

Q  You are not aware that he had any involvement in the treatment of your son?
A  No.

D  Q  You have no complaint to make against him?
A  No.

Q  About your son’s treatment in hospital?
A  No.

E  Q  In fact as I understand it you have no complaint to make against anyone about your son’s treatment at hospital?
A  No.

Q  You have no complaint to make about the CNEP or the CNEP trial?
A  No.

F  Q  You and your husband, although it was your husband who consented you were told about the trial after you came awake and you at no stage said, “I want him taken out of the trial”?
A  No.

G  Q  You were content for him to be in the trial and to be treated in the CNEP tank?
A  Yes.

Q  Your son survives and has not in any way been damaged by CNEP or the CNEP trial?
A  No. He suffers from asthma but he could have been born with that.

H  Q  As far as material that was given, nobody at any stage when you asked questions about CNEP, you said you asked questions of the nurses, nobody refused to answer your
questions or did not help you with any information that you needed?
A No.

MISS O’ROURKE: Thank you.

MR FOSTER: No thank you, sir.

MS SULLIVAN: No re-examination.

THE CHAIRMAN: Mrs Duncaelf, that then completes the lawyers’ questions. As I indicated at the beginning, if any member of the Panel wants to ask you anything, now is their opportunity to do so, so I will just see whether anyone does. No, it seems none of the Panel want to ask you any questions so it simply remains for me to say thank you very much for coming this morning, for the assistance you have been able to give us, and you are now released. Thank you very much.

(The witness withdrew)

THE CHAIRMAN: Ms Sullivan, I see that the time is quarter-to one and we seem to be taking about half an hour with each of these witnesses. I think that your next witness is also a parent in the trial.

MS SULLIVAN: That is right, yes.

THE CHAIRMAN: I would be quite happy, if everyone else is, to carry on now and then we will break for lunch when that witness has finished, unless anyone has any reason to think that it is going to be much longer.

MS SULLIVAN: I do not think so.

MISS O’ROURKE: No, sir, it seems to me the next parent witness is going to be very short because she was not the one who gave consent, so I think it is going to be quite quick.

THE CHAIRMAN: In that case let us carry on.

MS SULLIVAN: The next witness, sir, is Mrs Demaine – that is Hazel Demaine – who is the mother of Patient 79, who is the son.

Hazel Ann Demaine, sworn
Examined by MS SULLIVAN

Q Hello, Mrs Demaine.
A Hello.

Q Would you mind starting with your full names?
A Hazel Ann Demaine.

Q As you know we want to ask you about your son who was born on 8 September
1990. Before he was born you were admitted to hospital, is that right?
A   Yes.

Q   First of all to Stafford General Hospital and then you were transferred to North Staffordshire Hospital, is that right?
A   Yes, that is right.

Q   Was that because you had gone into labour prematurely?
A   Yes.

Q   How many weeks pregnant were you, do you remember?
A   28 weeks.

Q   Having been taken to North Staffordshire Hospital did you give birth naturally to your son?
A   Yes, I did.

Q   Was that at around 7.30 on 8 September 1990?
A   Yes.

Q   Were you able to hold him for a little while once he was born?
A   A very short time, yes.

Q   Was he then taken straight to the neonatal unit?
A   Yes.

Q   Was that because of his prematurity?
A   Yes.

Q   Was he having some difficulties breathing?
A   He was crying but they said that because of the prematurity that they would take him down and assess him, so he was taken straight down.

Q   I think they had an incubator all ready to take him down?
A   Yes.

Q   When did you next see your son again?
A   Not until after ten o’clock on the night time.

Q   Had your son’s father, I think his name is?
A   Andrew Sheridan.

Q   Had he been to see your son before you went to see him?
A   He did, yes. I had to have stitches so I was kept up in the delivery room.

Q   I think you had a bath before you went to see him?
A   Yes.

Q   Were you then taken along, as we have heard from other people, in a wheelchair?
A Yes.

Q To see your son on the unit. When you got on to the unit were you asked anything about your son’s treatment when you arrived?
A I can remember we were stopped --- I was stopped going on in and we were asked whether we wanted to take part in this CNEP trial.

B Q Can you remember who it was who stopped you and asked you about this?
A I remember Dr Phil Bullen who was the paediatrician who had taken my son away out of the delivery room.

Q So he spoke to you as you were going into the neonatal unit. You said he spoke to you both, did I understand that correctly?
A Yes, we were both there together.

C Q How were you feeling at that stage? Had you had any drugs at all at that stage?
A I had had gas and air only while I was giving birth and then I was anaesthetised locally for the stitches but no other drugs at all.

Q So could you understand what was being said to you at that stage?
A Yes.

D Q So just help the Panel if you would not mind, Mrs Demaine, what did Dr Bullen say to you about CNEP?
A He explained that it was a negative pressure on the lungs to stop having like one hundred per cent oxygen pumped into very fragile lungs and because my son’s lungs were sticky a lot of cases of the lungs perforating resulted from high oxygen. Whereas the CNEP unit put negative oxygen on so they did not have to put so much oxygen into the baby.

E Q Were you asked to give your consent?
A We were, yes.

Q Did you give consent?
A I did not because I was impatient and wanted to get in to see my son so I left that to dad.

F Q Does dad have knowledge of these sorts of things?
A Dad is an engineer for Caterpillar so, yes, he was asking more technical questions than myself.

G Q So you were impatient to go in and see your son but for how long did you talk to Dr Bullen about the trial yourself?
A Probably about ten minutes. He explained the situation and he got the consent form out and asked us to sign and that is when I just said hand over to dad because I just wanted to get in to see him.

H Q When Dr Bullen was speaking to you was there anyone else present apart from you and your partner?
A Not as I can remember.

Q Having spoken to Dr Bullen you then leave the consent formalities to your partner. What treatment did you understand that your son was going to receive if consent was given?
A That he would be placed into one of the CNEP units as soon as possible. At the time when I went in he was in a normal incubator with oxygen going through a ventilator.

B

Q Was anything else said about CNEP to you?
A Not as I can remember, no.

Q You have told us that you understood that your son would go into a CNEP tank or incubator. You first saw him and he was in a normal incubator but was he later transferred?
A I think he was transferred when I went up to the ward because when I came down the next morning he was in a CNEP unit.

C

Q Can I ask you, prior to your partner signing the consent form were you shown any written information about CNEP?
A I do not remember seeing any.

D

Q Can I just ask you, please, to look in that file to your left-hand side a moment, behind tab 3 at page 336, the first page behind it. Do you have it there, Mrs Demaine?
A Yes.

Q It is entitled “Information for parents about neonatal ventilation study”?
A Yes.

E

Q Apart from when you were shown it when you made your statement have you any recollection of having seen this document before?
A I do not, no.

Q If I can ask you to turn on to page 341 through to 364 where there is a more detailed information booklet. Again, apart from when you made your statement, have you any recollection of seeing that?
A No, but then I did say that I had left a lot of it to Andrew.

F

Q You left a lot of it to him?
A The technicalities, yes.

G

Q Can I ask you this, please, you say that after a while your son was transferred into a CNEP tank. Were there any problems with it at all whilst he was in it?
A I think after a short time, about twelve hours, a little bit more, a crack appeared in the unit and they had to increase his oxygen intake while they had another unit prepared ready for him to go in.

H

Q How was he in the meantime?
A It was nice because I got to hold him but obviously he was on one hundred per cent oxygen which was not helping. He was struggling a little bit.
Q Yes. Did he recover?
A Yes, he was put back into the CNEP unit but he had perforated both lungs after that.

Q So he was put back in CNEP where he stayed, I think, for how long?
A A couple of weeks, I think it was. Two to three weeks maximum.

Q Whilst you were on the unit did you ask any questions about CNEP?
A Loads. The nurses and the doctors were fantastic. Any questions we had got they answered. If they could not answer them at the time they got somebody to come and speak to us and give us the answers.

Q Then I think your son later had to be transferred elsewhere?
A Yes, that is right, yes.

Q Can I ask you look at page 416 in that same bundle. Perhaps I should just ask you this, is that the signature of your partner at the time and the father of your baby?
A Yes, it is.

Q Then there follows a bonding questionnaire there, Mrs Demaine. Have you any recollection of completing this?
A Not really. I do not but when I did see it again and I went through the questions they are what I would answer.

Q So the answers are consistent with what you would have said?
A Yes, they are.

MS SULLIVAN: Thank you. If you wait there, there may be some more questions.

MISS O’ROURKE: Sir, Mr Forde has had to leave to go back to his IOP. I think he is happy that I can ask whatever questions there are and it may be he is back anyway by the time I have finished, so I am going to obviously go first.

Cross-examined by MISS O’ROURKE

Q Mrs Demaine, I just want to run through and check that you are happy with the following. Firstly, you have no complaint about the use of CNEP on your son?
A No, I do not.

Q You have no complaint about any of the doctors or the nurses that you dealt with in North Staffordshire Hospital?
A None, no.

Q If anything it might be said you have got the opposite, you used the words there they were fantastic and I think you use words in your statement to the effect that you could not fault them?
A No, I could not.
Q You say not only did they keep you informed all the way but if you asked a question they could not answer they would make sure to find someone who could answer it?
A That is right, yes.

Q You have no complaint, not only against the hospital but against none of the three doctors who are here?
A None at all.

Q You have no complaints about the consenting process?
A No.

Q Although you personally did not sign the form you were spoken to for about ten minutes?
A That is right, yes.

Q You were aware that at any stage you could pull your son out of the trial?
A Yes.

Q You chose not to do so. In fact, you were worried for the short time he was out of the CNEP tank and you wanted him back in. Yes?
A Yes, very.

Q You felt that between you and your partner you fully understood what CNEP was - the whole negative pressure ventilation concept?
A Yes, we did.

Q Your partner was someone who had a little bit more than the usual knowledge because he was an engineer?
A Yes.

Q You were happy that he was asking technical questions and getting appropriate answers?
A Yes.

Q If you had wanted to see any diagrams, photographs or other leaflets there is no reason to believe the nurses and doctors would not have made it available for you?
A No.

Q At the time that you were asked to look at two different leaflets by Ms Sullivan, one was the one page leaflet and one was the booklet. At the time your son was born my instructions are that there would not been the booklet, that came later as your son was one of the earliest people into the trial in September 1990?
A Yes

Q But there was a one page patient information leaflet, the first document she showed you but you do not have any recollection of that?
A I do not, no.
Q But it could well be that Andrew, your partner, saw that?
A More than likely, yes.

Q Because he was the one who was asked to sign the form and would have been
given the leaflet?
A Yes.

Q As far as the trial is concerned you were happy that it was a trial?
A Yes.

Q And you at all times understood that?
A Yes.

Q You were happy that at any stage you could stop it?
A Yes.

Q You, therefore, have no complaints about what has happened and are here simply
because somebody asked you about the consenting process?
A Yes.

MISS O’ROURKE: Thank you, I have no further questions.

MR FOSTER: No questions, sir, thank you.

THE CHAIRMAN: Dr Spencer, I ought to just check with you as Mr Forde is not here
that Miss O’Rourke seems to have covered much of the ground that he would have done?
Are you happy to leave matters as they are?

DR SPENCER: Yes, that is fine, thank you.

MS SULLIVAN: I have no re-examination, thank you, sir.

THE CHAIRMAN: It seems the Panel have no questions either so that completes your
evidence. It just remains for me to thank you very much for coming here today and for
the assistance that you have been able to give us. Thank you very much.

(The witness withdrew)

MS SULLIVAN: We have been quicker than we anticipated, sir. There is only one more
witness to come this afternoon who is Barbara Canning.

THE CHAIRMAN: We are presumably under no pressure of time as far as that witness is
concerned?

MS SULLIVAN: I do not think so. Not that I am aware of.

THE CHAIRMAN: In that case although we had a late start we will take the usual hour
for lunch and we will come back at two o’clock.
THE CHAIRMAN: Welcome back, everybody.

MS SULLIVAN: The next witness is Barbara Cannings. She is not a parent. She is coordinator of National Research Ethics in North Staffordshire.

Barbara Anne Cannings, sworn
Examined by MS SULLIVAN

Q Good afternoon, Mrs Cannings.
A Good afternoon.

Q Would you give us your full names first of all?
A It is Barbara Anne Cannings.

Q Mrs Cannings, what is your position?
A I am the coordinator of the North Staffordshire Research Ethics Committee.

Q Can you help us to when you first started work as coordinator?
A I first started work with the NHS in April 1994 when I was employed to administer a number of committees, which included both the Scientific Merit Committee and the Research Ethics Committee.

Q Those were the committees for North Staffordshire?
A Yes. At that time, yes.

Q Were you working full-time in that capacity?
A Part-time.

Q We know that there was an ethics committee at North Staffordshire. Can you just assist us to the Scientific Merit Committee, for how long had that been in existence, do you know?
A I am not sure how long it had been in existence when I arrived. I just was introduced to the system whereby all research projects went, first of all, to the Scientific Merit Committee, where they looked at scientific aspects of the studies and then they - the outcome of their meetings would inform the Research Ethics Committee, but the Research Ethics Committee made the final decision and could override any comments that the Scientific Merit Committee had made.

Q Your role, as far as the ethics committee and the scientific committee were concerned, was what, exactly?
A In 1994, as I say, it was one of a number of committees that I administered, and it was purely a matter of opening the post, getting all the paperwork together, meeting with the Chairman to agree the agenda, attending the meetings and minuting the meetings. I would then dictate the minutes and a secretary would type them up. From those minutes, the letters would be made. I would meet up with the Chairman after the meeting for any ad hoc letters.
Q Yes. Was that a new role, or had somebody else been in that role prior to you taking over?
A No, someone else had been. To the best of my knowledge, I think there had been a couple of people who had had it just attached to their jobs because the original person had left, until I came into post.

Q Now, you know that what we want to ask about, in fact, is documentation in relation to the CNEP trial which, of course, had been finished by the time you began in post?
A Yes.

Q Can you help, first of all, as to when you became aware of that trial? What year was that?
A I am not sure it was '95 or '96. When we were first requested to copy papers to the GMC original hearing, but before the Griffiths report.

Q So before the Griffiths report...
A Yes.

Q ...you were asked by the GMC...
A Yes, I think it was the GMC at the time.

Q ...to copy documentation?
A Copy all the documentation relating to the CNEP trials.

Q Whenever that was, and we can probably clarify that in due course, did you then locate all the papers that you could find in relation to the CNEP trial in North Staffordshire?
A Yes. We went into our archive storage and we retrieved all the documentation relating to those studies, and we photocopied them, both for the GMC and for the researchers so that they got everything as well. Because we had been asked for them, and we knew there was an inquiry going on, we then kept those papers altogether, separately, for future reference.

Q Yes. When, in due course I think it was Ms Morris, who sits beside me, who asked you for the papers, were you able to send a copy of those papers to her?
A Yes. We copied everything we had on file relating to those studies.

Q I think you copied papers in relation to a number of studies.
A Yes.

Q But one was the study with which this Panel is concerned.
A That is right.

Q Therefore, what we have in our possession, is that the full extent of papers that are available in relation to the CNEP study?
A That is all we hold at North Staffordshire, yes.

Q I am just going to ask you a moment to have a look at a file with us, if you would
not mind. If you take up file 1. I am going to ask you to look at the very start of it behind tab 1. If you just glance through those documents a moment, Mrs Cannings, behind tab 1, so from pages 1 through until 25, that is the numbers in the top right-hand corner. Do you recognise those as being part of the documents that you forwarded to Ms Morris?

A I cannot guarantee. I do not recognise the letter.

Q Which one is that?

A Dated 29 November 1989. I do not recognise that.

Q No problem. I do not think there is any dispute about that. That is a letter from Dr Spencer to the then Chairman of the Ethical Committee. Do you recognise the application that accompanied it?

A I think so. I think that is one of the ones that I copied.

Q Yes. That is the application for the trial that follows there, with a protocol attached. If you just go on to page 17, do you there see a letter from somebody called Russell, who was the honorary secretary to Dr Spencer?

A Yes.

Q Did you know Dr Russell?

A No.

Q Did you provide this material as well, Mrs Cannings?

A Yes.

Q And the letter that follows on 11 January 1990, indicating that the study was considered by the Ethical Committee on 10 January and was approved?

A Yes.

Q There then follow a number of letters, which I do not need to trouble you with, because they are letters between the various doctors concerned. I just want to ask you this, please: obviously your knowledge of how the ethics committee works stems from April 1994?

A Yes.

Q That is after this trial had completed, but can you just help us to what guidance was in place in 1994 in relation to the conduct of ethics committees?

A When I first started, the only piece of guidance was what was called a red book and, unfortunately, we destroyed our copies many moons ago, but that was the guidance from central government, and it was guidance, I suppose, to standard operating procedures, which we work to now.

Q Yes. I am sure things are quite different now.

A A lot different, yes.

Q I am not going to ask you about that. I wonder if you could just help us with a document that we have in that same bundle, behind tab 2, at page 232, in the top right-hand corner.

A Yes.
A

Q Parts of it are copied through until, I think, page 239.
A Right.

Q We are told that this is a document - I am going to ask somebody else about it, but we are told this is a document that goes back to 1991. I wondered whether you could help us as to whether this is the red book concerned, whether you recognise it or not?
A It looks familiar, is all I can say.

B

Q It looks familiar.
A At the time, it was the Chair who had the red book, and who tended to the one that referred to it. As I said, my involvement in the committee at that stage was not very hands-on. So when it came to guidance, I took the lead from the Chair.

C

Q Yes. So it would be the Chair of the committee who would have...
A He would have that as his guidance.

Q ...that as his guide?
A Yes.

D

Q I think, apart from that, can you assist us at all as to what the requirements were in relation to reporting matters to the ethics committee prior to 1994 at the time when the CNEP trial was in operation?
A I have no idea what it was prior to 1994. I can only tell you what it was in 1994. There was no - there was nothing in any of the letters that went out to people to ask them to contact us, if certain things happened.

Q That was the position in 1994?
A Yes. It was just a straightforward approval letter.

E

MS SULLIVAN: I have no further questions. If you wait there, there may be some more for you.

Cross-examined by MR FORDE

F

Q Mrs Cannings, good afternoon. I represent Dr Spencer. I have got some questions for you. Unlike my learned friend, I am actually quite interested to know how things have changed since 1994. I want to explore with you how things were even in 1994. You have provided us with a witness statement, and you indicate in that statement that, in recent times, you are much more hands-on in your role...
A Absolutely.

G

Q ...than you would have been back in the middle 90s?
A Yes.

Q Can you give the Panel some impression as to how your role has changed in the last 14 years?
A We now have governance arrangements for research ethics committees, which we have to work to, which sets down the role of the ethics committee, the membership, all

D15/29
that type of stuff, and then we also have standard operating procedures, which take us through the process so that, throughout the country, everybody is working through the same process.

Q Is it your understanding and impression that in 1994 that different ethics committees did different things to different standards?
A Absolutely.

Q Now you have proper national protocols in place?
A Yes.

Q Is it also your understanding that in terms of ethical approval, the Ethics Committee now have the ultimate say as to whether research can go ahead?
A Yes.

Q Although that was the case – is this correct? – back in 1994, things are looked at now with a great deal more rigour than they were when you first started?
A Yes, they are.

Q Not uncommon to simply have, as we have in this case, a two line letter saying this study was considered on 10 January 1990 and approved?
A Yes. I think by 1994 we put a little bit more in the letters but not a lot more than that.

Q That is our page 18, for those who want to look at it, behind tab 1 in file 1. Let us just deal with the position in 1994 as you recall it. I think this is correct, because I have got an attendance note of various conversations you had at the time, that your witness statement was taken and it would appear that there are a number of things that you were keen to express a view upon as far as your experience is concerned in 1994.

The first matter I wanted to ask you about related to adverse events. Do you now know there was a problem with the neck seal at Queen Charlotte’s Hospital?
A No.

Q My understanding of your witness statement is that there were no formal requirements for the reporting of serious incidents to the Research Ethics Committee even in 1994?
A No.

Q You say, “I would have expected such an incident to have been reported, considered within the hospital where it occurred”?
A Yes, at that time.

Q At that time.
A Yes.

Q I know it is difficult and it has been difficult for all of us, but we are being expected to try and reconstruct the appropriate standards in 1989/90 but I am also interested in exploring with you the standards in 1994, some five years later. Even in
1994, is this the case, your experience was there were no formal requirements for the reporting of serious incidents to the Research Ethics Committee and you would only have expected an incident to have been considered or reported within the hospital where it occurred?

A I am certainly not aware, I do not recall any researcher ever coming back to us with adverse incidents to the committee at that time.

Q You say also, interestingly, that where there were developments in protocols or changes in the approach to an ethical study you say this:

“From 1996 local researchers were encouraged to feed back developments, so if there were changes these would come back to the Chair of the committee.”

Am I wrong in reading into that that for you that is the beginning of that process, 1996? It was not something that was occurring in 1994?

A No. That sort of thing was being introduced as a result of the original enquiry.

Q Right.

A As we were getting feedback we were being encouraged to do that and certainly the then Chair, Dr Simon Ellis, took it upon himself to try and develop the committee.

Q So let us just take that in stages. Is this as a result of the internal enquiry by the Trust that you are saying this happened?

A I am not sure about the dates.

Q We can date it.

A When we first started, people were asking questions about the CNEP trial and then we were being asked about processes then, it rang alarm bells for the then Chair who decided that we should be looking at developing standard operating procedures for us to work from.

Q OK, so we will attempt to date that but from the moment of an internal Trust enquiry beginning to feed back to the Benefits Committee – I see the Henshalls shaking their heads but I am asking you questions at the moment – your impression is that the fact of the Trust enquiry led others to consider changing their approach to Ethics Committees?

A Yes.

Q So it definitely had an influence upon practice thereafter?

A Yes.

Q Right. Then you say this, in 1994 you might have expected some response being sent back to the Ethics Committee about things such as scoring systems, and there is an issue as to whether they changed, but again, was it your impression that when you started there was no standardisation in relation to the approach to matters of that sort?

A No standardisation at all.

Q Nothing nationwide?

A Not that I am aware of. Certainly not in operation at North Staffordshire.
Then I wanted to ask you about this paragraph. You say this, and I will read it to you and this is in 1994 – I will read you two, actually:

“I am not sure what the situation was prior to April 1994 but when I joined there was no formal requirement to report back to the committee any changes to the scoring system or adverse incident included in the final approval letter.”

Is that your recollection?
A Yes. As I say, the final approval letters were, as you see…

Our page 18?
A Yes.

“In 1994 there was a very ad hoc situation where after receiving approval from the REC, researchers would approach the Chair and run something past him relating to their research proposal and he might say, ‘Fine’, there and then. There might be a letter to confirm the decision or there might not, so in 1994 if there was a variation on an approved trial, I would have expected it to be brought up with the Chair of the committee. I have no idea what happened prior to 1994.”

Obviously the only things we have records of are the ones where the Chair has had the discussion with the researcher and they then go back to the Committee for ratification.

I was going to ask you this, because it appears that in the middle 1990s – even in the middle 1990s – there was a great deal of discretion on the part of the Chair as to what he brought back to committee?
A Yes.

You go on to say:

“The Chair would decide whether the variation needed to go to the full committee or would simply tell the researcher to go ahead. The Chair could agree the variation and do it in the form of a letter, as opposed to referring it to the committee. This is an example of the lack of formal regulation.”

Yes.

Do you to your knowledge – and if it is not the case then do say so – in 1994 do you think there were occasions when variations might have been verbally approved and there might have been a failure to reduce that to writing?
A I think it is more than likely.

More than likely. That brings me back to documents. You were asked for the
Griffiths Inquiry, I think, to look for that which you could find relating to the CNEP trial?
A Yes.

Q We think the Griffiths Inquiry certainly took place during 1999, reported in 2000, may have first come into being, I am sure others can correct me, in 1998 and I was just slightly curious because your statement suggested if you had been asked for the documents a month later they would have been shredded.
A Mmm.

Q The application was November 1989, the approval January 1990, so it may be that some of these documents were already eight or more years old. Do you recall now whether there was any standard time that the Trust kept documents?
A I cannot remember. It was three or five years. At different stages I think it has been different times, depending who has been running the Ethics Committee.

Q If you were being asked to look in 1998, it must have come as somewhat of a surprise to you that you could find documents in 1989?
A Mmm.

Q Did you find all the documents archived in one place or in many places?
A They were in a couple of different filing cabinets because they would have gone by date. When they had completed we put them in project order number, which would be related to the time that they were originally submitted to us.

Q All right, but you did not find any minutes of the Ethics Committee going back to 1989 or 1990?
A No.

Q When you were operating in 1994, it sounds as if, looking at your statement, you were dictating minutes to secretarial staff in 1994?
A Yes.

Q But you could find no such document going back to 1989 or 1990 in relation to this trial?
A No.

Q Did that surprise you?
A I cannot say that it did particularly because I think we had these destruction dates and certainly when I first started it took me a long time before I realised how long projects, because people did not tell you, you had to find out for yourself, it took me a long time to find out how long we had to keep documents before we destroyed them.

Q Get rid of them.
A Because obviously there is an awful lot of paperwork in research.

Q If it were the five year period, do you countenance the possibility of some of the documents relating to this trial having been destroyed?
A They could well have been. I would not be able to tell you.
A

Q Finally, if you go to our page 18 I just wanted to ask you, because obviously from our perspective it would have been rather nice for us to have been able to question Mr Hughes, who was the relevant Chairman of the Ethics Committee, whom I do not think the GMC propose to call, or your predecessor, and I just wondered whether, if you look top left you see a reference, “GIR/MJ”, whether those initials ring any bells with you?

A That is this GI Russell, is it not, Honorary Secretary, and I have no idea who that person is.

B

Q You know there was somebody called GI Russell?

A Only from this paperwork.

Q Who signed the letter?

A Yes.

C

Q You do not know who MJ is?

A MJ is the typist, Marie Jukes.

Q Any idea where GI Russell might be found or located now?

A No. I do not know who the person is. I have no idea.

D

Q Not somebody who you worked with?

A Never, no.

Q You do not recognise him as the person you succeeded in post, do you?

A No.

MR FORDE: Thank you very much indeed, Mrs Cannings.

E

Cross-examined by MISS O’ROURKE:

Q Mrs Cannings, I represent Dr Southall, who is not here today but I think you may know. Dr Southall I think after you came dealt with some Ethics Committee material with him. Would that be right?

A I have never met him. My assistant, I think, photocopied some stuff for him.

F

Q Right. I want to ask you about the documentation that you produced, because we have got in the bundle, the file in front of you, pages 1 to 25 in that file, the whole of the first divider is documentation which, as I understand it, you produced although I think you questioned page 1, you could not recall seeing that one?

A I could not recall seeing that one, no.

G

Q But the rest of it is the material that you produced?

A Yes.

Q In addition you actually produced to the GMC solicitors some more pages, did you not, relating to, as you said in answer to questions from Ms Sullivan, other studies?

A Yes.

H

Q Indeed there was another CNEP study done at the back end of 1992 into 1993 in
patients, older patients with bronchiolitis?
A The bronchiolitis one, yes.

Q You produced some documentation relating to that and it included correspondence in November 1992 and 1993 between Professor Southall, as he then was, and Mr Hughes, the Chairman of the Research Ethics Committee?
A Mmm.

Q That related to another study?
A Yes.

Q I have got a copy of it if you want to look at it but it was relatively voluminous including protocols and other documentation?
A Yes.

Q The material in the bundle relates to the study that we are concerned about?
A Right.

Q I think you can confirm with me, can you not, that in fact there is no documentation in relation to it that comes from Professor Southall to the Ethics Committee?
A No.

Q The reason for that would be that Professor Southall during the period of this documentation, which goes through to the beginning of 1992 - or end of 1991 I think we see on page 25 – was not in fact employed at Staffordshire?
A No.

Q Yes?
A Yes.

Q You would be able to confirm that applications to a Local Ethics Committee are made by those who are employed by the Trust and are Trust employees?
A That is right, yes.

Q So it would not surprise you to find that Professor Southall – Dr Southall – was not communicating with or making an application to the Ethics Committee because he had nothing to do with Staffordshire?
A No.

Q Indeed, we can confirm that the letter on page 1 applying, looking like it is applying for the study to be considered, comes from Dr Spencer?
A That is right, yes.

Q On page 4 we see that Dr Spencer signs the application form, 29.11.89?
A Yes.

Q That is because it is his application?
A Yes.
Q Then the responses back giving approval and, indeed, telling him that he did not have time to consider it in December, page 17, we see the letter from GI Russell goes to Dr Spencer saying, “I regret they did not have time?”
A Yes.

Q Then the 11 January letter also goes to Dr Spencer saying it has now been approved?
A Yes.

Q All of that is on the basis that Dr Spencer is the person who applied?
A Yes, who was the Chief Investigator.

Q He was the person who was given the approval?
A Yes.

Q Dr Southall had nothing to do with the Research Ethics Committee because he was not at the hospital?
A That is right.

Q But when the second study comes along---
A I am assuming all that because all the paperwork, as you say, relates to Dr Spencer.

Q More than that, we see, do we not, on page 25 a letter from Dr Southall and he is at the Royal Brompton Hospital at the relevant time?
A Yes.

Q I think there are also letters on 17 and 18 that show the same?
A Yes.

Q In complete contrast you have seen and I can provide it to you but it was you who, of course, provided it, documentation from November 1992 that is written to the Ethics Committee about the bronchiolitis study and it is all signed by David Southall?
A Yes.

Q That is because by that stage he has arrived at Stoke and he is the one who on a different study is the applicant?
A Yes.

Q And he communicates with the Ethics Committee and that is how you would expect it?
A Yes.

Q In respect of CNEP trial number one, the applicant and the person who liaised with the Ethics Committee was Dr Spencer and it appears Dr Spencer alone?
A Yes.

Q And nothing to do with Dr Southall?
Re-examined by MS SULLIVAN

Q Mrs Cannings, can you help, that correspondence between Dr Southall and the Ethics Committee in relation to bronchiolitis, did that relate to any changes to the protocol at all?
A I cannot remember off hand, I really cannot.

Q We can see that for ourselves at a later stage if we need to, but just in relation to the question you were asked about Dr Southall’s involvement in the application for CNEP, can you just look behind tab 1 at page 2 a moment? Do you see who is shown as responsible investigator for this particular trial?
A Yes.

Q There are two names there, you will see?
A Yes.

Q Dr Spencer and Dr Southall?
A Yes. I do not know how they accepted it in those days but certainly all the time that I have worked for the Ethics Committee the Chief Investigator has had to be employed by the organisation.

Q Yes, so the Chief Investigator---
A The Chief Investigator would definitely be employed.

Q Would be employed and that would be Dr Spencer in this case?
A Yes.

Q You were asked about 1994 and what you would expect in terms of documentation and communications with the Ethics Committee at that stage when you first arrived. Can you just clarify for me, when you first arrived, what was the period of time for which Ethics Committee documents were retained?
A I cannot remember if it was three or five years. I really cannot, because during the period I have been with the NHS, it has changed back and forth between three and five years.

Q So somewhere between three and five years?
A Somewhere between three and five, yes.

Q What is it now?
A Now it is three years following completion of the study.

Q Again, when you arrived in 1994, what process would you expect if there was a variation in a trial protocol? What involvement would you expect the Ethics Committee to have had at that stage?
A As far as I was aware there was no formal process. Certainly people did not
actually write in and notify it and any changes were generally discussed with the Chair. The Chair would then decide whether it needed to go to the committee or not.

Q So how would you be aware that there were such variations being discussed with the Chair?
A I would not. I would not, unless the chair decided it went to committee. Those were the only ones I would be aware of.

Q What sort of changes would go to the Ethics Committee at the time when you first arrived?
A I cannot remember. I really cannot remember. We did not have that many. We really did not get a lot of notification on changes to studies.

Q Yes. We know, for example, in the CNEP trial that there were a number of changes made to the trial protocol, one of which was the introduction of a drug, surfactant. Were you aware of any such changes, for example, of that type being communicated to Ethics Committees?
A I cannot remember. I really cannot remember.

MS SULLIVAN: I have no further questions, thank you.

THE CHAIRMAN: Mrs Cannings, that completes the questions which the lawyers have for you and, as I indicated in my introduction, Panel members have the opportunity to ask questions if they have any.

Questioned by THE PANEL

DR SHELDON: Good afternoon. Thank you for your very clear details of what has happened when you first started. At that time in 1994, was there a requirement that each study send in an annual report?
A I am not aware of it. Whether it was and I do not remember it, but I am not aware of it.

Q Certainly none of them have been kept in the documentation…
A No.

Q …that you have got?
A No. I have not come across any in the older documentation.

Q What we have got on pages 1 to 18 is the total paperwork that you were able to find about this study?
A Yes.

DR SHELDON: Thank you.

THE CHAIRMAN: Mrs Cannings, There may be something which you can help me with. Can you have a look in file 1, page 382, it is a form of consent form. Do you have that?
A Nearly, yes.
A

Q It should be headed “North Staffordshire Health Committee Ethical Committee consent by proxy to conduct of a research investigation”?
A Right, yes.

B

Q I wonder if you can help if this is the sort of document you would have an interest in? Whether that is a form which is created for a particular study or whether it is what I would call a template form for use in any study? If you do not know say so.
A I have absolutely no idea. In my experience the emphasis of the Ethics Committee tends to be on the patient information sheet as opposed to the consent form. I think that is where most of the questions are---

C

Q You are unable to help us as to whether this was a blank consent form or whether it was created specifically for the study?
A No, I would not know.

THE CHAIRMAN: Thank you very much indeed. Anything arising out of the Panel questions?

MR FORDE: Sir, not something arising out of questions, something I hope I can be permitted to ask because Dr Spencer is concerned about some of the terminology this witness has used.

Further cross-examined by MR FORDE

Q You were suggesting that a phrase “chief investigator” might have been used?
A Yes, that might be modern terminology. Your lead investigator.

E

Q If you go to page 2 of behind tab 1 we see two people described as “responsible investigators”. Is that a term that you are familiar with?
A That was the form that was used when I first became an administrator.

Q Are you used to the concept of having a local investigator---

MISS O'ROURKE: Sir, I am sorry, I am going to object to this question.

MR FORDE: Why?

MISS O’ROURKE: Because it is not appropriate. Mr Forde had his opportunity to ask questions and I am afraid I do object to this question and it is not something that this witness is going to answer. He is trying to lead evidence from a witness that he was seeking to establish was not present at the relevant time and did not deal with this documentation. Sir, I do not see the basis for which he is seeking to establish the answer to this question.

MR FORDE: Numerous questions were asked on a hypothetical basis about this documentation which arose five years before the witness was here. I am asking about her 1994 experience, I make that clear.
MISS O’ROURKE: Then, sir, I do not see how she can answer this question in respect of what is typed on a form that is on page 2. Sir, so that the Panel understand my position, Dr Southall did not consent to his name going on that page. It is the North Staffordshire form. He did not see it. He has not signed that form and you have had no evidence led before you that he signed any documentation and made any application. I am wondering what Mr Forde is doing here because it does not relate to a charge against him, it relates to a charge against my client. I do not understand what point he is trying to make. His client’s name is on the form as the investigator, his client was employed at the relevant time. His client has signed the letter of application and his client has signed the form of application and his client has made admissions of those heads of charge. So I do not understand what Mr Forde is trying to do by this question.

THE CHAIRMAN: I understood when you started, Mr Forde, that it was a matter of terminology which you were exploring?

MR FORDE: Yes, it was chief investigator and she said that may have been something in the modern era. I am happy with that answer. The only other thing I wanted to ask which has got nothing to do with this documentation is whether she has any experience of the administration of multi-centre trials and if she has not I will not ask the question.

THE WITNESS: At that time I did not.


MISS O’ROURKE: Sir, that is why I jumped to my feet because that was the point. Why was he asking this witness, I think his words were, the shorthand-writer can read them back to us, are you familiar with a procedure where you may have one applicant from one centre and somebody else, an investigator at another centre and so he was trying therefore, as I understood the question and what was coming next, to bring into this Dr Southall who was at another centre and to refer the second line and I do not understand what he is doing when he tries to do that. He should deal with the case against his client. The case against his client is that he has admitted that he was the applicant and he should leave me to deal with my case which is what I was putting to this witness.

THE CHAIRMAN: Mr Forde, if you could perhaps explain what you are going to do and then if necessary if Miss O’Rourke continues her objection then we will consider it.

MR FORDE: Not a problem at all. You will have seen from the admissions that have been made by this doctor that he has not made any admissions in relation to scoring systems and I simply want to ask this witness whether she has any experience of multi-centre trials. If she says she has then I will want to ask her whether or not she is used to the concept of a local investigator. That is it. I am not naming any names at all.

MISS O’ROURKE: Sir, she is not an expert. She is a factual witness. She has been produced to produce the documentation in respect of this particular trial. I restricted my questions to that and up until now Mr Forde has restricted his questions to that. She is not an expert. If he wants to ask about multi-centre trials he is going to have witnesses called who are experts and can answer questions. It is inappropriate to put that to a factual witness who is here to produce documentation and talk about what happened in
North Staffs and I do object to the question.

MR FORDE: It is all right, he does not need to give any advice. The position is, and you have seen it, that Miss O'Rourke was quite prepared to cross-examine this witness upon documents which pre-existed her period of employment and I am quite happy to leave that question for another witness if it is going to cause such a difficulty. I am not in any way, shape or form seeking to do anything because I have not indicated who was responsible for scoring and I am going to be saying that it was none of these doctors but that is why I wanted to ask the question. I will establish it by other witnesses.

THE CHAIRMAN: Thank you. Mrs Cannings, that completes your evidence. Thank you very much for coming this afternoon and for the assistance you have been able to give us. Thank you. (The witness withdrew)

MS SULLIVAN: Sir, that completes the witnesses for today. I am sure we can all use the time that is left in the day usefully.

THE CHAIRMAN: Before we rise for the afternoon it looks from the list that there are five witnesses identified on the schedule for tomorrow two of which are awaiting confirmation.

MS SULLIVAN: Yes. I think one was still awaiting confirmation this afternoon, that is Jill Hulme but I am pretty sure, sir, the others are confirmed as attending. I hope that she will be here as well.

THE CHAIRMAN: Whatever else happens tomorrow Dr Wilding needs to be dealt with tomorrow?

MS SULLIVAN: That is right, sir, yes. The first four are all parents so on the basis of the time they have been taking so far I would be confident that we would have a realistic timetable for tomorrow.

THE CHAIRMAN: Yes. Then for the rest of the week, again, presumably the witnesses who are there are likely to be somewhat longer are they than...

MS SULLIVAN: That is right, sir. We did discuss this matter on Friday and it was felt by all concerned that these were, in fact, realistic time estimates on the basis of the likely cross-examination of these witnesses who we have been told, certainly in the cases of one doctor each day, will be quite lengthy witnesses.

THE CHAIRMAN: Is it a fair summary of what is to come that the rest of this week is taken up by witnesses who one could perhaps describe as giving factual evidence about the trial and then next week we move into experts?

MS SULLIVAN: That is right, sir. We have only one witness next week who is really a factual witness but we cannot call him until next week, that is Dr Raine. He we are told is not available until Wednesday but there is no objection to Dr Stimmer giving evidence before Dr Raine, although Professor Hutton will now follow Dr Raine and will not come
before. So Professor Hutton we are anticipating calling on Thursday of next week and then Dr Nicholson thereafter.

THE CHAIRMAN: Thank you. That is helpful. In that case we will carry on tomorrow with the witnesses who are here and if possible we will look if we can to finish half three, four o'clock on Friday.

MS SULLIVAN: Yes, sir.

THE CHAIRMAN: So that those who have to travel on a Friday are able to do so and start at 9.30 on Monday.

MR FORDE: I regret having to do this at the end of every day but we are still awaiting service of the Stimmler report and we understand he was back from holiday on 23 May and I believe it was suggested on Friday it was imminent from my reading of the transcript. I am also still awaiting confirmation of the fact that, as my client has reminded me, the General Medical Council are not advancing a positive case that CNEP was responsible for the death of Patient 7 or the brain damaging events that were occasioned to Patient 6. I do not know yet whether Ms Sullivan is able to go on record in those two respects?

MS SULLIVAN: Sir, can I say first of all that Dr Stimmler’s report has arrived and will be given to my learned friends straightaway now. In relation to the second matter, I was not able to talk Mr Forde this morning because he was otherwise engaged but I did indicate to Miss O'Rourke and Mr Foster that I would not be dealing with that second matter until I have spoken to Mr and Mrs Henshall who want to know what is going to be said and I would propose to use the time now to speak to them and hope to be able to answer his question tomorrow morning.

MR FORDE: Thank you.

THE CHAIRMAN: Very well, thank you, Ms Sullivan. In that case we will adjourn now and---

MR FORDE: Sorry, sir, my client reminds me he will not be here tomorrow because he has an outpatient clinic to perform.

THE CHAIRMAN: Very well. We will resume tomorrow morning at 9.30.

*The Panel adjourned until 9.30 a.m. on Tuesday, 3 June 2008*
GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council’s Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988)

On:
Tuesday, 3 June 2008

Held at:
St James’s Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

STEPHEN ANDREW SPENCER BM BS 1976 University of Nottingham
Registration No: 2305893

DAVID PATRICK SOUTHALL MRCS 1971 Royal College of Surgeons of England
Registration No: 1491739

MARTIN PHILIP SAMUELS MB BS 1981 University of London
Registration No: 2732178
(Day Sixteen)

Panel Members:
Mr D Kyle (Chairman)
Mrs V Brickley
Mrs S Hollingworth
Dr T Okitikpi
Dr M Sheldon
Mr A Forrest (Legal Assessor)

MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hempsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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THE CHAIRMAN: Good morning, everybody. We continue with the case of Dr Spencer, Dr Southall and Dr Samuel and I think the fact that Dr Samuel is the only doctor present this morning is expected, is it not? (Agreed)

MS SULLIVAN: Sir, before I call our first witness today, may I mention two matters. The first is the statement that has been requested by Mr Forde and others on the defence side. That is being finalised at this moment and I hope to be able to give Mr Forde and my learned friends a copy of it shortly. Secondly, we have made some adjustments to the witness list and can I therefore suggest that everyone be given a new copy in order that you can see what changes have been made. (Same handed to the members of the Panel)

Sir, perhaps you could regard this as a substitute list and I will just explain the changes. Gillian Hulme, who we were hoping to call today, is not available today; she has a funeral to go to and cannot attend until Thursday, but we have put her in first thing Thursday morning. So, today we will have the remainder of the witnesses who were anticipated. The position for Wednesday remains the same. On Thursday, we now have Dr Morgan on Thursday whereas previously he was going to be coming on Friday. Dr Wheatley who is at the moment on Thursday and, if it is too much for us to do on Thursday, he can be slotted in on Friday after Dr Palmer. Those are the changes as far as this week is concerned, so that my learned friends are aware of the position. What we have perhaps more fundamentally managed to achieve is that Dr Raine is now going to be coming on Tuesday. So, Dr Stimmmer will be on Monday going into Tuesday if necessary but that may not be the case, Dr Raine can then give his evidence on Tuesday and, if necessary, going into Wednesday, followed by Professor Hutton and finally we have Dr Nicholson. I hope that means that we will be able to fill all the days and there will not be a gap as there might have been had Dr Raine not been available until Wednesday. I hope that is clear for everyone.

MISS O’ROURKE: Sir, I am afraid that there might be a slight problem with that timetable. We were served Dr Stimmmer’s report yesterday; I think you heard that we were going to get it when we rose. I then went to look for my learned friend but she was in conference with Mr and Mrs Henshall. I waited a while and she continued to be in conference, so I did not have an opportunity to speak to her. As a result of reading Dr Stimmmer’s report, it appears, contrary to what I for one certainly anticipated, that he now deals with scoring systems which I had not expected him to do; I thought that was going to be the problems of Professor Hutton and Dr Nicholson. If he is going to give evidence on scoring systems, then obviously I need to speak to my learned friend to find out whether he is or whether what he was doing in his report was simply commenting on the outstanding charges, but I am afraid that I am going to be saying to the Panel that it is not appropriate for him to give evidence before Dr Raine because the only factual witness that you are going to hear dealing with scoring systems – and indeed one of the people responsible for the scoring system – is Dr Raine and, if Dr Stimmmer is going to criticise the scoring system, then he needs to come after the evidence of Dr Raine. I do not know if Dr Raine is in fact available on Monday but, if he is not, then the position would be that it certainly would be my submission that Dr Raine should give evidence before Dr Stimmmer unless my learned friend chooses not to have Dr Stimmmer deal with scoring systems.
THE CHAIRMAN: That is a matter which perhaps you can talk to Ms Sullivan about and we will see where we get to both in terms of what Dr Stimmler is now going to cover and also any adjustment which might flow from that, but perhaps you can talk to Ms Sullivan about that and we will see where we are later in the week.

MS SULLIVAN: I do not think that Dr Stimmler is covering much more than he covered originally, but perhaps we can talk amongst ourselves about that. Sir, that is the position as regards witnesses and therefore the first witness for today is Andrew Sheridan.

THE CHAIRMAN: Who is the partner of Hazel Demaine and deals with Patient 79.

MS SULLIVAN: That is exactly right.

ANDREW PAUL SHERIDAN, Sworn

THE CHAIRMAN: Good morning, Mr Sheridan. Please sit down and make yourself comfortable.

A As comfortable as I can be!

Q We anticipate that we will be hearing evidence from you about the birth of your son and we have been referring to him throughout these proceedings by a number, Patient 79, and I think that probably the number and name is on a piece of paper in front of you.

A It is.

Q This is not because we wish to be impersonal or insensitive but simply to preserve patient confidentiality and it may be difficult to avoid naming him and to call him by a number but, if you could try to do that and avoid giving his name, that would be very helpful.

A Sure.

Examined by MS SULLIVAN

Q Good morning, Mr Sheridan. Would you begin by telling us your full names, please.

A Andrew Paul Sheridan.

Q And your occupation, Mr Sheridan?

A I am a marketing manager.

Q I think we heard something about your engineering qualifications from your former partner.

A Yes, I am educated as a mechanical engineer.

Q We know that you are the father of the baby we have called Patient 79 who was born on 8 September 1990.

A That is correct.
Q And, at that time, you were the partner of Hazel Demaine.
A That is correct.

Q We know that your son was born prematurely, Mr Sheridan, and, on the day that he was born, I think that there was a rush to hospital.
A On my part there certainly was, yes.

Q And that Miss Demaine went into labour very quickly and gave birth to your son naturally.
A Indeed.

Q Can you remember what time you arrived at the hospital or anything like that? Do not worry if you cannot.
A No, I cannot remember at all. I think it was during the hours of daylight and that is as much as I can remember.

Q Immediately after his birth, your son was taken to the neonatal unit.
A That is correct.

Q Because it was clear that, being born prematurely, he was in distress.
A Yes.

Q Were you told what to expect at that stage?
A The doctors at the time made it very clear to us that the survival of the baby was touch and go at that point in time and they said that there were certain hurdles that had to be overcome. There is a very important 24-hour hurdle and secondly a 48-hour hurdle. The changes of survival if you got through those hurdles became greater and greater. So, certainly during the first 24 hours, there was a lot of emotion present shall we say at that point in time.

Q Following your son’s birth, we established that he went straight to the neonatal unit and did you go there to be with him?
A I certainly went down before his mother, yes.

Q And I think we heard that his mother followed not long afterwards.
A That is correct.

Q Being brought down in a wheelchair.
A Yes.

Q How would you describe your state at that time?
A It was a very emotional state. He was the first child I had and, having been instructed by the medical staff not to get our expectations high at that moment in time in terms of survival, it was obviously a very emotional time for us.

Q When you went to the unit, did a doctor speak to you about your son?
A Yes. We had constant communication from both the nursing staff and the doctors at the time.
A Q  At some point, were you spoken to by medical staff about a particular type of treatment for your son?
A  Yes, it first came about … The one thing that I do remember quite clearly is that the doctors had mentioned the fact that the boy had lung disease and, at that point in time, I found it very strange because I associated lung disease with old people who smoked and so forth. I did not realise that a child could be born with lung disease. They then explained what lung disease was in terms of lung function and the fact that the lungs were not fully developed, so the child was in need of respiration assistance, and then they went on to explain the trial that they were carrying out and explained that in some depth.

B Q  I want to ask you about that. First of all, do you remember whether it was a doctor or any of the nursing staff who explained this to you?
A  It was definitely a doctor who explained it.

C Q  I am not asking you to remember any names obviously after this length of time but are you able to say whether it was a male or a female doctor?
A  It was a male doctor and the only thing I can remember about the doctor who I spoke with at the time – I could not tell you his age profile – was that he was a white doctor. That is the only piece that I can tell you and I apologise for not being able to give you more detail.

D Q  That is all right. What did this doctor tell you about the trial?
A  First of all, he explained that it was a trial that they were going through at the hospital.

E Q  What did you understand by a trial?
A  That it was not common medical practice at that time and that they were looking to prove that the concept would work.

F Q  What concept was it that they were looking at?
A  The concept that they explained quite clearly to me was that the child would be in an incubator, full stop. The trial that they were talking about was that the incubator would be negatively pressurised to take some of the pressure off the external side of his lungs, so to speak, to make the work of the respirator easier. That was the way in which it was explained at the time.

G Q  What else was said about that treatment? Were there any advantages or disadvantages to it?
A  The advantages we talked about at length which were, as I said, purely to do with the fact that the respirator would not have to work as hard to push air into his lungs because of the depressurisation on the outside, so that was made perfectly clear. In terms of the negative side, I cannot remember anything being specifically discussed other than the fact that this was still in the trial period.

H Q  Were you asked for consent for your son to go into the trial?
A  We were both asked for consent at that point in time and my partner at the time handed that responsibility over to me, so I had authority to make that call.
Q I am going to ask that you look at the form you signed. I wonder if you could be handed the original. *(Same handed)* If we take up our file 1, we have a copy of the form at page 416 behind tab 3. Mr Sheridan, can you confirm that that is the form you signed?

A I can confirm that, yes.

Q Help us as to which writing is yours. Obviously, the signature from what you said.

A The signature and I think the date.

Q The date underneath?

A Actually, no, just the signature.

Q Can you remember how long it was from being first told about this trial to signing the consent form, how long the process was?

A I am thinking hard; it is a long time ago. *(Pause)* It was a relatively short period of time and, by relatively short period of time, I mean less than an hour. How much less than an hour I cannot remember.

Q That is all right.

A However, during having discussions with the doctor – and the discussions that we did have with the doctor were quite lengthy; it was not a 30-second discussion, it was a good 15-minute discussion on the apparatus and the whys and wherefores behind the trial, and then I was also given the full information pack to consider as well before providing my signature.

Q I was going to ask you about that in fact. As far as the original of the form that you have there is concerned, we know that the form refers to information overleaf. Is there anything on the other side of your form, the original form that you have there?

A On this one, no.

Q So you say that you recall seeing some information. Can you just help generally as to the nature of it?

A The information that I remember, that I recall, related again very much to the apparatus. I remember seeing diagrams on the information sheets, which basically looked like a simple incubator with the baby’s head protruding out of the one end and then the fact that it is pretty rudimentary in terms of showing a vacuum cleaner on the end so to speak, in terms of providing negative pressure. Then just the basics describing the apparatus and how the apparatus would work.

Q Was that handwritten or typed information?

A It was typed and photocopied, if my memory serves me correctly. It was not in a formalised booklet or anything.

Q I wonder if you could just have a look – there is a file just to your side which I anticipate is our file 1. If you look behind tab 3 in there at page 336 in the top right-hand corner?

A Yes.

Q Just look at page 336 a minute. Do you recognise that?
A

Yes, that is exactly the type of material that I was provided with.

Q

What we also have at 341, if you go further on, 341 to 364 is a much more detailed booklet?
A

This is the kind of material that I was provided with.

B

Q

Were you given anything to keep, Mr Sheridan?
A

Both of these were available to keep – they were left with me.

Q

They were left with you, and could you keep them and take them home with you?
A

I was not told otherwise.

Q

Did you keep them in fact?
A

Yes. Do I have them to this day? No.

C

Q

What I want to ask you is this. You gave your consent, as you told us, to your son entering this trial. What treatment did you understand that your son was going to receive if you consented to him entering this trial?
A

The first piece of treatment I expected from the medical staff was to keep my son alive. That was the one overriding factor that was my base expectation at that moment in time. It had been made very clear that that was not a certainty, so obviously it was in my interest, based on the information that I had given, to provide as much chance as possible to maintain his life. If you like, the additional treatment over and above the standard care that is provided by the medical staff is related very much to the apparatus; in other words, I expected no difference in treatment other than him being placed into a negative pressure incubator.

D

Q

Did you understand the concept of a control group for the trial?
A

Yes.

Q

What did you expect the control group to receive by way of treatment?
A

A standard incubator.

Q

By consenting for your son to be part of the trial, what did you understand he would be in?
A

He may or may not have been in a negative pressurised incubator.

Q

On what did that depend?
A

As with most trials, it is a lottery, is it not? A control group is exactly that, it is a control group which is taken at random.

G

Q

So as far as your son was concerned were you expecting him to be in the control group or in the group that were receiving CNEP?
A

I hoped he would be in the CNEP group.

Q

I think you have indicated that you were able thereafter to talk to the staff about your son’s treatment?
A

Constantly, constantly.
MS SULLIVAN: Thank you. If you wait there, there will be some more questions.

Cross-examined by MR FORDE

Q Good morning, Mr Sheridan. I am asking some questions on behalf of Dr Spencer, who is not here this morning, he is attending upon patients. You have provided for us some very detailed and significant evidence – you probably have not necessarily realised that---

A I certainly did not think of it that way, no.

Q I would like to explore it in a little more detail, if I can. Your son was born at 26 weeks?

A Yes.

Q And you were immediately aware that particularly in 1990, some 18 years ago nearly, it was going to be touch and go initially. You have told us very carefully that you wanted to give him the best chance of survival and you expected the staff to do their best for him, is that correct?

A That is absolutely right.

Q I just want to ask you about the CNEP trial. As I understand the position, and your former partner gave evidence yesterday, you had initial discussions which involved both of you. She told us, however, that she was very anxious to see your son, who we are describing as Patient 79, and was happy to hand over the detailed consultation to you. Is that your recollection?

A That is absolutely my recollection.

Q So you were put in the slightly unenviable position of making the final call, is that fair?

A I would not call it unenviable. As a father you do have some responsibilities.

Q What your witness statement tells me is that you were educationally trained as a mechanical engineer, although you now tell us you were a marketing manager?

A Yes.

Q So from your perspective, as you say in your statement, you were familiar with the idea of pressures and physics, is that correct?

A That is correct.

Q From your perspective, this all made sense in terms of basic physics, is that fair?

A That is a fair comment.

Q You were able to ask, from a well-educated perspective, detailed questions about the mechanics from a mechanical engineering standpoint?

A That is correct.

Q Did you find that the doctor that you spoke to was able to explain to you, with your enhanced qualifications, how the tank worked in an acceptable manner?

A Very much so.
Q What you said in your statement is:

“I had a discussion with the doctor about differentials, how much negative pressure was used…”

So you wanted to know how sub-atmospheric it was, is that fair?

A That is a fair reflection.

Q Right.

“It transpired that the amount was very low”

- obviously, you would have been concerned about it being too low?

A No, on the contrary. The question which I was probing the doctor at the time was the quantity of negative pressure. The last thing I wanted was for him to be in a negative atmosphere zone. All that they were doing was taking the basic atmospheric down by a small amount.

Q Did you appreciate the dangers of it being taken down by a large amount?

A Indeed I did, yes.

Q What were they as far as you were concerned? What were the essential risks?

A Those just related to a condition – it is not a natural condition to be under-pressurised.

Q Then you discussed, and I think you understood, that the positive pressure would be put into the baby’s lungs but the degree of positive pressure could be a little lower?

A Indeed.

Q Do you remember having a discussion about the fact that there are some potential negative effects of standard positive pressure ventilation in terms of a premature baby’s lungs?

A Yes, and that was, again, the driver behind the negative pressure that we could reduce the positive pressure into the lungs.

Q So although this was a trial, from your perspective and with a background in physics, it seemed to be something that ought to work?

A From my perspective it made eminent sense.

Q You then say you were asked whether you wished to be part of the trial and you say that the doctor reiterated that it was a trial?

A He did indeed.

Q I just wanted to ask you about some of the information you received. You recognise our page 336 in file 1, which is the parents’ leaflet?

A Yes.

Q You told my learned friend that you were given a pack of some sort?
A Yes.

Q I just wanted to check with you that the information that we see on that page is information that you were given both verbally and in writing. If we just go through the topics, the first paragraph suggests it is an evaluation of a new technique – did you appreciate that?
A Yes.

B The next deals with the appearance of the incubator and the sucking on the chest wall rather like the old iron lung. Was that something that you were aware of?
A Yes.

Q Then this is said:

“Although the technique has been shown to be safe and effective we now need to find out whether it is better than the usual treatment, which involves blowing air into the baby’s lungs.”

Is that something you appreciated?
A Yes.

D Then this:

“Should you give your consent to your baby being entered into the study, we will use a method of random allocation”

- you have explained you understood that?
A Yes.

E But from the explanation you got, you rather hoped your son would be on the CNEP trial?
A I did indeed.

Q Then there is information about oxygen and blood pressures being monitored, but I think your understanding is those are basic signs you would expect to be monitored anyway?
A That would be part of the normal treatment.

Q Then were you aware of the fact that if you wished to, there was no compulsion, you could decline the invitation to enter the trial?
A Absolutely.

Q And that if you were to decide (as the last paragraph says) to enter the study but later changed your mind, you could withdraw your child from it?
A At any time.

Q Then if we go over a few pages to page 341, if not precisely this document then something similar was given to you?
A Yes.
Because you recall photographs and diagrams?
A Yes.

Were you given adequate time to look through the booklet you were given?
A In my opinion I was, yes. I was certainly never pressurised for an immediate answer.

Then finally I just wanted to ask you about the attitude of the staff. In your statement you say this:

“The nursing staff were a million dollars. The doctors did their normal consulting. They spoke to us about his progress and his next steps. The fact that Patient 79 was in a negative pressure incubator did not seem to have any bearing on the way we were consulted by the doctor. Indeed, he was treated in the same way as babies in standard incubators.”

Is that a fair reflection of your experience of this trial?
A The unit that the baby was in at the time was a shared unit with other cots and other incubators which were standard incubators, so they were side by side. I saw first hand, because we spent a lot of time with the baby during the first days obviously, so we saw the doctors in action both with our child and then with babies in incubators close by. There was certainly no differential treatment or consultation that was offered.

Finally, you say this:

“The doctors and nurses certainly understood the equipment. In terms of the nurses, they were well trained and understood the way the negative pressure tanks worked.”

A Yes.

That is you speaking as somebody with a mechanical engineering background?
A Yes. To go one stage further, the nurses also, if you like – I do not want to say they trained us in how the equipment worked but they certainly explained to us very clearly how the equipment worked and showed us where the various monitoring devices were and what the appropriate ranges were so we were able to take an active interest in the equipment ourselves because that was explained clearly to us.

Would that be things such as the amount of oxygen in the blood, the pulse, or was it simply relating to CNEP?
A No, more to do with CNEP; more to do with the pressure at which it was operated.

So what the minus figure was, you had that all explained to you?
A Yes.

MR FORDE: Thank you very much indeed, Mr Sheridan. That is all I ask.
Cross-examined by MISS O’ROURKE

Q Mr Sheridan, I ask questions on behalf of Dr Southall and I have only got two for you. The first is this. In your statement you are asked about whether you were explained any down sides of the trial and you said this:

“I believe that the only negative side to the treatment was the fact that it was an unproven technique but that was made clear. It was a technological solution that was yet to be proven.”

Therefore it was the unknown and that was the negative side to the treatment. Is that a fair comment?

A That is a fair comment, yes.

Q So what was being told to you is “It’s a trial. We don’t quite know yet. We hope it is of benefit” and you have explained the reasons that were told to you as to why it might be, but that because it was a trial then until the end of the trial they would not know whether there were negatives to it because it was unproven?

A That is a fair statement.

Q The only other question I have got for you is this. You were asked some questions there by Mr Forde about the nurses and how they understood the equipment. Would it be fair to say this, that all the staff that you saw, nursing and doctors, appeared to be well trained and to understand the equipment, its use and to understand the trial?

A Absolutely, yes.

MISS O’ROURKE: Thank you.

MR FOSTER: No questions, sir, thank you.

MS SULLIVAN: No re-examination.

THE CHAIRMAN: It seems that the Panel do not have any questions for you, so that completes your evidence and it just remains for me to say thank you very much for coming this morning and for the assistance you have been able to give the Panel.

THE WITNESS: Thank you all very much.

(The witness withdrew)

MS SULLIVAN: Sir, the next witness is Lynn Alcock.

THE CHAIRMAN: We heard from her husband a few days ago. We are talking here about Patient 42.

MS SULLIVAN: That is right, sir. Thank you.

Lynn Ann ALCOCK, sworn

D16/11
Examined by MS SULLIVAN

Q  Good morning, Mrs Alcock.
A  Good morning.

Q  Would you start with your full names?
A  Yes, it is Lynn Ann Alcock.

Q  Mrs Alcock, as you know we want to ask you about the birth of your son, Patient 42, and we know he was born on 27 November 1992?
A  Yes.

Q  We have heard already from your husband. I think it is right that prior to you giving birth to Patient 42 you were being monitored carefully?
A  Yes.

Q  Because we heard that you had lost a baby not long before that?
A  Twelve months, yes.

Q  Then on 27 November 1992 did the doctors at North Staffordshire Hospital decide to carry out an emergency Caesarean section?
A  They did, yes.

Q  We heard how your husband came to the hospital?
A  Yes.

Q  Can you remember what sort of anaesthetic you had?
A  I think it was a spinal block.

Q  Do you remember, therefore, your son being born?
A  Yes.

Q  And going into the recovery room afterwards?
A  Yes.

Q  How were you at that stage having had a spinal block?
A  I was not well at all. I was shaking, shaking really badly and I could not stop my teeth chattering. I was feeling quite poorly.

Q  How aware were you of what was going on around you at that time?
A  At first I was aware, I was aware of what was going on at first.

Q  Did that remain the case?
A  No, no, no.

Q  Do you know why that was?
A  No. No. I do not know. I do not know whether it was shock or because it had been very emotional for me beforehand. I do not know. I really do not know.
Q Do you remember any doctor coming to visit you to speak to you about your son?
A No. No.

Q When did you first see him? Was it the same day that he was born?
A I do not know. I really do not know. From being in the recovery room to waking the next morning I do not know. I know I went to see him. I know someone took me down in a wheelchair but I do not know when.

Q You do not know when? Which day it was?
A I do not know when.

Q I am going to ask you to look at a consent form a moment. We are going to give you the original. So if you have that. (Same handed) We will all look at a copy which is in file 1, tab 3, page 404. Were you shown this when you made your statement, Mrs Alcock?
A I was, yes.

Q We see what is written there. We see a signature and your name to the left of it and the relationship “mother” and then we see the date underneath which is 27 November of 1992?
A It is, yes.

Q Have you any recollection of signing that form?
A No, none whatsoever.

Q We see it is dated the date of your son’s birth?
A I know, yes, I know.

Q How does the signature compare with your signature?
A Compared with my signature now, no. It is the end of the signature that seems strange but I mean the “As” are the same and the “Al” is the same, so it is my signature.

Q It is your signature, you say?
A It is my signature but not as I would write my signature now. That is the only way I can put it.

Q Have you any recollection of how your signature came to get on the form?
A No, I did not know I had signed this form.

Q So did you have any idea that your son was part of a trial?
A No.

Q Did any medical staff speak to you about your son’s treatment?
A No.

Q Did your husband say anything to you about any difficulties your son was having?
A Yes, he did say that Patient 42 had had problems with his breathing, I think he said for a while but he is okay now.
Q Did he say anything to you about what treatment your son was receiving? You have referred to the fact that he had breathing difficulties. Did you know how they were being dealt with?
A I think I can remember him saying that he was --- he had been on a ventilator for a short time, I think that is what he said.

Q So we see from this form that it mentions CNEP, Mrs Alcock?
A Yes.

Q Have you any recollection of being told anything about CNEP?
A No.

Q Or about different types of incubator being used?
A No.

Q When you first saw your son what sort of equipment was he in? Was he in an incubator?
A Yes, he was in an incubator, yes.

Q What type of incubator was that?
A I do not know. It just had two things that you could put your hand through. I do not know. It was --- he was just in an incubator.

Q I wonder if you would look at that file to your left-hand side a moment, behind tab 3 to the first page behind it which is page 336. Do you recognise that page? Have you seen anything like that before, that first page, 336?
A No.

Q Again, if you just go on, please, to page 341 which is the start of a booklet that goes through to page 364. Have you any recollection of seeing anything like that?
A No, not at all.

Q We were looking at your consent form a minute but can I just ask you to look further on in that file to page 406 in the top right-hand corner?
A Yes.

Q We see that that is a bonding questionnaire which appears to relate to your son because his name is at the top?
A Yes.

Q Is the name at the top in your writing?
A No.

Q There are not only ticks on this form, well, in fact, there are only ticks on the first form but on a second form that follows at page 409 to 411, do you see that at page 411 there is some handwriting?
A Yes.

Q Have you any recollection of completing that?
A Yes, I can remember writing something before I left, yes.

Q So is this your writing here?
A It is, yes.

Q You have indicated there, Mrs Alcock, that the nurses you found to be very helpful in every way. Was that your recollection?
A Yes.

Q And that you then go on to say that the doctors never related to you at all?
A No.

Q They never explained any of the treatment---
A No.

Q ---that your son was given and never gave you any indication as to how he was getting along?
A No.

Q Does that accord with your recollection or not?
A It does, yes.

Q You refer, of course, to going through a very bad time emotionally because, of course, your son was born prematurely and you had lost a baby the year before?
A Yes.

MS SULLIVAN: If you wait there, there will be some more questions for you.

Cross-examined by MR FORDE

Q Mrs Alcock, thankfully very few. I have got some questions to ask you on behalf of Dr Spencer. We have a copy of a witness statement signed by you on 26 February 2008 and there is another date on it which may be when it was drafted which is 25 January 2008. Can I ask you this, when were you first asked to recall the events surrounding your son’s birth in the sort of detail that you are being asked about today? Was it this year?
A Yes.

Q We know that your son was born in November, was he not, of 1992?
A Yes.

Q So realistically if it was even the end of last year you were being asked to try and recollect as best as you could events that happened 15 or so years ago?
A Correct, yes.

Q I asked your husband some questions and I asked him if it was fair to suggest to him that it was difficult to recollect over this distance in time and his answer was very fair, he was quite emphatic. Do you feel the same way?
A Yes.
A

Q Do you appreciate now, it is not necessarily clear from your answers, that your son actually received standard treatment?
A I do not understand.

Q You do not understand. Do you think that your son received CNEP treatment, in other words, or do you think he got the treatment that---
A No, he could not have had CNEP because I would have known.

Q Do you recall now seeing some babies that were getting CNEP because their heads were actually poking out of the incubator?
A No, no.

C

Q You do not recall that at all?
A No, no.

MR FORDE: Mrs Alcock, that is all I ask. Thank you.

MISS O'ROURKE: No questions, sir.

MR FOSTER: No questions, sir, thank you.

MS SULLIVAN: No re-examination.

Questioned by THE PANEL

DR SHELDON: Good morning.
A Good morning.

Q It is just a simple little question and I know it is a long, long time ago.
A Yes.

Q But it is fairly clear from your bonding questionnaire you felt the nurses were very communicative?
A Very.

Q And talked to you?
A Very.

Q But the doctors were not?
A No.

G

Q What was your reason for that?
A I can remember the reason I wrote that when I came out of that hospital I was very upset about it. I was emotionally very disturbed, most upset, I was terrified of something happening and I just needed some reassurance but no doctor spoke to me all the time I was there and I was there a month and I was most upset when I left that hospital.

H

Q Did you talk to your husband about this? Were the doctors talking to him?
A No, not that I know of, no, because he would have told me.

DR SHELDON: Thank you very much.

DR OKITIKPI: Mrs Alcock, just one question. Did your husband talk to you at all about the experiment that was taking place at the hospital?

A No, no, I cannot remember him talking to me about it, no.

DR OKITIKPI: Thank you.

THE CHAIRMAN: That completes the questions which members of the Panel would like to ask you, Mrs Alcock, so that completes your evidence this morning and it just remains for me to say thank you very much for coming and giving your evidence and the for the assistance you have been able to give us. Thank you very much.

(The witness withdrew)

MS SULLIVAN: Sir, the next witness on our list is Katherine Gatensbury. She is, in fact, the mother of Patient 1 who is a son.

THE CHAIRMAN: Did you say Patient 1?

MS SULLIVAN: Yes. I know what you are going to say. We gave this patient a different number earlier, did we not? I think I was struggling for the number and somebody supplied it to me. Actually, if we look in our index to the panel bundle, he is in fact referred to as Patient 1. Sir, would you remind me what number we did give him.

THE CHAIRMAN: Number 121.

MISS O’ROURKE: Which is his trial number.

MS SULLIVAN: Number 121 which is his trial number. That would explain it. Patient 1.

KATHERINE ANN GATENSBURY, sworn

THE CHAIRMAN: We are anticipating that you will be giving evidence to us about the birth of your son and, for the purpose of these proceedings, we are referring to him by number, Patient 1. That is not because of impersonality or insensitivity, it is simply that we would like to maintain patient confidentiality because this is a public hearing. So, I would be most grateful when you are giving evidence if you could avoid referring to your son by his name. I think that there may be a piece of paper in front of you with a number and your son’s name on it. It is difficult for a mother to talk about her son by a number but, if you could avoid using his name and either call him Patient 1 or “my son”, that will be absolutely fine.

Examined by MS SULLIVAN

Q Good morning, Mrs Gatensbury. Would you mind starting with your full names.
A Katherine Ann Gatensbury.

Q What is your occupation?
A I am a practice nurse.

Q Were you a practice nurse at the time when your son, Patient 1, was born on 12 August 1993?
A Not a practice nurse; I was a nurse though.

Q What sort of nurse were you?
A An adult nurse on a general medical ward.

Q So what would your qualifications be?
A Registered general nurse.

Q Casting your mind back to when your son was born or just beforehand, I think it is right that you had to have a planned caesarean.
A That is right.

Q Because you were suffering a problem with your placenta.
A Yes.

Q Were you in fact in North Staffordshire Hospital for a couple of weeks prior to the planned caesarean section?
A I was.

Q What was the baby’s gestation at the time when the caesarean took place on 12 August?
A It was 37 weeks but there was a question after his birth as to whether it was 35 weeks.

Q I think there was a concern by you about whether the dates were right or not.
A That is right.

Q Can you explain your state of mind at the time just prior to the caesarean.
A Naturally I was concerned, as any mother would be, in those circumstances having a caesarean before the baby was due. I was concerned that he would be okay.

Q Had you had any children before this?
A No.

Q So, on 12 August, on the day of the birth, what sort of anaesthetic did you have for the caesarean?
A A spinal block.

Q Were you fully aware of what was happening?
A I was.
Q Were you able to have a look at your son once he was born?
A Very briefly. They whisked him away more or less straightaway; they just showed him to me briefly.

Q So, they took him away to the neonatal unit.
A Yes.

Q And obviously they had to look after you in the meantime. How were you feeling at that stage after his birth?
A Straight after, I was quite happy that I had a son. At that moment, I was not too concerned. I felt that he was in safe hands.

Q Obviously you had had the spinal anaesthetic. When that was wearing off, did you receive any other medication at all?
A I did whilst still on the operating table. I panicked a little bit and thought that I was getting my feeling back and I was given something which I presumed to be pethidine or something similar via a cannula in my hand.

Q How did that make you feel?
A I remember that it made my feel quite sickly shortly after, but I cannot remember other than that how it made me feel. I just remember being very nauseous some time after.

Q Obviously your son had been taken away to the neonatal unit. Did you know how well he was at that time?
A Somebody told me that he had problems with his breathing or that he was in respiratory distress, but I was not too clear how serious the problem was at that moment.

Q Was there anyone with you at the time?
A My husband.

Q Did anyone tell you what type of treatment your baby was going to get?
A I think I can remember my husband coming back to see me after he had been into the neonatal ward and telling me that he had some sort of problems and that he was being treated. I think that was the time when he told me that there was a new treatment that they were going to use on him.

Q When he told you that there was a new treatment that they were going to use on him, did he tell you anything about what type of treatment it was and the nature of it?
A I cannot honestly remember about that, but I do remember him saying that it was part of a trial and that, because I was the mother, some doctors would be coming to speak to me later to get my consent because they needed my signature, me being the mother.

Q Did he give you any indication of how the new treatment compared with the normal treatment that would be received?
A I do not know if it was my husband who told me or somebody else who told me, I cannot remember that, but I remember it being implied that it was a more gentler method of treatment than the traditional ventilation.
A

Q Were you aware of what type of treatment it was and what it was called?
A At that time, I do not think that I was but, in the days later, I was aware.

Q What did you learn that it was in the latter days?
A It went by the name of CNEP or continuous negative extra thoracic pressure or something like that.

B

Q I was not asking you for all of those, CNEP would have been fine. You told us that you were given the impression by someone, you are not sure who, as to the nature of the treatment being a gentler treatment.
A Yes.

Q Why was it a gentler treatment? Were you aware at that time and, if you were not, just say so.
A No, I was not aware why. I think basically because it was not invasive. I think that was the rationale.

C

Q At that stage when you were speaking to your husband about it, you told us that you had morphine, so what were you feeling at that stage? How aware were you of what was going on?
A At that stage, I was not too concerned, to be honest.

Q Meaning what?
A I was not too concerned about my child’s state of health. I was quite happy that I had had a baby and that he was alive and being looked after.

D

Q Yes, of course. You said that your husband had indicated that somebody would come and speak to you at some stage about getting your consent.
A Yes.

Q Do you remember at what stage that discussion took place?
A It was some time later; I had been moved on to the postnatal ward and I was in a single room. I seem to remember that it was later that day. I am not sure how long after, but I remember two or three doctors coming into the room and saying, “Has your husband told you that we will be coming to get your consent for the treatment?”

E

Q Yes. How were you feeling at that point in terms of recovery? Had you recovered from the effects of the anaesthetic?
A I cannot remember exactly at that point how I was feeling. I do remember in the time afterwards that I felt very sickly and I did sleep for some time after being taken up to the postnatal ward, but I cannot remember at the moment when the doctors came how actually I was feeling at that time.

F

Q You say that doctors came to see you; do you remember how many doctors came to see you?
A I cannot remember exactly. I am sure that there was more than one. I think that there were two or possibly three.
Q Can you remember whether they were male, female or what the position was?
A I cannot honestly remember. I have the impression that one was a lady but I cannot be certain.

Q Can you remember what they said to you when they did come to see you about consent?
A Again, I cannot remember the exact words but basically they just reiterated what my husband had told me earlier, that it was a trial and that it was again thought to be of a more gentler method, less invasive, but I cannot remember exactly what they said.

Q Were you made aware of any advantages of disadvantages of the treatment that you recall?
A I cannot honestly remember.

Q Were you asked to sign/give your consent?
A Yes.

Q I wonder if you could have the original consent form. (Same handed) We have it behind tab 3 at page 382. That is the original of your consent form, Mrs Gatensbury. Is your signature on it?
A It is.

Q It looks as if the doctor has signed underneath by mistake and then your signature is above it. Do you have any recollection of that?
A No.

Q It is dated, we see, the same day as your son’s birth, so 12 August 1993. Apart from the signature, is any of the other writing on that form yours?
A No.

Q Is there anything on the back of your form, the original that you have there?
A No.

Q Do you remember whether you received any written information at all about the trial prior to giving your consent/prior to signing this form?
A I cannot remember.

Q You obviously had a discussion with the doctors about the trial. What was your understanding about what treatment your son would receive?
A My understanding was that he would receive the CNEP treatment.

Q Were you aware of whether CNEP had been used before or not?
A I cannot remember if I was aware of that or not.

Q In terms of the quality of treatment that your son was to receive, what were you expecting from what you were told?
A I was expecting the highest of quality.
Was your son in CNEP for very long?
A Not at that time, no. I cannot remember exactly how long he was in it after his
birth, to be honest.

Did he need any other form of ventilation?
A Yes. Again, I cannot remember but a couple of days later, I am not quite sure
how long, he did. He did not seem to be responding to the CNEP, so he was ventilated in
the traditional way.

Was that instead of or as well as CNEP?
A It was instead of, I think.

I think that you spent a little time in hospital thereafter with your son.
A Yes.

Your recollection is that he was in CNEP for quite a short time by the sounds of it.
A Yes.

Were there any particular problems with the CNEP tank that he was in at that
time?
A Not that I am aware of.

I think that you were sent home after a few weeks.
A Yes, I think about two weeks altogether.

But I think that your son required oxygen for some time thereafter.
A Yes.

I think that in fact you participated in a further study.
A About five years, he participated in the follow-up trial. He did receive CNEP
when he was about five months old but, as far as I am aware, he got bronchiolitis and it
developed into pneumonia, so he required further treatment. As far as I am aware, that
was not a further trial, it was just the treatment he required.

At that stage, was there any problem at all with you ---

What does that have to do with anything?

I will not ask that. Would you look in the files in the left-hand side
there behind tab 3 at page 383 in the top right-hand corner. That is a bonding
questionnaire which appears to relate to your son, we see the name at the top. Do you
recall completing this?
A Yes.

Do the answers that you have ringed reflect your reaction at the time to the
questions that you were asked?
A Yes.
Q: How did you come to fill that out, do you know?
A: It was on the neonatal ward. I think I remember one of the nurses bringing it to me. I had forgotten about it but I sort of remembered recently with all the…

MS SULLIVAN: Thank you. If you wait there, there will be some more questions.

Cross-examined by MR FORDE

Q: Good morning. I am asking some questions on behalf of Dr Spencer. Your son was admitted under his care – were you aware that he was your paediatrician?
A: Yes, I think so.

Q: Did you know that Mr Redman was your obstetrician?
A: Yes.

Q: Your son seems to have been seen, just going through the notes, by a number of doctors. Do you remember a Dr Morgan?
A: No.

Q: Or a Dr Palmer, Kate Palmer?
A: Yes, a registrar, I think.

Q: Do you recall Dr Arya, because it is her name we see countersigning your consent form?
A: I cannot remember.

Q: A lady we have seen, probably of Asian or Sri Lankan appearance?
A: I cannot honestly remember, apart from thinking one of the doctors was a female.

Q: Do you remember being discharged home by Dr Brookfield, who was the senior paediatrician?
A: I cannot remember.

Q: One other question. In your witness statement, which is dated 12 February 2008, you say this:

“However, the doctors did a ward round every morning and we were quite impressed. It was a full ward round with a full entourage and they gave us a lot of information regarding our son’s condition.”

Can we take it that you were happy with your interaction with the doctors and the nurses?
A: Yes.

MR FORDE: Thank you very much.

Cross-examined by MISS O’ROURKE

Q: Mrs Gatensbury, I ask questions on behalf of Dr Southall – just a couple for you. As you have told us, you were qualified as a nurse at the time?
Q You would therefore, presumably, even as a nurse on an adult ward, be familiar with the consenting process and things like consent forms?
A Yes.

Q In other words, this was not the first time you had ever seen a consent form because you would have seen them in the course of your work; they would have been filed in medical notes and you would have had access to notes?
A Probably.

Q You also would have found yourself more at ease with the hospital setting than many patients because you are used to working in a hospital?
A Possibly, but I was very anxious at the time. It was completely different – I had never been in neonatal before.

Q I understand that, but many patients will be intimidated or anxious about talking to doctors and nurses are not familiar with them and therefore do not know how to interact with them. You were not going to face that problem; you would have found it easy to talk to the nurses and speak their own language and they would know that you were a nurse and you would have found it easier than many to talk to the doctors – yes?
A Probably.

Q You say in your witness statement at paragraph 18 “I was happy with what I had been told and so I gave my consent”?
A Yes.

Q And as a nurse you would have been in a position to ask questions of nurses or doctors if you had been unhappy or felt you needed to know more?
A Yes.

MISS O’ROURKE: Thank you. I have no further questions.

MR FOSTER: No questions, sir.

MS SULLIVAN: No re-examination.

G MRS BRICKLEY: Good morning. Miss O’Rourke just said that you would have been familiar with your surroundings as a nurse and the consenting process. Were you familiar with the consent process as far as trials were concerned?
A No.

Q So it was a completely new area to you?
A I do not think I remember being involved in a trial, other than giving medication out on a ward round, drugs, but taking part in a consent procedure I was not involved in.

H MRS BRICKLEY: Thank you, that is all.

D16/24
THE CHAIRMAN: That completes all the questions that everyone has for you, Mrs Gatensbury so that therefore completes your evidence. It just remains to me to say thank you very much for coming this morning and for the assistance you have been able to give us.

THE WITNESS: Thank you.

(The witness withdrew)

MS SULLIVAN: Sir, I do not know whether that would be a convenient moment for a break?

THE CHAIRMAN: Yes, I think it probably would, Ms Sullivan. Is Dr Wildig here?

MS SULLIVAN: She is, yes.

THE CHAIRMAN: We will take a break now and come back at ten-past eleven and carry on then. Thank you very much.

(The Panel adjourned for a short time)

THE CHAIRMAN: Welcome back, everybody.

MS SULLIVAN: As I said, sir, the next witness is Catherine Wildig.

CATHERINE ELISABETH WILDIG, sworn

Examined by MS SULLIVAN

Q Good morning, Dr Wildig. Would you mind starting with your full names, first of all?
A It is Dr Catherine Elisabeth Wildig.

Q Dr Wildig, what are your qualifications?
A MB ChB, FRCPCH, MMed Sci.

Q What is your current appointment?
A I am a consultant paediatrician at Bradford Hospitals NHS Trust in Neuro Disability.

Q I want to take you back a number of years, as you realise, to an earlier stage in your medical career and to the time when you worked at North Staffordshire Hospital. When was that?
A I worked there between August 1990 and July 1992.

Q In what capacity did you work there?
A I was a senior house officer in paediatrics. It was my first paediatric job.

Q You had qualified when?
Q So that was your first paediatric job, and what did you spend the first year of the rotation doing?
A I did six months paediatrics and six months neonatology.

Q What about the second year that you were there?
A I think it was paediatrics again and community paediatrics, but it is a bit hazy because it was 17 years ago.

Q When would you have worked in the neonatal unit over that period of time, for the two years that you were there?
A As far as I can remember, it was the second six months I was in Stoke and then covered it on call for the second year. That is as far as I can remember.

Q When you were covering it on call, can you help us as to how often you would be on call?
A It was about one in three to one in four nights and weekends.

Q And the six months that you spent working there, were you there the whole time that you were on duty?
A I would have been there every day plus the on call.

Q Do you remember CNEP tanks being in use in the time that you were there?
A I do remember that, yes.

Q Do you remember caring for babies in CNEP tanks?
A Yes, I do.

Q Had it already been introduced, the CNEP trial, when you arrived or did it start whilst you were there, do you know?
A It is all a bit hazy. I think it was introduced when I was there but I could not be sure of that.

Q Do you recall, whenever it was introduced, whether you received any specific training about the trial?
A I think there was training. I cannot remember it clearly but I think there was some training, and I can remember when Louisa came over and showed me some handouts I can remember they were very familiar, some of the documents.

Q We will come to those in due course. Any training that did take place, was that in Stoke or was it elsewhere?
A It would have been in Stoke. I do not remember going elsewhere. I mean, neonatology was not a particular interest of mine; I did it as part of my rotation because I needed to get trained but it was not something I was hoping to specialise in.

Q If we could just go back to that time when CNEP was introduced on the neonatal unit, obviously if you had a premature baby being born what was the first priority?
A Obviously to assist the baby, see what sort of condition the baby was in, get there
quickly, give them oxygen and make sure the baby was breathing or getting enough oxygen.

Q Once the trial was in place, was consideration given to whether any premature baby fulfilled the criteria for the trial?
A I would say that would be secondary. I would be there first for the baby absolutely and then get things calm and then start to think about that. I am absolutely clear about that – the priority was the baby’s health.

Q At this point in time, Dr Wildig, can you recall the criteria for the trial?
A I cannot recall the criteria. I know there was a list and I know there were exclusion criteria, but I could not tell you exactly what they were.

Q I think you were shown a number of documents when you made your statement. I wonder if we could just take up for the moment the file to your left there, and I wonder if you would just, for example, look at page 340 behind tab 3? The numbers are in the top right-hand corner. I think we are unclear whether this was a document prepared for nurses or for doctors, but is it a document with which you have any familiarity looking at it now?
A The sort of type looks familiar but it is not very family. I could have seen it before, 17 years ago, I do not know. I might have done.

Q But would you have been aware at that time 17 years ago of the various inclusion and exclusion criteria for babies if they were to enter the trial?
A I believe there was a list of exclusion criteria that I would have referred to.

Q If the baby met those criteria, what would you then have done?
A If they did not, they were not excluded, then I would have phoned for randomisation.

Q Who would you have phoned for randomisation?
A I think I would have consented them first, but I would have phoned – I think there were some numbers to phone. It was either Dr Samuels or Dr Southall. Whatever hour of night, you would ring and there would be an envelope that they would open and tell you which group they would be randomised to.

Q You have just indicated that you would have taken consent before that. Could you just help the Panel as to how at that time you would have gone about taking consent? You must have been involved in that process many times since, but if I can ask you to cast your mind back to that time how would you have gone about it?
A It is very, very hazy. I would have explained to the parents that we were hoping that there was going to be a treatment that would help premature babies with their premature lungs and we were doing a trial to see if this new treatment was better than the treatment we were offering. It is all hazy but this is what I recall. Just to explain what it was about, but I would not put any pressure on them at all, as it says later in my statement.

Q Prior to this time, had you been involved in consenting anyone for a trial?
A Not for a research trial.
Q In terms of who you would have approached, would you have approached both parents or just one?
A This is completely clouded by what is in my mind now in the last 17 years and what has gone through in that last 17 years. Now, of course, I would hopefully speak to both parents if I could but this is not always possible. I could not tell you 17 years ago what my mind was then.

Q And, of course, these were mothers who had given birth in a variety of different ways but a number by Caesarean section and sometimes with a general anaesthetic. If a mother had had a general anaesthetic what would be your approach to consent at that stage?
A I can tell you what it would be now and I think it would be the same then – you should never consent somebody who is still under the effects of general anaesthetic and probably that would be what I say now but I cannot say for 17 years ago. I think that is what I would say but I cannot say for definite.

Q I think we see your name on one of the consent forms that we have in the course of this case. If you look at the original and, perhaps, if we just stay in the same bundle and look at page 396, is this your signature on the bottom of this form which relates to a baby we are calling Patient 11?
A That is my signature, yes.

Q So if I could ask you to refer to the baby in the same way. So that is your signature. Can you just help as to how much of the form is completed by you?
A All of it actually. That is all my writing.

Q …apart from the signature of the parent, is that right?
A That is correct, yes.

Q Again, if you can just help, because you have the original, is there anything on the back of the form that you have, any information at all?
A No.

Q So when you approached the parents for consent did you have any written information at all?
A I believe there was written information.

Q So you know in what form that was?
A Very hazy again. I seem to remember some A4 sheet with typing on it – I cannot remember clearly.

Q What would you have done with that, can you remember, with that information when you were asking for consent?
A I cannot remember. I would think I would have gone through it with them and given them the sheet but I could not claim that.
Q Can you recall, we talked about training earlier, did you have any formal training that you can recall prior to taking consent from parents for this trial?
A I cannot clearly remember.

Q You were shown, I think, again when you made your statement some information about the trial and perhaps you could just look in that file now to your left-hand side, behind tab 3 at page 336 in the top right-hand corner. How does that compare, Dr Wildig, with your recollection of the sheets of paper that you thought you might have when you approached parents for consent?
A It could have been those sheets. One thing I particularly remember is the option at any time that the parent could pull out, I really remember that bit saying that if at any time the parent did not want to continue with the trial they could pull out at any time without their treatment being affected. I do clearly remember that.

Q Then just behind there we see a sheet that relates to a different process. Do you recollect this one at all?
A I do not remember talking about the near infrared spectroscope or intra cranial pressure monitoring. I wonder if that was after my time. I do not remember consenting at all for that.

Q Do you remember those forming part of the CNEP trial, these particular forms of monitoring?
A I can remember some monitoring that took place during the CNEP trial. I can remember a research registrar coming in at night to do near infrared spectroscopy which I was not involved with. She used to just come and consent the parents herself. I remember her coming in at any hour, getting her own consent for that and studying the babies but I was not part of that.

Q That was part of a separate trial. We will be hearing from that witness in due course but as far as CNEP was concerned was that part of it?
A Sorry, I do not quite understand the question.

Q Yes, I am sorry. Was the near infrared spectroscopy part of CNEP or not?
A When I was there, which was I think at the beginning of the trial, I do not think it was.

Q What about inter cranial monitoring, do you recall that being part of CNEP?
A Hazy. I cannot remember clearly.

Q Doppler ultrasound?
A Possibly. Possibly. I do not remember very clearly.

Q We were just looking at those two leaflets. If we could go forward in the bundle, please, to page 341 through to page 364, do you recognise those documents at all? Were they in use when you were there or not? If you cannot recall say so.
A I do not think they were there when I was there unless the nursing staff gave them out but I would probably have seen the parents with them if that was the case. I do not think so.
Q So going back, if we may, to the consenting process with the parents. Are you able to say how long you would have given the parents to decide whether or not to consent?
A I cannot say but I do not think I would have rushed them.

Q We know that as far as the trial was concerned there were particular criteria?
A Yes.

Q What is your recollection of when the consent process had to be completed by?
A I know there was always a time limit by which you had to have made a decision but I could not remember, I would be guessing. I cannot remember.

Q We saw the exclusion criteria, etcetera, and we know, I do not think it is in dispute, that there had to be an assessment of two and then four hours if that is of any assistance to you. Once the parents had given their consent what was the next process?
A After consent that would be the phone call for the randomisation.

Q Would you when you were describing to the parents what was involved in the trial give them any verbal description of what the treatment was likely to be?
A I think I would but it is 17 years ago but I think I would have done, yes.

Q Can you help at all now as to what you would have said or how you would have described it?
A No, no, I cannot remember. I think I would have probably described the tank but I would be guessing at exactly what I would have said that long ago. I just cannot remember but I am sure I would have physically described what it involved.

Q What about whether there were any advantages or disadvantages?
A I cannot remember what I would have said. I would have answered questions but I cannot remember clearly what I would have said.

Q Were you aware of any difficulties at all with the CNEP tanks in the time that you were there involved with the babies?
A Yes, but I mean that is only since the solicitor came to see me in Bradford my memory was jogged. I had not thought about it since then but I am aware of them, yes.

Q What were they?
A I remember problems with the neck seal that they could not keep the pressure negative inside the tank. I can remember times of that and we had to look and see why the pressure was not being kept negative. I know the nurses used to put Stockinette around their necks always as far as I can remember. I cannot remember any major problems with redness round the neck while I was there. Temperature control was a problem. The main problem for me myself was handling and getting procedures done inside the tank.

Q Yes, I think we have heard a little about that. How easy was that?
A It was tricky which is why I said in my statement we would not pressurise the families because it was basically less work for us if they did not go in the tank. So we
wanted to promote this treatment because at that time there was very little treatment for premature babies and I think the people leading the trial thought that there was chance to find a wonder treatment that would really help when we were not really --- surfactant was not readily available. I think I admired the people for trying out something they thought could really help and prevent the damage and that is why I think we thought it was good and we were going for it but it was more difficult for us. We thought if it helps the babies in the long run we will go along with this and we will try this.

Q You have said it was more difficult for us, is what you said?
A And the parents to handle the baby, yes.

Q What about the nurses as well?
A Oh, yes, it was more difficult for everybody.

Q You have described how you remember some form of protection for the neck. Did you see any problems with necks at all whilst you were there?
A I might have seen slight redness but I do not remember any major problems.

Q I think, in fact, again when you made your statement you were shown a photograph of a child's neck. I make it clear this did not happen in Stoke, this was something that occurred in London in Queen Charlotte's. Were you aware of anything similar happening in Stoke?
A Not in Stoke. Not like that, no.

Q Were you aware of this particular case that had happened in Queen Charlotte's? Were you aware at the time of it?
A It might have been after my time. I do not know. I do not remember. I think if I had seen that picture I would remember it.

Q What would you have said, if anything, to parents about advantages and disadvantages of the trial?
A I am just saying what I would say now, I cannot remember what I said at the time but I would say we were hoping that there would less trauma to the lung from not having to put such positive pressure down and maybe even get away without the need for intubation.

Q In order to assess whether a baby met the exclusion criteria, I know you cannot remember them now, although we have looked at page 340 there, Dr Wildig, how would you go about assessing whether a child did fulfil the criteria or not?
A When I first admitted a baby to the Special Care Baby Unit regardless of whether in the trial or not you would look at the mother's notes, you would look at the family history, see if there is a history of diabetes. I think they are things that you would have looked at anyway.

Q Would scans have been done at that time or not?
A Not always.

Q Would you, in fact, have done scans?
A No, I was not qualified, I could not do it personally, no.
A

Q Who would have been able to do them?
A I guess an ultrasonographer or some of the consultants could have done them or some of the registrars who had a particular interest in neonates. I do not know any senior house officers that would have done scans at that time.

B

Q I think you have since looked at scans for Patient 6?
A Yes.

Q I think you were shown---
A The report.

Q The report, yes, not the actual scans because they are missing but the report. I wonder if you could be given file 2, tab 5, pages 161 and 162. That is not a patient with whom you were involved at the time obviously because you were not there at the time, as I understand it, but are such scans scans with which you are now familiar given your particular specialty?
A Not acutely but I may see a child, you know, twelve months down the line who has had a scan like this.

C

Q You were told, I think, that this child was subsequently diagnosed with cerebral palsy. Is that something with which you are familiar?
A Yes, very.

Q I think that is now really your area of expertise?
A Yes.

D

Q So far as these scans are concerned, Dr Wildig, looking at pages 161 and 162, do they show any abnormalities?
A There is abnormality, yes, but not major abnormality.

Q I was going to ask you that, so abnormalities but not major. Would those changes have necessarily led to any significant disability or not?
A Not necessarily. They could do. It does not always tally. If you get a mild scan you can get severe disability. If you have a very severe scan you can be surprised sometimes.

E

Q Looking at the results of these scans are these results which should be communicated to parents or not?

MR FORDE: I think that is probably a matter for expert evidence and I have sat patiently while this doctor who coincidentally looks at scans is being asked questions about scans that she did not see at the time relating to a patient that she never treated and she was an SHO. So I think we are probably stretching things a little, sir.

MS SULLIVAN: Yes, sir. She is being asked in her present capacity rather than her role at the time.

MR FORDE: If it is made clear that this then SHO is being asked to cast her mind back
and say what the appropriate degree of communication should have been between a consultant, we emphasise not necessarily present at any time when the scans were done in Dr Spencer's position, and parents 17 years ago then I will sit back and watch my learned friend do her best.

MS SULLIVAN: I will ask her whether she can help as to that. First of all, when you were an SHO on the unit do you recall what the practice would have been at that stage in relation to communicating results of this nature or not?
A I think it would fall to a more senior person to talk somebody now but I cannot recollect then. That is what I think would happen. I cannot remember what happened that long ago and I was not there at the time.

Q I know you were not there at this particular time. Can you help as to what the practice would have been at that time as to communications between parents and the doctors about such scans in your capacity now?
A When I worked in Stoke I would say the consultants' communication skills were very good indeed actually, the paediatricians communicated very well with parents, I would say.

Q I was asking you particularly about scans of this sort and whether you would have expected the information to be communicated to parents?
A If I was seeing this child in my clinic now I would be talking through the scans with the parents but I do not deal acutely with children. So I would be seeing a child twelve months down the line, I would be assessing the level of disability and looking back at the scans and talking through with the parents.

MS SULLIVAN: I will leave it at that. Thank you.

Cross-examined by MR FORDE

Q Dr Wildig, I will return briefly to that issue in a moment. I am asking questions on behalf of Dr Spencer. The first thing that is apparent from your evidence is this, that you are finding it, as we on this side of the room predicted, very difficult to recollect with much precision your medical practice and that of the unit 17 years ago?
A That is correct, yes.

Q Subtleties and nuances and precise recollection of conversation impossible, I suggest?
A Yes.

Q You can give us evidence in the most general terms but your fear, as you have taken your oath seriously, is that your evidence will in some way be contaminated by everything you have learned since?
A Absolutely, yes.

Q So the difficulty for you is this, I suggest, that sometimes it is difficult to distinguish between what Dr Catherine Wildig would have done and thought in 1990 to 1992 as an SHO and what the experienced consultant does now?
A That is correct, yes.
Q With all those difficulties and restrictions I am still going to try and explore some of the issues with you. Please indicate if you are finding it difficult to recollect or if you are not sure that your evidence is not tainted by after acquired knowledge. The first thing is this, you had a friend working at the hospital who spoke, I think, when you were working elsewhere as a medical student in Birmingham, very favourably about the paediatric unit in Stoke. Is that correct?
A That is correct, yes.

Q By very favourably can I take it that she thought it was a centre of excellence?
A I think that is correct, yes.

Q During your initial six months you have told us you worked in paediatrics and six months on the neonatal unit. The consultants used to share the on-call. Is that correct?
A They did, yes.

Q Can you recall in the neonatal unit what medical cover you had late in the evening or in the early hours of the morning?
A As a first year SHO there would be a registrar who would be covering general paediatrics and the neonatal unit and there would be a consultant at home.

Q But you did not have a consultant present after five, six o'clock in the evening until the follow morning. Is that correct?
A Not generally but I would say people were very good at coming in if there was a problem, very good and at the weekends the same. The consultant would come in at the weekend but they were always approachable without exception.

Q I just wanted to establish with you (and I am grateful for the comments that you have made) that the consultants were not expected then, things may be different now, to remain on the ward overnight and into the early hours of the morning?
A They were not expected to, no.

Q So the most senior clinician actually physically present would be the registrar?
A Or second year SHO. When I was a second year SHO I would be the most senior paediatrician.

Q When you were the most senior paediatrician would you agree that the clinical decisions and the noting of care and relevant observations would be primarily your responsibility?
A Noting of observations, yes.

Q Checking that they had been done, for instance?
A Yes.

Q This is what I want to explore with you, the vital signs, such as blood pressure, saturation levels, those notes were actually entered both into the nursing notes and on to the intensive care large sheet, we have got an example if you need to see it, but it is quite a complicated A3 size chart. Do you recall that?
A I seem to recollect that, yes.
Q But the nurses would physically enter the readings?
A The nurses would enter it, yes.

Q You might get a snapshot when you walked into the room?
A Yes.

Q If there was a problem and you were called you would be able to have a look and see what had been happening?
A Yes, and you might write some medical notes and you might take some observations and put them in your medical notes.

Q That would go into your clinical notes?
A Yes.

Q If you had mandated 15 minute obs, or 30 minute obs you would expect the competent neonatal nurses to actually undertake that duty?
A Yes.

Q You would not expect a consultant to be standing by the bed at one o'clock in the morning writing down saturation levels?
A No.

Q You would also expect those nursing staff to recognise and either deal with or seek medical help in relation to hypoxia.
A Yes.

Q Because one of the things that they are trained to do is to recognise, in this type of unit, respiratory difficulties.
A Yes.

Q They are also qualified to provide advanced life support.
A I think they would have been, yes.

Q I know that neonatology is not and was not then a specific interest of yours, it is something that you had to do to move into the post that you have now, but I want to remind you of some of the things you said in your witness statement. In paragraph 5 you say this:

“I do not clearly remember now details of any specific training at the beginning of the trial. However, I do remember being told that it worked in a similar way to the old iron lung, so there must have been some teaching but I do not remember who provided it”.

A Yes, but there was a lot of teaching that went on this. One of the reasons for going there was because there was such good education and such good meetings and I am sure that it would have been covered at one of the meetings.

Q Do you have a recollection – other witnesses have told us about this and, if you do
not, do say – of a research nurse called Theresa Wright?
A Yes, I remember her.

Q In a seminar room with a CNEP tank and possibly a doll?
A I do not remember the room but I remember Theresa, yes.

Q Do you remember her being competent around the issue of CNEP?
A She was very good, yes.

Q And the nurses had a full understanding of how the tank worked.
A I believe that they did.

Q And could recognise depressurisation.
A In the main, yes.

Q They, I think, were in charge in the main dealing with problems around the neck seal.
A Yes.

Q One of the observations to be recorded – you may not recall this and do say if you do not – was the neck.
A I think it probably was. I am a little hazy.

Q You exhibited to your witness statement – and we will get these documents copied if they are needed – a doctor which showed how to utilise the latex and also to make the stocking edge. Do you recall that documentation?
A I do not recall it, no. I would not have been involved in doing that; it was the nursing staff who did that.

Q In terms of material available on the ward, unfortunately we have lost some of the protocols, but you exhibit a document headed, “A Randomised Control Trial of Continuous Subatmospheric Extrathoracic Pressure” which is a one-page document dealing with entry criteria. Do you remember seeing that? (Indicating)
A That page looks vaguely familiar.

Q You have also produced some documentation from the Hammersmith and then a one-a-half page CNEP introductory paper which summarises what it was designed to do. Do you recall that being on the wall?
A Is that in here.

Q If you have your witness statement, it is CW5 if you want to have a copy or you are more than welcome to look at mine. I wonder whether the witness could be given a copy of her statement or, more particularly, CW5 to CW8. (Same handed) The first document behind CW5 that I have is one that deals with entry criteria and exclusion criteria.
A That page looks vaguely familiar.

Q If you go to the next page there is a document dealing with “Explanation of the Research Project”. Do you recall seeing that?
A  That page 682 does not look so familiar.

Q  And then we have pages 683 and 684 at the top which is “An Introduction to the use of CNEP”.
A  We used to have these books of guidelines on the unit and that looks similar to what was in there with the ring …

B  Q  Then the next document “Indications for CNEP”.
A  Hazy but I have possibly seen that before.

Q  Then a description of the CNEP tank.
A  I am not clear. I might have seen that, I do not know.

C  Q  This deals with the chamber, the neck seal, the neck protection, the suction unit and the pressure monitor.
A  That possibly came out of the guidelines booklet.

Q  There is another document called “Use of the CNEP Tank” which is two pages. It should be pages 688 and 689 at the top in manuscript or 405 and 406.
A  I have possibly seen that before but I cannot clearly remember.

D  Q  Then a one-and-a-third page document with some diagrams which is all about how to make the latex seal.
A  That is not very familiar.

Q  So, that would have been a nursing responsibility you think?
A  Yes.

E  Q  Then a problems document about inadequate pressure, cool infant, soreness on the neck and inadequate oxygen in the head box.
A  That is not very familiar. I may have seen it, I do not know.

Q  Behind your CW6, page 694 at the top, there is a list of the people involved and a summary about the scoring.
A  That page 694 is vaguely familiar. I may have seen that paper before.

F  Q  Then we have the parent information sheet.
A  That is vaguely familiar.

Q  And then another three-and-a-half paged document which explains the early use of CNEP and criteria and gives some references which we think may be an extract from a paper.
A  I may have seen that; I am not clear.

Q  I do not think that you have necessarily seen the next document. You have been asked about the document which has 739 at the top by my learned friend which is the inclusion/exclusion criteria flowchart which we do have in our bundle. It looks like this.
A  I think I may have seen that.
Q Your last exhibits are the scans to which I shall return in a moment. Your basic impression appears to be however: a well-run unit with lots of teaching.
A Yes.

Q Can I take it that you would not have consented any parent if you did not feel competent to answer their questions about CNEP?
A If they had had questions that I could not answer, I would have got somebody who could answer or not consent them, so I believe. That was 17 years ago but that is what I think I would have done.

Q Again, it is a matter of clinical impression but whether consenting for CNEP or any other procedure, you were well aware that you should not be trying to obtain informed consent from anybody who gave the clinical appearance of being under the influence of a general anaesthetic.
A That is clear in my mind now and I believe it would have been then but I could not be completely clear.

Q Do you not think that that was part of your basic training?
A Yes.

Q And you have to, through questions and answers, almost as a matter of instinct, try and ascertain whether or not a patient is understanding what you are explaining.
A If a patient was not alert and did not seem to understand what I was saying, I certainly would not consent them at any time.

Q And you were aware – we all accept that it was a stressful time – that, for the trial to work, you were asking patients to make decisions close to birth.
A Yes.

Q In any event, these children needed treatment.
A They did.

Q They were desperately ill.
A They had to have treatment, yes.

Q So, you were not consenting before providing standard treatment, for instance.
A We just provided standard treatment.

Q You just provided it.
A Yes.

Q If you had a parent who woke up after a caesarean section who said, “Actually, I am anti IPPV”, it would be too late.
A Yes, it would have been done already.

Q Your priority is to look after that child.
A Yes.

Q And keep it alive.
A Yes.

Q In your witness statement, you make it clear – and I want to try and deal with this with you – that you would have emphasised that it was a trial.
A Definitely, yes.

B Q You would definitely have emphasised that the parents had the option as to whether or not to enter the trial.
A Yes, definitely and also it is clear in my mind that they could withdraw at any time. That has stuck in my mind as well.

Q You were aware of the process of randomisation taking place after you obtained consent.
A Yes.

C Q So far as you can recollect, did you attempt at least to make it clear to the parents that the mere signing of the consent form did not mean that their child would automatically enter a CNEP tank?
A I would have hoped that I had made it clear, yes.

Q Because you were consenting before you made the phone call.
A Yes.

Q So, at the time you were consenting there were two things that must have been going through your mind: firstly, I do not know whether the response to the phone call I am going to make post-consent will enter the child into the trial.
A Yes.

Q Secondly, I rather hope that the randomisation process allows for standard treatment because CNEP makes my life a lot more difficult.
A Yes, but I wanted the baby to do as best as possible, so it is within those.

Q But that would contra-indicate – and tell me if I have this right – you wanting to apply pressure to any parent to enter CNEP.
A Exactly.

Q Is that fair?
A Yes.

Q You were asked finally about the head scans and you were shown the head scans and I think we have them at our page 161 and 162 in bundle 2 which you should have with you.
A Yes.

Q In fact, you exhibited them behind tab 4. Do you have those available?
A Yes.

Q The first one: increased density, suspicious of clot; the second one: mild symmetrical dilatation. Given your experience – and I know that you tend to deal with
children – is this right? – where there is already an established diagnosis of cerebral palsy or …
A Not necessarily. I might make the diagnosis.

Q Do you see the second scan as being more reassuring than the first?
A It is lateral dilatation on one and symmetrical bilateral on the other.

B Q Which is a more significant change?
A The second one, I would say.

Q Do you agree – because we have looked at other notes – with the description of these being mild changes?
A They are not severe changes. I have seen much, much worse scans.

C Q If you go to page 212, in 1994, Dr Spencer was describing matters in this way:

“… I would note that [Patient 6] had mild symmetrical dilation on the lateral ventricles and at one stage there was the possibility of a clot attached to the choroids plexus on the left side. These ultrasound changes could be considered virtually normal in a pre-term infant and would not, in any event, be associated with an increased risk of handicap.”

That was in 1994. Can I remind you that when you gave your witness statement, you said that you would explain the results to parents.

“However if [Patient 6’s] parents were not told about the scan, it may not have changed her outcome as there is no cure for cerebral palsy” and I think that you were actually dealing with the communication that you would undergo now.
A Yes.

F Q As a description, mild and not necessarily causative of cerebral palsy, would you agree with that being a reasonable description?
A Yes, I think so.

MR FORDE: Thank you very much.

Cross-examined by MS O’ROURKE

G Q Dr Wildig, I ask questions on behalf of Dr Southall who is not here today but I think is known to you because you did work with him for a short period at the unit.
A Yes.

Q And I think that it was only a short period because he arrived and you left within about a month of him arriving.
A I think that I was there a little longer than that.
Q We will come back to that in a moment. I want to ask you about the form you were shown. In the bundle, it was page 396 of file 1 but I think that you were shown the original and you probably have the original there.
A Yes.

Q It is of the patient who we are going to consider whom you consented.
A Yes.

Q Her mother should have given evidence this morning but we were told this morning that she was not coming and she is going to come on Thursday instead.
A Yes.

Q The downside of that is that she would have given evidence before you about her recollection of the consenting process and we could have then asked you about it. What I am going to have to do instead, I am afraid, is read you what she said in a statement and see if you would agree with this or indeed suggest that her recollection is failing her. What this mother says is that it was a few days after her daughter was born – and her daughter was born on 17 November 1991, I think you have the form in front of you and you can confirm that the form is dated 17 November 1991 ...
A Yes.

Q What she says is that a few days after her daughter was born,

“I cannot remember the timing exactly, I recall that a nurse came to see me. I actually knew her from school. Her name was Katy Growcott. She recognised me. She suggested that my daughter should be moved from an incubator to a tank to help with her breathing. I did not think that my daughter was having any trouble at that stage but the medical staff must have felt that she needed a little help. I said to Katy, ‘If you think that it’s for the best, we will do it’. I cannot remember exactly what Katy said but it was something along the lines that it was a trial and they would use continuous oxygen and it would benefit my daughter. I do not recall whether it was explained to me how the CNEP tank worked. If this was explained, this was done in very basis terms. I have no recollection of anybody mentioning there would be any risks or disadvantages of using the equipment. I was not shown any other babies that had been put in the tank. I was not shown a tank before I agreed that my daughter could be put in one. I agreed that she could go in the tank. As far as I was concerned, the medical staff knew what I was doing”.

Therefore, what she is suggesting is that it happened three or four days after the birth, it happened under the auspices of a nurse called Kay Growcott and it happened in circumstances where she was not shown any information or given any information. Obviously, you do not remember the patient.
A No.
A

Q But you have signed that form.
A Yes.

Q You have signed it on the day of that little girl’s birth.
A Yes.

B

Q As far as you are concerned, would you have signed that form unless you had
explained to the mother that it was a trial?
A No.

Q That there was randomisation and what the purpose of the trial was?
A I would not have signed it unless I had explained that, no.

C

Q And you are confident about that?
A Yes.

Q So, if the mother does not remember you, does not remember that process and
says that it was a nurse several days later, what would you say was the situation?
A That does not sound correct because I would not have put that date on if it was not
that date.

D

Q There was of course a time element in this trial, was there not?
A Four hours, yes.

Q Just so that you know in case anyone is suggesting that this might be a mother
who was under an anaesthetic, the mother also says in her statement that it was a normal
delivery on gas and air.
A Right.

E

Q Would you expect her to be *compos mentis* after a normal delivery on gas and air?
A Yes.

Q I want to ask you one thing about Dr Southall. You say in your witness statement
that you do remember working with him when he came to the unit.
A I do.

F

Q “He had so much energy and was incredibly intelligent. It was my
impression that he always had the children’s best interests at heart”.

A That is correct.

MISS O’ROURKE: Thank you.

MR FOSTER: I have no questions.

Re-examined by MS SULLIVAN

H

Q I have a couple of matters, Dr Wildig. How much time did Dr Southall spend on

D16/42
the unit to your recollection?
A I could not say because I was not on the unit when he came; I was not working on
the neonate unit anymore, but he was around on the general paediatric wards. He was
around, he was approachable and you could contact him easily. He was a visible
presence in the paediatric department, but I was not working on the unit, only on call.

B Q In relation to consent forms, would you ever have signed a consent form when
someone else had given an explanation of the treatment?
A No.

MS SULLIVAN: Thank you.

Questioned by THE PANEL

C DR SHELDON: Good morning. I have not quite gathered, how many times did you give
consent? Can you remember a rough number for this particular trial?
A I cannot remember but it was very few.

Q It was a few?
A Yes.

D Q Was it a job that was always done by the doctors?
A The consent?

Q Yes.
A As far as I can remember, yes. When I was on the unit, yes.

E Q Lastly, was there any guidance as to whether the mother or the father were the
preferable person to sign the consent form? Did you always try and get the mother rather
than the father or did you use your judgement as to which was the better---
A I know what I would think now but I cannot remember what I would have thought
then.

DR SHELDON: Thank you.

F MRS BRICKLEY: Were you aware of whether nurses approached parents with regard to
the trial? By that I mean by a way of introducing the concept before handing it over to a
doctor to take consent?
A They might have done but I cannot clearly remember that. I think they might
have been in there first, I cannot clearly remember now, but they were very involved.

G MRS BRICKLEY: Thank you.

THE CHAIRMAN: Doctor, I appreciate of course that you are talking over a long period
of time – as, indeed, everybody who has been asking you questions does. I think that you
said in answer to Ms Sullivan that you recalled what you described by way of a
significant handout concerning the trial?
A Yes.
Q Then you were shown some specific documents by Mr Forde, some of which seemed familiar. Can you help at all as to how this material was presented? Was this material all in one file or was it material that was introduced as time went on and changed?
A I cannot remember. I just remember A4 with typing on, that is all I can remember really.

B Q Sorry, you just remember what?
A A sheet of A4, or maybe more, with typing on. That is all I can remember – it is just so hazy.

Q That was in relation to the consenting process?
A The information about the tank as well.

Q That, I think, was what you were describing when you were undertaking the consenting process?
A Yes.

Q Perhaps I did not make myself clear. I was more interested in hearing about the training material and how that was presented. Was it all in a single folder or did it come in---
A No, there were different pieces.

Q Which came at different times as the trial progressed?
A I can remember having different documents stapled together, papers, maybe that had been published. I can remember having different pieces of paper but I do not remember everything. I remember things coming in, extra bits coming in. I cannot remember having one pack and that was it.

Q Can you remember when you were first introduced to the trial presumably you were given something?
A I cannot remember what it was.

THE CHAIRMAN: Thank you very much indeed. Any matters arising out of Panel questions? (No response) Then, Dr Wildig, that is all the questions which we have for you and that completes your evidence. It just remains for me to thank you very much for coming today and for the assistance you have been able to give the Panel. Thank you very much.

THE WITNESS: Thank you.

(The witness withdrew)

MS SULLIVAN: Sir, those are all the witnesses we have today but hopefully we can all use the time usefully, looking at transcripts and so on.

MR FORDE: Would it assist the Panel – I do not know whether you all need to have a copy, but indicate if you do – if I had the documents that I put to the last witness that I do not think are in the bundle copied for you? It seems to comprise at least potentially some
training material.

THE LEGAL ASSESSOR: I did wonder about that, Mr Forde. At the moment they are unspecified documents, some of which---

MR FORDE: She remembered and some she did not. It is possible that---

THE LEGAL ASSESSOR: None of them, as I recall, were in the bundle that Mrs Cannings produced as to what she had been able to---

MR FORDE: That is correct.

THE LEGAL ASSESSOR: Is there agreement as to what the documents are or where they came from?

MR FORDE: I do not think we will ever know exactly. It was a very, very astute question on the part of the Chair as to whether things were introduced and came in over time and we are probably never going to know. Miss O’Rourke indicates that a Joe Raine, who is coming next week, may be able to help as the author of some and I might want to put some of them to Dr Brookfield, who was the senior paediatrician, and possibly to Dr Palmer who took the consent for Patient 7 and was later accused of forgery, as you know. It might just be worth you having them at least and if we can ever work out---

THE LEGAL ASSESSOR: As I understood it the GMC team has shown those documents to Dr Wildig when they were taking a statement from her. The prosecution must have obtained them from somewhere and I wonder if that could be put on the record at least.

MS SULLIVAN: I am not sure I am going to advance it much further because they have come from the bundles of material that were before the Preliminary Proceedings Committee but that does not necessarily indicate exactly where they have come from. My feeling at the moment is that if we are going to put in documents we ought to try and be clear who they have come from and also when they were introduced, because I think it is quite clear on both sides that documents changed over the course of time and that I would prefer if documents are going to go in the witnesses are able to say at least that they have a recollection of them, because this last witness obviously was not clear about what documents she could remember and what she could not. I think it might be preferable if they go in via a witness who has some more certainty about their provenance and date.

THE LEGAL ASSESSOR: What if the witness says, as this witness says, “I may have seen it, I don’t know. It looks familiar”.

MISS O’ROURKE: Sir, can I indicate, certainly looking at the list of prosecution witnesses, if we ever get to a defence case there are defence witnesses who can deal with it because Theresa Wright will be coming to give evidence and will be able to identify them and talk to their origin. Looking at the list of prosecution witnesses, I suspect the one who is best going to be able to deal with it is Dr Joe Raine because some of the
documentation, as I understand it, does actually originate in Queen Charlotte’s in Hammersmith and that is, of course, where he was involved in the trial. I suspect that he, if asked, will be able to identify them and say something about them, but I do not know of Ms Sullivan’s other witnesses that any of the doctors, possibly Dr Brookfield but I do not know – he does not mention them in his statement – I would certainly want them photocopied to be put to Dr Raine but that is some time next week.

MR FORDE: Can I just make the point very simply that I am happy for them to have a neutral status, for them to be provenance unknown; it was just that I thought you would make sense of the transcript of today if you could see what I was putting to the witness. Although I am encouraged by the suggestion that Theresa Wright may be a witness you know that we are, of course, all hoping that no defence witnesses darken the door of this hearing. That is another reason why I think you should have them now.

THE LEGAL ASSESSOR: So far as the documents are concerned, there seems to be no dispute – and Ms Sullivan may need instructions on this – that those are genuine documents which pertain to the CNEP trial at either Queen Charlotte’s or Stoke or possibly both but that is so far as any agreement would go at this stage.

MR FORDE: It is, sir, and because of---

THE LEGAL ASSESSOR: Evidentially, that of itself may be of some importance in showing that there are documents which cannot be explained.

MR FORDE: Yes, and you know, and I do not want to labour the point, that because of the difficulties that we perceive with the length of time and delay, we may never be able to produce a witness on either side who can remember either being the author of the document or seeing it in the past. We may only be in possibility territory with everybody. I just thought that if you had them you would be able to see which this witness thought she might have seen as against those which she said she had not a recollection of seeing. It is only for that purpose; I am not suggesting that their provenance is clear or that they were definitely with any training package given to junior doctors because we are not in a position to assert that and may never be.

MS SULLIVAN: Perhaps I could seek to clarify their provenance, certainly as far as how they came to be part of the PPC bundle. Sir, perhaps it is something that we might, again, usefully discuss between ourselves so that we can agree something about the documents and, if so, which ones it would be useful for you to see.

MISS O’ROURKE: Sir, can I indicate as far as I am concerned and my instructions, and indeed conversations my instructing solicitors had with potential defence witnesses, we do know who wrote them and who approved them. The difficulty is quite as to the timing, because of course the trial went on over a period of almost four years and so the witnesses cannot remember exactly when each page was added or whatever but we are, as far as we are concerned, able to identify pretty much the authors.

THE CHAIRMAN: I think the suggestion that has been made by all of you in your various ways – from the Panel’s point of view we do recognise the problems which arise with documentation because of the lapse of time and because of the difficulty of
identifying provenance and timing of the documents. As and when we come to consider the totality of the evidence at whatever the appropriate stage may be, I think, speaking for myself certainly – and no doubt for other members of the Panel – that given the allegations particularly in, for example 11, so far as Dr Spencer is concerned, it will be repeated for the other doctors, that we will be assisted, I am sure, by material which is relevant to the question of training and what the staff at Stoke were in a position to explain to the parents. Depending on the way it is presented to us, we will be able to assign appropriate weight to the material, but I certainly do think that if there is documentation available which is accepted to have come into existence, if you like, within the course of the trial, then it is likely to be helpful to us, but we will attach weight to it according to the extent to which it can be identified and timed.

I think, Mr Forde, in view of your initial suggestion, I think the concept of your suggestion is a good one but it probably is worth seeing how it can best be presented to us.

MR FORDE: I am content with that. We can discuss it out of the hearing.

THE CHAIRMAN: If there is nothing else then we will adjourn now and meet again at 9.30 tomorrow morning.

(The Panel adjourned until 9.30 a.m. on Wednesday, 4 June 2008)
GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council’s Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988)

On:
Wednesday, 4 June 2008

Held at:
St James’s Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

STEPHEN ANDREW SPENCER BM BS 1976 University of Nottingham
Registration No: 2305893

DAVID PATRICK SOUTBALL MRCS 1971 Royal College of Surgeons of England
Registration No: 1491739

MARTIN PHILIP SAMUELS MB BS 1981 University of London
Registration No: 2732178
(Day Seventeen)

Panel Members:
Mr D Kyle (Chairman)
Mrs V Brickley
Mrs S Hollingworth
Dr T Okitikpi
Dr M Sheldon
Mr A Forrest (Legal Assessor)

MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hampsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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THE CHAIRMAN: Good morning, everybody. We continue with the case of Dr Spencer, Dr Southall and Dr Samuels. Ms Sullivan.

MS SULLIVAN: Dr Newell is the first witness, sir.

CLARE ELIZABETH NEWELL, affirmed
Examined by MS SULLIVAN

Q Good morning, Dr Newell. Would you start with your full names for us, please?
A Dr Clare Elizabeth Newell.

Q Was your previous name Stanley?
A It was.

Q Clare Stanley?
A Yes.

Q Dr Newell, could you just tell us what your qualifications are, please?
A Bachelor of Medical Science, Bachelor of Medicine, Bachelor of Surgery and a member of the Royal College of General Practitioners.

Q Do I take it from that that you are now a general practitioner?
A I am.

Q I want you to think back, as you know, to the time when you were working at North Staffordshire Hospital. In what capacity did you work at North Staffordshire Hospital?
A I was an SHO in paediatrics.

Q What period were you there as a senior house officer in paediatrics?
A It would have been I think from August 1991 to January 1994.

Q Your first six months as a senior house officer, where were they spent?
A They were on the general paediatric wards.

Q After that six months, did you go on to the neonatal unit?
A I did.

Q How long were you on the neonatal unit?
A At that time for six months.

Q So from I think February. Is that right?
A That is right, February ---

Q February 1992 until July of 1992?
A July.

Q So six months then. Thereafter, did you return to general paediatrics?
A Yes, for a further six months on the paediatric wards.
Q. That takes us to about January/February 1993. From February 1993 until January 1994, what were you doing then?
A. I was a paediatric community SHO.

Q. Apart from your six months on the neonatal unit from February 1992 until July 1992, would you have spent any other time covering the neonatal unit?
A. Yes, from my second stint in general paediatrics and throughout my community paediatrics I covered the neonatal unit when on-call out-of-hours.

Q. Yes, so I think that takes us from about August 1992 until January 1994 you would have covered it when on-call?
A. That is right.

Q. Therefore my next question is how often you would have been on-call in that period?
A. The on-call would alternate between covering the paediatric wards and the neonatal wards, so I am guessing it would have been approximately once a week covering the neonatal wards.

Q. You know that we want to ask you about a trial that was being conducted all those years ago in North Staffordshire, the CNEP trial. When were you first asked to recall what had happened in this trial?
A. I was approached by some solicitors - and I am afraid I do not know who they were representing - it must be more than nine years ago to give a statement.

Q. That was the first time when you were asked to recall it?
A. Mmm.

Q. How much can you now remember of your involvement in it?
A. I am afraid very little. It was only a small percentage of my actual workload and, of course, it is 15/16 years ago since I was involved. I am afraid I do not remember very much about the details.

Q. No. I wonder if you could just help us a little about what the aim of the trial was of?
A. The aim of the trial, as I remember it, was to compare two types of ventilation systems: the standard positive pressure ventilation and the new CNEP trial, which worked on the principle of the old iron lung by providing negative pressure. The aim was to see whether that was more effective than the standard treatment at reducing neonatal complications.

Q. Were you aware at the time that there were two sites involved in the trial?
A. Yes.

Q. Not just North Staffordshire but one in London as well?
A. Yes.

Q. Do you remember at what stage it was it was considered whether a baby would fit
the criteria for inclusion in the trial?
A I am sure it was four hours.

Q At what point would consent be sought from parents to enter the babies in the trial?
A If at four hours they fulfilled the criteria, I would approach the parents for consent then.

Q When you approached parents for consent, what would you tell them about the trial?
A As I said, it is difficult to remember, looking back, exactly what I said. All I can give you is really what I think I said after this time. The first thing I would tell them is that it is a trial that is taking place to compare two different types of ventilation systems, that if they decided to take part it was completely voluntary, there was no pressure or obligation to take part, and if they decided they did not want to take part then the baby would have the conventional treatment which was standard throughout the UK. If at any time they wanted to withdraw the child from the trial that was quite acceptable and, again, it would not influence the care they received in any way. I would have told them a little bit about how the treatment worked and what they could expect to see, and that at the moment we did not know which was the best form of treatment which was why the trial was going ahead, to find out whether this new treatment had any advantages or was a better treatment than the old one, but at this stage we did not know.

Q Is that your actual recollection of what you would have said?
A It is very hard to remember. I think in essence it is. What I would have said is that it is a trial, “We do not know what is best and that your participation is voluntary”. Quite how much extra information I gave, I am afraid I find it hard to remember.

Q At that stage, Dr Newell, for how long had you been a senior house officer?
A By the time I started taking consents I would have been a senior house officer for a year.

Q Prior to taking consents for the CNEP trial, had you ever sought consents for a trial as opposed to other surgical procedures?
A No.

Q Can you recall whether you were given any specific training on the issue of obtaining consent for a trial?
A I do not recall any but that is not to say I did not, I am sorry.

Q When you sought consent from parents, apart from explaining to them yourself what was involved in the trial, was any written information available for parents or not?
A I was asked this when I gave my statement and the honest answer is I cannot remember. I do remember there being some pictures that we could show parents, but I was asked if I remembered a patient information leaflet and I am afraid I could not say one way or the other.

Q Yes, we will come and look at some documents in due course. In terms of the photographs, what sort of photographs would they be?
A  They were colour photographs showing what the CNEP tank looked like and then pictures of the babies in the tanks with and without a head box.

Q  Once you obtained consent, what was the next stage in the procedure?
A  The next stage was to ring the consultant who was on-call for the CNEP trial, and I would tell them that I had had consent for a baby who fulfilled the criteria and then I would wait to hear from them what treatment the baby was randomised to.

Q  Would you be asked any questions by either of the doctors whom you phoned?
A  I remember sort of giving them clinical details of the baby, but I cannot remember whether they asked me any questions.

Q  Can you remember who it was you phoned?
A  It was usually Professor Southall or Dr Samuels.

C  I am going to ask you about some particular consent forms, Dr Newell. I will ask that you have the original first for Patient 6. We can find our copy at tab 3, page 390. (Same handed) Perhaps just before we do that, perhaps you could also have open that file to the left-hand side of you, Dr Newell, behind tab 3. If you just look at pages 370 onwards this is the log for the CNEP trial. Does this ring any bells with you?
A  This log here?

Q  Yes.
A  No, I do not think I have seen that before.

Q  If you just glance through it from page 370 and look down the column which is the fourth from the left-hand side which says “Name of caller”, do you see?
A  Yes, I do.

Q  I think on the first page we do not see any “Clare”. I do not think we would expect to at that point from what you have told us. If you just go through those pages and indicate to us when you think your name first appears.
A  There is one on 11 November, “CS”, which are my initials.

Q  Yes, is that the first one you come across there?
A  Yes, 11 November ‘92.

Q  I think if we go down to 27 November 1992 ...
A  Yes.

Q  ... we see another one there ...
A  Yes.

Q  ... which we know is a consent for Patient 42. If we go down to the bottom of the page, we see there again I think your name, 14 December 1992, and we see that that, we know, relates to Patient 6. Going over the page, going on, do we see any reference to you on the next page?
A  No, I cannot find that. There is one on the page afterwards on 12 May ‘93.
Q Yes, I see that. If we go over again, do you feature at all from what you can see on the following page?
A There is a “Clare” on 6 August ‘93.

Q Yes, and I think you do not feature on the last page there. From that log those would appear to be the occasions when you had taken consent in relation to the CNEP trial, so that might help you a little as to how often you were involved in it.
A Okay.

Q I was about to ask you about this particular consent form that you have the original of and we have at page 390, which is the consent form for Patient 6. If you could refer to her in that way as well, that would be very helpful. At this stage, 14 December of 1992, from what you have told us earlier would that have been a time when you were on-call …
A Yes.

Q … on the neonatal unit? So not working there …
A No, that would have been on-call.

Q … throughout because you had only been there for the six months from February to July of 1992?
A That is right.

Q On looking at that form, can you just help as to which is your writing, please?
A The first three entries at the top, “CNEP”, “Stanley” and “[Patient 6]” and then right at the bottom where I printed my name and the signature and the date.

Q The signature above that, is that yours in any way?
A No.

Q Or the name that is written next to it …
A No.

Q … of Deborah Millicent Davies. Do you in fact remember the mother of this baby at all?
A No, I am sorry, I do not.

Q Nor indeed the baby herself?
A No.

Q I wonder if you could just cast your mind back to what you looked like all those years ago, Dr Newell, and help us as to this: were you wearing glasses at that time?
A No.

Q What sort of age would you have been?
A 25.

Q I think we have heard reference to you being summery and tanned.
A No, I doubt that very much.
Q Also, a reference to I think long eyelashes.
A Sadly not.

Q We know that Mrs Henshall, as she now is, had had another baby in the CNEP trial. Would you have been aware of that or might you have been aware of that at that time?
A I am not sure. I might have been if we had old notes, for example, but I am not sure.

Q If you had known, how would you have approached the obtaining of consent? Would it have been any different?
A I would have asked what they knew about the CNEP trial and basically worked on from there. How much information I gave or what I gave would depend on what they knew already or understood about it already.

Q What do you believe you would have told her about the trial?
A I think basically, as I said before, that it was a trial to try out a new type of ventilating system; that it was part of a trial taking place in two hospitals; that although the equipment itself had been tried and tested, this was a trial to find out whether it gave any advantages or whether it was a better treatment than the conventional treatment.

I explained with the pictures what it looked like and a little bit about how it worked and that the study was to find out whether it reduced some of the complications that conventional treatment had but that we did not know that at the moment and that is why we were doing a trial; and that there was no pressure to take part at all, they could choose whether they wanted to take part or not. If they decided to take part and later changed their mind, that was fine also, they could withdraw their child. If they decided not to take part in the trial, they would receive the standard therapy which was conventional treatment that was being used throughout the country.

Q Did I hear you correctly in terms of how you would describe the CNEP treatment as opposed to the positive ventilation? How would you describe it?
A I am afraid that my memory is not very good but, from what I remember, I would say that it is a box that the baby is in and basically what it does is lower the pressure which helps the baby’s lungs to function and the hope of doing that is that you can actually reduce the pressure of the air you are blowing into the baby’s lungs with a tube and perhaps reduce the amount of extra oxygen the baby needs as well.

Q I will be corrected if I am wrong but did you say that it was a gentler treatment?
A You cannot say that it is a gentler treatment. I do not know if I said that at the time. All I can say is that the aim was that it was hoping that by reducing the pressure you might cause less lung damage but that we did not know that at the time and that was part of the trial, and that was the sort of theory behind why the trial was going ahead.

Q In terms of advantages and disadvantages, would you indicate those to parents or what would you have done at that time?
A Yes. The theoretical advantage, as I said, is reducing pressure. I do not know or I do not think that I knew at the time of any disadvantages of the trial.
Q Just help us as to how it would have come about that this consent form would have been signed.
A After I had gone through it, I would obviously ask the parents whether they had any questions or anything that they wanted to ask or whether they wanted some time to think about it and, if they were happy and agreed that they wanted to take part, I would ask them to print their name and sign next to it after I had completed the first top half of it and, once they had signed and completed it, I would sign mine as well to witness that they had signed it.

Q Would the form ever be signed at any later stage?
A No.

Q Either by you or by the parent?
A No, it would all have been done then.

Q You referred to the parents in the plural; would you have approached both parents or what would have been the position?
A Ideally you would approach both parents but I think that the consent for the trial only needed one parent to sign the form.

Q As you have recalled, Dr Newell, the randomisation process needed to take place by the time the baby was four hours old or certainly the baby needed to be within the criteria at that stage. As far as approaching mothers was concerned, that is not long, as we know, after the birth of a baby.
A No.

Q So, how would you approach that?
A You are quite right, it is a difficult time. Often, if the partner was there it was easier and I would ask if it was okay for me to talk about it and, if they were particularly distressed or unwell, I would ask if I could come back later or I would leave them and I would not proceed any further with it.

Q For example, some women may have had a general anaesthetic.
A Sure.

Q So, what would your approach be to them?
A It would be the same. I would ask them if it was okay and whether they were feeling well enough to talk to me about it and, if they said, “no”, then I would not proceed with it. If they said, “yes”, that it was okay and they were feeling okay, then I would carry on as I have said.

Q Would the same apply if, for example, a mother had had a spinal but may have had some morphine afterwards to help relieve pain?
A You take it on each individual case, really.

Q I want to ask you, please, about another consent form and that baby is Patient 42 and I ask that you have the original and perhaps we could go to page 404. (Same handed) Do you have the original of that?
A  I do.

Q  Would you mind confirming for us, is there anything on the back of either of those forms, either for Patient 6 or Patient 42?
A  On the back, no.

B  We know that this baby was born on 27 November 1992, so a little while before Patient 6, a matter of a few weeks. Again, we seem to see your name at the bottom there. Can you confirm on this form what it is that is in your writing and what is not.
A  The bit that says, “CNEP Stanley” at the top and then the patient’s name, Patient 42, and then right at the bottom where it has “C. Stanley”, my signature and the date. Where it says “relationship” and it has “mother” underneath, that is possibly my writing and may be the date but I am not sure about that, only because it looks similar.

C  What about the name of the patient above it?
A  No, the name of the patient and the signature is not my writing.

Q  We see that both of those forms refer to information set out overleaf. Apart from the photographs which you mentioned to us earlier, have you any recollection of any other information?
A  I am sorry, I really could not say “yes” or “no” to that question.

Q  I think that when you made your statement, you were shown – and perhaps you could just have a look, please – tab 3, page 336. Did that ring any bells with you when you were shown it?
A  It sort of did but I have a feeling that I was also shown similar information when I gave my statement nine or ten years ago. So, although it did look sort of familiar, I could not honestly tell you whether I remember it from the trial.

Q  Likewise, if you would turn on, for the sake of completeness, pages 341 to 364, which is a much more detailed leaflet; does that ring any bells with you or not?
A  No. I was asked that by the solicitor. The wording seems very familiar, the type of things we would say, and the pictures looked almost identical to the pictures that I remember in the neonatal unit.

Q  In terms of the pictures, you have obviously indicated that you had some to show to parents at the consenting process stage. Do you remember there being any pictures on any of the tanks within the neonatal unit and the incubators?
A  I am sorry, I cannot remember that.

Q  I think in fact you were shown a picture with a teddy bear logo on it and did that ring any bells with you?
A  It sort of did. I think that I probably remember it but again I could not say for certain.

Q  You would have been aware, I think, of the protocol at the time; that is what you have told us.
A  The protocol for what?
A

Q I am sorry, the criteria for whether the baby would or would not be in the trial.
A Yes.

Q How would you assess that yourself? Would it be you who assessed whether the baby fulfilled the criteria?
A Yes.

B

Q How would you do that?
A I cannot remember the criteria now but you would look at the readings of how much oxygen the baby needed, whether the baby was ventilated and what pressure it was ventilated to.

C

Q You say that you do not remember any problems/disadvantages with the CNEP treatment.
A No.

Q Were you aware of any problems with the neck at all?
A No, I was not at all.

D

Q Can you help as to how the babies were dressed in the tank and such like?
A I am afraid that I cannot.

Q Those would be matters that doctors would be concerned with?
A No; the nurses were involved in setting up the babies in the tank.

E

Q I also want to ask you, please, about Patient 6 and your entries in the notes which I think again you have looked at before, Dr Newell. Would you put that file to one side and I ask that you be handed file 2. (Same handed) Behind tab 5, if we go to page 22, can you confirm that that is your signature at the bottom of page 22.
A Yes, it is.

Q Read to us what you have written there, Dr Newell.
A I have put:

“Reviewed at 4 hrs –
40% [oxygen in a] head box [with] 94% [saturation].
Ph 7.26  PCO2 6.7  PO2 6.3  be” I am not sure what that says “.8
Consent for CNEP obtained” with a tick
“Randomized to CNEP”

and my signature at the bottom”.

Q If we look back to the previous page, the baby here – and I think that the same applies in relation to the CNEP log that we looked at – is referred to as a girl, a female infant, but without a first name at this stage. Can you help as to that at all?
A That would either be because I asked the parents or whether it was in the nursing notes that they had a name.
Q Apart from that entry at page 22, can we see when you were next making an entry in the notes in relation to this baby. I think that it is page 26 but just go through the pages in between to make sure that that is correct.
A Yes, it is page 26.

Q Where is your note here?
A It is down the bottom.

Q So, it is the entry which says, “19/12 Day 5”?
A That is right.

Q What is the position as far as this baby is concerned at this stage just in general terms?
A It says that it is still in the CNEP but is “out for long cuddles” and with 24% head box oxygen. It is feeding 150mls per kilogram via a nasogastric tube and “starting TPN today”, not on any medication and examination was all normal. The plan was to “try out of CNEP today” and just in head box but, if the plan was of increasing oxygen requirements, to go back into the CNEP and to continue increasing oral feeds.

Q Yes and we see your plan there at page 27. Your next entry, I think, is the one that says, “20/12 Day 6” still on page 27.
A Yes.

Q How is the baby generally at this stage?
A The baby is in air and feeding via a nasogastric tube and with TPN. All the observations were stable. Not on any medications. The plan was to continue and to take the umbilical arterial catheter out.

Q That was the plan at that stage and then your next entry after that, Dr Newell, if we just go on is I think at page 30 but again look at the pages in between if you would not mind.
A Yes, on page 30, day 18.

Q How is the baby at this stage?
A It says:

“Very well
Breast feeding well
[nasogastric] top-ups overnight
On [twice a day] theophylline”

and not having any apnoeas or bradycardia.

“Plan to [once a day] theophylline
Aim home next week”.

Q On the occasions when you were on call in the neonatal unit, do you remember seeing or having any contact with the three doctors here? So, Dr Spencer first of all; did
you have much contact with him?
A Yes; the consultants were always available if you had any problems and, at weekends, they would come in routinely to do ward rounds.

Q What about Dr Southall?
A The same applies.

Q And Dr Samuels?
A Yes.

Q We know that they were not there initially in Stoke but do you remember them arriving?
A Yes. I think that by the time I was working on call, yes, they were there.

Q In term of who was supervising you, obviously Dr Spencer was one of the consultants, but who was directly supervising you at that time when you were on call?
A It would be a consultant at home.

Q Who would have been directly above you, so to speak, at registrar level?
A I was acting registrar; I was a senior house officer, so the next step above me would have been a consultant at home when I was on call.

Q I see. So, other doctors such as Dr Arumugam?
A When I did my first stint there as an SHO when I was working there full time, Dr Arumugam was the consultant who oversaw all the SHOs.

Q And there were obviously a number of other staff with whom you worked at that time and you also remember the nursing staff who were involved with the CNEP trial. Do you remember who they were?
A I can remember that there were two specialist nurses: Kate Lockyear and I cannot remember the other lady’s name off the top of my head.

MS SULLIVAN: There is no dispute that that was Theresa Wright. If you wait there, there will be some more questions for you.

Cross-examined by MR FORDE

Q Good morning, Dr Newell. I ask questions on behalf of Dr Spencer and I have a number of questions to ask you, I am afraid. The first thing that I would like you to be shown – and I have copies for my learned friend – is a witness statement that you made on 18 June 1997. (Same handed to Ms Sullivan and to the witness) I do not know whether Ms Sullivan is happy for these to go to the Panel just yet, so perhaps we ought to go through it first. I will have to go through some formal processes. Would you go to the end of the statement, please, and is that your signature?
A It is.

Q I think I mentioned June but it is clear on the final page that it is dated 18 August 1997.
A That is right.
Above your signature, does it read:

“This my statement consisting of four pages is true to the best of my knowledge and belief”?

That is right.

May we go back to the first page and can I ask you a question which seems to have an obvious answer. Do you think that your recollection in 1997 was better than it is now?

Yes, almost certainly.

Were you shown this witness statement when you were asked to provide a witness statement to the General Medical Council?

No, I have not seen this since I made it in 1997.

Again for the record, your GMC witness statement is dated 25 September 2007. So, this was not shown to you?

No.

If you look at the heading, it is in the proposed matter between Patient 6 and the health authority and this was a witness statement that you provided to the Trust’s solicitors when litigation was being threatened. Does that ring any bells with you?

Yes, I think so.

You set out uncontroversially your dates and, by this time, August 1997, you were a general practitioner principal in Staffordshire, so you had left hospital medicine.

That is right.

You say in the third paragraph that you were aware of allegations being made by Mr and Mrs Henshall in relation to the treatment afforded to Patient 6, you had read the notes and you could not recollect even at this earlier stage the particular patient but you looked at the notes and you recollected some procedures and protocols. If we go over the page, you were taken to your entry in the records which Ms Sullivan has just taken you to and you say this:

“I note the first entry I made in Patient 6’s records was when Patient 6 was four hours old. I reviewed Patient 6 and wrote in my handwriting that Patient 6 was stable and requiring 40% oxygen via a headbox which at this time was standard treatment.”

Then you say you reviewed a chest X-ray which showed moderate respiratory distress syndrome common in premature babies. You go on to say:

“At four hours Patient 6 fulfilled the criteria for CNEP study”

and then I wanted to ask you about this:
“I do have a recall my standard practice was to approach the parents preferably together if at all possible…”

MS SULLIVAN: Can I ask you to read the first bit?

MR FORDE: I have made it clear she does not recollect the patient. All right:

“Although I do not recollect what I did in this case”

- and I think that has consistently been your view and it is something you told my learned friend when she was asking questions –

“I do have a recall that my standard practice was to approach the parents preferably together if at all possible. I would then in general terms have explained how the baby was, i.e. Patient 6 was in a stable condition but required extra oxygen for breathing. A photograph of their baby would then have been given to the parents if they had not already received one”

and we, I am sure, can all recollect there is a nursing entry about a photograph being given.

“The parents would generally either have been the recovery room or in the maternity ward or on the neonatal unit during this discussion.”

Then you go on to say:

“I would then have gone on to explain that the hospital was involved in a study looking at the best way to provide ventilation for premature babies such as Patient 6 who required extra support to help them breathe. I would then have stated that the study was called the CNEP study and explained what CNEP stands for and how it operates. I would have shown them a picture of what the equipment looked like and also a picture of the baby inside the equipment. I would have explained that at the time Patient 6 was still having standard treatment which she would get in any other hospital.”

That is you doing your best five years after the events in question to recollect your usual practice. Do you have any reason to think now that you departed on this occasion from your usual practice?

A I cannot think of why I would have done so, no.

Q Thank you. You then go on to say this:

“The next stage would have been to explain the aim of the study was to see if the CNEP equipment had any benefits over the conventional treatment. I would then have explained that CNEP had been used in trials in our hospital since 1989 and had been trialled in a London hospital. I would have indicated that at the time there was no way of
knowing whether CNEP had advantages or disadvantages over the conventional treatment. At the end of the trial we would be able to compare the outcome of babies in CNEP to the outcome of babies that were treated conventionally."

Again, any reason to think you would have departed from your usual practice on this occasion?

A No.

Q “Hopefully this would then give us the answer as to which was the preferred treatment.”

Then the next paragraph reads:

“I would then explain that if they agreed to their baby being involved in the study, then Patient 6 would be randomly allocated to either CNEP or to carry on with the conventional treatment.”

Again, any reason to think you would have departed from your usual practice?

A No.

Q “I would have expressed to the parents that they were not under any pressure to take part and if they did not wish to be involved in the CNEP trial, this would not affect the care which Patient 6 would receive from the hospital. I would have explained that if they agreed to the trial but were later unhappy at any stage, they would be able to pull out and Patient 6 would go back to having conventional treatment and this would not jeopardise the baby’s care in any way.”

Then paragraph 9:

“I would then have advised the parents that if they had any questions or if they wished to have more time to think about this, then they were clearly allowed to do so. If they wished to have time by themselves then I would have left them to think about the information given and returned later for their decision.”

In your evidence this morning you have struggled to recall whether your standard consenting process has in some way been tainted or influenced by either after-acquired knowledge or how you would do things today. Is it fair to suggest to you that in 1997 you would have been closer, having reasonably recently left hospital practice, to having a better recall of your standard consenting process?

A Yes. It is still five years after the event but it would have been I am sure better memory than I have now.

Q Yes, better than 16 years?

A Yes.
Q It seemed to be being suggested there was some magic in the fact that this was a trial. Can I make this suggestion to you, that because it was a trial and because more information had to be given in relation to the fact that it was a trial, that it was voluntary, in basic terms what it was hoped the study might demonstrate, the comparison with positive ventilation and standard treatment, that you would be more likely to have adhered to this mantra-like script then if you were consenting for removal of an ingrowing toenail, for instance?

A Obviously, it is a big study and there are a lot more implications so yes, it is an important part of the trial, the consent, so yes.

Q Then you say this:

“If the parents had agreed I would have read the consent form through with them and then asked them to sign it if they were happy. I would have witnessed their signature in front of them. This I did on 14 December 1992”

- and you have described her as “Mrs” but I will read it for accuracy –

“after Mrs Davies had signed the form.”

Q Are you quite satisfied in your own mind that Mrs Henshall, as she now is, signed the consent form that you have been taken to in front of you?

A Yes.

Q Any doubt about that at all?

A No.

Q “I had been involved with the trial and in consenting patients for 18 months before this particular case and therefore had a lot of exposure to the trial and to the registrars who were involved in it.”

A I am not sure whether that is accurate, although I had been involved as a junior SHO working on the neonatal unit for six months and then prior to that I would have had about another four months of being involved in the neonatal unit on call and taking consents, so that bit is not accurate.

Q All right, so it is ten months rather than 18. Is that the correction you wish to make?

A Yes.

Q Can I just ask you more generally about consenting? Quite often after proper training the responsibility of the more junior staff, is that fair?

A I am sorry?

Q Is it quite often in a hospital setting after proper training and observation the responsibility of the junior medical staff to take consents, in general terms?
A Yes, I think so

Q All I am really asking you is this, had you, regardless of whether you had been involved in trials or not, been trained in the taking of consent and taken consent on many occasions as a junior doctor?
A This was the first trial I had been involved with.

B Q Forget the trial. I am asking you in general terms about medical education. Would you agree with me that the taking of consent is something in which junior doctors are initially rigorously trained and then tend to take on that responsibility?
A Certainly taking consent was a responsibility of junior doctors right from being a newly qualified JHO taking consent for surgical procedures. If you are saying “rigorous training” for taking consent, I would have problems recalling having rigorous training for taking consent.

C Q But what happens in the hospital setting, is it not, is that when you first enter it you see the more senior staff taking consent?
A Yes, definitely, absolutely.

Q So you learn on the job?
A Yes, I agree with that

D Q I am not suggesting that you get a telephone directory hand out?
A Sure. No, absolutely.

Q When you initially do it the senior staff watch you do it and will comment if you have missed out vital information?
A Yes, I certainly remember on here as a junior SHO sitting in with a registrar during the day taking a consent for the trial.

E Q Were you quite confident in your competence in terms of the taking of consents?
A Yes, I do not remember having any worries about taking consent.

F Q If you had had concerns, was the atmosphere within that hospital one where you could have gone to more senior staff and asked for their advice and assistance?
A Yes. The whole atmosphere really was one of education and support, because the neonatal unit is so different from anything I had encountered before. Certainly starting as a junior SHO you do not even know how to do the basic things like taking blood so yes, there is a lot of support and a lot of training, so I would not have had any qualms about asking for help.

G Q Also when you come into this environment as an SHO, is it right to say that you tend to find yourself operating with highly trained and experienced nursing staff?
A Oh yes, definitely.

Q In many ways they take the lead, do they not, with the junior doctors?
A Oh yes, they tell us what to do, yes.

H Q They are experienced in taking observations, they know their notes have to be
A accurate and complete, they would recognise concern in bradycardias, apnoeas or even the onset of hypoxia? Is that fair?
A Definitely.

Q That is the every day stuff of life for a neonatal nurse. Is that fair?
A Yes, I would say the nurses were---

B Q What you have said in your statement that you gave to the General Medical Council about CNEP was this:

“I do not remember specific training.”

- this is paragraph 36, for everybody else’s benefit –

C “All I can say is that there would have been a lot of training as it was all brand new and I had never worked with neonates before. There was lots of supervision as well. Dr Arumugam”

- who I think you erroneously described as a consultant?
A No.

D Q “…was my registrar at the time from February 2002 until July 2002. If I was doing things for the first time I was always supervised. I remember that they had baby models which you could practise intubations on. I cannot remember training specific to the CNEP trial.”

E Do you stand by that part of your statement?
A Yes.

Q Do you remember the involvement of Teresa Wright within the trial?
A I can remember she was one of the nurse specialists involved in the CNEP trial and being involved in hands-on care and helping the nurses set up the babies.

F Q Did she strike you as a well-informed and highly competent individual in this area?
A Yes.

Q Can I ask you a little about the information that may or may not have been available to parents? You cannot remember the Patient Information Sheet, you have told us?
A No.

G Q You seemed to find the booklet that you were taken to – I think it is at page 340 in our bundle, if you need to look at it again – a little more familiar? It is our bundle 1 behind tab 3. 336 I think you were unsure about but the booklet you appeared to find a little more familiar?
A Certainly the pictures seem familiar and it is very much the same material, there
were no surprised on reading it, put it that way.

Q When you look at the narrative, does that include some of the things at least that you may well have been saying to parents?
A Yes.

Q If you look, for instance, at 344, Refusal of Consent, is that how you might have phrased the fact that it was voluntary?
A Yes.

Q You make it clear certainly in your second statement that you would only have sought the advice as to randomisation following the obtaining of consent, not before?
A Definitely.

Q Can I just ask you to look at the Patient Information Sheet for a moment, which is our 336, and although you do not recall the document, can you just scan it and tell the Panel whether or not it as well contains the sort of information that you think you would have communicated to parents? (Pause)
A Yes, it does.

Q As far as the clinical notes are concerned, we have got an entry which you have been taken to where it says I think, “Consent for trial” and a tick in the clinical notes, you have identified your writing. Can you confirm that you would not have written that note unless you had obtained consent?
A No, I would have written that after obtaining consent.

Q Thank you. Can I just ask you to consider a couple of matters which the Panel have heard in evidence? The first is about Mrs Henshall’s conscious state. She made the suggestion – and for the benefit of the Panel this is Day 9 and in chief it is Day 9 page 17; in cross-examination, I think it is, by Miss O’Rourke, it is Day 9 page 77. Two themes ran throughout her evidence in relation to the consenting for Patient 6. One was that she was, it would appear, either drifting in and out of consciousness or unable necessarily to give informed consent because of her conscious state, would you have first of all recognised, do you think, from a clinical perspective a mother who was unable to absorb that which you were communicating to her?
A Yes.

Q Would you ever have sought to consent a patient who was obviously unable to understand what you were saying to her because of her conscious level?
A No.

Q You have been asked about the recollection of your dress and appearance and you have said that you do not recognise that as a description of yourself, I think is the shorthand. In cross-examination – I am now on Day 9 page 77 – many questions were asked about the signing of the form in relation to patient 6 and in essence it came to this; Mrs Henshall accepted that the signature looked like hers but she did not know how her signature came to be on the form and she was to say – this is Day 9 page 78 letter B – effectively the child was not named at four hours, “I was not asked to sign a form for CNEP. I have no recollection of signing a
form for the Caesarean section.

Later she was to say that she was denying – this is Day 9 page 891 at letter E – that she gave informed consent and I think you are aware that there has certainly been the hint, if not the obvious suggestion, that her signature is a forgery. Are you aware of that?

A I was not aware of that, no.

Q Can I ask you this – would you be party to any conspiracy to place a forged signature of a mother in these circumstances on a consent form?

A Definitely not.

MR FORDE: Thank you very much, doctor.

Cross-examined by MISS O’ROURKE

Q Dr Newell, I ask questions on behalf of Dr Southall. I have only got a few for you. Firstly, and it may seem a strange question but it is because I think, as you know, Mrs Henshall has given a description of the doctor that she says came to talk to her. You think at the time you made your statement had that description put to you. I think the thing that struck me most when you walked into the room was your height. Can you tell us what height you are?

A Five foot ten.

Q Which would be well above average height for a woman and presumably you are used to people saying, “Gosh, you are tall” or something like that. Is that fair?

A Yes, that is fair.

Q It is just that Mrs Henshall I think is less than five foot, so to her you would have seemed very tall. Yes?

A Yes.

Q So it would be something you would have expected her to comment up on in her description rather than saying that you had long eyelashes, yes?

A Seems reasonable.

Q You said in respect of the taking of consents – and I think Ms Sullivan took you through the log and it looked like there were six in total that you had taken there, yes?

A Yes.

Q I think the first one was something in the autumn of 199, it was October or November, I think the beginning of November 1992, yes?

A Yes?

Q You can check the log if you want to. By that stage you would have been 15 months into your SHO post in paediatrics?

A That is right.

Q I think you said in answer to a question from Mr Forde that you remember sitting in with the registrar during the day taking the consent. Do I take from that that during the
A day when there would be a full complement of staff on, consents for this trial would have been taken by someone at registrar level?
A They would, yes.

Q You were only doing them on-call?
A That is right.

B Q The six that we heard coincided with the period when you started doing night on-call?
A That is right.

Q I think, if I understood you correctly, you said you were in fact the acting registrar when you were on-call?
A Yes, I suppose ---

C Q So when you were taking those consents, you were in fact doing it in the role of acting registrar?
A Yes.

Q It was recognised within the trial that someone with a bit more experience, acting registrar other than brand new SHO, should be taking consent?
A Yes, second year SHO.

D Q In respect of taking the consent for Patient 6, we have looked at the consent form and you have identified the handwriting on it. I think you have the original there?
A (No audible reply)

E Q What I am concerned about is the name, the writing at the top, Patient 6’s name, but in particular her actual given name. That is your writing, is it not?
A It is.

Q You are sure about that? Do you want to look again at the original?
A No, I am positive that is my - oh, well ---

F Q It is just in case there is a suggestion that somebody added that in later?
A No, I am pretty confident that is my name - that is my writing, sorry.

Q That is your writing where it begins with the letter S?
A (No audible reply)

G Q Yes. You were taken to your note and your note indicates consent taken and then the tick. That appears to take place at four hours?
A Yes.

Q This child was actually born at five-to seven, or something like that. That would suggest that your review and your note and the consent taken is some time around about 11pm?
A Yes.
Q So at 11pm you had a name to write down?
A Yes.

Q The reason I ask you that, it might seem strange, is Mrs Henshall was suggesting that child was not named until the next day.
A I could only have got the name from two sources: either it is by asking one or other of the parents or it would have been in either the nursing notes that the child had a name.

Q Would you have gone back and written the name the next day?
A No, no.

Q Just a couple of other questions about things in your statement. You mentioned in your statement the various things that you would have raised, because obviously you cannot remember exactly what. Is it correct that you have raised, as part of your introduction to the trial, the question of randomisation? In other words, the moment you spoke to the parents you could not tell them whether they were going to be CNEP or standard?
A Absolutely, yes.

Q Are you satisfied that if you had given an explanation to Mrs Henshall, you would have said that?
A Yes, if I did not - yes, I would, that I did not know which form of treatment she had and that ---

Q Was there ever any way where it came the other way round that you randomised first and then took the consent?
A No, never.

Q You would not have been able to tell the parent when you consented?
A No, not at all.

Q Just following up a question I asked you a moment ago about adding on Patient 6’s name the next day, presumably because you were doing this consent on-call you would not actually be there the next day?
A No, almost certainly.

Q So you would not be able to change the name on the form?
A No, unless it was a weekend and if it was a Saturday I would be there on the Sunday.

Q You were also asked about I think it was Patient 42, the other one for whom you took consent. It is in November, you have it there. Yes?
A Yes.

Q We heard from that mother yesterday and we heard from her husband I think last Friday. She has no recollection at all of signing the form. She had a C-section but she had it under a spinal anaesthetic. The same question that Mr Forde asked you effectively about Mrs Henshall: would you in respect of taking consent of this mother - I am
presuming you cannot remember her?
A No.

Q But would you have satisfied yourself that this mother, before you signed the form, was competent to give you consent?
A Oh yes. If she obviously was not competent, I would not have asked.

Q As far as that form is concerned, are you happy it is your signature? There has been nothing altered about the form as far as you are concerned?
A No, I cannot see anything altered.

Q I just want to ask you two other questions about what Mrs Henshall said in respect of the taking of consent and what would have been said. The doctor that she describes as the one with the summery dress and the tanned appearance she says would have said two things: firstly, they want to use the same method as before and therefore there was no need to explain it. Would you have said something like that?
A No, for a start I would not know what the same method was because that child had not been randomised and then in terms ---

Q Secondly, she said that she was being told that this was the best known treatment for her baby. Would you have made such a statement about CNEP at that time?
A No, I would have told them we do not know what the best treatment was and although there were theoretical advantages the aim of the trial was to find out which was the best treatment.

MISS O’ROURKE: Thank you. I have no further questions.

MR FOSTER: I have no questions, sir, thank you.

Re-examined by MS SULLIVAN

Q Just a couple of matters, Dr Newell. You said that you supposed you were acting registrar at the time. What in fact was your appointment?
A I think my title was still SHO.

Q You have agreed with Miss O’Rourke that I think it was on six occasions, it seems from the log, that you took consent and that those were whilst you were on-call. Is that right?
A That is right.

Q Can I just ask you to look at the log again behind tab 3 at page 373 and look at the very bottom entry in relation to Patient 6? That is 14 December 1992.
A Yes.

Q Is that your writing there?
A No.

Q I wondered if you could help at all as to why the patient’s name is shown there as just “female infant”, by the looks of it?
A It is not my writing and my name is spelt wrong. It is definitely not my writing.

Q Can you recall how this log came to be completed? Where, for example, there was an entry further up which related to Patient 42, 27 November 1992, is that your writing there?
A I have never seen these sheets, I am sure. I do not remember seeing these sheets at all.

B You do not remember ever seeing sheets?
A I cannot say I do, no.

MISS O’ROURKE: Sir, just for the avoidance of doubt, these are the sheets that Dr Samuels and Professor Southall kept. They would not have been in the hospital; they are kept by - they are randomisation sheets.

C MS SULLIVAN: Thank you. (To the witness) When you did take consent and make a call, randomisation, where did you note it then?
A It would be in the medical records, in the notes, I would have written it.

Q Not on any separate sheets at all?
A No.

MS SULLIVAN: Thank you.

THE CHAIRMAN: Dr Newell, that completes the questions which the lawyers have for you. As I indicated at the outset, this is now the opportunity for members of the Panel to ask questions if any does have questions for you.

E Questioned by THE PANEL

MRS BRICKLEY: Correct me if I am wrong, I think you said that you saw a junior SHO taking consent with a registrar?
A No, I was a junior SHO and I watched a registrar taking consent.

Q That was during this time during the trial?
A Yes, when I was - the first six months when I was working full-time on the neonatal unit.

Q Did you ever take a consent by yourself as a junior SHO?
A No, never.

G Q Do you know how many other doctors were eligible - for want of a better word - to take consent?
A I am sorry, I cannot recall.

Q Were you given any specific training to take consent for this trial in particular, rather than consent in general?
A I cannot recall. I cannot answer yes or no, I am sorry, to that.
MRS BRICKLEY: That is fine, not a problem. Thank you.

THE CHAIRMAN: Can I just ask you about this: you were looking a moment ago at the log entry, which you had not seen before but it records the randomisation which you called - made in relation to Patient 6. That is shown as being at 11.30 at night.
A Yes.

Q Presumably that was - as you said, you were on-call and you would have been called to the neonatal unit for the purpose of evaluating Patient 6?
A I would probably have been working on the neonatal unit anyway ---

Q You were probably there anyway? Can you help - and I appreciate, as you have been at pains to point out to everybody, that you are thinking back a very long time ago - how long do you think you would spend in discussion with a parent on the consenting process?
A I think that varies so much depending how much information patients wanted, whether they wanted to think more about it. I cannot answer that. I think it varied a lot.

Q Yes, but you have explained to us what your standard approach would be in terms of the explanation that you would give?
A Yes.

Q That, you say, you would have done on each of the half dozen or so occasions in which you did this?
A Yes.

Q You were asked about whether there was any written information about the trial but you say you have no real recollection of that?
A Honestly I do not think I could answer that question yes or no. I am not sure.

Q If you have a quick look at the consent form - we will take the consent form for Patient 6, which is at page 390, or if you have the original there you can see it. One of the things which can be said about this, this particular form, is that I do not think it says anything about randomisation. That is right, is it, if you look at the form?
A No.

Q So a parent or parents who were - if they were restricted to the consent form, if that was the information, if that was what they were looking at, they might be led into thinking, if there was no further explanation, that the consent would mean that they would get CNEP treatment?
A But that is not likely to happen. There is lots of material that is missing off there anyway ... 

Q Yes.
A ... but it would not be just the case that you sat down with the parent and read what was on there.

Q No, but you would have taken them through the form?
A Yes, at the end of it when I have explained it and said, “Are there any questions?”
If they said, “Yes, I agree”, I would say, “Well, in that case I need you to read the form so that you can sign it at the bottom”.

Q The only way in which a parent would understand that this was not consenting to the treatment but was consenting to the randomisation would be either if you explained it to them verbally or if they were given some other written information which contained that?

A Yes, that is right.

THE CHAIRMAN: Thank you very much indeed. Any questions arising from Panel questions?

Further cross-examined by MISS O’ROURKE

Q Yes, sir, just arising out of yours. In fact, Dr Newell, what they were consenting to in this consent form was being in the study. Is that right? In other words, the study had two arms to it: CNEP and standard treatment?

A That is right.

Q But both sets of patients were in the study?

A Yes.

Q So you needed a consent form even if you were going to be on standard treatment?

A Oh absolutely. This is consent to be ---

Q So this consent form is not, as might have been suggested, to the treatment or to being treated with CNEP ...

A No, not at all.

Q ... this was consent to being in the study, whatever side you got into?

A This was the consent for the child to be randomised to the study.

Q Right, but it was therefore - well, it was consent to be in the study full stop?

A Yes.

Q It did not matter whether you got randomised; every child in the study needed a consent form?

A If they are in the study they would have been randomised.

Q Yes, so what you are doing on the consent form is consenting to being in the study?

A Absolutely.

Q Whatever the treatment?

A Yes.

Q The information leaflet on the other hand does say, “Should you give consent to your baby being entered into the study, then we will use the method of random allocation
to decide which treatment”?
A Yes, that is correct.

MISS O’ROURKE: Thank you.

Further cross-examined by MR FORDE

B Q Sorry, just one other aspect arising out of the last series of questions that you were asked. Is there any doubt in your mind as to whether or not, with any parent that you consented for the study, you would have indicated that the process involved randomisation?
A No, that would be one of the very important things you would tell them.

MR FORDE: Thank you very much.

MISS O’ROURKE: Sir, I was rising anticipating you were going to release Dr Newell to raise just one point and it is this. As we know, Mrs Henshall described a doctor that she says is the one that came to talk to her. Mrs Henshall has also given evidence that she does not remember giving consent. I was not clear whether she was saying, “Well, if I did give consent it was that doctor in the summery dress, who was tanned and had long eyelashes and was in her mid to late 30s”.

I have been watching Mrs Henshall shaking her head at various stages throughout Dr Newell’s evidence and certainly she appeared to be saying something when Dr Newell came in. I wonder if it is appropriate, before Dr Newell leaves, so that we all know where we stand, to know whether Mrs Henshall says this is not the doctor in the summery dress in her mid to late 30s with the long eyelashes, and that therefore if this doctor is the one who took consent it was at some other time.

I raise it now before the doctor leaves. If Mrs Henshall does have something to say - and I also saw that a note was coming forward - then I think we should know it now before this doctor leaves so that we can say to her, “In fact, would you have come back at some other stage or been involved at some other stage and not made a note?” Sir, it is a matter for you of course.

THE LEGAL ASSESSOR: In principle, I cannot see any objection to that, Ms Sullivan, in the sense that if all the doctors had been available, one could have held, as it were, an identity parade in the course of evidence in-chief and one normally would have done.

MR FORDE: I would have loved to have seen the male doctors in a flowery dress!

THE LEGAL ASSESSOR: Is it something that you would wish to think about? If you are going to recall Mrs Henshall at any stage to say yes or no about the various doctors, I suppose it would be better at least to declare as each one goes through the witness box whether that is or is not the doctor.

MS SULLIVAN: I was not planning to recall Mrs Henshall. I think it is entirely a matter for the Panel. Of course, the same problems arise at this stage as arise in relation to other witnesses, and that is this is a long time after the event and it is rather in the nature of a
dock identification, so to speak.

MISS O’ROURKE: Sir, can I make it clear the reason I raise it now before Dr Newell leaves is I do not know whether Mrs Henshall now says, “No, this is absolutely not the one that I was describing. This is not her”. If she is going to say that, then we need to know if it to say to Dr Newell, “Well, are you absolutely sure you were the one that was there at four hours”, and whatever. On the other hand, if Mrs Henshall is going to say, “Actually, now I see her I do recognise her and I do remember that it was a tall doctor”, or whatever else, then that indicates that we have the right doctor and it is just then a question of Mrs Henshall having forgotten that she signed the form.

If she does not want to help - it is just I noticed Mrs Henshall at various stages shaking her head and mumbling things when this doctor came in.

MS SULLIVAN: Sir, I get the impression that Mrs Henshall does not mind giving evidence about it. It is entirely a matter for you, sir. I am not seeking her recall but I am not going to stand in the way of it if she is happy.

MISS O’ROURKE: Sir, I do not think it is a question of her giving evidence again; she has done that. It is a question of her indicating is this the doctor that was in the summery dress with the long eyelashes who looked in her mid to late 30s? If it is not, does she remember this doctor and now is saying, “I was mistaken when I described somebody who was in her mid to late 30s who was tanned. Now that I see her of course I remember it was her because it is very striking how tall she is”.

I do not think we need to recall her. I think we need Ms Morris to get a note saying, “Yes, this is her and I was wrong in my previous description”, or “No, this is not her and I stick by my previous description”.

THE CHAIRMAN: That could certainly be done, could it not, Ms Sullivan? If it is done, and whatever the answer is, what Miss O’Rourke is wanting to do is to have the opportunity while Dr Newell is here, depending on the answer which is communicated for - it would be desirable for those further questions to be put.

Of course, what we would all have to do is to understand that Mrs Henshall, as is Dr Newell, is recalling something which took place a very long time ago, and as we all know matters of purported identification going back over that period of time may or may not have a reliability and certainty about them. Therefore, whatever the answer is, the answer would have to be considered by all of us in the light of the fact that it is an answer which is being given a long time after the event.

MS SULLIVAN: Perhaps in fairness to Mrs Henshall, we could just consider the matter with her and take it from there, sir. Perhaps if we had a break at this stage, we would be able to consider it and consider how best to approach it.

MR FORDE: Sir, we only have one more witness today as I understand it. I wonder if I could make a request for a slightly longer break, perhaps 25 minutes rather than 15. The reason I ask is because we, I think, need to discuss something with Ms Sullivan about the next witness whose statement goes beyond CNEP, just to see whether that is something
she wishes to explore with that witness. There is also potential for a couple of papers to be put to this witness and I need to discuss that with my learned friends on this side of the room and, in fairness to Ms Sullivan, let her see them if we are going to do that.

THE CHAIRMAN: Thank you, Mr Forde. Dr Newell, you have been listening to that exchange and Miss O’Rourke is quite right, I had been in the process of drawing breath to say that that completes your evidence. As you heard from the exchange, there has been a matter which is raised which would be sensible to resolve while you are still here, in the sense that if we leave it and then have to call you back that would be a waste of your time and everybody else’s. If I could ask you to wait for the time being, we will take a break now. Mr Forde has asked for a slightly longer one; shall we say until quarter-past eleven?

MR FORDE: Thank you.

THE CHAIRMAN: We are going to take a 25 minute break. During that period Ms Sullivan will make the enquiries that she said she was going to do a moment ago and then we will come back at quarter-past eleven and see how the position will be resolved. I am sure someone will look after you and make sure you get something by way of refreshment. Please do not talk about the case to anyone during the period. We will rise for 25 minutes and come back at quarter-past eleven.

(The Panel adjourned for a short time)

MS SULLIVAN: Sir, in answer to the issue that was raised by Miss O’Rourke just before the break, I can indicate that Mrs Henshall’s position is that the lady she described in her evidence who approached her bedside at her request to discuss her baby’s care was not Dr Clare Newell. She has no recollection of Dr Clare Newell at all.

THE CHAIRMAN: Thank you, Ms Sullivan. Miss O’Rourke, is that an answer to the question?

MISS O’ROURKE: Sir, I think that I have probably then covered it with Dr Newell because I have asked her to establish that she was the one who was there at four hours and she was the one who took the consent. I do not think that I need to take it any further in the circumstances. There may be, for the avoidance of doubt, one further question but I think that I probably have covered it.

THE CHAIRMAN: Thank you very much. (To the witness) Thank you very much for waiting, Dr Newell. The matter has been discussed and resolved by counsel during the break. There are now no further questions for you and that completes your evidence. It remains for me to thank you very much for coming this morning and for the assistance that you have been able to give us. Thank you very much.

(The witness withdrew)

MS SULLIVAN: Sir, as you know the next witness is Dr Livera.

THE CHAIRMAN: Is Dr Livera another consenting doctor?
MS SULLIVAN: Yes, she is. She was a research registrar.

THE CHAIRMAN: I only ask because I omitted to mention the fact of endeavouring not to mention names of patients to Dr Newell, but I will with Dr Livera.

MS SULLIVAN: In fact, although Dr Livera did consent, we do not have any consent forms which she signed, so we probably will not have the same difficulty.

THE CHAIRMAN: In that case, I will leave you to deal with it if it arises.

LESLEY NICOLA LIVERA, affirmed
Examined by MS SULLIVAN

Q Dr Livera, would you start with your full names, please.
A My name is Lesley Nicola Livera.

Q What are your qualifications?
A I have MB ChB, DCH, FRCP.

Q Would you keep your voice up because it is quite a large room. I think it is right that you are not working in medicine any longer.
A That is correct.

Q But you were for a number of years. When was it that you qualified?
A I qualified in 1981.

Q And you worked, I think, as an SHO in Nottingham.
A Yes.

Q Then did you work at North Staffordshire Hospital in Stoke on Trent from January 1987 until January 1991?
A Yes, that is correct.

Q Just so that we can understand in what capacity you worked there, were you first of all a paediatric registrar?
A Yes.

Q Was that from January 1987 to July 1988?
A Yes.

Q Over that period of time, what rotations would you have done?
A I was a general paediatric registrar and a neonatal registrar.

Q For how long were you on the neonatal unit in that time?
A I think it was for six months.

Q Between August 1988 and July 1990, were you a clinical research fellow?
A Yes.
A Q I think that you were then involved in a different research project than the one that this Panel is considering during that time.
A Yes.

Q Which is known as NERS – we have heard reference to it – Near Infrared Spectroscopy.
A Yes, that is right.

B Q Between August 1990 and January 1991, did you work as a neonatal registrar?
A Yes.

Q That then takes you to the end of your time in Stoke and I think that thereafter you were a senior registrar in community paediatrics in Birmingham and then had two appointments as a consultant paediatrician.
A Yes, that is right.

C Q As you will appreciate, Dr Livera, we want to ask you about the CNEP trial. Have you any recollection of when that started?
A I do not know the exact starting date of it, no.

Q I think you have been made aware that approval was gained from the Ethics Committee in January 1990. Were you involved in the CNEP trial from the beginning in Stoke or not?
A Yes, I was.

Q In fact, just help as to this: had CNEP itself been used in Stoke prior to the trial starting?
A Yes. My memory is that it was used for chronic lung disease prior to the actual trial.

Q So, it had been used for chronic lung disease in what sort of age groups?
A In neonates.

Q Therefore, when it started, had you familiarity yourself with CNEP?
A Yes.

Q You say that you were familiar with it but was there any training for the medical staff in relation to the use of CNEP?
A Yes, there was. I am afraid that I cannot remember details of the training but I remember being trained along with colleagues.

G Q Was that training in Stoke or elsewhere?
A Some training was in Stoke and I remember going to the Brompton Hospital to be trained as well.

Q Was that training in relation to the trial or to the prior use of CNEP?
A Do you mean the visit to the Brompton?

H Q Yes.
A: I am afraid that I do not remember exactly which.

Q: Do you know which doctors were involved in the training?
A: The training at the Brompton are you referring to again?

Q: Yes.
A: Dr Southall was there, I remember him very clearly, and Dr Samuels but I do not remember any other individuals.

Q: We know that in terms of placing the babies in the CNEP tanks, that was something that was done by the nurses. Is that your recollection, Dr Livera?
A: Yes.

Q: What I want to ask you about is the extent to which you were involved during your time at Stoke in consenting parents for entry of their babies into the trial and I wonder if you could have a look at a document for a moment in file 1, just to your left-hand side. Behind tab 3 at page 367 – and this is not a document completed by you, Dr Livera, and you may not have seen it before – do you see in the fourth column on the left-hand side the name of the person calling in order to randomise the children into the trial?
A: Yes.

Q: We have a number of pages that relate to this process in Stoke. We see on the first page there that there is reference, I think, third from the bottom to “Nicky” and is that you?
A: Yes.

Q: Just glancing through then on the next page, Dr Livera, we see a couple of Nickies at the top of the page, about three, and then your name appearing quite frequently below in the last three columns. Do you see that?
A: Yes.

Q: Again, I think on the next page, I am not sure that you feature at all there. Am I right?
A: No, I do not but, if I am looking at the dates correctly, I was not working there then.

Q: Exactly. Then I think as we go through the pages we do not see your name featuring with quite the same frequency.
A: I am not there at all because I was not working there.

Q: Not at that stage. That gives us some indication of your involvement in the consenting process by reference to the patients who were in the trial. When you were consenting for the trial, Dr Livera, in what capacity were you working then? Were you a research fellow at that stage or a paediatric registrar or did you do it in both capacities?
A: In both.

Q: Explain how it was that you would come about giving consent if you were the research registrar. Would that be during the day or what would be the position?
A  That was usually when I was covering the unit on call at night because I was not responsible for day-to-day care during the day when I was doing the research work.

Q  How often would you have been on call?
A  I cannot remember the exact rota, I am afraid. It was about a one-in-five I think, but I am not sure.

Q  Then of course when you were working as a registrar on the unit, at that stage you would have had responsibility for care of the babies.
A  Yes.

Q  Would you have consented during the day then, when appropriate?
A  I would have taken consent during the day for relevant babies, yes.

Q  If a baby was eligible to be entered into the trial, Dr Livera, what grade of doctor would have been responsible for obtaining the parent’s consent? Can you help us as to that?
A  My memory is that it was usually the middle-grade doctors, so the registrar and, when I was the registrar, it would have been me.

Q  What process would you go through? Explain what you would do in order to obtain consent for the CNEP trial.
A  If the baby was eligible to be entered into the trial, then I would go and speak to the parents.

Q  Would you speak to one or both parents?
A  We tried to speak to both if both were available. I do not think that it was always possible, but both if they were available.

Q  In what circumstances would it not be possible to speak to both?
A  Sometimes only one parent was present and involved.

Q  Yes, obviously that. What about the position if the mother had had a general anaesthetic, for example.
A  I do not remember clearly but, at the time that we were taking consent, it was usually some time after the baby had been born, so the mother was no longer anaesthetised. We did not take consent the minute the baby was born.

Q  When taking consent, would you give an oral explanation about the trial?
A  It was oral and written. There was some written information which we discussed with the parents and I would talk about the trial trying to explain what the purpose of the trial was and the actual components of the trial.

Q  What would you have explained? Can you help us now as to what you would have said about the trial?
A  Obviously it is quite a long time ago so it is difficult to be absolutely certain what exactly I said, but I think I would have explained that the condition that their baby was
suffering from – so I would have explained that their baby had RDS and was in need of some form of support for their breathing requirements.

Q Yes, so RDS?
A Respiratory distress syndrome, I am sorry.

Q Yes.
A Because the babies, to be eligible in the trial, were needing oxygen and were therefore suffering from that condition, so I would have explained what the problem was with their baby and that the trial was intended to look at two different forms of supporting the baby’s respiratory problems and that there was a conventional form of treatment and that there was a new form of treatment and that we were looking at both, at the new form of treatment to see whether it had any advantages when compared to conventional treatment. I had to explain that I could not tell them at that stage which treatment their baby would be receiving because there was a process whereby the babies were allocated to one of the two types of treatment.

Q Yes, we have heard how there was a randomisation process. How easy was that, because you consented a number of parents by the looks of it, Dr Livera – how easy was it for parents to understand that concept?
A It is difficult to remember but I know it is a complex process and it took quite a long time to talk through the whole discussion about the trial and the randomisation. I think I tried very hard to ensure that parents did understand what was going to happen, what was going to be involved to make sure that they had as much understanding as I could enable them to have of what was going to happen.

Q Yes, I am sure you were trying your best to ensure that they understood what was happening but from their point of view, from what you were able to see from how they reacted, how easy was it for them to understand a concept such as randomisation?
A I think it took time but I think by the end of our conversation and discussion they had an understanding of what that meant. Whether or not they would have been able to then explain it to somebody else I do not know but I think they understood what I was talking about. I do not remember feeling that I was leaving parents without an understanding of what the trial involved and what randomisation was.

Q Of course, these parents had just had a premature baby with breathing difficulties, so what sort of state were they in generally when you were speaking to them?
A They would be distressed and concerned for their baby and there was an awful lot for them to take in which I think is why I tried very hard to ensure that they did get as much information and have as much opportunity to ask questions and that sort of thing as was possible.

Q Yes. How long did you spend – can you help us just generally – in explaining this process to parents?
A I am afraid I cannot give you an approximate time because I do not remember it. It was quite time consuming but I cannot – I was not there for more than an hour, I do not think, but it was more than – it was a considerable amount of time in most cases talking through the trial.
Q As a research registrar, how did your knowledge of the trial compare with doctors who were primarily involved in caring for the baby? Did you have any extra knowledge through your research, is my question really?
A I do not think I did, no.

Q When you were describing the treatment to the parents, how would you describe how CNEP compared with conventional treatment? Would you have described any advantages and disadvantages, in other words?
A I think I tried to describe the physical differences in the way that the baby would be nursed and treated. I do not remember whether I talked in detail about advantages or disadvantages.

Q Do you in fact recall any problems with the neck seal, for example?
A No, I personally never saw any problems with the neck seal.

Q Were you aware of any having occurred not in Stoke but elsewhere?
A I knew there was a potential for problems, which is why the neck seal was a very important part of the setting up process but I was not aware of any significant problems occurring anywhere.

Q When you say you were aware of a potential for problems, what problems was there potential for?
A That the neck seal could rub on the neck and therefore the neck of the baby had to be looked after carefully and the seal fitting had to be checked and done very carefully and that the babies wore special little vests, for want of a better word, to actually protect the neck.

Q Was anything else used to protect the neck at any stage?
A When I was first questioned for this hearing the use of a gel was mentioned to me but I have no personal memory of that.

Q You say you were aware of the potential for neck problems. Were any such problems mentioned to the parents, do you know, by you?
A Not during the taking of consent that I recall, no. I think it was discussed with parents during the time – if their babies were receiving CNEP it was discussed because the neck was obviously an area that was taken good care of, for want of a better term.

Q So what would happen? Having taken consent from the parents what was the next stage?
A Then the baby needed to be randomised so I would telephone whoever was on call that day for the randomisation procedure, which was either Dr Southall or Dr Samuels.

Q Do you remember what, if anything, they asked you in the telephone calls that you had? Were you asked about consent, for example, or not?
A I do not remember.

Q Or the exclusion criteria?
A Again, I do not remember those conversations.
Q Then thereafter we know that it was the nurses who actually set up the tanks as we mentioned before?
A Yes. It would depend a little bit on the clinical state of the baby but the actual setting up within the tank, fitting the neck seal, etc, was done by the nurses.

Q You referred to their being information for parents. Do you remember in what form that was prior to them giving their consent to their babies entering the trial?
A It was a written leaflet or sheet.

Q I wonder if you could just look in that file that you have to hand there for a moment at page 336 behind tab 3, if you just go back a little. You were shown this when you made your statement, Dr Livera. Do you remember whether that leaflet was in use when you were working in Stoke or not?
A It could well have been. I cannot say exactly whether this was the leaflet or not. Some of the wording is certainly very familiar to me, but I could not say for certain that this is the leaflet that was used.

Q If you would not mind just turning on again to page 341 which goes through to page 364, I think again you were shown this when you made your statement?
A Yes, I think this is the one.

Q Have you any recollection of that?
A No, this one does not look familiar. Again, some of the wording is familiar but the actual document with the pictures is not familiar to me.

Q Was there any information about CNEP on the unit itself?
A Yes, I remember there being written information for the staff about CNEP, background to the trial and its use.

Q Apart from the information for staff, do you remember any other information for parents?
A I do not remember any specifically, no.

Q Or anything on the tanks of the babies?
A I am sorry, you mean written information on the tanks?

Q Yes.
A There was a lot of information but I cannot remember precisely what the contents of it was. The research notes held a lot of information as well but again I cannot tell you the detail of it.

Q No. I just want to ask you this, please. If you would not mind just turning right to the front of that bundle and you will find behind tab 1 at page 2 - I think you were shown this again when you made your statement, Dr Livera?
A Yes.

Q This is the actual application to the Ethics Committee which was granted on 10 January 1990. I just wonder if you would turn on to question 12, which is at page 4?
A Yes.
Q Do you see a description there of the various procedures which were to be applied to each patient in CNEP?
A Yes.

Q Do you see that?
A Yes.

Q Really what I wanted to ask you was this, about the forms of monitoring that were described there. Do you remember intercranial pressure monitoring being used as part of CNEP?
A I do not, no.

Q Or Doppler ultrasound?
A No, not during the time that I worked there.

Q We know that you were involved yourself in research in relation to near infrared spectroscopy?
A Yes.

Q Was that used in conjunction with CNEP?
A Not during the time that I worked there, although I am aware it was afterwards.

Q I think afterwards it was the subject of a separate application for a trial. Is that right?
A I think so, yes.

Q Was that after you had left, Dr Livera?
A The application or the work?

Q Yes, the application?
A There is an application which I was shown which I submitted for work using near infrared spectroscopy with CNEP, but I did not carry out the work itself.

Q You did not do that? I think I had asked you earlier about whether there were any problems with the neck seal and you said you were not aware of any problems with the neck seal in Stoke. Did you also say – I cannot quite recall – whether you were aware of anything that had occurred in London?
A I was not aware of any significant problems. I knew there was the potential for problems but I was not aware of any specific cases or particular problems that had occurred.

Q Again, I think when you made your statement you were shown a photograph of a baby at Queen Charlotte’s. Do you remember that?
A Yes, I remember seeing that.

Q Who had injuries to his neck and so, having seen that photograph, were you aware of that particular incident at the time?
A No.
Q Just can you help us please as to this? When you were involved primarily with the CNEP trial, Dr Livera, where was Dr Southall? You talked about phoning Dr Southall and Dr Samuels. Were they, either of them, present on the unit at any time that you recall?
A They did not work there but they were present at times, yes.

Q They did not work there at the time when you were there?
A They were not working at Stoke at the time that I was working there, no.

Q We know they came to work there later but can you recall how frequently they would be on the unit?
A I am afraid I cannot. Several times I can remember Dr Southall in particular being there but I do not know how many times over the period of time that we are talking about.

Q If you needed to ask either of them about anything, would they have been available on the telephone?
A Oh, yes. Very much so.

Q You described how there would be a continuing process of talking to parents about their babies?
A Yes.

Q What was the purpose of that?
A To keep them up to date with their baby’s condition.

Q To keep them up to date obviously with their clinical care, but with regard to the trial really, is my question?
A I think we continued to discuss the trial and its purpose and how their baby was doing with the particular treatment that they were receiving in the trial was discussed continually with parents. Some parents were more interested in the specifics of the trial than others but it was something that was ongoing throughout the baby’s stay.

Q Yes. What was the rationale for continuing to talk about the trial? Why was it felt necessary to do that?
A I think for many parents they were interested and wanted to know about the trial. We also wanted to make sure that they had and continued to have full understanding of what was happening. We talked to parents a lot about their babies and their babies’ condition and what was being done and why and the treatment that they were receiving in the trial continued to be discussed as part of that as well.

Q Can I just finally ask you this? Are you able to help as to how blood pressure was monitored?
A Are you talking about in a specific baby or in general terms?

Q In general terms in the trial I am going to ask you?
A Wherever possible babies with respiratory distress syndrome who were needing oxygen had an indwelling arterial catheter and blood pressure was available as a measurement through that. In babies who – I do not think there were very many but
babies who did not have an indwelling catheter, the blood pressure was taken manually using a blood pressure cuff.

Q Was that something that it was easy to do with the CNEP tanks?
A Using a blood pressure cuff, you mean?

Q Yes, using a blood pressure cuff?
A I do not remember it being a problem. It is possible that it was but I do not remember it being a problem at all, or it may be that in my time we always had catheters in. I do not remember.

Q You do not remember, no. Do you remember about scans either, whether they were taken before the baby went into the trial?
A I think we scanned babies prior to the trial when possible. I do not think it was always possible because it depended on the time of day or night but whenever possible scans were done as soon as possible.

Q Did it depend on who was available on the unit?
A If I was on the unit I could scan but not all of the middle grade staff could.

MS SULLIVAN: Thank you very much, Dr Livera. There will be some more questions.

Cross-examined by MR FORDE

Q Good morning, Dr Livera. I am going to ask you some questions on behalf of Dr Spencer. Can I start with some generalities first of all? I think you were Dr Spencer’s research fellow. Is that correct?
A Yes, I was.

Q So you worked closely with him?
A Yes.

Q I think you had a good working relationship?
A Very much so, yes.

Q Would I be right in suggesting to you that from your perspective he was a good trainer?
A He was, definitely.

Q He took his training responsibilities seriously?
A Yes.

Q In terms of staffing, you were just asked about scanning. If a child was born late at night or in the early hours of the morning, I think you pre entering into the trial had the ability to scan. Is that correct?
A Yes.

Q But not all the middle grade staff did?
A I do not think so, no. I cannot remember exactly but I do not think so.
Q If it were a situation where it was the SHO on call, would you expect them to be able to scan pre trial?
A No. Not all of them.

Q The real impetus, though, was to get a premature baby with respiratory distress syndrome treated?
A Yes.

Q You would not wait for a scan and not either give standard treatment or CNEP, would you?
A Oh no, no.

Q Like all things in medicine you have got to prioritise?
A Oh yes, certainly. Even if I was on call, if I did not have time to scan because the baby was sick and needed me to be doing other things, I would not have scanned purely for the sole purpose of getting a scan. I would have treated the baby.

Q I just wanted to ask you about training. You have indicated - and I have a copy of a witness statement that you signed in February of this year - that you received some training in that statement. Was February of this year the first time you were asked to recall in detail what happened back in the early 1990s?
A It was actually October of last year that I was first interviewed.

Q That was the first time?
A But, yes, that is the first time I had been asked about anything to do with the CNEP trial.

Q What you say in paragraph 4, for everybody’s else benefit, of your statement is:

(Document not available to shorthand writer)

“I recall we were trained and I can remember going to the Brompton Hospital at least once for training with other people from Stoke but I do not remember who else was there.”

Can I take it that the other people from Stoke were members of the medical staff at least that you went with?
A Yes, and I think the research nurse.

Q And the research nurse? So were they, to your recollection, middle grade doctors or junior doctors or might they have been a combination of both?
A I think it was middle grade doctors as opposed to the SHOs. The people who would be in the middle grade rota.

Q So probably - and again I am not going to put it any higher than that - the registrar sort of level ...
A Yes.
Q ... of doctors? Again, if you cannot help then do say, do you have any recollection of the approximate number of people that went on the day that you went?
A It was a small number. It was three or four. It was not more than ten, but I cannot be more certain than that.

Q That is fine for my purposes. Do you know whether there were other middle grade colleagues of yours that may have gone on any other occasion?
A I do not remember.

Q But you do recall the research nurse being ...
A Yes.

Q ... part of the group?
A Yes.

Q Was that a lady called Theresa Wright?
A It was, Theresa, yes.

Q What you say is this:

“When we first started to use CNEP it was a completely new technique to us and we had to be trained in its use.”

Do you recall also receiving some training within the setting of Stoke as well as at the Brompton?
A Yes, I do.

Q Do you recall who trained you?
A I think it was Dr Southall himself.

Q Yes.
A He is the person I remember most seeing in Stoke in relation to CNEP but ...

Q What you go on to say is:

“I do not remember the details of the training or who conducted it. I have no reason to believe that any of the staff who worked with CNEP did so unless they had been adequately trained and competent in its use.”

G Do you stand by that comment?
A I do, yes.

Q Is that nursing staff who were dealing with the neonates on the ward, or within the unit I should say, and the junior and middle grade staff?
A Yes.

Q Would it be fair to say that from your stand point they were all competent in the use of CNEP?
A Yes, they were.

Q I just want to ask you about CNEP because my understanding - and please correct me if I am wrong - is that you did have experience of CNEP outwith the trial?
A Yes, that is right.

Q There is a criticism been made as to how CNEP was presented to parents. I just want to explore that with you for a moment. When you were dealing with babies who were not within the CNEP trial, they were also neonates?
A Yes, some of them were quite old neonates but ...

Q But do you recall that some were premature?
A They had been born prematurely, yes.

Q And might then have gone on to develop, within a matter of two or three weeks, either bronchiolitis or a respiratory distress problem?
A Yes, they developed chronic lung disease or the babies I am remembering had bronchopulmonary dysplasia.

Q I just want to suggest to you that some of those that were treated with CNEP outwith the trial might have been as young as 28, 29, 30 weeks?
A Yes. They were still very small, very immature babies, yes.

Q So if your experience of such premature babies outwith the trial was that it had not caused a problem, is that your experience?
A Yes.

Q That CNEP itself had not harmed anybody?
A No, it was very beneficial.

Q Would you agree with me, based upon that experience, if anybody was suggesting in literature that it was safe, that that would be a reasonable assumption?
A Yes.

Q Then you were asked about adverse consequences. I just want to try and place in context the neck seal. To your knowledge, there was never any particular problem with the neck seal at Stoke. Is that correct?
A That is correct, yes.

Q In fact, the nursing staff knew it was something they knew they had to keep a particular eye upon?
A Yes.

Q Your experience, is this correct, was that they carried out those duties conscientiously?
A Yes.

H Q Checking the seal, checking the state of the baby’s neck?
A Yes.
A
Q  Again, to try and help the Panel put matters in context, if an ECG electrode is placed upon the skin, it has the potential, does it not, to remove the layers of skin surface?
A  Yes, it does.

Q  That would not stop you using it though, would it?
A  No.

Q  If it is not observed quickly, it has the potential at least to leave a permanent scar?
A  Yes.

Q  Have you seen that happen during your paediatric training?
A  Yes, I have.

Q  I think the same is true if you use a transcutaneous probe, that can blister the skin...
A  Yes.

Q  ... if it is not closely observed?
A  Yes.

Q  Does that have the potential to leave a permanent scar?
A  Yes, because it can form a type of burn in fact.

Q  If you are using an endotracheal tube over a lengthy period of time, that can cause both damage to the skin of the face and erosion of the gum?
A  Yes.

Q  Again, that is something that has to be closely observed?
A  Yes.

Q  Would you place the potential for damage with the neck seal as being about the same as the three other examples I have given you?
A  It is difficult for me to answer that because I have never seen it. I have seen the other problems.

Q  You have seen the other three, so in your experience do you say to anxious parents of premature babies whose children need to have their hearts monitored by an ECG electrode, “I ought to warn you that in carrying out this vital observation, the skin could be damaged”?
A  No, I would not say that.

Q  Thank you. Can I then move to a different topic, please? I am going back, for the benefit of others, to your witness statement, paragraph 6. You have given the Panel - or you have given evidence that you were involved in discussing the trial and taking consent from parents and you were often the out-of-hours on-call registrar. Is that correct?
A  Yes.

Q  You say that the neonatal unit registrar would be responsible for consenting
babies into the trial during the day. Is that your recollection?

A That is my recollection, yes.

Q It was done at middle grade level.

“When taking consent we used an information sheet or leaflet and the consent form itself.”

A Yes.

Q Were those documents that you left with parents or did you go through them line by line? What was your usual technique?

A As far as I can remember, I went through the documents. The information sheet was left with the parents. The consent form was I think kept in the baby’s notes. I cannot remember exactly, but I do not think that was left with the parents but the information sheet was.

Q You go on to say:

“If the baby was eligible to be entered into the CNEP trial the middle grade doctor responsible for the baby’s care at the time would talk to the parents and explain what the trial involved.

I believe that during training we were advised about the best way of explaining the trial.”

That is your recollection, is it?

A Yes.

Q “We were familiar and comfortable with using CNEP and discussing it as it was already being used for treating babies with chronic lung disease.”

We have already explored that issue.

“I believe that it was explained that CNEP was a different form of supporting babies with lung disease due to prematurity. I recall that we tried hard to make sure that parents did not feel pressurised and that the consent form abided by the rules at the time. The information given to parents explained that if they did not want their baby to be included in the trial this would not in any way prejudice their care.”

A Yes.

Q Were those important features of the trial that you explained to parents when you consented?

A Yes, we definitely wanted to make sure that parents were not feeling that they had to give consent or they would not ---
Q You are allowed the water if you need it. Just a couple of areas, if I may. You believe you would have used the words trial or study in explaining these matters to parents, you tell us in your witness statement. You say:

“I believe we would have talked through the details given on the information”

- which you have been shown by my learned friend -

“I do not remember how we explained the randomisation procedure, but it would have to be explained otherwise it would not have been clear to parents what was going to happen. However, I appreciate randomisation is not an easy concept to grasp and that the parents under the pressure of having had a premature baby they may not have fully taken things in.”

I just wanted to ask you about that. Have you experience as a paediatrician of explaining matters in detail only to find that the parents are asking you, perhaps three days later, about something that you are confident you have explained?

A I find it happens nearly all the time, particularly in serious complex situations. I would never allow one explanation - it is common to need two to return to similar ground on many occasions.

Q Is that what you were explaining when you said you were available to answer questions when you saw parents on the unit after a baby went into the trial?

A Yes, I would talk about whatever the parents wanted to talk about, if they had questions about any aspect of the trial.

Q You have specialised in paediatrics in neonatology, but can I ask you this: in comparison with other areas of hospital practice and life, would it be fair to suggest that the dialogue between parents, nursing staff and doctors within a neonatal unit is of an enhanced quality? It is one of those things that you are very astute to ensure occurred. Is that fair?

A Yes, I think that is right.

Q You have anxious parents, you have neonatal patients who cannot speak for themselves, so it is a constant dialogue of explanation?

A Yes, and also there is always a very strong presence; the medical staff are always there. It is not like some types of medicine where there is ward rounds and the doctors go away again. You are there nearly all the time because of the nature of the babies’ problems require that.

Q The nursing staff are entrusted to carry out detailed regular observations as well?

A Yes.

Q So they are ---

A They are there all the time.

Q You never walk into a neonatal unit and find no nurses or doctors?
A

Q There are alarms going off, blood pressures monitored, there is saturation levels being monitored. Is that fair?
A That is right, yes.

Q There is an important part of your statement I wanted to discuss. Others have suggested that one of the inducements into consenting to CNEP was it was being described as the kinder and gentler treatment. You, in paragraph 9 of your statement say this, and I just wanted to explore this with you:

“I do not remember using this term and I do not believe it likely that I would have done so because if the baby was randomised to the conventional limb of the trial, the parents would then have been worried that they were receiving inferior treatment.”

Is that your view?
A Yes.

Q It would appear you are saying far from suggesting it was better or kinder or gentler, “I would have been astute to avoid enhancing the view of CNEP in the mind of parents because if they then went into the neonatal unit and found their child was receiving standard treatment, they might be rather worried and upset”?
A Yes, indeed.

Q Just one final topic, it is blood pressures. If the umbilical arterial catheter was in place, your recollection is it would give constant blood pressure readings?
A Yes, I think they did. I am afraid it is a long time since I have been on a neonatal unit ---

Q No, I understand. On a digital display of some sort would it be?
A Yes, it is a display.

Q You would expect trained neonatal nurses, would you not, to immediately recognise a concern in blood pressure?
A Yes.

Q To immediately recognise a baby who was desaturating?
A Yes.

Q And to immediately recognise the potential - never mind the actuality - the potential for hypoxia?
A Yes.

MR FORDE: Thank you very much.

Cross-examined by MISS O’ROURKE

Q Dr Livera, I ask questions on behalf of Dr Southall. I only have a few. You said
you remembered going to the Brompton Hospital to be trained and that Dr Southall was there and you certainly remember him very clearly. The training session that you went to, were you satisfied that it met your needs for the work that you were going to have to do for the trial?

A That specific session?

Q And indeed all the sessions.

A Yes, once the training was complete I was very happy that I was adequately trained.

Q You felt well trained, well supported, adequately able to cope with whatever was going to be asked of you as a doctor in the trial?

A Yes, very much so.

Q I think you said that you left Stoke in January 1991?

A Yes.

Q Dr Southall did not in fact come to work permanently in Stoke until the middle of 1992, so you did not ever actually work with him on the unit?

A No.

Q But you said he did come to Stoke several times, you remember him being there?

A Yes.

Q When he was there, any questions that you might have had you could have asked him and if you did ask him they were adequately answered?

A Yes, not just when he was there, I mean on the telephone as well.

Q You would have telephoned him for the randomisation process?

A Yes.

Q You therefore had access to him in the sense you had a telephone number for him?

A Yes.

Q Again, if you had any queries about any aspect of the trial, you could have taken them up with him?

A Yes.

Q You presumably do not recall any occasion where you were not given an adequate answer?

A No.

Q In terms of CNEP I think you said CNEP was being used before the trial began on the unit?

A Yes.

Q It was being used for lung disease?

A Yes.
Q I think you said the words, but you may have said them quite softly, that as far as you were concerned it in fact was very beneficial?
A Yes, it was beneficial.

Q So it would not be right to describe it as a new technique when the trial started because it was not a new technique, it was one that had been used indeed on your unit?
A Yes.

B Therefore, it was something that not just you but in fact the nursing staff were also familiar with?
A Yes, it was.

Q As far as the nursing staff were concerned - and I think you say this during your statement - you were all familiar and comfortable with using CNEP and discussing it because it was already being used for treating babies with chronic lung disease, so it was explained that CNEP was a different form of supporting babies with lung disease due to prematurity?
A Yes.

Q So you and the nursing staff felt familiar with it and able to explain it and indeed able to use it?
A Yes.

Q Finally, you said in your statement, paragraph 31:

“As I remember there were very clear protocols and documentation for the trial. Theresa the research sister and the nurses were well trained. They were of general experience and many have worked on the unit for a long time, in some cases ten to 15 years.”

A Yes.

Q So your recollection is that there were protocols and other documentation for the staff?
A Yes, there were.

Q Separate for the patients?
A Yes.

Q Therefore, again, there was, apart from having doctors that you could refer to, there was also material you could refer to?
A Yes.

MISS O’ROURKE: Thank you. I have no further questions.

MR FOSTER: Nothing from me, sir. Thank you.

Re-examined by MS SULLIVAN

Q Just in relation to UACs, the umbilical arterial catheters, as far as taking blood
pressure is concerned, in order for blood pressure to be taken in that way is it necessary for a particular type of probe to be in the catheter?
A Yes, I think there were specific probes that we used - were usually used in order to give blood pressure as well as a sampling line.

Q Would it depend upon whether there was such a probe within the catheter as to whether blood pressure would be taken or not?
A Yes, it is possible to put in umbilical arterial catheters that do not have blood pressure monitoring probes in them, though they were not normally used.

MS SULLIVAN: I have no further questions.

THE CHAIRMAN: Dr Livera, that completes the questions which the lawyers have for you. As I indicated at the outset, members of the Panel have an opportunity now to ask questions. I will just see if anyone has any questions.

Questioned by THE PANEL

DR OKITIKPI: Regarding the oral and written documents, when you spoke to the parents, did you leave behind any written document for them to take away at all or did you just explain the nature of the trial to them?
A The information leaflet was left with the parents. There was an information leaflet and a consent form and the information leaflet was left with the parents.

THE CHAIRMAN: Dr Livera, I understand when you were being asked by Mr Forde about the expression “kinder and gentler treatment” and I understand what you were saying as to why you would not have used such an expression at the time of consent because I think that you were saying that that might leave some concern should the baby then be randomised into standard treatment.
A Yes, I would avoid at all cost trying to give the parents the impression that either of the two treatments available was better or not than the other.

Q So, you might not have expressed that view to them but, from your experience of CNEP, would you think that that is an accurate or a fair way to describe it? Would you describe it as kinder and gentler than the standard treatment?
A At the time, I thought that it was a very effective treatment. I did not use the term “kinder and gentler”.

Q You thought that that was a way in which it could be described.
A I could see that it might have been because it did not involve positive pressure ventilation and intubation, so it is not invasive, but the phrase itself if not something I would have used or particularly thought. I actually thought that it was an effective treatment. It is kinder if you ask me that now in the sense that you do not have to intubate the baby in some cases and therefore it was less likely to cause endotracheal trauma.

Q The reason why I ask is because of course you were talking specifically at the point of consenting at a time when it was not known whether the baby would go into CNEP or receive positive treatment. Once a baby had been allocated to CNEP treatment,
you are saying that the process of updating parents and giving them information and talking to them about it would continue.

A Yes.

Q Can you recall whether you might have at that stage, in other words after the baby had gone into CNEP, talked about the nature of the treatment and use of the expression such as “kinder” or “gentler”?

A I do not think that I would have ever used that expression. I think that I might have talked about the advantages of one treatment or another treatment or what was different and why those treatments were different, but I do not think I would have ever expressed to parents that I thought that a particular treatment was “kinder and gentler” for a number of reasons. One is that I was not sure what the outcome of the trial was going to be – I had no idea what the outcome of the trial was going to be – but also I might be talking to a set of parents whose baby was receiving CNEP but, if the baby next door was receiving positive pressure ventilation, I would not have dreamt of using terms that indicated that one or the other of those modes of treatment was better or kinder or gentler. I would not have dreamt of doing that.

Q Being conscious that it was a trial and that outcomes had yet to be demonstrated, what I think you are saying is that, from your point of view, you would have been diffident about discussing with parents whatever you may have thought were advantages or disadvantages.

A Yes. One is always careful when talking to parents to make sure that you do not in any way prejudice their feelings about their child. My experience on the day-to-day basis was that CNEP was an extremely good and beneficial treatment for some babies, but I would not have voiced that to parents at that stage particularly in the context of receiving parents being in different arms of the trial.

THE CHAIRMAN: Thank you very much. Are there any questions arising?

Further cross-examined by MR FORDE

Q I have a couple of further questions. Again, I am trying to help the Panel, through your evidence, get a real-time/real-life perspective of life on a neonatal unit. You will regularly find several sets of parents within the unit in close proximity, will you not?

A Yes.

Q You also have parents who are allocated rooms to stay overnight.

A Yes.

Q They can, if they both have 28/30-week old babies both in the neonatal unit, form quite close friendships and bonds.

A Yes, very long-lasting friendships.

Q In a sense, brothers and sisters in suffering, as it were.

A Yes.

Q Those bonds and relationships can continue for many years thereafter.

A Yes.
Q: So, it is quite often a fairly gossipy environment.
A: Very much so.

Q: So, if you were to be promoting a treatment with one set of parents within one arm of the trial, would you not expect those parents whose children were receiving standard treatment to be confronting you and saying, “I have been talking to Mrs Smith who says this is kindler and gentler, why on earth isn’t my child receiving this treatment?” Is that a scenario that you can imagine?
A: I can well imagine that.

MR FORDE: Thank you very much.

THE CHAIRMAN: Dr Livera, that completes your evidence. It just remains for me to say thank you very much for coming along this morning and for the assistance you have been able to give us.

(The witness withdrew)

MR FORDE: Sir, may I raise one matter with Ms Sullivan? It will not mean us leaving the room. (Pause while Mr Forde and Ms Sullivan conferred) Sir, so that there is no mystery because I am conscious that Mr and Mrs Henshall are in the room, that discussion was about whether or not, because I do have available copies, we should make available to you and exhibit the statement of Clare Newell, as she then was, dated 18 August 1997. In fact, the position is that I went through pretty much every relevant line of it and you will recall Ms Sullivan prompting to go back and read something I think around paragraph 8. So, it will be on the transcript and therefore – and I say this so that Mr and Mrs Henshall can hear what the discussion was about – we do not think it necessary for you to have the statement. If at any time you should wish to see it, there are copies available.

THE CHAIRMAN: Presumably this is something which is going to happen … Well, it already has happened, it is not just with Dr Newell, where, particularly having regard to the length of time which has elapsed, you are anxious to refer them to the statement they have made ---

MR FORDE: If we have one, yes.

THE CHAIRMAN: If you have one and it seems to me that if the context of the questions you are putting is sufficiently demonstrated on the transcript, then it probably is not necessary for us to have extra paper.

MR FORDE: I think you have enough. As I said, if there is any point of clarification that is needed, we have them here.

THE CHAIRMAN: Thank you very much.

MS SULLIVAN: Sir, again we have gone rather faster than some of my learned friends might have thought. May I inquire therefore of them. Tomorrow we have four witnesses
– so we should have a much fuller day tomorrow – and whether that is realistic in the circumstances. Gillian Hulme is coming first; she is a parent and will not be long; followed by Dr Morgan, Dr Brookfield and then Dr Wheatley but Dr Wheatley would be available on Friday if that is too much.

MISS O'ROURKE: Sir, I would have thought that we would easily get Dr Wheatley in tomorrow and indeed I would anticipate, on that timetable, we might well be finished with Dr Wheatley by the afternoon tea break.

THE CHAIRMAN: Thank you. On that basis, it looks as if the four witnesses you have arranged for tomorrow will use up most of the day and hopefully it will not have us sitting late or anything.

MS SULLIVAN: No, it will not have us sitting late and I do not think that Dr Palmer on Friday will have us sitting late on Friday either.

THE CHAIRMAN: We are all thinking of terms of being able to get away at a reasonable time on Friday because there are many people who have travel to accommodate, so that will be fine. The suggestion is that we break now and return tomorrow morning at 9.30. We will do that; we will meet again at 9.30 tomorrow morning.

(The Panel adjourned until 9.30 a.m. on Thursday, 5 June 2008)
The page contains a document from the General Medical Council's Fitness to Practise Panel, held on Thursday, 5 June 2008 at St James’s Buildings, 79 Oxford Street, Manchester M1 6FQ. The case concerns doctors Stephen Andrew Spencer BM BS 1976 University of Nottingham, Registration No: 2305893, David Patrick Southall MB BS 1971 University of London, Registration No: 1491739, Martin Philip Samuels MB BS 1981 University of London, Registration No: 2732178. The panel members include Mr D Kyle (Chairman), Mrs V Brickley, Mrs S Hollingworth, Dr T Okitikpi, Dr M Sheldon, Mr A Forrest (Legal Assessor).

MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hempsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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THE CHAIRMAN: Good morning, everybody. We continue with the case of Dr Spencer, Dr Southall and Dr Samuels. Ms Sullivan.

MS SULLIVAN: Sir, the first witness is Gillian Hulme, who is the mother of Patient 11, who is a daughter.

THE CHAIRMAN: Thank you very much.

GILLIAN ANNE HULME, affirmed
Examined by MS SULLIVAN

Q Good morning, Mrs Hulme. Would you mind starting with your full names, please?
A Gillian Anne Hulme.

Q Mrs Hulme, as the Chairman has indicated to you, we want to ask you about the birth of your daughter, Patient 11, who was born I think at North Staffordshire Hospital. Is that right?
A That is right.

Q On 17 November 1991?
A That is right.

Q Was she your first child or had you had other children?
A No, she was my first.

Q At that time, Mrs Hulme, in 1991, where in fact were you working?
A Ward 23 at the North Staffs Royal Infirmary.

Q What sort of ward was that?
A Neurosurgery.

Q In what capacity were you working?
A Health care assistant.

Q Did you have any formal nursing qualifications?
A No.

Q But working on the ward that you just told us about, neurosurgery, how much responsibility were you given?
A We were given quite a lot actually, more so than health cares on other wards because it was classed as an acute ward and we were always short-staffed. We were trained well. We were trained by the nurses and the sisters.

Q Yes, I think you carried on working at the hospital. Is that right ...
A Yes.

Q ... for a number of years I think until 1996?
A That is right.
A
Q Going back to the time when your daughter was born, were you due to go on night duty when you started getting what you thought were cramps?
A Yes, I was.

Q As a result, were you admitted to a ward?
A Eventually, under much reluctance from me, yes.

Q Did they then monitor you?
A Yes.

Q Were you told that you had in fact gone into labour?
A Yes.

Q How many weeks pregnant were you by that stage?
A 28.

Q So not therefore expecting, obviously, to give birth at that time?
A No.

Q I think the cramps subsided after a while?
A Yes, yes.

Q Were you soon in fact in the delivery suite?
A Yes, I was.

Q What sort of delivery was it for your daughter?
A Normal. Normal.

Q What did you have to cope with the pain?
A I think it was gas and air, the normal, but to be honest I did not really - it was that quick I did not need it that much.

Q So she was born very quickly?
A Very quick.

Q After her birth, was she taken straight out of the delivery suite to be looked after?
A Yes.

Q When was it that you went to see her for the first time?
A I cannot remember exactly. I know I went to have a bath because obviously you have to give them time to set things up, the staff to set things up down there. So I had a bath and then - I could not really say - it was early mornings and I went down to see her.

Q Yes, because I think you were probably on the second floor. Is that right?
A I think it was. I could not swear but I think it was.

Q Were you able to walk down yourself and see your daughter or did you need a wheelchair?
A They make you have a wheelchair, although I could have walked.

Q Whereabouts was your daughter?
A She was in special care.

Q Is that on the ground floor?
A I think it is, yes.

Q How did she look when you first saw her?
A A cross between a baby doll and a skinned rabbit, to be honest, because she looked so downy.

Q Yes. Was she in an incubator?
A Yes.

Q What sort of incubator?
A Well, just the normal incubators, connected to loads of tubes and a ventilator and that.

Q Yes, and she was being monitored?
A Yes.

Q How would you describe your state of mind at that time? Were you able to take in what was happening?
A No, it was shock.

Q Did she remain in that incubator for any length of time?
A Yes, she - if I can remember - I cannot remember but she was in - I would not say - it depends what you mean by length of time. It was probably a matter of days.

Q I was just going to ask you of your recollection of how long she was in the incubator.
A You are probably talking days.

Q How did she progress during that time?
A I was told very well.

Q Do you recall a time when anyone came to see you about her?
A In what respect?

Q Did she remain in the incubator?
A She did, yes, yes.

Q Did that change at any time?
A Only when I was asked about the CNEP.

Q That was what I want to ask you about, Mrs Hulme. At what stage do you recall being asked about CNEP?
A Oh, I really cannot remember. I mean, from when she was born to when she came
home you are talking about four/five weeks tops, so it is during that time, obviously. I would say probably - I could not say. I really could not.

Q Are you able to say how long after she had been born, approximately, you were approached and asked about CNEP?
A I cannot remember.

Q Do not worry. Can you help at all as to who approached you?
A Oh yes, yes. It was a nurse actually. Katy her name was.

Q How can you be so confident it was a nurse?
A Because we went to school - well, she knew my brother better than me but we went to school together.

Q In fact, you know not just her first name, but ---
A Katy Grocott.

Q Katy Grocott as she was then?
A She was then, yes.

Q What did she say to you?
A I am assuming it was words along the lines about the trial and that my daughter would benefit from it.

Q Did she explain to you how your daughter would benefit?
A If she did I am afraid it is just - when they bombard you with so much, it is just over your head.

Q At that stage, when you were approached, how was your daughter doing in terms of her breathing?
A As I thought, okay. Well, she had still got the help with the breathing.

Q Was anything said about how the trial might help or not?
A Again, I just honestly cannot remember.

Q Do you remember whether any explanation was given to you about a CNEP tank?
A If it was, I mean, I have obviously signed things and if it was I cannot - I just cannot remember. You are talking 16 years ago.

Q Yes. Let me just ask you about the form that you signed, Mrs Hulme, because you agreed to your daughter going into the trial. Is that right?
A Yes, yes.

Q What was your understanding of what you were agreeing to in terms of treatment?
A It was just the fact that it would help with her breathing and she would come home that much quicker.

Q What would help with her breathing?
A This new tank.
A
Q Had you seen the tank at all ...
A No.

Q ... before you agreed?
A No.

B
Q Or any babies in it?
A No.

Q Or any information about it?
A If I did, I cannot remember.

C
Q Let me ask you, please, just to look - and we are going to show you the original of a consent form. If you have the original and we will look at the copy we have, which is at tab 3, page 396. (Same handed) I think you were shown a copy of this, Mrs Hulme, when you made your statement. Is that right?
A Yes. That is my signature anyway, yes.

Q Yes, I was going to ask you whether that is your signature and you said that it is.
A Yes.

Q Apart from the signature there, is any of the other writing on the form yours?
A No.

Q Have you any recollection of actually signing it?
A No.

D
Q Now you have referred to how you spoke to Katy Grocott, a nurse. Apart from speaking to her about the trial, did you speak to anyone else about it?
A Not that I can recall, no.

Q Any doctor?
A No.

E
Q Again, just whilst we are looking at documentation, perhaps you could just be given file 1, please. (Same handed) Behind tab 3, page 336, I think again you were shown this, Mrs Hulme, when you made your statement. Is that right?
A Yes.

Q Have you any recollection of seeing it before that time?
A No.

F
Q Again, if you turn forward to page 341, in the top right-hand corner - it is a bit blurred by the copying - but it is an information booklet for parents that goes through to 364. Have you any recollection of seeing that?
A I probably had it but I just cannot remember.

G
Q I think, just to be clear of the chronology, your daughter was born on
17 November 1991?
A Yes.

Q Do you recall seeing any information at all prior to signing the consent form?
A Not that I can remember.

B Q As far as the tank that your daughter was in - because I think your daughter received CNEP. Is that right?
A Yes.

Q Was there anything on the tank by way of information that you recall?
A Again, if there was, I cannot remember. I cannot remember seeing anything.

C Q If we just go forward to page 397, I think again you were shown this when you made your statement, Mrs Hulme?
A That is right, yes.

Q It has your daughter’s name at the top. Is that your handwriting or not?
A No.

D Q Then various answers there have been ringed. Have you any recollection of completing that form either?
A No.

Q As far as your daughter’s father was concerned, was he there at the hospital?
A Not at the actual birth, no, because we were not together at the time.

E Q Did he come in at some later stage?
A Oh gosh, yes.

Q But I think he has now passed away, is that right?
A Yes.

MS SULLIVAN: I have no further questions. If you wait there, there will be some more for you.

Cross-examined by MR FORDE

Q My name is Martin Forde and I am acting for Dr Spencer. I just wanted to ask you a very few questions about the birth of your daughter. The first matter I want to deal with is time. You said, at least on one occasion, this is 16 years ago?
A Yes.

Q Would it be fair to suggest that you have some difficulties in recollecting precisely what happened around this time?
A I think anybody would.

Q We have been looking at some of the contemporaneous notes and I just want to explore with you whether or not you think certain things could have happened but you
might have forgotten them in the interim. You clearly have a clear recollection of having a conversation with the nurse whom you knew from schooldays about CNEP?

A Yes. Well, I think you would do because she was---

Q Somebody you knew?
A Somebody you knew, yes.

B Q What I want to suggest to you is you obviously were not necessarily on friendly terms with the medical staff working within the neonatal unit. You obviously knew the staff working where you worked?
A Yes.

Q And you knew your friend who was the nurse from schooldays. If I were to ask you about Catherine Wildig as a doctor, would that name ring any bells with you at all?
A Only what I have seen there.

C Q Just looking at the form – because we have heard from this doctor already giving evidence – you will see that it makes it clear that it is a study CNEP trial, do you see that? If you go down, she has put her name and your daughter “Baby girl Hulme” and then she has put another name above it?
A Yes.

D Q With a different surname – yes?
A Yes.

Q Do you understand why the surname might be different there? Sorry, I had not understood. Those are two Christian names?
A That is two Christian names.

E Q That is right, is it?
A That is right, yes.

Q So she has got that correct, and she must have got that information from you presumably?
A Yes.

F Q Then she is suggesting in the first paragraph that she has explained “The aims and procedures of the investigation in which the person named above is to take part” – that is obviously your daughter?
A Yes.

G Q Then she has dealt with some further information. She says that you have been given the opportunity to ask questions and consider the answers given; that the study is voluntary and you can remove your daughter if you wished – do you recall anything along those lines? No?
A No.

H Q It goes on to say, to get you to sign a form – I think you have confirmed that is your signature on the day that your daughter was born?
A

Q    That you are giving fully informed consent – as a nurse, presumably you had witnessed the taking of consent before, had you?
A    Yes.

Q    So you understand the importance of it. Would you accept this, that it is unlikely that your daughter would have been entered into the CNEP trial unless you had agreed to it?
A    Yes, she would not have been, would she?

Q    What you say very fairly in your witness statement is this, that:

    “I agreed that she could go into the tank. I was blasé about it. As far as I was concerned, the medical staff knew what they were doing and I left it in their capable hands.”

A    Yes.

Q    Do you think that might be another reason why you may not have a recollection of a conversation between yourself and this doctor about the trial; that from your point of view you are taking what you want – “Yes, doctor, if you think it might be a good idea in the future that’s fine by me”?    
A    I think that is what you would do, would you not? At the end of the day they are the experts, same as you would expect the ward I worked on as the patients to take what ours said just the same.

Q    I do not think you are saying, are you, that this a forgery---
A    Oh gosh, no.

Q    …or the conversation could never have taken place?
A    No, no, no.

Q    I think it is just that you do not yourself remember?
A    I just do not remember, no.

Q    We have got a clinical note (which if anybody needs to see it, it can be shown). One of the doctors has written a note on the 17th which says “Thank you. 29 weeks gestation. Normal vaginal delivery” – which I think you have told us was correct?
A    Yes.

Q    Do you mind me mentioning your age then? It says “Mother 34 years old”, was that correct?
A    No, I had just gone 35, had I not?

Q    “Good condition at birth. Good heart rate”. Then, “Transferred to the special care baby unit on a ventilator”, then various other entries. Then right at the bottom of the page I have got it says “Consent for CNEP”; that is a doctor writing in a clinical note that they sought your consent for CNEP, but you do not remember that?
MR FORDE: Mrs Hulme, thank you very much. That is all I ask.

Cross-examined by MISS O’ROURKE

Q Mrs Hulme, I ask questions on behalf of Dr Southall. I am guessing that you do not know Dr Southall and that he never treated your baby? You do not remember him, you do not recognise him?
A No, I am sorry.

Q Your child was born in November 1991?
A Yes.

Q And was in the hospital, I believe, for a couple of weeks?
A Probably four or five at most. She was discharged before Christmas.

Q Dr Southall did not in fact come to work in the hospital until 1992, so you would have had no dealings with him?
A So I would not have seen him anyway, no.

Q You have therefore got no complaints about him?
A No.

Q Do you have any complaints about any of the doctors who treated your daughter in hospital?
A No.

Q And you have no complaints about CNEP?
A Absolutely none.

Q And you were very happy with the treatment that your daughter had in hospital?
A I have got a thriving 16-year old who is doing GCSEs now and she is very clever, so I have got nothing to complain about.

Q No complaints at all?
A No.

Q You said that you had a normal delivery on gas and air but you said “I didn’t actually have the gas and air for very long because it was very quick”?
A That is right, yes.

Q So you did not have any morphine or any other drugs---
A Oh gosh, no.

Q Therefore, after the birth you were as right as rain, or as right as rain as you can be?
A Yes.
Q So if you saw a doctor within three to four hours after birth, other than being tired because it was late at night you would be absolutely fine to talk to a doctor?
A I would have been.

Q Just to confirm this – Mr Forde asked you – that is your signature on the form?
A Yes.

Q You are not saying it is forged?
A Oh no.

Q If a doctor gave evidence, as she did when she was here two days ago, to say she would not have signed her name on the bottom unless she had had a conversation with you. You would accept that it is more likely than not she had a conversation with you?
A She probably did.

Q And you have simply forgotten it?
A Exactly, yes.

Q The form I think you have got in front of you, you will see it signed on the same day as your daughter’s date of birth. Is that your daughter’s date of birth on the---
A Yes, yes.

Q Your daughter was born at teatime, was she not, or after teatime I think you said?
A 1.35 in the morning, so early Sunday morning.

Q In which case we have a log which shows that the phone call was made by the doctor to somebody about the trial at 4.30 in the morning, so that would be three hours after your daughter’s birth?
A Yes.

Q Therefore this doctor would have taken your consent some time before 4.30 in the morning?
A Yes.

Q Is it possible that that happened and you just do not remember?
A There is that much going on.

MISS O’ROURKE: Thank you. I have no further questions.

MR FOSTER: Nothing from me, thank you.

Re-examined by MS SULLIVAN

Q Mrs Hulme, is there anything on the back of the form that you have there?
A No.

Q What is your recollection of how much you saw doctors as opposed to nurses during the time that you were in hospital with your daughter?
A I cannot recall at all. At the end of the day, it is a very busy unit and they are
milling about everywhere. I think because I knew Katy and I knew Pat, another lady who worked there, I tended to have more to do with them and conversations with them and they relayed things on to me. That is the only way I can remember things.

MS SULLIVAN: Thank you.

Questioned by THE PANEL

DR SHELDON: Good morning. You started off by saying that it was this girl, the nurse, Katy, who you knew, who approached you about – did you say putting your daughter into the tank?
A Yes.

Q Do you remember when that was?
A I cannot. I honestly cannot.

Q Was that at the time when your daughter was actually put into the CNEP tank? Can you remember that?
A No. I know she was not in it for very long – that is all I know, that she just was not in for very long.

Q Have you talked with Katy about this since?
A I have never seen her.

Q You have never seen her since?
A Never seen her. I have never been back to special care.

DR SHELDON: Thank you very much.

THE CHAIRMAN: No-one else has any questions for you, Mrs Hulme, so that completes your evidence and it only remains for me to thank you for coming along this morning and for the assistance you have been able to give us. Thank you very much.

(The witness withdrew)

MS SULLIVAN: Sir, the next witness is Dr Morgan.

COLIN MORGAN, affirmed
Examined by MS SULLIVAN

Q Good morning, Dr Morgan. Would you tell us your full names to begin with?
A It is Colin Morgan.

Q Dr Morgan, what are your qualifications?
A BM BS from Nottingham, BMed Sci, an MD from Keele and MRCP from London and FRCPCH.

Q I think you are currently a consultant, is that right?
A Yes.
Q A consultant paediatrician?
A Neonatologist at the Liverpool Women’s Hospital.

Q I think you have been there since 2004?
A Yes.

Q When did you qualify?
A 1989.

Q I think thereafter in the usual way you had house officer jobs?
A Yes.

Q I then want to ask you about the time when you came to North Staffordshire, to Stoke. When was that, Dr Morgan?
A August 1990.

Q In what capacity did you come to work at Stoke?
A That was my first senior house officer job in paediatrics and it was a two-year rotation.

Q Was that your first position in paediatrics?
A Yes.

Q You were there for two years?
A Yes.

Q On your senior house officer rotation?
A Yes, although in the second year you became a senior senior house officer and acted on the registrar rota.

Q Then following that did you spend a further two years as a registrar in Stoke?
A Yes, until June 1994.

Q Then thereafter you took on various appointments – I do not need to ask you about those at the moment because obviously the time we are concerned with is the four years that you spent in Stoke. At the beginning of your rotation, so in the first six months as an SHO in Stoke, what were you doing?
A I was attached to the neonatal unit.

Q Were you responsible then for clinical care of the babies on the unit?
A Yes, as part of a one in three rotation with two other SHOs.

Q Then for the remainder of your time as an SHO what was your involvement in the neonatal unit?
A From February 1991 for six months I did general paediatrics, so there was no neonatal involvement at that time, and then from August 1991 I was on the registrar on-call rota. I was not attached back to the unit in terms of daytime cover but I would have been doing night-time on call from August 1991 until I left in 1994 because the
subsequent post was also essentially providing on-call cover for the neonatal unit.

Q Can you recall how often you would have been on call?
A One in four.

Q Was it one in four throughout that time?
A I think so, yes. It may have got a little bit better but was around that sort of level of commitment.

Q We know that Dr Spencer and Dr Brookfield were consultants on the unit?
A Yes.

Q As far as the SHOs with whom you were working, can you identify any of those?
A Kate Wildig was my…there are two SHOs appointed on each two-year rotation and Kate Wildig was the other half of my appointment.

Q I think you were followed by Claire Stanley?
A Claire Stanley and Sarah Edwards, from what I remember.

Q Do you remember other members of the team?
A Obviously the ones that we had most contact with were those immediately preceding us on the rotation and that was Julia Nitrich(?) and Lydia Bowden, and then obviously having been there for four years there were quite a lot of doctors coming and going.

Q I am not going to ask you about all of those. In terms of Dr Southall and Dr Samuels, were you there when they came to Stoke?
A Yes, I do not know exactly when it was but I think it was 1993 at some point.

Q Prior to them actually coming to Stoke did you have any contact with them?
A I think there was a lead up to it, partly because whenever an academic department is being established clearly the links are there but I am sure they must have come and presented at meetings and things but I cannot recall any formal contact.

Q As you know, this Panel is concerned with the CNEP trial and I want to ask you about that, Dr Morgan. When you arrived on the neonatal unit – that was in August of 1990. Is that right?
A Yes.

Q At that stage had the trial started?
A Yes.

Q Was it something that you had come across before, CNEP, or was it new to you?
A It was new but then so was neonatology.

Q In fact had you come across a conventional incubator before that time?
A Only as a student, so very brief contact.

Q Did you receive any training in relation to the use of CNEP?
A The training came as part of an apprenticeship, which is how we learned really all our clinical skills, so I received the same training for the CNEP as I would have done for conventional incubators and ventilators and all the other equipment that we used at the time. That is how we learned our clinical skills.

Q So you learned them as you were going along?
A It is difficult, I cannot identify any specific training for CNEP. I do not recall whether there was a specific training exercise.

Q How did you learn to work with CNEP?
A The same way as I learned all my other clinical skills, which was working with the other, more senior doctors under supervision until we got to the point where we could manage patients safely in whichever environment they were in and that point obviously varies according to whichever particular clinical skill you are acquiring.

Q Do you remember any of the nursing staff and their involvement in CNEP?
A I remember the nursing staff, obviously having worked there for quite some time I remember the nursing staff reasonably well.

Q Let me ask you this. When you first arrived on the unit, when you were a new SHO, as you have told us, did you at that stage discuss the trial with any parents with a view to obtaining their consent?
A Not as an SHO, I do not think, no. Not at SHO level.

Q At what level do you think you were when you got involved in that process?
A I am pretty certain it would have been once I was on the registrar rota, so it would have been from August 1991.

Q At that stage when you were on the registrar rota in 1991, how did you gain your understanding of how CNEP operated?
A I think we had regular protected teaching sessions for all aspects of clinical care and I recall that CNEP was part of that general learning process and, as I say, the rest of it really came from apprenticeship and as SHOs, although we would not be taking consent, in the early stages of our training we would actually see people who were doing it and how things were explained and so we learned that process and how to approach the situation from our more senior colleagues.

Q Yes. I wonder, it might help actually if you just have a look, Dr Morgan, at a log that we have. There is a file just to your left there - if we look behind tab 3 at page 367. Did you see these when you were making your statement?
A I have seen extracts of logs. I do not know whether I have seen this particular page.

Q This page is, I think, the beginning of the log for the trial in Stoke and I think what we need to do is just look at the name of the caller there to see whether your name appears. I think on that first page, at page 367, I do not think I can see any reference to your name there. Is that right?
A Yes.
Q If we go over the page to page 368, we see reference to your name, Dr Morgan, as the caller?
A Yes.

Q On 22 September 1990 – do you see that?
A Yes.

Q What would you have been at that stage?
A I would have been an SHO.

Q Then if we go over I do not think we see your name on the next page, page 369. Is that right?
A That is right, yes.

Q Page 370 I think we see a couple of references to you, Dr Morgan, on 6 August – I do not know whether it is July or August, it must be August – 1991, there seems to be a reference to you and again on 17 August 1991 and at that stage what would you have been?
A Registrar level, senior SHO.

Q Senior SHO?
A Senior house officer, as it was called.

Q Then I think there is another reference to you on 21 October 1991 on that same page and would you then have been on call?
A Yes I would have been – I think the times of those are – there is one at three o’clock in the morning on 6 August you have described there and one at four o’clock in the morning, so I think it is clear that I was on call at that stage.

Q Yes. I think the other one is in the middle of the afternoon?
A If there was a Saturday or a Sunday or a Bank Holiday.

Q Of course.
A Then I would still be there.

Q Again, if we turn over the page to pages 371, we see your name featuring again, do we not, on that page?
A Yes.

Q Particularly in February of 1992 there are two, I think, consents there?
A Yes.

Q A further one in April 1992 – a further two, actually, in April 1992?
A Yes.

Q You would then have been in what capacity?
A Still on the registrar level rota.

Q Then finally I think on the next page we see again a couple of references to you
taking consent in June 1992 and September 1992?
A Yes. As I understand it, the log is of a caller and in most cases that would be
equivalent to the person who has taken consent, but it is presumably feasible for
somebody to have taken consent and then with the person on the end of the phone calling
on their behalf once the consent had been established as part of the team that were on call
at that time.

B Q Yes.
A It depends on what workload was going on.

Q Yes, of course.
A Because this essentially is the randomisation process rather than a record of who
was getting consent, although normally they would be very closely related, obviously.

C Q Let us go back to the consenting process and what I want you to do is to think
back and to tell us how you would have conducted that process in relation to the CNEP
trial when you were working at Stoke. What would you have said to parents when you
were taking consent?
A Obviously it is a long time ago and the recollection of that process is going to be
affected by consent and processes that I have taken subsequently because one’s process
of taking consent is always going to be modified with time, so obviously trying to recall
back to how you performed things when you were first taking consent is going to be a
little bit difficult, but I think that the standard process would be to approach one or both
parents, depending on how they were after delivery. Obviously some mothers were not
able to talk and discuss things with you fully so we would approach the father in those
situations, but ideally we would approach both parents.

Q Can I just ask you to pause there? In what circumstances would you envisage
approaching the father and not the mother?
A I think if we felt that the mother was not able to communicate with us fully or
because of recovering from either delivery or an operative procedure.

Q So, for example, women who had had Caesareans, what would be your approach
to them?
A I think it maybe depends what anaesthetic they have had and what stage of
recovery they were in but I think we would do our best to involve both parents and I
would have anticipated that even if the mother was recovering we would want to discuss
things with the father present and the mother present. We would not take the father away
from the mother to have the discussion but we would accept that there would need to be
both parents there if we felt the mother was still in the recovery stage. It was not that we
were excluding the mother from the process; just that we wanted to ensure that there was
as much understanding from the parents as was possible under the circumstances.

Q Yes.
A This all relates to the difficulty of obtaining consent within the first four hours.

Q That is right. That was what was needed in this particular case?
A Yes, and we just had to deal with the situation as best we could and make our
judgments as, indeed, we did for all the clinical decisions and passing information on. In
any other clinical decision we were making that would also be the case, that we would be
talking with the parent that was most able to communicate with us effectively but ideally
both parents at once.

Q How easy was it to explain the process of this trial, which we know involved
randomisation?
A I think the concept of randomisation is still quite difficult for parents to grasp
simply because you are explaining that you are investigating a new treatment, that you
hope that treatment will improve things but that we do not know that it does and in order
to understand whether it improves the baby’s care – in this case the breathing support – it
is necessary to do this sort of study where we look at those babies who received the
standard treatment versus the new treatment. Having explained why the trial is being
conducted, you then have to explain that the baby may well not receive the new
treatment. In fact that is often the bit that is hard for parents to grasp.

Q Yes, and from your experience in taking consent at this sort of stage, how easy is
it within a few hours of what is obviously an emotional time for parents, how easy is it to
convey these concepts to them?
A It is difficult. It is not easy at all and I think every study in neonatal medicine that
has investigated treatments that are required within the first few hours, and often they are
the most critical treatments, it is difficult to obtain consent in the way we would like if we
had more time to work through the process. If you have got two or three days then you
would leave the information with the parents and let them think about it for a much
longer period and I think that is the ideal for all studies, but if you have got to initiate the
treatment from the outset, you have to make some sort of judgment and compromise as to
how to get that information across and how you establish a level of understanding that is
acceptable for you to then go on and randomise the child.

Q So what sort of compromise would be envisaged in a situation such as this?
A Simply the time scale and the time that the parents have to think.

Q As far as your recollection is concerned, Dr Morgan, was there any written
information for parents?
A Yes.

Q Was there any written information for them to keep?
A I am pretty certain there was, yes.

Q How would you have described the type of treatment that CNEP delivered as
opposed to standard treatment?
A I think the way it was described was as a different form of breathing support that
would mean that we would not either have to ventilate a patient or would not have to use
as high a pressure to ventilate a patient.

Q In explaining about the trial, would you tell parents about advantages and
disadvantages or not?
A I think we would. It is very difficult this far on to recall your specific process and
each individual potential complication but I think the key thing that one tries to get across
is that we do not know whether the treatment is actually going to be better or not and I
think the focus tends to be on that in the time scale that one has.

Q  Were you aware of any disadvantages at the time?
A  I think that is quite hard for me to recall.

Q  In terms of the neck seal were you aware of anything?
A  I was aware with the neck seal and I cannot really remember whether that came into the consenting process or whether that was part of an understanding that we developed having watched babies being managed by the nurses on the unit. We were aware that there was a special procedure for sealing the neck and that it was something that was clearly different to things that we had seen in other incubators and so on and so the reasons for using that special seal were discussed by the nurses. That is part of our understanding of how things were. How that was incorporated into consent discussions I cannot recall specifically.

Q  Yes. Do you remember what potential problems may have been highlighted with the neck seal?
A  I know there was concern about trauma to the skin of the neck. Wherever you have got a seal or a pressure point on a patient, especially a baby, where the skin may be a little bit more delicate, there is always a concern that that area of skin may be damaged. I do not really recall seeing any episodes of that but were aware that that had been an issue from previous experience with the tank.

Q  I think you indicated you were not aware of seeing anything like that at Stoke?
A  No.

Q  Were you aware of any incident having taken place elsewhere where there was a problem with the neck seal?
A  I think that was discussed but that came up as to – there was quite a procedure in putting the Spenco gel around the neck and everything else and because it was quite a lengthy nursing procedure it is inevitable that people discuss why is that necessary and as an SHO before you are even involved in the consenting process you learn that that is what you do and why you do it and I am sure that the previous cases have experience from previous use and early use of the tank came up in discussion.

Q  Yes, I think when you made your statement you were shown a picture of a baby ...
A  Yes.

Q  ... from Queen Charlotte’s who had suffered neck trauma. Were you aware of that at the time?
A  It is difficult to be certain about a specific case and the trouble is, having been shown the picture, you are aware that there were discussions, but I cannot recall whether we were shown that particular case or not.

Q  You cannot recall that particular case, but do you recollect any discussions about the potential for neck trauma?
A  Yes, as part of the whole - as our whole training. As I said, the procedure for dealing with the neck was very distinctive and therefore that led us on to discuss why that was necessary.
Q Why was it necessary? What could happen to the neck?
A Trauma to the skin and pressure points.

Q Did you see any problems with the neck at all? I know you have indicated nothing of the nature that occurred at Queen Charlotte’s, but did you see any problems with the neck at all?
A No.

Q As far as the babies in the trial were concerned, was there anything on the CNEP tanks to indicate whether the babies were in the trial?
A Yes, there was a sort of A5 sticker of a bear that said, “I am in the CNEP trial”. I am pretty certain that the control group in standard therapy also had a sticker.

Q Yes, I am going to ask you, please, just to look at some documents whilst we are considering the consent process. I wonder if you could just take up, please, file 3 that we were looking at before and just go back to page 336.
A I have page 337. I presume 337 - is that the parent’s leaflet?

Q 336 it should be. The previous page.
A Yes, sorry.

Q It is a bit difficult to see.
A There is a 330 at the bottom, which is confusing.

Q Yes, there is. Just look at the numbers at the top, if you would not mind, Dr Morgan. Do you recognise that at all?
A It is difficult to recall any of the documentation specifically.

Q Can I just ask you to look at 341 in the top right-hand corner - it is a bit difficult to see - through to 364? Have you any recollection of this?
A I am aware that there were information booklets around but, beyond that, I cannot specifically say whether this was the one that I saw. It is just too long ago to be definite really.

Q These are entitled “Information Booklets for Parents”. Apart from any information for parents, was there any other information on the ward that you recall? If you cannot, just say so.
A It is difficult for me to recall, but I am pretty certain there was some guidance in terms of eligibility criteria and everything for that, because we used that information as part of the process.

Q We see, for example, some reference to the criteria at page 340. Would you, at the time, have been aware of the criteria for whether a baby should be entered into the trial or not?
A Yes, I think obviously once you have done it a few times you are aware of who is eligible and who is not, although one always checked up before one then went on to the process of getting consent.
Q Once the babies were entered into the trial, what sort of monitoring of them took place?
A The monitoring, from what I recall, did not differ to the monitoring that one would use in conventional treatment. Indeed, to meet the requirements of a trial where you are randomising patients to receive a standard treatment and a new treatment, it would be quite important for the monitoring to be the same.

Q Yes. In terms of when you took consents from parents, what is your recollection of whether they consented to their babies going into the trial or not?
A I am not quite sure what specifically you are asking.

Q The parents that you took consent, did they agree or not to their babies going into the trial?
A On the whole I think there was agreement, but I did not really have a feel for whether we got a lot of people refusing or not. I do not think individually we consented enough to have much of a feel for that.

Q How many times are we talking about you consenting over this period of time? Does the log that we looked at accurately reflect the number of times?
A Yes, I mean from there it was identified probably about somewhere between nine and twelve patients in the space of a year and 18 months or so on what we have just looked through. It is difficult to be certain from that what the sort of uptake was in terms of agreeing to consent to the study.

Q I am going to ask you about a particular patient and your involvement with her. We are calling her Patient 6. I am just going to let you have a piece of paper there to show who we are talking about and to ask you to refer to her in the same way.

(Same handed) Do you recognise that name, Dr Morgan?
A Yes.

Q I am not going to ask you to recollect obviously without looking at the medical records. Perhaps if we could put file 1 to one side and take up file 2. We need to go behind tab 5. There you will find the medical records for this patient, Dr Morgan. If you just turn over to page 1, just to familiarise yourself. She was born on 14 December 1992. Do you see?
A Yes.

Q And discharged from hospital on 7 January 1993. Therefore, as far as any involvement in her care was concerned, at that time would you have been a registrar?
A I would have been, yes, and on the registrar on-call rota.

Q Therefore, you would not have been involved in her day-to-day care?
A Day-to-day care, no.

Q But I think you know from having looked at these notes previously that you did see this little girl on some outpatient appointment ...
A Yes.
Q ... when you were a registrar?
A That is right.

Q Just before we have a look at those, could we just, please, have a look at page 161 and 162? The numbers are now at the bottom right-hand corner.
A Yes, I have those.

B Q We see there the results of two ultrasound scans for this little girl. Would you have been aware of those when you were seeing her after she had been discharged?
A I would presume that they would be filed in the notes. I mean, it is difficult to know, but one would expect them to be available in the outpatient notes or perhaps a summary of them.

C Q Yes. If we look forward - sorry, if you go back a minute again. Just keep your finger in there a moment and go back to page 35 behind tab 5. It is cut off slightly at the top, Dr Morgan, but we know that that first date there is 22 September 1993?
A Yes.

Q The second date there appears to be 19 January 1994. Are those your notes?
A They are.

D Q Do they relate to seeing this little girl in outpatients after her discharge from hospital?
A Yes.

Q If we just look back over the previous couple of pages, were you involved at all in seeing her prior to those dates, according to the notes?
A No.

E Q Let us look at what you would have done when you did see her on 22 September 1993 and 19 January 1994. It might help you just to look forward to the letters that you wrote following those outpatient appointments. If you would like to turn on to page 195.
A Yes, I have that, thank you.

F Q Does that refer to the clinic on 22 September 1993?
A It does, yes.

Q Are you there writing to the general practitioner?
A Yes.

G Q And reporting about how this little girl was doing at that time?
A Yes.

Q How was she doing at that time, looking at a combination of your note and the letter?
A Her development was acceptable, so was within the normal range. Although it does sort of comment she is not sitting but her tone seems within normal limits. Although it is within the normal range, it is clearly something that needs monitoring, which was why she was reviewed again four months later.
Q Yes, so reviewed again on 19 January. If we go on, we see at page 196 you were asking for a consultant ophthalmic surgeon to look at a squint at that stage?
A Yes.

Q Then we go on and we see a report from Mr Brown and then we see reference to the clinic on 19 January of 1994 at page 200?
A Yes.

Q How was she developing at this stage?
A Her development had stalled really and her development progress was actually very poor from her last visit. At this point she quite clearly had developed mental delay.

Q Yes, and was her mother expressing concern about her degree of development at that point?
A She was. Mother had clearly identified that there was a problem and I agreed with her.

Q Obviously you were registrar to Dr Spencer at that stage. Would you, in the course of outpatient appointments of this type, have had access to Dr Spencer if you wanted to speak to him at all about a patient?
A Yes.

Q In relation to this case, can you recall whether any such discussion took place or not?
A No. It is not specifically noted in the letter, but it was such a routine thing to do, particularly if you had identified a problem. The fact that there is a referral to the child development centre would indicate that I would have discussed it with Dr Spencer. That is what you would do.

Q You would discuss it?
A Yes.

Q Again, I asked you earlier whether you would have been aware of the results of the scans at the time of these appointments. Would you have had all the patient’s notes? What would the position be?
A That would usually be the case, yes.

Q Would you have spoken to the parents about them yourself?
A The scans?

Q Yes.
A I do not think at this point you would be discussing scan results specifically, unless that came up in the conversation. I think the focus here is on what clinical findings are identified at the time and what they meant. The focus of the discussion is on that and where to go from there really. There is no other information in my correspondence in terms of whether I had any discussion about the scan, so it is difficult for me to recall ---
Q  It is difficult for you to say what would have been discussed or not?
A  Yes.

Q  I am sorry, there is just one other matter I wanted to ask you about, the trials. Just going back a moment and then I will sit down. Do you recall whether surfactant was used in the trial?
A  I am pretty certain it was, yes.

MS SULLIVAN: Thank you. I have no further questions, but there will be some more for you.

MR FORDE: Sir, I am going to be some time with this witness. I do not know whether you want your morning break now. I will be probably about 45 minutes to an hour.

THE CHAIRMAN: Thank you, Mr Forde. I think it would be sensible if we are going to have a break to have it now so that we do not interrupt the flow of your questions. Let us have a break now, 15 minutes, quarter-past eleven. We will take a break, Dr Morgan.

(The Panel adjourned for a short time)

Cross-examined by MR FORDE

Q  Good morning, Dr Morgan. My name is Martin Forde. I am going to be asking you some questions on behalf of Dr Spencer. What I will try to do is to introduce topics so that you can orientate yourself in terms of the areas that I wish to explore. The first area I want to explore with you is difficulties of recollection. You have been asked I think about events going back into the early ‘90s. Would it be fair to suggest to you that there are occasions when it is difficult for you to give evidence of your recollection, secure in the knowledge that it is not tainted by any after acquired procedures, particularly in the area of consent?
A  I think that is absolutely the case, yes. I think particularly when one starts off early in your training, your skills develop and get fine-tuned. That is part of what training is, so it is difficult to go back and look at things at the beginning.

Q  I am going to come to training as a discrete topic in a moment. I just want to ask you about your career. You qualified, you tell us in your statement, in 1989. Your first paediatric position was in Stoke in August 1990?
A  Yes.

Q  You then became, in your second year, a senior SHO on the registrar rota?
A  Yes.

Q  Although we have seen an example I think of you making a telephone call when you were a junior SHO ...
A  Yes.

Q  ... we have also seen an example of a telephone call being made in relation to I think it is Patient 7, when it is clear that the consent that was taken was taken by a registrar, Dr Arumugam?
A Yes.

Q Would this be fair: there were occasions, in case anybody is excited about junior SHOs consenting, where the registrar or senior SHO would consent but the junior within the firm would make the randomisation telephone call?
A Yes. As I stated earlier, it is a randomisation log, not a log of consent as such.

B Q One of the reasons for that might be, dealing with the youngest, sickest patients in the hospital, a senior SHO or registrar might be better employed treating a baby who was seriously ill than making a telephone call?
A And at the time the registrar also covered the general paediatric side, which was a fair distance away and so had responsibilities on both sites. The priority obviously was clinical care.

C Q Following your two year rotation, where you move from junior SHO to senior SHO, you then spent a further two years as a registrar?
A Yes.

Q You then worked as a lecturer in Leeds between 1994 and 1999?
A Yes.

D Q Was that a lecturer in neonatology?
A No, it was a lecturer in paediatrics.

Q Then between 1999 and 2004 you were a consultant senior lecturer at the Royal Free Hospital in North London?
A Yes.

E Q Again, is that in paediatrics or in neonatology or both?
A That was in neonatology.

Q Is your current post at Liverpool Women’s Hospital as a consultant?
A Yes.

F Q Is that a job that is split between clinical work and academic work?
A It is not formally, although there is as it is part of the large tertiary centre there are academic and teaching components to any clinical consultant post.

Q Is your job title that of a consultant neonatologist or a consultant paediatrician?
A Consultant neonatologist.

G Q The next matter I want to ask you about is really training in combination with standard treatment, so not trial-specific questions for the time being. In the 1990s, and I would suggest even now, a great deal of the training that you receive is on the job?
A Yes.

Q You assimilate information by observing senior practitioners at work?
A That is right.
Q It is slightly more formal now because you have a lot more form filling to do in 2008, I suggest, and for instance you will have your 360-degree appraisals and matters of that sort?
A Yes.

Q Is it fair to suggest that as concepts these were not around in the early 1990s?
A I think you can say it is very different now for a junior trainee than it was then.

Q When premature babies are born it is often the case, is it not, particularly if they are in respiratory difficulties, that you have to act very swiftly?
A You do, yes.

Q Your absolute priority is to keep that child alive?
A Yes.

Q The suggestion seems to be being made that there is something possibly sinister about parents being pressured within the first four hours of life into consent, and I just want to explore that with you if I can. Given the fact that sometimes premature babies are delivered via Caesarean section, is it not the case that you regularly have to treat neonates when the mother is still anaesthetised?
A Yes.

Q So there will be many instances, never mind, as we have here, a consideration of forms, information sheets and the like, when you are, strictly speaking, treating a child to keep it alive without there being any parental consent at all?
A That is right. You are acting in the interests of the child – that is who our patient is.

Q When you work in this area is it correct to suggest that you have to develop a sensitivity to the parents’ ability to understand information and take it on board during what must for them be an extremely sensitive and concerning time?
A Yes.

Q You will often be working with parents who are distressed, is that correct?
A Always.

Q You will often have, for instance, to broach the delicate subject of whether or not a child should be baptised because you are having to make the parents aware of the fact that the child might not live?
A Yes.

Q You might be having that conversation alongside a conversation about consent for treatment?
A Yes.

Q But you have to develop the skills to ensure yourself that there is an appreciation of that which you are discussing with the parents?
A Yes.
Q I read your statement carefully – you seemed to be suggesting that it is not uncommon for you to find that the parents, because of the stress of the situation, have very real failures of recollection around the consenting process?
A Yes, they do.

Q I think you are able, are you, to confirm that in this way, that you may well be asked questions which you have been asked before, maybe days before by parents, which you have answered, but they do not appear to have taken in the information that you gave at the time?
A That is very common. In fact, when I speak to parents I often say “Don’t worry about asking all the same questions again” – this is not specifically about clinical trials, this is about clinical care. It is quite common for us to have to answer the same questions several times because people’s ability to retain and understand what has been said is limited.

Q Can I just then ask you some questions specific to your training so far as the CNEP trial is concerned, then I want to move on to the quality of information that you had available to you that you communicate to parents. The first topic, training. You say this in paragraph 6 of your witness statement:

(Statement not supplied to shorthand writer)

“I have been asked if I received training for CNEP. I must say that the approach to training back then was very different to the training now. All training then was learnt by watching other people. We were trained on the job. We had a mixture of supervision by doctors of varying levels of experience. You learnt everything by doing it under supervision. Generally supervision was done by the registrar but the consultants were around a lot providing direction.”

You, I think, at one stage were Dr Spencer’s research registrar, is that correct?
A Yes.

Q I have asked Dr Livera this question: would you also be in a position to confirm that he was an excellent trainer?
A Yes.

Q And he took his training duties seriously?
A Very much so.

Q You say this:

“To put the level of supervision I received in Stoke in context, the level of supervision was way beyond that I had received in the house jobs when I was only provisionally qualified.”

Do you stand by that comment?
A Yes.
Q Do you also stand by the comments that you made in your evidence-in-chief about protected teaching, and I just remind you of what you say in your witness statement:

“I have been asked how I came to understand the rationale behind the trial. I was learning from scratch. We were doing a lot of background reading. Our work was a combination of background reading and protected teaching”

and you explain that that concept is one where you cannot be dragged away to deal with clinical problems.

“These involved case presentations and updates of new advancements. I cannot remember if CNEP was discussed in the early sessions but there certainly were sessions where CNEP as a mode of treatment and the progress of the CNEP trial was discussed.”

That is your recollection?
A Yes.

Q Do you recall any seminar sessions with Theresa Wright, who was the research nurse, at the distance in time – and if you cannot, please say so?
A I cannot, although I am aware that she did run all sorts of training sessions for nurses and doctors.

Q You went on to say:

“Even now SHOs would not discuss a trial with parents. It is only at registrar level that you would talk about clinical trials. I would have had some bedside teaching as I was involved in the direct clinical care of babies in the CNEP tank.”

Is that your recollection of how things operated?
A Yes.

Q When you were a senior SHO, I do not think it is a rank that exists now, were you the equivalent of being at registrar level?
A Yes.

Q Just so we can clear that up?
A Yes.

Q Thank you. Your recollection about those involved in consent was you mentioned Julie – is it Nitrich(?)?
A Yes.

Q Lydia Bowman and Nicky Livera, whom we heard from yesterday. Then you went on to describe what you would have done in the consenting process. You say:
“It is very hard because it is such a long time ago. As a result of the experiences of many neonatal research studies, including the controversy that has subsequently surrounded CNEP, the issue of consent has received a lot more scrutiny. It is difficult for me to recall exactly how I would have taken consent as this is going to be influenced by the way I would do it now. We approached parents as soon as babies were stable and we were happy with their condition. I think we would normally update parents on their baby’s condition and consider whether the baby was eligible for the study. I am fairly certain there was written information for the parents and there was definitely a tank that was used to show parents what it was like. Where possible, we would bring one or both parents around to look at the unit. It was very difficult to talk about the CNEP tank without the parents seeing it.”

That is your recollection?
A Yes.

Q Others, I think, are going to deal with the literature that was available. You describe the CNEP treatment as “a potential treatment option”. When you were consenting parents, were you careful to make it clear that you could not at the time of consenting guarantee that they would receive CNEP rather than standard treatment?
A Yes. That is one of the key components of a randomised controlled trial and I think, as I said earlier, it is one of the hardest things conceptually for parents to understand. You explained the rationale behind why you need to consider a new treatment and the importance of looking at it and then you have got to explain why their baby might not receive it, having had the conversation.

Q What you have said about this, and I am looking at paragraph 18:

“I have been told that some parents have said they did not know that CNEP was a trial. I think it was clear that CNEP was a trial because you had to address the issue that their baby might not go into the CNEP tank that you had discussed. You would have to leave the parents and have the baby randomised, then you would return and tell the parents either that their baby would receive CNEP or the usual treatment.”

Is that your recollection of how things operated?
A Yes.

Q Do you think randomisation may have been a difficult concept for the parents to understand?
A I think it is, yes.

Q Have you been involved in other trials?
A Yes.

Q Have you found that it remains a difficult concept?
A It does, yes. The issues surrounding consent, particularly in the first four hours, are just as difficult today as they were then.

Q Would you have consented any parent – it would probably have to be the mother by definition – who was obviously suffering from the after effects of anaesthetic such that you could not be certain of their conscious state?

A I think if clinically we felt we could not have a reasonable conversation about the condition of their child and ensure that they had a reasonable understanding of the things that you were discussing with them, then you would not consent them.

Q What you have said about this is:

“You would not usually get consent from someone who had just had a Caesarean unless they had recovered sufficiently that you could talk with them. Instead you would ask the father. At four hours different mothers would have recovered at different rates.”

Is that something that you and your colleagues were aware of at the time as being a potential problem?

A I think you are aware, as with any sharing of information, whether it is about the clinical condition or a study, that you try and talk to the people who are going to have the clearest understanding. As I said, you would try and talk to both parents together and obviously that was the usual case. That way you were avoiding the issues of recovery from an operative delivery.

Q Kindler and gentler in the consenting proves: we spoke to Dr Livera about this yesterday and one of her concerns was that if that term were used parents who were not placed into CNEP might be protesting about only being on standard treatment. Would you also see that as a potential problem if that phrase were used?

A Yes. I think you are always in a difficult position with randomisation because you have to explain why you are doing the study and if you are introducing a new treatment you are obviously doing that because you think the new treatment is going to improve care. So that is part of the rationale, but what you have to be clear about is that we do not yet have that evidence that it will improve care and so we have to compare directly with babies who have received the current standard care. Obviously, it is quite common for parents to say “I’ll have the new treatment then” and you have to say “No, that isn’t on offer. It is either the trial or standard treatment and not being part of the trial”.

Q Information available, first of all to you: we do not, I am afraid, have available to us at this distance in time protocols on the ward but do you have any recollection of training information and perhaps even academic papers being available to you to give you some background into CNEP at the time?

A Yes, I think there was information. It is difficult to be certain, obviously, that any document that is put in front of you 15 years later were the ones that you were using.

Q I quite understand. For instance, is it fair for us to assume that if you were having to assess eligibility for the trial – you have seen the flowchart at least – that you must have had something in documentary form---

A We did, yes.
A

Q …to allow you to make the assessment?
A Yes.

Q We have heard about laminated photographs, and you have indicated taking parents down to the CNEP tank itself. Do you think you had available to you information in documentary form that you could convey and, if necessary, leave with parents?
A Yes.

Q Do you recall the patient information sheet that we have at our page 336?
A I do not recall it specifically. I am aware that there was information but, as I have said, it is very difficult to say that was it.

C

Q I think you are in the same position with the booklet as well?
A Yes.

Q Are you satisfied in your own mind that you and your colleagues were aware of the need to convey sufficient detail to parents for them to be giving genuinely informed consent?
A Yes.

D

Q Is that something which is important generally in medicine, that you are satisfied that informed consent is being given, never mind the context of the trial?
A Yes. I think you have to use your judgement. It depends on the treatment and the interests of the child, but obviously in a research study you have to satisfy yourself that the parents have understood the nature of what you are saying before you agree to go through the consent process.

E

Q Would part of that process include you offering the parents the opportunity to question you if they were left unclear on any matter?
A Yes. In fact, it was usually that the information and the form were left with them to have a think about. I have always regarded it, even in a short space of time, that you need some time for them to be without you there to have a think about it, rather than you hovering around waiting for them to sign a form. That has never really been what I have regarded as the correct approach.

F

Q Advantages and disadvantages is the next topic I would like to explore with you. You say you have a recollection of being in some way aware of the potential for neck problems, is that correct?
A Yes.

G

Q Was that something that you knew would have to be carefully managed by the nursing staff?
A As I have said previously, there was evidently quite a procedure that was dealt with – securing the neck seal and putting the babies in a CNEP tank – and that was an additional process when it compared to putting babies in a conventional incubator and therefore – talking about learning on the job as an apprentice – you naturally ask questions and discuss why this is being done and the nurses will discuss that in great detail with you; even though it may well be part of nursing rather than medical care, it
becomes very clear why things are being done in that way. That is how you learn.

Q You have told us you never saw a problem with the neck seal at Stoke. Again, I explored this with Dr Livera. Damage can be caused to the skin surface of neonates using conventional treatment, and the examples I gave her were electrodes possibly blistering or removing skin, but necessary for monitoring; endotracheal tubes causing gum damage, but again necessary to keep the child alive. Are you able to confirm that there can be skin lesions caused in conventional treatment?
A Absolutely. Every form of invasive procedure that requires some form of dressing or protection can potentially injure the skin.

Q I would now like, if I could, to ask you to look at some of the notes relating to Patient 6. We have copied for everybody a better copy of page 84 behind tab 5. (Same handed) There will be an issue in this case about whether or not Patient 6 was at any stage hypoxic. As a neonatologist are you reasonably au fait with these charts? Is that fair?
A Yes.

Q The importance of the new page is that if we look (because the original page was cut off on the left-hand margin) we can see some “As” next to some values?
A Yes.

Q Would you agree with me that those would denote arterial blood gases?
A Yes.

Q And that the probability, if not certainty, is that the absence of an “A” next to the other values means they were capillary samples?
A Yes.

Q Capillary samples are not particularly reliable if one is trying to work out the likelihood of the hypoxia in a child?
A I do not think you can use capillaries or gases to identify.

Q So any reliance upon those values which are capillary you would regard as being of dubious value?
A Yes.

Q If we then go within the bundle to some periods of time where there seems to be an absence of mean blood pressure readings, it will mean you turning on, for instance, to page 86 – it is quite hard to read, actually.

THE LEGAL ASSESSOR: Just before you do move on, Mr Forde – I am sorry, Chairman, to interrupt - is it accepted on all sides that this is a copy of the document which is in Patient 6’s notes?

MR FORDE: You will see that it has got the name of the child, it has got the very same date and it comes from the original. It has got the hospital number.

THE LEGAL ASSESSOR: That is what I wanted. It is accepted that the original has
MR FORDE: Yes, the copy was made by Eversheds for us some possibly even years ago, but we have got these copies made, or some copies made by my learned friend’s instructing solicitor, I believe – I see them nodding.

THE LEGAL ASSESSOR: That clears that up, just so that we are all clear. Thank you.

MR FORDE: You have told the Panel that the monitoring of children within CNEP was almost exactly the same as the monitoring you would expect for a child in standard treatment?
A Yes.

Q So if we are looking at what is being monitored, you have got rather than “headbox O2 CNEP”, so those are the negative pressures. Is that correct?
A Yes.

Q Then you have if we look at “O2 headbox”, the percentage of oxygen that is being delivered to the child?
A Yes.

Q That is the next column down. Then some temperature settings. Then we have got some oxygen saturations varying between, I think, 94 and 99. Would those saturation levels denote to you the extreme unlikelihood of this child suffering hypoxia?
A Yes. They are not consistent at all with hypoxia.

Q There may be some of us in this room with saturation levels of 96 or 95?
A Probably.

Q Can we then look across to the right-hand side? Do you confirm that you have got heart rate being monitored there?
A Yes.

Q Then if we go over to the next page, which is our page 87 though we appear to have some blood pressures absent – the blood pressure mean you can see about half way down the right-hand column – again I am only going to ask you about the saturation levels. You see the O2 saturation. Again, would those levels – which I think again vary between 95 and 99 – to your eye as a neonatologist contraindicate the likelihood of hypoxia?
A Yes.

Q Finally – and I do not know whether you can help us with this – if we look at page 88, the next page, we can see transfer from other chart and then because we have got CNEP but without any negative pressures initially and then we get the negative pressures here, -4. Do you see those? Coming in at about, I think---
A Oh yes.

Q She is being ventilated I think also, at three o’clock?
A Yes.
A

Q Then again the saturation levels between 95 and 97. Would you regard those as reassuring in terms of the likelihood of hypoxia?
A Yes.

Q I do not know whether you can see this but can you see the arterial PO2 Tcp O2?
A Yes.

B

Q Then as we deciphered it, next to that in manuscript somebody has written “Searl” – S-E-A-R-L?
A Yes.

Q Can you help the Panel, what does that mean, Searl?
A There was a continuous oxygen monitoring probe that was available on intra-arterial catheters that would allow you to read off, I think a digital or possibly an analogue display of what the PO2 was at any given point, so it was a continuous form of oxygen monitoring.

Q Right.
A So although you have got intermittent hourly readings, obviously they were read off every hour, the reading was actually continuous.

D

Q Right, so what that would suggest, is this correct, that the umbilical arterial catheter has fitted to it a probe, known as Searl, which would give a continuous reading in relation to PO2, saturation levels of oxygen in the blood?
A Yes.

E

Q Would you expect any competent neonatal nurse, able to read the continuous monitoring, to be acutely aware of any values likely to be suggestive of hypoxia?
A Yes, you would expect them to adjust the inspired oxygen concentration accordingly.

Q What we see is, if we look at this period, it looks to have been set at about 40, that is “insp time”, and then the O2 seems to be varying between 62% and 72%. Is that right?
A Yes, there is the fact that the inspired oxygen concentration is being manipulated suggests that they are responding to the information from the patient, which is what you would expect them to do.

Q So that is an indication of somebody adjusting the rate of inspiration and the percentage of O2?
A Yes.

G

Q Is that to your eye again indicative of the fact that this child is being relatively closely monitored?
A Yes.

Q The final page I would like you to look at in this regard, if you go on, is pages 125 and 126. We can deal with this with others but just to orientate you, we believe this is during a period of time where hypoxia is claimed to have occurred and I just want to
explore with you that unlikely possibility.

We have got down the left-hand columns the time, so we have got 1930, 2030, 2130, so those are the times at which these values are being taken. Then 02 we see 24 – is that the percentage of oxygen that is being delivered? That is the next column in from the left at 1930?

A  Are you on page 126?

Q  125. I will take you to 126 in a moment. Times down the left-hand column I am suggesting?
A  Yes.

Q  From 1930, then next column is that the percentage of O2?
A  Yes I have got that. Yes.

Q  A saturation level of 95?
A  Yes.

Q  Again, would that to your eye contraindicate the likelihood of hypoxia, that saturation?
A  Yes.

Q  Particularly in combination with that being achieved with only 24% oxygen.
A  Yes.

Q  What is the percentage of oxygen likely to be in this room?
A  20, 21.

Q  So in almost breathing in air this child is achieving a saturation of 953%?
A  Yes.

Q  We see that by eleven o’clock it has been increased to 50% but the saturation is being maintained at 96%?
A  Yes, it is.

Q  So she is needing a greater percentage of oxygen to maintain a reassuring saturation?
A  Yes, and the fact the oxygen is going up and the saturation is being maintained suggests that there is that feed back process going on from the monitoring to the nursing care.

Q  Then if we go over the page to 126, it would appear, if you go three columns from the left, that somebody has interpreted that “Tcp O2” as meaning that the values in that column relate to a transcutaneous probe monitoring the child’s saturation level, but somebody has written underneath it, “CNEP”, and then we have got minus values. Can you help me? Do you think this is a note that is recording a transcutaneous monitoring of blood or is this a child having her negative pressures recorded under CNEP?
A  They look like negative pressure recordings for CNEP.
A: Are you aware of the possibility of any negative readings when you are monitoring via a probe?
   A: No.

Q: Is it a medical impossibility which should be obvious to any competent practitioner?
   A: You would not record it. In fact, I do not think you can actually get a negative value from the device.

Q: Thank you.
   A: You would not record it anyway.

Q: So we then see – and we may need to get the original to get the times but we can see 1030 in the morning, 11.30, 12.30, do you see at the bottom, but it is folded over above?
   A: Yes.

Q: We can probably reconstruct back to find out the earlier times in the morning – obviously 9.30, 8.30, 7.30, etc. It is from about midnight onwards, it would appear. We have got 45% oxygen, a -4 pressure and a saturation level of 100. If you follow your eye down the columns, I think the maximum percentage of O2 being delivered is 50%, the negative pressure is also being adjusted between 3.8 and 4.4?
   A: Yes.

Q: But the saturations, it would appear, are between 95 and 100?
   A: Yes.

Q: Can I take it that you make the same comment – that shows close monitoring because there are adjustments being made? Is that correct?
   A: It is. It shows that when CNEP was started that the amount of oxygen the baby was in fell, if what you would expect when negative pressure is being applied, and then as part of the natural history of the illness the oxygen levels and the amount of respiratory support increases, even though the baby is on CNEP. The responses to that in terms of oxygen being delivered are adjusted by the nurse in responding to the monitoring is typical of that.

Q: The saturation levels reassuring and contraindicating hypoxia?
   A: Yes.

Q: Thank you. Just let me check my list of topics. Ultrasound next. I am sorry if it feels like a viva. You had some involvement with Patient 6, as we know, in terms of check ups and I think the first involvement was 22 September 1993. You have been asked about availability of notes. Behind tab 5 first of all, could you turn to pages 161 and 162? These are the ultrasound reports.
   A: OK.

Q: We do not have the scans. Could you just read both the reports and then I want to take you to another document if I can.
   A: The first one, dated 22 December 1992 says:
“There is increased density on the left suspicious of clot attached to the choroid plexus and in association with mild lateral ventricular dilatation.”

Q Correct, and then the next one speaks in terms of a symmetrical dilatation consistent with haemorrhage although the clot could not definitely be identified?
A Yes.

Q Your colleague who saw Patient 6 on 2 March, page 193, J Doherty – I do not know if you remember J Doherty, I think a female doctor? Lists five matters but describes the post haemorrhagic ventricular dilatation as “mild”. Do you think that is a reasonable description?
A Yes. That is consistent with what is written in the report.

Q Then just dealing with your letters on 22 September 1993, you wrote this post clinic about weight gain, head circumference and a squint and you referred?
A Yes.

Q We can see your letter – 195 is the letter to the GP, 196 is the letter to Mr Brown, the ophthalmic surgeon. The next page is a duplicate, as far as I can tell. Then he writes back to you as a registrar on page 198 and you are concerned with the squint and he has put her on the waiting list for squint surgery. Then we have another copy of the same letter, I think at 199. Then on page 200 – this is your letter dated 19 January 1994 – you have as your diagnosis, you have not got five features, you have got three, unlike Dr Doherty – prematurity, convergent squint, developmental delay. We can see the terms of your letter there. We can see the terms of your letter there.

Q Can I suggest to you that if you felt that this child’s developmental delay had been caused by that mild brain bleed, you would have said so in this correspondence?
A That is likely, yes.

Q Because you deal with this in your witness statement, to some extent. Can I just remind you of what you said towards the end of your statement?

F “Delay in achieving one or more developmental milestones is not uncommon”

- this is paragraph 51 –

G “Many of these infants show normal developmental progress in the long term. Sequential developmental assessment allows neonatal follow up to identify those who have permanent neurological problems. Because this is an evolving process I am very careful about saying to parents that developmental delay is as a result of permanent brain injury like cerebral palsy. I am equally cautious about interpreting normal development in high risk babies as signs of developmental delay and/or neurological abnormality may not be apparent till the end of the first year.”
A

Was that your practice in 1992/93/94 and is it still your practice?
A Yes.

Q Would you be surprised if I told you that a suggestion has been made in this hearing that as early as September 1993 you were saying in terms to Mr and Mrs Henshall, “Your daughter has suffered a brain injury caused by a mild haemorrhage identified shortly after birth”?
A It does not fit with my correspondence. Obviously I have got no recollection of a direct consultation, I can only go on my correspondence, but reading that and knowing how I approach the problem, that does not fit.

Q Does not fit – is that shorthand for unlikely for you to have had the conversation without recording it in your letter?
A Yes.

Q Dr Morgan, the final topic. Can you now recollect – and if you cannot please do say – in 1992/93 Dr Spencer’s fixed sessions, weekly sessions? If I were to suggest to you that on a Tuesday afternoon he often shared, in 1992, a clinical neonatal follow-up clinic with you, is that something that you can now recollect? If you cannot then do say and I will sit down?
A Yes.

Q Then on a Wednesday morning he had a general paediatric clinic? Do you recall that? You may not have been involved in that?
A Yes, that is a bit harder.

Q You do recall the Tuesday afternoon clinic?
A Yes, I did one clinic. I am not absolutely certain it was a Tuesday but, yes.

Q The day of the week I can explore with others but if it is an afternoon clinic, would it span a time approximately shortly after lunchtime to four or five o’clock?
A Yes.

Q To your knowledge did the consultants, although they might remain on call, tend to depart from the hospital six o’clock-ish, something like that?
A Something like that, yes.

Q Surfactant, which I think was introduced by my learned friend. I am instructed, and I wonder whether you can recall this, that the use of surfactant was not trial specific. The region mandated that it be used in appropriate circumstances, so it was given to all neonates who fitted the criteria regardless of whether they were in CNEP or not?
A Yes.

Q Is that your recollection?
A Yes.

Q Because about this time, I think 1991, it was licensed for use?
A That is right, yes.
MR FORDE: Thank you.

Cross-examined by MISS O’ROURKE

Q Dr Morgan, I ask questions on behalf of Dr Southall. I only have a few questions for you. Firstly, neck problems. You said it was your recollection there were no neck problems at Stoke, but you think you may have been aware that there had been a problem in the past at Queen Charlotte’s?

A Yes.

Q Presumably, you have no knowledge as to whether at Queen Charlotte’s they were using the same type of neck seal or indeed the same type of tank, or indeed whether they were using gel?

A No, no.

Q But what you can say is that at Stoke there were not any problems and your time at Stoke was after there had been problems at Queen Charlotte’s ---

A Yes, my understanding was that the whole neck seal and everything else was an evolving process to get the optimum seal possible.

Q Absolutely. You said in your witness statement, “From August 1991 my on-call commitments were at registrar level”?

A Mmm.

Q If I understand correctly, what you mean by that, it is when you became a senior SHO when you went on the on-call rota you were on the registrar’s rota?

A Yes, I would be supervising other SHOs.

Q You would be supervising an SHO below you?

A Yes.

Q And you would be reporting directly next up to a consultant?

A Yes.

Q You were asked about the randomisation log?

A Yes.

Q You very fairly made the point it is a randomisation log, not a consent log?

A Yes.

Q Mr Forde, I think, made you aware that we know of at least one case where we have seen the consent form and the randomisation log and it is a different person took consent and made the phone call?

A Yes.

Q You would say you can remember that happening or you think that happened?

A It is difficult to recollect individual episodes, but I can see that the on-call firm and the set up of the on-call and the fact the registrar was split between two sites made
that fairly inevitable on some occasions.

Q Can you just elaborate on that, when you say the registrar was split between two sites?
A The registrars were covering the neonatal unit and the paediatric wards at the same time and therefore, potentially for very sick children, had to be in two places at once.

Q They could take the consent and then run off to do something else and leave someone more junior to make the call?
A Yes.

Q You make the first call it looks like in the randomisation log on 22 September 1990. You answered Ms Sullivan’s question saying, “I would have been an SHO at that stage”?
A Yes.

Q But it is made 16.40 in the afternoon. Is that during a day shift?
A Yes.

Q Would there have been other people around at that time to take consent?
A Yes.

Q Whereas the other ones I think that we looked at, all of them appeared to be on the night or else on days that you say may have been a Sunday because they are post 1991 when your only involvement would have been on the on-call rota. Is that right?
A Yes.

Q You said in your witness statement that you watched other people taking consent and, in particular, you identified some registrars you watched. You said you were not sure whether the consultants took consent or not. Dr Brookfield is about to be the next witness and he is going to say that he did take consent on at least one occasion. Would that fit with a consultant could do it if it is during the day?
A Oh yes.

Q Randomisation process, you talked about in your witness statement:

(Document not available to shorthand writer)

“There would be a control group receiving standard treatment and we did not know if the new treatment was better or not.”

You presumably would have made that clear as part of your consenting process?
A Yes.

Q You then make reference in your witness statement to:

“I do vaguely remember some sort of plastic holder with a booklet in it but I have no idea whether ...”
- and then this is a booklet that you were shown -

“... is the right one.”

Can I show you what we believe to be the original, which came into existence in February 1992? It is a red folder written by Theresa Wright and Katy Lockyear. *(Same handed)*

Do you want to have a look at that and see if that jogs your memory or rings any bells?

A *(Pause)* I mean, it is part of the fact I remember there was a lot of documentation around, but specifically saying *this* was part of that documentation is quite hard I think in that timescale.

Q Can I put to you what we will say it is? It is a document put together by Theresa Wright and Katy Lockyear for doctors to take - I think you talked in your statement about laminated photographs. It was to allow you to bring photographs to show to parents before or as part of the consenting process. There was just that one, the folder, and it was an evolving document; you will see it is loose leaf pages and pages get added. It was taken along and the photographs were flipped over and the parents could have a look at it. It was kept on the ward; it was not given to the parents to keep. Ring a bell?

A Yes, as I said, it was quite hard to describe the CNEP tank without actually having the picture or indeed going to show it to them directly. I can certainly recall doing that, but that was not always possible.

Q It is just you do actually say in your witness statement - it was paragraph 42 - you remember a plastic holder?

A Yes.

Q You might say that that is a plastic holder folder, so you have remembered something of that sort?

A Yes.

Q That was in the context of being shown the pages as photocopied, because they appear in our bundle - I think you will confirm it - at 341 onwards. If you look at those pages, they are in fact photocopies in the bundle that you have, but this is the original.

A Yes.

Q I am just asking if this could be the plastic folder ---

A It certainly could be. I think it is the sort of thing that we were showing parents pictures of the tank.

MISS O’ROURKE: Sir, if I can explain. This folder has turned up overnight. We believe - indeed it is my instructions - it is the original of what is at page 341-356 in your bundle. It is now available. Sir, we would be inviting the Panel to have a look at it because you will see that there is clarity of it compared to - there are certain things written on it that have not come out in the photocopying and there are certain photographs that obviously come out much more clearly.

THE LEGAL ASSESSOR: Given the sensitivity of documents, I think the Panel would be better to have a further explanation as to how it turned up overnight. Perhaps that
could best be done after this witness has completed his evidence.

MISS O’ROURKE: Sir, I am content with that. I have no further questions for this witness.

MR FOSTER: No questions, sir, thank you.

Re-examined by MS SULLIVAN

Q Dr Morgan, just a couple of matters. You were looking in tab 5 at pages 161 and 162, which are of course the reports of the ultrasound. Would you have reported those results to parents?

A I think I can only comment on my practice now really. On the whole we tend to report everything to parents. In this sort of scan result I would say that there was nothing on this scan that would increase the risk of handicap beyond that already associated with the prematurity.

Q Does it reveal any abnormality?

A It is not normal because there is a description of clot, but the abnormalities that are described are not the reasons why we do the ultrasound scanning, which is really to identify major brain abnormalities that have long-term sequelae and it does not fit in with that group.

Q Could I ask you just to take up the new page 84? I think it is the separate page that you were given earlier. You have indicated that the oxygen saturation levels for this patient were what you would regard as normal ...

A Yes.

Q ... when you were looking at other documents?

A Yes.

Q But looking at this particular chart here, would you agree, looking at the levels that are shown - and the time with which the Panel is interested is 15 December at 00.03, do you see that? It is the second entry I think on that particular page. The date is a bit difficult to see.

A The second line down with a pH of 7.23?

Q That is it. The end time with which the Panel is concerned is 12.30 on that same day. I just wanted to ask you this: bearing in mind those times, would you agree that the pO₂ level appears to be over that timeframe somewhere between 4.5 and 4.7?

A On those figures, yes.

Q And that the pH level we can see recorded there appears to be between 7.23 and 7.28?

A Yes.

Q And the pCO₂ level between 6.3 and 7.4?

A Yes.
MS SULLIVAN: Yes, I have no further questions.

THE CHAIRMAN: Dr Morgan, that completes the questions from the lawyers. As I said at the start when you came in, now is the moment when the Panellists have the opportunity to ask questions, if any Panellist has any questions.

**Questioned by THE PANEL**

DR OKITIKPI: Dr Morgan, one of the points you made was that the consultant sometimes moved between two different sites. Is that correct?
A I think I was referring more to the registrar covering two sites.

Q Is it possible that when they - because they are so busy on two different sites, that they delegated the consenting process to either one of the nurses or the more junior doctors?
A I was not aware that that would have been the case, no.

Q The other question is to do with the teddy bear you mentioned. Why does that stand out in your mind so much?
A Because I borrowed the idea for my own research.

DR OKITIKPI: Thank you.

THE CHAIRMAN: That seems to be all the questions which we have for you, Dr Morgan. That completes your evidence. It just remains for me to thank you for coming along this morning and for the assistance you have been able to give us. Thank you very much.

THE WITNESS: Thank you.

(The witness withdrew)

MS SULLIVAN: I think Miss O’Rourke is about to explain the folder, if she would.

MISS O’ROURKE: Sir, before the next witness is called and in response to your Legal Assessor’s invitation, sir, two documents have turned up overnight. The first one is what we say - and I am firmly instructed - is the original booklet, of which you will see the pages at 341 and following in your folder. Sir, the original does rather more for us than the photocopies, because you will see on the front cover there is a date as to when it came into existence that has not come up on the photocopy. Also, not all of the photocopies have the inside front page that shows the names of the authors, and you will see that. Also, you will see the photographs are clear in colour. Some of the photographs that you have in your bundle you cannot see very clearly because they are photocopied in black and white.

Sir, my instructions and understanding are that this booklet was taken, at the time of the Griffiths Inquiry in ’98, ’99, into safekeeping because it was to form part of the documentation for the Griffiths Inquiry. It was kept so safe that it was not provided again until enquiries were made in the last few days and it turned up yesterday.
Clearly at some stage it has been made available in some form to the GMC solicitors because you have the photocopied pages of it. Sir, my instructions are this is the original. I would be inviting the Panel to look at it at this stage, because you will see some of the photographs are much more clear. You will see there is one photograph in particular that you may find quite striking that is not obvious from your photocopy.

Sir, what there is as well is the original of the randomisation log. You have that again in your bundle, I think starting at page 360. What you will find as well is you have now the brown envelopes. You will recall there was the description of the process whereby either Dr Southall or Dr Samuels pulled open a brown envelope and there were cards inside. You will actually find there are some of the brown envelopes with the cards inside here and you will find telephone numbers, bleep call numbers and you will find other instructions for them in the carrying out of the randomisation process. Then you will find the originals of the logs of which you have copies, and you will see that of course some of it is in blue and some of it overwritten and some of it is in red and that is why it has not photocopied so well. You will see again how the folder is divided; there are some handwritten notes.

My firm instructions are that this is the document that either Dr Southall or Dr Samuels kept at all times and they wrote in this document and they are able to identify, and will identify, their handwriting and indeed their document. Sir, it is the same; it was held for the purpose of the Griffiths Inquiry and it has now come to light. Again, my learned friend’s instructing solicitors have had access to some of the material in it because they photocopied the randomised log and it is in your papers. I do not know whether they were ever previously shown the broken envelopes or anything. Ms Sullivan has now seen it and understands it is available.

Sir, we would be saying you should have both of these to look at because it is better quality documentation than the photocopies that you have.

MR FOSTER: Sir, I can add something to that. We have been pressing for these documents for some time. We have been repeatedly assured by the Trust that they do not exist, but we continued to press. Those documents were produced from the Trust headquarters. They were apparently in a secure room there. They were produced by the Director of Human Resources at the Trust and they were both couriered to Dr Samuels last night.

MS SULLIVAN: Sir, I can confirm that those documents were never shown to my instructing solicitor by the Trust, despite a number of visits to inspect documentation.

In the light of the fact that they are now available, it seems to me that it would only be fair to allow Mr and Mrs Henshall to see them. They have not seen these documents at all. It must be right that as they are complainants in the case they can have access to them now. Sir, I think I would like them to have a look at them.

THE LEGAL ASSESSOR: My problem just at the moment is that none of the witnesses who have given evidence so far could identify the log book because that came from London, so it does not have an evidential status beyond the photocopies in the bundle, nor
strictly, I think, has the plastic folder got an evidential status in the sense that no witness has been able to positively identify it as that is the document which was there.

What I am not clear about - and this may need to be investigated over the adjournment - is whether the GMC solicitors ever saw original documents at all or they were just given photocopies which had been - because you kindly forewarned me of this and I was therefore looking at Mrs Canning’s evidence. What I am wondering is once the Henshalls have looked at it, we need to have a discussion as to whether it would be necessary to prove in evidence and, if so, who should do it, the immediate provenance of the document.

MISS O’ROURKE: Sir, can I indicate, the red folder, I anticipate the next witness - who I understand is going to be Dr Brookfield - is likely to be able to identify it, because he, in his witness statement, talks about a plastic folder. I anticipate tomorrow’s witness, Dr Kate Palmer, will also be able to identify it. If may be that we get people there who can produce it.

As far as the GMC solicitors, sir, I would just sound this note of caution because I see Ms Morris shaking her head. Of course, Messrs Eversheds have only been the GMC solicitors in this case I think since 2004. The complaint was made in ’97. The GMC solicitors at that time - I think as the Panel have heard as a result of questions by me to the Henshalls - were Field Fisher Waterhouse and, in particular, partner Matthew Lohn.

It may be well be - and I am sure it is probably right - that Ms Morris did not see it because she was involved after the Griffiths Inquiry and the suspensions that took place at the Trust where this documentation would have been material.

On the other hand, Field Fisher Waterhouse, as the GMC solicitors, were involved at an earlier stage and it may well be that Ms Morris got photographs because this photocopy all went into affidavits back in ’97, ’98, ’99. That is where she got it, whereas the GMC solicitors may, once upon a time, have had this because this document was clearly taken into safe custody in ’98, ’99.

Sir, I simply make that point just because Ms Morris may say she has never seen it is not the answer to the question in terms of the GMC solicitors, because they are at the very least the second set of solicitors involved.

MR FORDE: Sorry, I have not said anything on the subject. It seems to me, if there is doubt about provenance and there is doubt about whether subsequent witnesses can identify the folder, the simplest thing is for the GMC solicitors to contact the Director of Human Resources, get a two paragraph statement saying where the document was found and in what condition and then, hopefully, a formal admission will be made by the GMC as to the validity of the document.

THE LEGAL ASSESSOR: That is the sort of thing I was hoping could be arranged without calling further evidence but clearly Ms Sullivan will need instructions.

MISS O’ROURKE: Sir, I would agree with that – that would leave no doubt.
MS SULLIVAN: We can certainly make that enquiry, and also as to whether there is any further documentation in the light of the fact that this has emerged at this stage.

THE CHAIRMAN: Again, we are talking about events which have been going on over a long period of time and we know that there have been other inquiries, and therefore there will have been photocopying of documents and it is very difficult to know if one is looking at a photocopy now what the provenance of that photocopy is – it may be a photocopy of a photocopy. Certainly I think at the moment the sensible thing would be to do, as is suggested, to get a statement from the Director of Human Resources as to the location of the documents which are now being referred to.

MISS O’ROURKE: Sir, could I indicate, since I am the one who introduced it, the potential significance of this folder? We had, of course, been cross-examining on the basis of there was a folder at some stage and it was not at the outset and a date. There is now, as I have said, a date on this. That will become significant in the context of the Henshalls and their evidence as to whether or not they would have seen an information booklet.

Sir, can I make it clear as well – and you will know it when you see it – there is something in this folder that may mean Mrs Henshall needs to be recalled and I for one probably will want her to be recalled to ask her about something in this folder. You actually have it in your bundle and photocopied but you will not be able to see the significance of it because of the quality of the photocopying. It is, in my view, potentially of some significance and I may yet be asking for her to be recalled. It is why I want this folder in as part of the prosecution case. Of course, this folder can be produced by at least two witnesses on this side of the room in due course but that is going to be too late because I for one think I will probably want Mrs Henshall recalled.

THE CHAIRMAN: Certainly. Let us take it in stages. If you are happy to do that, Ms Sullivan, then that can be done, then the further consequential use of the folder once it has been proved in evidence (if I can put it that way) we can deal with at the time.

MS SULLIVAN: Yes, sir. I am just anxious that Mr and Mrs Henshall obviously have an opportunity to see it because they have not seen it yet and I would like them to be shown it sooner rather than later.

THE CHAIRMAN: Yes. I presume there is no problem with that, Miss O’Rourke?

MISS O’ROURKE: No.

THE CHAIRMAN: Can I just ask, because my eyesight lets me see a big notice on the front of that saying “Do not remove”, but that is a reference to the inquiry?

MISS O’ROURKE: We think that is a reference to at the time; that is not put on by the Griffiths Inquiry. In other words, what has been said is because these are originals nobody on the ward should take them away.

THE CHAIRMAN: That is what I want to know. So you think that is an instruction from the ward?
MISS O’ROURKE: You will see the way it is built into it.

THE CHAIRMAN: I am thinking of the evidence particularly from Mr Sheridan yesterday where he looked at pages 341 onwards and was sure that they were familiar, which would tend to suggest that he had certainly seen the document, but I think he was also suggesting that he may have kept that document as well, so presumably there were other---

MISS O’ROURKE: There may have been the opportunity to take photocopies and take pages away.

THE CHAIRMAN: Thank you very much.

MISS O’ROURKE: Sir, I do not know if the Henshalls want to see the randomisation…\textit{(inaudible – microphone off)}.

MS SULLIVAN: Perhaps they could just have a little time to look at it, sir, rather than just briefly looking at it now?

THE CHAIRMAN: Yes.

MS SULLIVAN: We could always come back early, sir.

THE CHAIRMAN: If it suits everybody, and I think your next witness is Dr Brookfield…

MS SULLIVAN: Yes.

THE CHAIRMAN: …we could adjourn for lunch now and come back at half-past one.

MS SULLIVAN: I think in the light of the fact that this material has been produced which they have not seen, I would like them to see it now.

THE CHAIRMAN: In that case let us stop for lunch now, then we will come back at half-past one.

\textit{(The Panel adjourned for lunch)}


MS SULLIVAN: Dr Brookfield is the next witness.

THE CHAIRMAN: Can I take the opportunity of saying that we intend to finish at about half-past four this afternoon, though I see from the list that if we have not finished with Dr Wheatley by then he can come back tomorrow.

MS SULLIVAN: I think we are probably hopeful we will get through both witnesses actually, sir.
DAVID SAMUEL KIRKALDY BROOKFIELD, sworn
Examined by MS SULLIVAN

Q Good afternoon, Dr Brookfield. Would you begin with your full names, please?
A David Samuel Kirkaldy Brookfield.

Q Your qualifications, Dr Brookfield?
A MB ChB, FRCP, DCH and FRCPCH.

Q And your current appointment?
A I am retired and have been retired since March 2007.

Q Prior to that?
A I was a consultant paediatrician with an interest in neonatology at North Staffordshire University Hospital in north Staffordshire, since February 1980.

Q Working during part at least of that time with Dr Spencer?
A Yes.

Q I want to ask you, as I think you know, about the CNEP trial which began in North Staffordshire in fact in 1990. First of all, what was your involvement as a consultant within the trial?
A I was one of the two consultants on the neonatal unit – there was Dr Spencer and I – and the patients were all under either one of us at the time as a named consultant. Therefore, patients that were under my care went into the trial and I had to have sight of the trial and supported it and was in agreement with it.

Q But you were not one of the investigators---
A No, I was more a clinician. I think I was probably on the Ethical Committee’s submission because I was a clinician on the unit but I was not actually a research investigator as such.

Q So obviously at the time you would have been aware of the approval of the trial and of its protocol?
A Yes.

Q I will come back to that in a moment, but before we discuss the trial can I just ask you whether CNEP had been in use at all before the trial began in 1990 in Stoke?
A Yes, it had. We had used it as a form of treatment for babies who had severe respiratory problems, usually pre-term neonates. These babies were referred in from other hospitals, some of them in the West Midlands region and some of them outside. We probably (though it is difficult to remember) treated about 15 to 20 babies before the trial was started. The treatment appeared to help these babies; they were referred in to us often in oxygen levels of 60 or 70 per cent and within three to five days the oxygen levels would drop by about 20 per cent, indicating that there was an improvement.

Q So that was your prior experience of CNEP?
A Yes.
Q We then have the approval being given by the Ethics Committee to the trial for neonates. Can I ask you how involved Drs Samuels and Southall were at that stage before they moved to Stoke?
A They were significantly involved because they came up and gave us advice about CNEP and how to set it up before we started the trial. These were the babies that we had used it as rescue treatment which were referred in from other centres and they were up from the Brompton Hospital frequently, probably – I do not know, it is difficult to say – probably two or three times or more per month.

Q In relation to the babies that you had been treating before the trial or the trial itself?
A Probably both but it is difficult to remember.

Q Can you remember whether there were any lectures or suchlike from either of them?
A Yes, there were. Certainly when the trial was started there were talks and explanations given on a fairly formal basis in the seminar room on the neonatal unit by Dr Samuels and Professor Southall at that time. I did attend at least one but it is a time ago and I cannot remember the details I am afraid.

Q Do not worry, Dr Brookfield. Obviously you were a consultant on the neonatal unit. To what extent were you therefore actually involved in the consenting process for parents in the trial?
A I certainly took consent on at least one occasion – I may have done it on more but I cannot remember it myself – so I knew about the randomisation and how to undertake that. There were instructions which I think were in a folder at the nurses’ station on a notice board if there was a child that might be eligible for the trial and what to do in those circumstances. We had phone numbers to ring either Dr Samuels or Professor Southall.

Q In order to randomise the babies?
A Yes.

Q We in fact have a log of the trial and I wonder if you could just look it up, just so that we can see the extent of your contact with the doctors about this. If you turn to tab 3 in the file that will be given to you now, file 1, page 367?
A Yes.

Q This is the log for the babies from North Staffordshire who were entered into the trial, Dr Brookfield. I will be corrected if I am wrong but I think your name only appears once actually on page 367 as against 11 June 1990. Do you see that?
A Yes.

Q It looks as if there was a call made at 22.08 and name of caller appears to be identified as you?
A Yes, I do recall this, somewhat vaguely. I thought it was later than that but it was certainly on the night shift that I rang Professor David Southall.

Q It looks as if it was Professor Southall that you phoned at that stage, but we do not...
A  actually see your name appearing at any other time?
A  No. I am not sure whether I did take any other consents or not.

Q  Do you remember at what sort of level of doctors was taking consent within the unit?
A  Not precisely. It was obviously registrars and it might be SHOs (senior house officers) – I cannot remember – and consultants as well.

B  Can you remember what consenting process you would have used on this occasion when you appear to have certainly phoned for randomisation?
A  Do you mean consenting process to the parent or parents?

Q  Yes, to the parents?
A  First of all you would discuss the clinical condition of their baby and the parents and what was going on and what sort of support they were requiring, especially with regard to the ventilatory aspects. Then you would ask them whether they would be interested in entering a trial which was evaluating a type of treatment to help with the breathing. You would have to say what I did say, that – you would have to explain about randomisation and that they could not select which arm of the trial they went into; you would explain why it was being done, that you hoped the hypothesis was that this would benefit the respiratory outcome for the baby, the breathing outcome, and they may require less time on the ventilator, possibly, and that is what we were wishing to look at, one of the aspects we were wanting to look at. Then I would ask them whether they were interested in being entered into the trial or not.

Q  We know the babies had to be randomised at four hours?
A  Yes.

E  How easy was it to explain to parents this trial process?
A  It could be very difficult and there were some that you could not randomise because the mother was too ill with pre-eclampsia, eclampsia or something like that and there might not be a father available, so those children did not get into the trial. You would talk to the mother about it and sometimes the father, if they were there and they could talk to you about it. We realised that obviously they were very upset because they had a baby that had been born much earlier than they had anticipated and they would be tired after giving birth, and we did appreciate these issues, yes.

Q  How difficult are they to overcome, those sorts of issues?
A  Sometimes you cannot overcome them and then the child would not be able to be entered into the trial. As far as I recall – and it is difficult because it was such a time ago – a lot of parents were able to consider it and agree to going into the trial.

Q  You talked about pre-eclampsia, for example?
A  Yes.

G  What about where a mother had, for example, had a Caesarean and was recovering from that? What approach would you take in those circumstances?
A  It depended whether the mother could come to the unit or not, because we used to encourage mothers to come to the unit to see their baby if she was able to from the
physical aspects of how she was. If not, you might go round to the labour ward to discuss the situation with her and father at that stage.

Q You have mentioned taking consents from mothers; what was the approach to fathers?
A You would take consent from fathers – again, it is a long time – but the law, I think, at that time was that you could take consent from mothers and from the fathers if the mother and father were married at that stage. So if they were married you could take from the father as well.

Q As far as the CNEP treatment itself is concerned, Dr Brookfield, how did that compare with positive pressure ventilation and how would you describe that to parents?
A Some of the babies just required CNEP and no ventilation because their respiratory distress and respiratory problems were not sufficient for them to require ventilation. If you are talking about that you could liken it to - and I did at the time liken it to – the fact that you were expanding their lungs in a similar fashion to the iron lung which was used for the treatment of polio and in some ways this might be a more physiological and less invasive technique than such other things as ventilation and as continuous positive airways pressure as well.

Q Yes. We have heard reference from some witnesses to be being kinder and gentler?
A Yes, I am not sure that I use that phraseology myself but it is possible that people might say that, yes.

Q In terms of any disadvantages and advantages of treatment, first of all were any disadvantages pointed out to you by parents at the time? Were you aware of any?
A I cannot really recall that. I have been asked this before obviously, here. In North Staffordshire we did not see significant disadvantages which I understand other units may have done. We did not have significant problems with temperature control, as far as I recall.

Q What about the neck seal?
A We did not have any problems with that as far as I recall.

Q Were you aware of it having been a problem anywhere else?
A I had heard that it may have been a problem at somewhere like the Brompton, but I did not know more than that.

Q What steps, if any, were taken to prevent the recurrence of any such problem? Do you know?
A We did not have a problem so we did not have to prevent the recurrence, as it were, but this is where the training of the nursing staff who looked after the seal was apparently very good because we did not see the problem.

Q So were any disadvantages mentioned to parents at all?
A I do not think they were because we did not see that there were disadvantages at that stage.
Q How would you explain it if, for example, a baby was to be in CNEP but also to need positive pressure ventilation as well? How would that be explained to a parent?
A If you use the CNEP the pressures that you had to give with the intermittent positive pressure ventilation were less than you would have to do with conventional treatment and this may be advantageous and might cause less damage to the alveoli and the lung parenchyma – that is the lungs themselves.

Q In terms of information, was any information given in written form to parents?
A I think it was, yes, as far as I recall.

Q I think you have been shown some documents. If you still have that same file open there, Dr Brookfield, if you look at page 336 where there is an information sheet, do you recognise that at all?
A Yes, I do recall it, yes.

Q You recall...
A I think this is one that was given to parents but it is such a long time ago that I could not be certain about that.

Q What about page 341, which goes through to page 364? Have you any recollection of that document?
A To 344? Is that right?

Q To 364?
A Yes, I think this was part of the lectures given by Professor Southall and Dr Samuels, but again, I cannot be certain.

Q Do you know when that came into existence?
A No, I do not know the precise date. I would think sort of 1990, but that is a surmise on my part.

Q I think you were shown a number of further documents at the time when you made your statement?
A Yes.

Q Would it be fair to say that you were not sure in what form you may or may not have seen---
A Yes, because of the time issue.

Q Just in terms of the trial itself a moment and what forms of monitoring were used in the course of the CNEP trial, we have heard reference to NIRS – Near Infrared Spectroscopy?
A Yes.

Q Was that part of or separate from the CNEP trial?
A It was separate from it.

Q Again, can you help as to whether intracranial pressure monitoring was used routinely for babies in the trial?
A The CNEP trial?
Q Yes.
A No.
Q No?
A It was not.

Q No it was not used, and can I ask you the same question about Doppler ultrasound?
A I do not think that was used, as far as I recall. That was not a clinical test available at the time in clinical terms.

Q Would babies have had head scans before entering the trial?
A Usually no, because you would not get them done before four hours.
Q Yes, and at the end?
A I cannot remember what the protocol was for the trial. We were meant to be doing ultrasound scans at certain times but I cannot remember the details.

Q I just want to ask you a couple of questions about two particular babies. We have given them numbers, Dr Brookfield, and you should have the relevant numbers there next to the names. I am going not ask you first of all about Patient 7, so if you could just be given file 2, please. Behind tab 4 you will see the medical records for Patient 7. We know you were the consultant, Dr Brookfield, for this baby?
A Yes.
Q As we can see from the first page. I do not need to ask you particular questions about her care but you will be aware, no doubt, that her records do indicate if you perhaps just turn to page 15, that this baby collapsed, as we see, at 10.15 on 14 February 1992 and was treated for renal failure. We know that the baby died on 14 February 1992. As far as this baby is concerned I wonder if you could just turn on to page 64. Can we see there, Dr Brookfield, the diagnosis as far as this baby is concerned, at the bottom of the page there, that she was extremely pre-term. Do you see that?
A Yes.
Q Also suffered perinatal respiratory distress syndrome. Do you have that?
A Yes.
Q Neonatal septicaemia, acute renal failure. Then if we turn on to page 66, we will see recorded there cause of death – do you see that? – extreme prematurity and again reference to respiratory distress syndrome.
A Yes.
Q Again, I do not think you were responsible for completing any of the scoring sheets, is that right, in relation to these children?
A No I was not, because I was a clinician as opposed to a researcher.
Q Yes, so for that reason you would not have done so, but were any scans performed
at all in relation to this baby?
A I do not know about that because I think – I do not think there are any scan reports
in these notes from what I recall, and the answer is I am not certain about that.

Q I want you, please, then, to look for a moment if you would not mind, at the
records for Patient 6. They are behind tab 5. I am just going to ask you first of all about
how blood pressure was taken for babies such as Patient 6. I am looking in particular at
the sheets that we have at 85 through to 89 where we see on the right-hand side a
reference to “blood pressure mean”. Is there anything recorded there?
A Whereabouts is the blood pressure mean on the right-hand side?

Q About half way down. Do you see the column which says “Time” at the top?
A Yes.

Q “BP mean” at the bottom there? (Pause)
A I cannot see it immediately, actually.

Q Perhaps we could just point it out to you. We will just give you some assistance
with that.
A I am sorry, I was looking in the wrong columns. There is not any recording of
blood pressure.

Q Yes, and how can blood pressure be taken?
A It is difficult to get the time scale right. I think we were using transducers, which
were on arterial catheters and the umbilical artery – I think we started using them in the
late 1980s but I cannot remember the exact time. In an ideal situation that would be the
best way to take the blood pressure. Sometimes, unfortunately, there are technical
problems with the transducer or with the line itself, the arterial line, and it is not possible
to get a reading so it may not be taken. You can take the blood pressure by a cuff but on
small pre-term babies this is not terribly satisfactory and not that accurate.

MS SULLIVAN: Thank you. If you wait there, there will be some more questions.

Cross-examined by MR FORDE

Q Dr Brookfield, good afternoon. I am asking some questions on behalf of Dr
Spencer. Can I just ascertain a few general matters from you? I think you worked with
Dr Spencer as your consultant colleague from about 1985?
A That is correct.

Q I think you enjoyed a good working relationship?
A Yes, we did.

Q You have respect for his medical abilities?
A Yes, very much so.

Q He took his training duties in relation to junior staff seriously?
A Yes, very much so.
Q  He was an approachable individual?
A  Yes.

Q  When the CNEP trial was proposed I think you were happy as the senior consultant, in age at least, to have it trialled because your experience of CNEP was that it had been beneficial in the past?
A  Yes, I was happy for it to be trialled.

Q  I do not think you had had a bad experience. You told us about the referrals from elsewhere in the Midlands with CNEP. You had not seen it harm a child?
A  Not that I recall, no.

Q  From your perspective when the trial was being proposed, it would have been, would it not, reasonable to excuse it as a safe form of treatment?
A  Yes.

Q  There are, of course, particularly in relation to drug trials some forms of treatment which might not be confidently described in that way? They might have more inherent risks?
A  That is correct, yes.

Q  This was not a trial which you saw as having any inherent risks. Is that correct?
A  No, and I did not have reservations about it at all. There were other trials at the time were multicentre and we were partaking in, and I had some doubts about.

Q  I think one of the perceived advantages at the time was that IPPV, the standard treatment, was known to have the potential to cause damage, as you have explained, to the alveoli and the lungs in general?
A  That is correct because it was before the days when surfactant was in use and therefore you only had virtually ventilation and pressures to help the babies. Some babies that had very bad lung disease and very immature lungs required very high pressures. The higher the pressures on the ventilator, the more likely there was to be damage to the lungs, the alveoli. You saw more chronic lung disease which ensues from the bad respiratory distress syndrome initially. We saw more of it in the 1980s and the first half of the ‘90s than we ever do now.

Q  One of the disadvantages of IPPV, as you have explained, was the positive pressure of itself could cause lung damage. You also, I think, had to monitor quite carefully in order not to cause what we now call retinopathy of prematurity; you could blind a child, could you not?
A  Well, yes, that is probably multifactorial. It may be the oxygen levels. I mean there are other things. The children had to be ventilated longer on - before surfactant and with IPPV and there was such things as a condition called subglottic stenosis, this is when you get irritation in the ...

Q  In the throat?
A  ... trachea, the windpipe, and we had to give certain babies tracheostomies because of that, which has risks.
Q Yes, and it is highly invasive?
A Yes.

Q And can cause infection as well?
A Yes.

Q Can I then just ask you a little about the role of Dr Spencer? Help me if you can. His recollection of his weekly duties at this time was that he used to do a neonatal follow-up clinic on a Tuesday afternoon. Does that ring a bell with you?
A Yes, it does ring a bell.

Q He would do a general paediatric clinic on a Wednesday morning. Do you recall that?
A Probably, yes.

Q But, in any event, even if a child had him as their nominated consultant, you would share your duties, it seems?
A We worked very closely together because there were only two of us at that time and there are now five or more. We had to and we had to look after each other’s patients when one or other of us was away. We did about half to two thirds of our time in the neonatology, but we did one third plus in general paediatrics because we had to cover the general paediatric wards and outpatients. We were on take for general paediatrics, see the children coming in with pneumonia and things like this.

Q It was a busy situation within the neonatal ward, as we understand?
A Yes, it was because there were about 6,000 deliveries. I think it was the second biggest neonatal unit in the UK at the time.

Q Did you have confidence in your junior doctors, consultant colleagues and nursing staff?
A Yes.

Q You will be aware that at one stage you were the subject of allegations being made against yourself by the parents of Patient 6 and 7?
A Yes.

Q I think you were accused of not intervening quickly enough to alert the world to the obvious dangers of CNEP. I do not know if you recall an affidavit being sworn which suggested that?
A I do not really recall that, but I did not have any problems with CNEP and I do not think there were great issues with it at all.

Q Thank you. Were you aware that, if not yourself but other colleagues, had been accused of forgery and even murder?
A Yes, I was, sadly.

Q How do you feel about those allegations?
A I think they are wrong. Completely.
A  You have helpfully explained - and I am not going to go over it again with you -
the situation as regards your process of consenting. I wanted to ask you a little about
the medical records pertaining to Patient 6. You will find those behind tab 5. I, first of
all, would like to take you - it is quite indistinct, but it is page 21 at the bottom. You may
find it more easily by finding page 22 and going back a page. It is bottom right.

A  Yes.

B  This is 14 December 1992. Child premature, 32 weeks, breech presentation, born
at 18.50. Then the maternal details, the delivery is by Caesarean section. There is a tubal
ligation, cried immediately, transferred to the special care baby unit. Then over the page
we have various vital signs taken. You can see the plan: incubator care, a chest x-ray at
four hours. Do you recognise the signature of that note? It is about two thirds of the way
down on page 22.

A  No.

C  We know the next note was written by Dr Newell, now, Stanley then:

   "Reviewed at 4hrs. 40% O2 [in a] headbox, 94% sats, pH 7.26,
   pCO₂ 6.7."

D  Chest x-ray revealed moderate respiratory distress syndrome and “consent for CNEP
obtained”. I think respiratory distress syndrome was an indicator in terms of entering to
the trial. Is that correct?

A  Yes, as far as I recall, yes.

Q  The next note on the 15th we believe to be yours. You have a rather distinctive
signature.

A  Yes.

Q  Would this note on the 15th - which I think we believe to be a Tuesday - be a note
of your morning ward round, do you think?

A  Yes, it would be.

Q  We can take it you saw this child in the morning?

A  Yes.

Q  She was in 40 per cent oxygen, her respiratory rate I think was I think 90 - is that
90 or 95?

A  90 I think per minute.

Q  And the CNEP, she having been randomised, negative pressure is minus four and
you have put, “?” UAC later this morning”, so that is the umbilical arterial catheter?

A  Yes.

Q  You make a diagnosis of respiratory distress syndrome?

A  Yes.

Q  You suggest continue “present support - hopefully with” ---
Q. Then at 12.30 on that date, we have a long note. I think we think that is Dr Arya, and it extends over to page 25. You can see a signature “RA”?
A. Yes.

Q. Again, we are doing our very best to try and reconstruct likely events at this time because it is a time where Dr Spencer is accused of ignoring obvious hypoxia. It looks as if you did the ward round on the 15th, as you have told us. It then looks as if in the afternoon at 12.30 Dr Arya, the registrar, saw the baby. Do you see that?
A. Yes, I mean what is likely to have happened is that she would have been called urgently by the nursing staff at 12.30 pm.

Q. Because of bradycardia?
A. Because of the apnoea and bradycardia.

Q. What we believe and what we know is that that afternoon, all things being equal, Dr Spencer would have been doing his neonatal clinic because it was a Tuesday?
A. Yes.

Q. Day three it would appear that - this is page 25 - somebody else sees the patient. That is a darker pen?
A. Yes.

Q. Then day four we have a lengthy note, and half way down page 26, “Seen by Dr Spencer”, and a signature?
A. Yes.

Q. We cannot identify the signature. As far as the notes are concerned, would you agree with me it looks as if there is not a noted encounter between Dr Spencer and this baby until the fourth day of life?
A. Yes, I think that is correct.

Q. You would expect the junior staff to note when a consultant was present or for the consultant to write in the notes himself?
A. Yes, probably, although there were only two of us in those days, so we may have seen the baby and the baby may have been stable and nobody wrote in the notes that we had actually seen the baby, because we used to go in usually at five o’clock when we would come back from clinic, or been to a meeting or whatever, to see whether there were any problems or issues.

Q. Yes, I understand that. We cannot identify any problem mandating the presence of a consultant, but would you agree with this: if it is not in the clinical note, normally - and again we are going back a few years - the nurses were fairly good at recording encounters between ---
A. No, they were very good at doing that.

Q. If there is an absence of a nursing note in the first three or four days of life ---
A. I thought you were meaning only these notes ---
A

Q No, no, we know the nursing notes are usually better than the clinical.
A Yes.

Q And we know that the clinical notes are usually best written by the most junior staff.
A Probably right, yes.

B

Q If you could now turn with me to the intensive neonatal notes. The first I want to ask you about is page 84. You should have, hopefully, a better photocopy of page 84. I do not know if it has been placed in the bundle or whether it has been kept as a separate ... (Same handed) I just wanted to see if you could help me with the benefit of your experience. At this time, if one were looking to take a blood gas, one could do it by way of an arterial stab, which tended to produce hypoxia following the stab, would you agree?
A Yes, arterial stabs were painful for babies, significantly more so than capillary stabs.

Q The kinder way of taking a blood gas was to take a capillary sample?
A It is also somewhat more practical because sometimes you could not get an arterial gas and there was a risk with that that you might cause haematoma by stabbing the artery, or even block the artery.

Q Would you agree with me that a capillary blood gas sample does not give you a true \( pO_2 \)?
A Yes.

Q Insofar as any expert called by the General Medical Council purports to rely upon a capillary sample as giving a \( pO_2 \), you would regard that as unreliable?
A I would. You have to take it in conjunction with the oxygen saturation levels as well.

Q If you look next to the left-hand column, can you see that there are some “A”s? I would suggest those would denote arterial blood gases. They are very faint. Is it a reasonable assumption that where there is an absence of an “A” it is a capillary sample?
A Yes, I think that is correct, yes.

Q You have talked about saturation levels. We do have some charts on pages 85, 86 and 87. Can I ask you this: in general terms if you are looking at saturation levels between 95 and 99, would you regard those saturation levels as contraindicating hypoxia?
A Yes.

G

Q Furthermore, if a child has respiratory distress syndrome, would you regard a \( pCO_2 \) level of something between 6.3 and 7.4 as being reassuring in the context of respiratory distress syndrome?
A Yes, that would be acceptable and I would not want to alter treatment if the levels were at 7.3 or ...

Q Similarly, again in the context of respiratory distress syndrome, would you be - perhaps not entirely happy, but relatively happy with pH levels of between 7.23 and
7.28?
A Yes, I would. If it is over 7.25, that is satisfactory. If it is under 7.25, I think I would have suggested that the gas should be repeated within an hour or two to check that it was not falling further.

Q At about 7.23, as long as there is monitoring by nursing staff - and we have been through this with Dr Morgan - and evidence of changes in the percentage of oxygen, for instance, and the inspiration rate, you would be satisfied that that child was being adequately monitored?
A Yes.

Q You were satisfied that your neonatal nurses had the skill, experience and ability to recognise brain damaging hypoxia?
A Yes.

Q It is one of the most fundamental observations that they do, is it not?
A Yes, they were very good - and still are very good - at picking up apnoeas, bradycardias.

Q As we see from Patient 6, you think Dr Arya, looking at the note that we were looking at before, was probably called to the ward? If you remember we looked at the note on page 23 and you say, “It says prolonged bradycardia and apnoea. I think that would have been a response to a nursing concern”?
A Yes, I ---

Q You are right because we have seen it in the nursing notes, but I am not going to take you to that at the moment.
A Okay.

Q Can I just ask you this, as there is another suggestion we are bewildered by: if you have a pH between 7.23 and 7.28 in a child with respiratory distress syndrome, and you have a pCO\textsubscript{2} of between 6.3 and 7.4, again in the presence of respiratory distress syndrome, would you agree with me that that does not indicate that there is a problem with the saturation monitor?
A Yes, I would agree with you.

Q Particularly if the saturations actually recorded are between 95 and 99?
A Yes. Saturation monitors in those days came in the mid ‘80s or early ‘80s and they were good and reliable.

Q Then could you go - and, again, it is quite difficult to see the page numbering - within that bundle behind tab 5 we have pages 125 and 126. These are blood gases taken during a claimed period of hypoxia. I just wanted to ask you about your impression of them. Do you have those pages? The numbers are quite hard to see. 125, which is partly obscured, but it starts with an entry at 19.30. Do you have that?
A Yes.

Q The O\textsubscript{2} percentage is 24 per cent, so just slightly more than exists in the atmosphere; we are told 21 per cent. A saturation of 95. We can see that the percentage
A

is increasing ...
A Yes.

Q ... over time but the saturations vary between 94 and 97?
A Yes.

B

Q The negative pressure we can see is at minus four?
A Yes.

Q If you go over the page, we have the oxygen percentage varying, I think at its lowest - this is once the child is in CNEP - is 35 and its highest 50?
A Yes.

Q Can you see, if you go to the very top of the page, you have “TIME” on the left-hand column and then the percentage of oxygen and then “Tcp O<sub>2</sub>”, we know that is the probe, but underneath someone has written “CNEP” in manuscript?
A Yes.

Q Does it appear to you that those minus values are negative pressures?
A Yes.

Q Can you conceive of any way in which they could be interpreted as probe measurements as minus values?
A No.

Q Would you agree that looking at the saturation levels on that page and the page before - and I think they fluctuate between 95 and 100 - that this child is not hypoxic?
A Yes, I would agree this child is not hypoxic in these measurements.

C

MR FORDE: Dr Brookfield, that has been very helpful. Thank you.

Cross-examined by MISS O’ROURKE

Q Dr Brookfield, I ask some questions on behalf of Dr Southall, who I think you know?
A Yes.

Q You worked with Dr Southall as a professional colleague for a number of years?
A Yes.

Q Would it be fair to say that you hold his abilities in high esteem?
A Yes.

Q You said in your witness statement that before the trial started in Stoke that there were meetings and educational lectures delivered by Dr Samuels and Dr Southall to educate nurses and doctors?
A Yes.

Q You would agree that that was the case?
A  Yes.

Q  And they came up from London to do that. You say in your statement from your point of view you had no problem with the way in which the trial was conducted?
A  Yes, that is correct.

B  Q  The lectures that they delivered, would you agree that Dr Southall was particularly good on the training that he gave at that time?
A  Yes.

Q  He had good familiarity with CNEP because he had used it before and written on it before?
A  Yes.

C  Q  And that in the explanatory lectures that he delivered, they were available to all the staff?
A  Yes.

Q  I think you say that in your witness statement, and they were accompanied, as far as you recall, by written material?
A  Yes.

D  Q  He was available to answer any questions on those visits that he came up from London on?
A  Yes.

Q  But in addition he was accessible by telephone to answer any queries that any of the staff on the unit had?
A  Very much so, yes.

E  Q  When he moved to Stoke to set up the academic department in 1992 he was then available directly to answer any questions on CNEP?
A  Yes.

F  Q  If you ever had any questions to ask him you found he was able to answer your queries?
A  Yes.

Q  As far as the conduct of the trial was concerned, he was involved in seeing that it ran well?
A  Yes.

G  Q  I think you said in your witness statement as well – it is paragraph 11 for those who are looking at it – that you believe that by the standards of the time it was a very well organised trial, there was a lot of information, more than would usually be available for that sort of period, the beginning of the 1990s?
A  Yes, that is my opinion.

H  Q  In terms of the information given to parents and the taking of informed consent,
you also said in your statement that your perception at the time was in comparison, again, to the standards of time, the amount of quality of the information provided to parents was very good?
A Yes.

Q And you had been involved in other trials presumably to be able to make that comment?
A Yes.

Q You were asked about the neck seal and you said “We didn’t actually have any neck seal problems at Stoke so we had no recurrence to prevent”?
A That is as far as I recall, there were not any problems with the neck seals.

Q But you had been aware in the past there had been problems at Queen Charlotte’s?
A Yes, I think it was there. The nurses dealt with the neck seal and they dealt with it very well, and it worked without problems from my perspective.

Q What I was going to suggest to you was that Professor Southall was in fact involved in looking at how the neck seal could be done and on the use of gel and on things that could be done to make sure there would not be problems?
A Yes.

Q They were specifically addressed?
A I cannot recall that but there were not any problems so it must have been addressed.

Q Exactly. It was addressed to make sure there were no problems?
A Yes.

Q Surfactant, which you mentioned, I just wonder if you can confirm this: when surfactant was introduced it was introduced for all babies, whether they were in the trial or not?
A Well, all babies that met the criteria for requiring it, yes.

Q In other words, it was not just that it was introduced in the trial---
A Oh no, no. Any baby that had respiratory distress syndrome and met the criteria -- which I think was set down regionally but I cannot remember precisely---

Q They were indeed set down regionally so it was effectively a mandatory treatment for those who met the criteria?
A Yes.

Q You said in your witness statement about information that was available. Can I just read you a passage? It is paragraph 7 of your statement. You say:

(Statement not produced to shorthand writer)

“There was written information for the doctors about the process for discussion with the parents. The written information was kept on the
notice board or in a folder on the neonatal unit. All of the medical staff and nursing staff knew where to find this information.”

Do you remember saying that?
A Yes.

Q What I want you to do is look at this folder and see if you recognise it as the folder that you are talking about that was on the neonatal unit and which the doctors could use to discuss information with patients (Same handed)?
A Yes, this seems very familiar.

Q That is the folder I am going to suggest to you was available at the nurses’ station and if a doctor wanted to consent a patient they could go and grab that folder and then show that to the parents?
A Yes.

Q Finally this. Mr Forde asked you about you yourself being the subject of a complaint to the General Medical Council by the Henshalls in 1997?
A Yes.

Q You presumably are aware that you are here today not at the request of any of these doctors but as what might be called a prosecution witness?
A Yes.

Q In a case brought by the Henshalls?
A Yes.

Q How do you feel about that, being a prosecution witness when you yourself were the subject of complaint and bearing in mind that you have said now in respect of two of these three doctors you hold them in high esteem, and I presume you would say the same about Dr Samuels?

MS SULLIVAN: I query the relevance of that.

MISS O’ROURKE: I think it is relevant if you are going to be considering the conduct of these doctors and serious professional misconduct. I think it is relevant from somebody who is a professional colleague and who himself has been the subject of allegations in respect of a treatment in a trial you are looking at.

MS SULLIVAN: I think Miss O’Rourke was just asking him how he felt about being here.

MISS O’ROURKE: I will put it more directly.


MISS O’ROURKE: You are being asked to be a prosecution witness in respect of Notices of Inquiry alleging serious professional misconduct---
A Very uncomfortable.
A  

Q  …against three doctors you know?  
A  Yes.

Q  On the basis of your knowledge of them and your knowledge of CNEP. What do you feel about being a prosecution witness and do you have any complaints about CNEP or these doctors?  
A  I do not have any complaints about CNEP or the doctors at all. I feel very uncomfortable about being here in this position but that is how it is and I have not got any option really.

MISS O’ROURKE: Thank you.

Cross-examined by MR FOSTER

B  

Q  I represent Dr Samuels. He is a clinician you hold in high esteem as well, I think?  
A  Yes.

Q  You have spoken in glowing terms about the training which was given by Dr Southall and Dr Samuels?  
A  Yes. They were very enthusiastic from my point of view and they did a lot, spent a lot of time and put a lot of effort into it and came up a lot as well.

Q  You found Dr Samuels’s contribution to that training helpful?  
A  Yes.

Q  And Dr Samuels too was available on the end of the phone?  
A  Yes.

Q  He being in Stoke for any queries which anyone might have?  
A  Yes.

MR FOSTER: Thank you.

Re-examined by MS SULLIVAN

C  

Q  Dr Brookfield, you were asked about surfactant. Do you remember when artificial surfactant started being used on the neonatal unit?  
A  No, I do not remember precisely. It may have been at the time of the trial but I cannot remember. I think it was introduced into the West Midlands all at once because I think it may have been funded from the region centrally because it was expensive at the time – I think it was about £500 for a course for each baby, which was a lot of money in those days. There were issues around that, which I cannot recall completely.

Q  You have told us about being on a morning ward round on 15 December?  
A  Yes.

Q  What time would your ward rounds have been in the morning?  
A  I cannot remember precisely but what I used to do was to go round at about nine
o’clock and I would go round until 10.30/11.00 – it may have been a bit later if there was a lot of work on the ward – and see all the patients, and that included intensive care patients and ones that were going home, right up to the time of discharge from the neonatal unit.

Q Would other doctors accompany you on the ward rounds?
A Yes, there would usually be a registrar and a senior house officer on the ward round and obviously various nursing staff as well.

Q We see from your note – I am looking at page 23 behind tab 5?
A Yes.

Q You have put “? UAC later this morning”, do you see that?
A Yes.

Q I just wondered if you could help as to the reason for that?
A This baby, I think, at that time she had been born the previous evening at 18.50, so that is 7 p.m. roughly. She would just be over twelve hours old, and with respiratory distress syndrome it is difficult to know what is going to happen but there was a distinct possibility that there might be further worsening of the respiratory distress, i.e. deterioration, over the first 24/48 hours after birth. Therefore, I think my thinking was that although hopefully this baby would do well she might deteriorate and we might have to ventilate and we might have to consider putting an umbilical arterial catheter in and unfortunately that is what happened.

Q Obviously you were not there at the time when there was an urgent call?
A I do not think there was but I cannot recall that all these years later. I was Clinical Director at the time, I know that, and that meant I was having to do a lot of meetings, management and these sorts of things.

Q I do not think we have heard any suggestion that you were there at that time, Dr Brookfield. In terms of the various levels that related to this patient, Patient 6, I think you said that in relation to her pH level, if it was under 7.25 you would have suggested repeating it within an hour?
A One to two hours, yes.

Q What is the reason for that? What does it suggest?
A Because the child is ill with respiratory distress syndrome you have to take the whole clinical picture of the baby, not just one result into account. There is a concern that the baby may deteriorate. What you are hoping is that the situation is going to improve and you will not have to do anything, but if it deteriorated further then you would have to consider whether you needed to implement more treatment.

Q Such levels might suggest, might they not, that she was acidotic?
A It depends what you mean. Certainly you would not want to give treatment in the form of sodium bicarbonate or Pham(?) at that stage, which are alkalis – you would not consider that at this level. It is just an indication that there might be possible deterioration over the next few hours and you need to be aware of that and watch for it closely.
Q Again, the pCO$_2$ level of 6.3 to 7.4, would you agree that that was raised?
A It is raised but it is raised in the context of the fact that this baby has significant respiratory distress and it is what you would expect in a baby such as this with a respiratory rate of 19 and oxygen of 40 per cent and also changes on the chest x-ray indicative of respiratory distress syndrome.

Q You have also said about the pCO$_2$ levels – I have heard what you have to say about the capillary stab being a less true picture?
A Yes.

Q But would you agree that levels of 4.5 to 4.7 are low?
A No, not on a capillary gas because that is what you expect. You have got to take that in conjunction with other readings. If your oxygen saturation is running over 92 per cent then this indicates, and it is so, that oxygenation of a baby is satisfactory at that time.

Q I wonder if you could just help? If the blood gases were acceptable, why would she stop breathing, this baby? Why would she crash?
A Because she is premature to start with, she does not have the same respiratory drive from the brain as a term baby, she has got stiff lungs because of the immature lungs and respiratory distress syndrome, and that makes breathing harder, and her musculature is not as well developed and things like the diaphragm and the intercostal muscles are not as well developed as a term baby. Therefore, unfortunately babies who have got respiratory illnesses and are pre-term like this do have bradycardic episodes and apnoeic episodes.

Q You have indicated the importance of checking the results to ensure that she does not deteriorate?
A Yes.

Q What would the consequences of deterioration be? You have said that in your opinion she was not hypoxic, but is hypoxia always a possibility?
A What you have got to do is if she becomes hypoxic you have to increase the oxygen levels, and if they get to a certain stage, perhaps above 60 per cent oxygen, then you have got to think about ventilating the baby basically.

Q In due course this baby was indeed ventilated?
A Yes.

MS SULLIVAN: Sir, I have no further questions.

DR SHELDON: Good afternoon, sir. Although I am the medical member of the Panel I have been a GP all my life so some of my questions might be a little bit simple but also my colleagues are lay members so I think there are one or two things we might like to explore. Firstly, you say you took consent on one occasion?
A Yes.
A  Q  Are you quite happy that the quality of the consent you took was perfectly adequate even though you only did it once?
    A  Yes, as far as I can recall, but I cannot recall the details after all these years.

B  Q  It is just that two scenarios have been put to us, one where one doctor always takes the consent, or nearly always takes it, and therefore is consistent, and the other scenario where on a ward such as this many different people may take the consent. Is the issue one not so much of how many people but rather the quality of the training they receive?
    A  I think that is true when you have got a situation where you have got to obtain consent by four hours of age and there is a time and it is an acute situation and the training has to be good, and I believe it was good.

C  Q  Would you expect that most of the staff on the ward would be able to take consent?
    A  Yes.

C  Q  And as part of the design of the research project that would be an essential part of the training?
    A  I do not quite follow the question.

D  Q  The taking of consent would be a part of the training?
    A  Yes.

E  Q  The second is the blood pressure. In this sort of a baby, a few hours old where they may be in an incubator and difficult to take the blood pressure, how important is it clinically to actually have the blood pressure measured rather than the other things that we can see here?
    A  It is difficult because in the early 1980s when we were ventilating patients we did not have transducers to monitor the blood pressure so we had to rely on the cuff method if we were going to take blood pressure, which was not very accurate for reasons of the baby’s arm being small and factors like this. I think blood pressure certainly is not the most important parameter; you have got to look at all the other parameters such as the oxygen levels, how the baby is clinically and whether the baby looks unwell, pale, shut down. Nowadays I think one would be expected to take the blood pressure and have a transducer in. It is not always possible to get one in, having said that, and there are occasions when we cannot do it very well and we have to use other parameters such as the blood gases, the oxygen saturation.

F  Q  Specifically, what does the blood pressure tell you that other measurements will not?
    A  It is merely telling you about the perfusion of the baby and whether the baby is shocked and shut down and whether you need to give extra boluses of fluid. You can to a certain extent do that by other clinical methods, especially observation of the baby.

G  Q  My next question refers to this page 84 of the records that we have looked at once or twice. We have observed that the time of the top five or six measurements show that this was through the night and in the early hours of the morning up until twelve mid-day?
    A  Yes.
Q There the pH pCO₂ and pO levels you are saying are all taken by the capillary method?
A Yes.

Q Which will be less accurate?
A The trouble is if you do an arterial stab it would be less accurate than a continuous measurement via an umbilical arterial catheter, but if you are doing an arterial stab into a radial artery that does not give a very accurate picture because the baby will cry and become hypoxic before you have got the blood out to measure it. I think then the most reliable, and now often the most reliable, measurement was by the oxygen saturation.

Q From 1417 hrs, the next five have all got an “A” against them which I think we have been told means that these were from the arterial catheter?
A Yes, I think that is probably---

Q Do you agree that all of those measurements seem to be within the normal range now?
A The 7.27 is still a little bit on the low side for the pH. This is where the baby had been ventilated and there was an arterial catheter in place, I think, yes? They show that the CO₂ had dropped, you would hope it would because you had intervened with ventilation at this stage.

Q Can you give any estimate of how much the difference in those figures is due to the ventilation and how much is due to the different form of measurement?
A I think it is probably due to the ventilation, would be my interpretation.

Q My last question concerns the oxygen saturation monitor. Do they often become faulty?
A No, not in the 1990s. In the mid-1980s.

Q How would you know whether one had become faulty?
A We had a technician on the unit who used to monitor them and check them and calibrate them regularly. I personally would not know, but he would know.

Q It was not something that used to happen every week, someone would say, “Oh, this monitor is faulty”?
A No, not at all.

Q Once a month?
A Possibly, I think. I cannot really recall all this detail but that is my thoughts at the moment, yes.

DR SHELDON: Thank you very much.

MRS BRICKLEY: You discussed monitoring of babies and the possibilities of hypoxia. Are there any visual signs of hypoxia that you could tell just by looking at a baby?
A Yes, the baby, when it is significant the baby would be blue, cyanosed.
Q Is that an instant visual reaction or can there be a slow process of discoloration, for want of a better phrase?
A It depends on the circumstances. If the baby suddenly deteriorates and has an apnoea and stops breathing and does not start breathing again, then the baby is likely to become blue within half a minute. Before we had oxygen saturation monitors in the early 1980s, we had to rely on arterial gases, which had their significant limitations, but also babies we noted were sometimes looking a little bit blue and that is one of the reasons, one of the ways that we clinically interpreted that a baby was hypoxic. This is in 1980, 1982, something like that.

Q So it is possible to be hypoxic without collapsing as a pre-term baby?
A Yes.

MRS BRICKLEY: Thank you very much.

THE CHAIRMAN: Dr Brookfield, I wonder if you can just help me with something and it is related to a topic which Dr Sheldon was asking you about. Could I take you back to page 85 in the folder? This, of course, is the chart which, as far as I can see, is manually completed?
A Yes.

Q It is not in any sense produced electronically.
A No. Well---

Q The figures which are recorded may have been produced, but this is not produced by a machine, is it, this?
A No, none of the ups and downs or the writing is not, no. It is all done by the nurses.

Q What they are recording may well have been produced electronically and, indeed, probably was, in the sense that the pulse rate is thrown up on a screen so you then note the figures down?
A Yes, although they may listen to the heart rate and take it from that.

Q It could be one or the other?
A Yes.

Q Am I right in thinking that this is a record which would be the responsibility of nursing staff to complete?
A Yes, predominantly, yes.

Q Ms Sullivan was asking you about the BP mean. Can you find that again on the chart?
A Yes.

Q I see that somebody has written in that line what looks to me like “extra to req”, so presumably “extra to requirements.” Can you help us as to what the might mean?
A Where it is feed and requirements?
Q If you look half way down the right-hand column where it says “BP mean” and go across to the right and there is writing in capitals which looks to me like “extra to req” – R-E-Q?
A I have not got that on this page 85.

Q I do apologise, it is on 86. I am so sorry.
A I think that is referring to extra to requirements and it is referring to the column below which has got “NBM” – which means nil by mouth - and then further along it has got “EBM” and that is expressed breast milk.

Q So the “extra to requirement” has got nothing to do with “BP mean”?
A No, it refers to the fact that we would be giving baby on Day 2 about 90ml per kilo per day and if we were starting nasogastric feeds we would not include that 1ml per hour of expressed breast milk in that 90ml. I think that is what it refers to.

Q Fine, I just wanted to be sure that it did not have any relevance to the BP mean column?
A No, I do not think it does. At least, that is my interpretation.

Q Given the answers which you gave to Dr Sheldon’s question about the question of taking blood pressures of a baby and the fact that they may not be that significant, as a consultant and putting yourself back to the time we are dealing with, 1992, if you were reviewing as a consultant the charts of a patient and you were looking at this and you saw no blood pressure recordings, would you be concerned or would you have reacted to that in any way?
A I do not think I would be unduly concerned. It would be always helpful to have blood pressure readings and it would be good but I would not consider it poor care or anything like that at all.

Q Would the absence of any recorded blood pressure prompt any query by you, or any reaction by you?
A That is difficult. It is whether it was recorded on another sheet and that sheet has got mislaid and that is another possibility but I just do not know the answer to that.

Q It was not so much a question of whether it might be elsewhere; it was whether the absence on a record you were looking at would have prompted any question by you?
A No, I do not think it would.

THE CHAIRMAN: Thank you very much. Anything arising out of any of the Panel questions?

Further re-examined by MS SULLIVAN

Q Just a couple of matters, if I may. Dr Brookfield, can you help us as to the type of saturation monitor being used at that time? If you cannot say so?
A No, I cannot remember.

Q Once a baby was intubated and a UAC was in position, would you expect blood pressure readings to be recorded?
A That depends because it was done by transducers which is in the arterial line and these were certainly to begin with quite temperamental and difficult to operate and I cannot remember when we got them, I think we had them at that time and therefore it would not surprise me if an arterial line – it would not surprise me if there was not blood pressure readings to an extent, anyway.

B If there were not readings at all?
A Yes, it would not surprise me if there were not readings at all.

MS SULLIVAN: Thank you.

Further cross-examined by MR FORDE

C Dr Brookfield, I want to revisit some of these matters and see if we can put them into context. A long-standing, twelve hour, brain damaging hypoxia would probably result in death, would it not?
A Yes.

Q A blue baby, by which I mean discoloured all over its body, is something you would expect any averagely competent neonatal nurse or member of the junior staff to recognise?
A Yes.

Q Hypoxia or cyanosis manifesting itself, or perhaps indicating hypoxia, would first of all be noted, you would hope, in the extremities – tip of the nose, blue lips, fingers, that sort of thing?
A Yes, probably.

Q Probably. You have been asked to look at page 84 and attempts have been made to deal with the pH and you have told us very helpfully round about 7.25 and above to be watched but not concerning; 7.23 consistent with a child with respiratory distress syndrome and I suggested mild acidosis?
A Yes, but that does not need treatment.

Q That is what you told us and you would not be filling this child, because she is acidotic, with an alkaline solution?
A No, not at all.

Q One of the reasons why you would not be doing that which you have not been asked about, would be because if you look at the base excess, which is the BE column, would you agree that during the period of time, for instance the 7.23 we have in the second entry, that the base excess would provide you with additional reassurance as to the condition of this child? Is that fair?
A Yes. We would not consider alkaline unless it was more than base excess of 10.

Q And the highest I think we get is 9.4?
A Yes.

Q So no need to treat?
A No.

Q In these circumstances, consistent with respiratory distress syndrome. When we look at our pages 85 onwards we see a well saturated child in terms of the fact that her saturation levels fluctuate between 95 and 100?
A Yes.

B Q Again, that is reassuring?
A Yes.

Q That contraindicates hypoxia?
A Yes, this child was not hypoxic.

C Q Thank you. In terms of responsibility for record keeping and the mean blood pressures, when the charts are filled in the nursing staff are taking at the approved hourly or half hourly or quarter hourly time the snapshot of that which they see?
A Yes.

Q You would also expect them to have an eye upon the continuous monitoring available via the transducer?
A Yes, if there was a transducer present, yes.

D Q If there was a transducer in place. If not, you would expect them also to be exercising their clinical skill and judgment to look at the overall condition of the baby?
A Yes.

Q If not you would expect them also to be exercising their clinical skill and judgment to look at the overall condition of the baby?
A Yes.

E Q The responsibility for filling in the charts we have looked at is that of the nursing staff?
A Yes.

F Q As a doctor, if you arrive upon the scene and the blood pressures have not been done, you cannot ask the nursing staff, can you, to make them up retrospectively?
A Sorry?

Q You cannot ask the nursing staff to make them up?
A No, not at all.

G Q If they have been omitted by the nursing staff, that is just an irretrievable error from the point of view of the medical staff?
A Yes.

Q It is not something that you as the doctor can put right?
A No.

H Q In fact the nursing staff will probably find themselves before the NMC if they
started putting in false values retrospectively?
A    Yes.

Q    The other difficulty for the member of the medical staff is, if he is conducting a clinic on a Tuesday afternoon when the problem is alleged to have first manifested itself and a clinic on the Wednesday morning, and is at home in the early hours of the Tuesday and asleep Tuesday evening into Wednesday morning, how on earth can it be his responsibility to ensure that blood pressures are recorded on the chart? Can you envisage any circumstance in which that could be seen to be a culpable failure on the part of a consultant; he is either not there or at home?
A    No.

MR FORDE: Thank you.

THE CHAIRMAN: Dr Brookfield, that completes your evidence. No-one has any more questions for you so it just remains for me to thank you for coming this afternoon and for the assistance you have been able to give the Panel. Thank you very much.

(The witness withdrew)

MS SULLIVAN: Dr Wheatley is here.

THE CHAIRMAN: Yes. We were just contemplating a short break but I am anxious if possible that we should finish Dr Wheatley this afternoon, because I would not want him to have to come back tomorrow because of the fact we are rising at 4.30. Is it anticipated how long - if we were to have, say, a ten minute break now would we have long enough in an hour and five minutes, or thereabouts?

MR FORDE: I have very little for the next doctor.

MISS O'ROURKE: If Mr Forde is not asking very much the maximum I would ask, if he has not already asked it, is ten minutes.

THE CHAIRMAN: Let us have a ten minute break then and come back at 25-past three. Thank you.

(The Panel adjourned for a short time)


MS SULLIVAN: Dr Wheatley, please.

THE CHAIRMAN: Am I off track in thinking that Dr Wheatley is the person whose initials, RW, appear in the CNEP log?

MS SULLIVAN: That is right.

THE CHAIRMAN: Thank you.
ROBERT WHEATLEY, affirmed
Examined by MS SULLIVAN

Q Good afternoon, Dr Wheatley. What are your full names? Would you mind starting with those?
A My name is Dr Robert Wheatley.

Q Your qualifications, Dr Wheatley?
A MB BS University of Newcastle 1986, Member of the Royal College of Physicians and Fellow of the Royal College of Paediatrics and Child Health.

Q Your current appointment?
A I am a consultant community paediatrician in Blackpool.

Q Dr Wheatley, you have just told us that you qualified, I think, in 1986?
A That is correct.

Q And following that no doubt had a number of house officer jobs?
A Yes.

Q I want to come to the time when you worked in Stoke at North Staffordshire Hospital. Can you tell us when it was you went to Stoke?
A Right. I think I worked it out from February 1990 I started in Stoke and worked for two years and nine months there.

Q So you left in about October 1992?

Q I just want to be clear as to where you worked at that time as a registrar?
A I have not brought my CV with me but from recollection I had the first six months attached on the neonatal unit and then progressed through attachments on different aspects of the children’s ward and finally I did I think a year and three months in community child health in Stoke.

Q Yes, so obviously when you were doing community child health were you on call at all then?
A I was, yes.

Q So your first six months were in the neonatal unit?
A That is correct. I believe that is correct.

Q You would then have had clinical care of the babies on the unit?
A Yes.

Q Thereafter would your involvement in the unit have been when you were on call only, or not?
A Yes, really just out-of-hours on call.

Q When you joined the unit, had the CNEP trial begun?
A I was certainly aware of the use of CNEP, though frankly I cannot recollect exactly when I first became aware of it. It was something that was certainly done on the unit. I cannot honestly recall when it started or when the trial started.

Q Do not worry about that because we have that from other information, but in terms of your own involvement in the CNEP trial in terms of consenting parents, for example, at what stage did you become involved in that? Do you know?
A Again, from recollection, I believe that I would have been involved from the commencement of the trial as it was generally the on-call registrar, as I would have been, who would have been taking consent for trial entry. I certainly was not doing it when I started the job and I certainly was when I finished, but at exactly what point it started I do not remember.

Q All right. Let us give you some assistance, hopefully, on that. If you look at file 1, which will just be identified to you, behind tab 3 at page 367.
A I have page 367.

Q Yes, I think if you look at “Name of caller”, because this is a log not kept by the doctors in Stoke but as a result of communications from them, we see there “Name of caller” in the fourth column along. Do you see that?
A Yes, I see that.

Q Do we see the first reference to your name Dr Wheatley on 28 April 1990?
A Yes, I have identified that.

Q I think I next see your name - correct me if I am wrong - on 12 July 1990?
A At the bottom, yes.

Q We see again your name on two or three occasions on the next page, which again is in the course of 1990?
A Yes.

Q Likewise, if we turn over the page, we see a couple of mentions of your name in 1991? Do you see those?
A I do, yes.

Q I think I do not see your name on the next page, but correct me if I am wrong.
A No.

Q Then on the page after that, might you be the “RW” that we see on 26 January 1992?
A I may well be. I do not think there was anyone else with those initials, but I cannot be certain.

Q Yes, then going over the page again, I think we see an “RW” there?
A Yes.
Q Does that give you some indication of your involvement in this process?
A It does.

Q I wanted to ask you about it. Was there any training in relation to CNEP at all?
A As I have said, it was something that was very much a part of working on the unit. There were certain aspects of working with infants in a CNEP tank that differed from working with infants in a conventional incubator. One certainly had to be trained about those. An awful lot of training at the time was practical hands-on, on-the-job training. As I recall, I felt reasonably confident in dealing with the CNEP tanks. They were a little more difficult than conventional incubators, but this was something that we learned and we got used to.

Q Yes. I was asking you, or about to ask you, about the process of obtaining consent, Dr Wheatley. Can you explain what process you would have gone through at that time?
A I have tried to recall this as best I can. Obviously it is a very long time ago that we did this. The picture that I have in my mind is that after an infant had been born, there were certain tasks that you had to get done on the neonatal unit to stabilise the infant. We would then go to see the infant’s parents, who by that time were either still on the labour ward or, quite often, had moved back on to the maternity wards. The picture I have in my mind of doing this was of both parents usually - not always but usually - being there. First of all obviously we have to discuss with them what has happened to their baby and how they were faring from the medical point of view. We would then raise the issue of the trial of CNEP and go through it with the parents. We did have a parent information sheet that we would give out. We would at that time, in the course of discussion, obtain consent or otherwise for the trial.

Q How easy was it to obtain consent or to explain the process as a result of which consent was obtained?
A Explaining the process, I do not think it was a particularly difficult process to explain. We were talking about the difference between helping a baby to breathe by blowing air into their lungs or helping them to breathe by helping to expand their lungs by effectively pulling from the outside. That was the difference.

I have to say, looking back, that I was talking about a new treatment. Often people seem to be - this is with the benefit of hindsight, I have to say - seem to be quite taken with the idea of a new treatment. I do not actually recall in my experience - though I may well be mistaken as it is so long ago - I do not actually recall anyone declining consent.

Q When you say they seemed to be “quite taken” with the new treatment, what were they attracted ---
A The impression I had was it was almost the word “new”. Bear in mind that we are looking here at the early ‘90s and new was a wonderful thing. It seemed once that word had gone down, nothing else took it back. I can remember saying, “We are doing this because we do not know whether this is better or not”. I can really remember labouring that and saying, “We cannot say”. The other big point I remember making quite often is, “I do not know whether your child in this trial will get the new treatment or not”, because the whole point is that half of them get it and half of them do not. I would labour that
particularly because I was always scared that they would come down to the unit and say, “Why is not my baby getting this new treatment that you talked about?” Again, people actually seemed quite keen to be involved was my overwhelming impression, even though I did try quite hard to point out that this was something new and the reason we were doing this was because we could not be sure whether it was better, worse or indifferent.

Q How easy was it for parents to grasp the randomisation aspect of the trial?
A To be quite honest, I am not entirely sure that I can actually answer that. I know I was concerned because I remember labouring the point quite hard. I was concerned that people would come up to me in the unit later and say, “Why is my baby not getting this new treatment?” I do not actually remember anybody actually doing that, so maybe that was my anxiety rather than anything else and perhaps they did grasp it.

Q What sort of state were they in, the parents, when you were seeking consent? Of course, we know that randomisation took place at four hours after birth.
A Again, I would have to - trying to recall it after 15 years is extremely difficult. I do not really recall very clearly. The picture I have in my mind is a relatively calm one. How well that reflects what actually happened, I really cannot say.

Q You say that you recall information that was, what, given to the parents or taken back? What was the position?
A There was a standard A4 information sheet that we gave while we were discussing the trial with them. The idea was, “Take this. Do read it. If you have any questions, do not hesitate to ask.” The other point was, “If at any time you change your mind”, assuming they have consented, “you are quite entitled to say you no longer want to take part in this and we will continue to treat your baby in the best manner possible”. I believe that was part of the information on the sheet.

Q Yes, what happened to the sheet afterwards?
A As I recall it was given to the family and it was for them to decide what they did with it. There was a supply of them as I recall. Again, it is 15 years ago.

Q Yes, I think you were shown various documents when you made your statement? 
A I was, yes.

Q It is difficult to remember what you had seen all those years ago, Dr Wheatley. Perhaps you would just look at page 336 in that file that you have there behind tab 3.
A Yes, “Parent’s Leaflet” in pen at the top.

Q Does that mean anything to you or not?
A (Pause) Well, yes, it looks - I have to say it is a piece of paper with a substantial piece of writing on it and it looks like the sort of thing we would hand out. I could not say whether it is the exact same wording obviously but, yes, it was that sort of thing that we would give out.

Q What appears at page 341-364, if you would not mind just looking at that, have you any recollection of that?
A 341, the “Negative pressure trial information booklet for parents”. That is not so
familiar to me but ...

Q  Do not worry if that is the case. In terms of the types of monitoring that were used within the trial, could I just ask you about this: have you any recollection of intracranial pressure monitoring being used within the CNEP trial?
A  I do not recall intracranial pressure monitoring being used.

Q  What about near infrared spectroscopy?
A  There was near infrared spectroscopy being done. I am not sure whether that was part of a separate study or certainly there was a separate study I believe around the infrared spectroscopy. I have to admit I did not get very involved with that.

Q  And Doppler ultrasound, were you aware of that being used within CNEP?
A  I was certainly aware of ultrasound being used, if we are talking here about cranial ultrasounds. I am certainly aware of that having been used. Whether Doppler as part of that was used I really would not know.

Q  In terms of your own experience of trials at that time, had you been involved at that stage in any trials at all?
A  I had been involved in some clinical trials as a very, very peripheral - I think I had been involved in drug trials when I was a house officer in Newcastle, but it was at a very peripheral and simple level, effectively collecting data more than anything else. I had not really been very closely involved in any clinical trials until I went to Stoke.

Q  As far as Dr Southall and Dr Samuels are concerned, we know that they were telephoned in order for the babies to be randomised?
A  Yes.

Q  Apart from that, did you see them in Stoke at all?
A  I have a vague recollection that they did come to the department on at least one occasion, but as to the exact details I really could not - no, I could not say.

Q  I want to ask you this: in terms of the CNEP itself, were you aware of any disadvantages of it at the time?
A  There were a couple of things. First of all, there was concern over the neck seal and the potential for trauma to the skin of the neck that that could cause. There were measures taken to try to minimise that. There was also a potential issue with temperature control, which I remember being flagged up but I do not actually recall us having any great difficulty with. Temperature control is an issue for all pre-term newborns anyway.

Q  Yes, we have heard that. Can I ask you about the neck? What measures were introduced in order to protect the baby’s neck?
A  Again, I have been shown some of the documents when I prepared my statement. I do recall the stocking net tubes being cut to make effectively little vests which were effectively like a roll neck around the infant’s neck. I have a vague recollection of the use of gel pads as well as a protective mechanism. It is very vague and it would be a bit hazardous of me to try to go any further, I think.

Q  What was the purpose of their introduction? What had happened to babies’ necks,
A

if anything?
A  In terms of what I had actually seen and experienced, I do not actually recall anything more than some reddening and soreness to some of the babies’ necks. I do not actually recall myself, but I could not be absolutely sure.

Q  I think when you made your statement you were shown a photograph of a baby from Queen Charlotte’s, whose neck had been the subject of severe trauma?
A  Yes.

Q  Were you aware of that at the time?
A  I think I was aware that there had been an infant who had had severe trauma, but I never saw anything remotely like the sort of trauma that was shown in that picture.

Q  Being aware, as you say you were, of that and the fact that you did sometimes see soreness to necks, was that something that was mentioned to parents or not?
A  I could not in all honesty - I could not say absolutely for certain. I do know it was discussed and I do know that this was brought up as a problem. The comment was made - I am not sure by who - that actually conventional ventilation can cause just as serious injuries to the trachea, which you cannot see but which is actually much more serious in terms of the potential impact on the infant. Every so often we would have problems taking infants off ventilators because of such trauma. So, yes, it was acknowledged that there was trauma, but actually it was not the worst trauma that could happen.

Q  I just want to ask you this: in relation to one of the patients - her name is Patient 6, I think you will see from the piece of paper that should be ...
A  There is, yes.

Q  I just want to ask you, we have some scans in relation to her. I am not going to ask you about them particularly, Dr Wheatley, except to ask this: who was it who would normally communicate the results of such scans to parents?
A  It was the sort of thing that would be done during the course of normal day-to-day contact with parents. It would be done either by the registrar or by the consultant.

Q  Have you any recollection of these particular scans?
A  I have no recollection - I do apologise, which particular scans?

Q  Yes, you have not looked at them and you ought to in the light of what you have just said. Perhaps you could just look behind tab 5 in file 2, which you will be given now, at pages 161 and 162. We are talking here about December of 1992?
A  Yes.

Q  So where would you have been at that time?
A  Working in Derby.

Q  You would not have had any knowledge of these at all?
A  No.

Q  But at the time when you were in Stoke, were the results of scans communicated to parents?
A As I recall, yes.

MS SULLIVAN: If you would wait there, please.

Cross-examined by MR FORDE

B Q Good afternoon, Dr Wheatley. I act on behalf of Dr Spencer. I have a number of questions to ask you. I have a copy of your witness statement. You worked on a two registrar rotation from February of 1990 at Stoke. Is that correct?
   A That is correct.

Q Would you agree with me that it was a well run unit?
   A I thought it was superbly run.

C Q In fact, the degree of training and continuing education you seem to suggest in your statement was better than any you had experienced up to that point and, is this correct, possibly since?
   A It certainly was better than I had experienced up to that point and, yes, I think it certainly matches up to anything I have experienced since.

Q One of the things that you said in complimentary terms about my client is this:

   (Document not available to shorthand writer)

   “He was very enthusiastic and hands-on. He was very keen on evidence-based medicine. His view was that if you do not know what the right thing to do is, how can you know that you are doing it? In meetings he would always want to know the evidence behind whatever was being said.”

Then you deal with the fact that the “approachability of the consultants on the unit was far greater” than in other places you worked. Do you stand by those comments?
   A Yes, I do.

Q You have been asked about the process of consenting four hours after a baby was born and you said this:

   (Statement not provided to shorthand writer)

   “There was tension in the time frame, especially if the mother had a Caesarean, as you would need the mother to be compos mentis.”

Are you quite satisfied that during your time at Stoke you only consented mothers who appeared, in the exercise of your clinical judgement, to be able to understand the process?
   A I do not think I could have done if they were not able to understand.

Q You say:

   “In my experience I tended to find that Mother and Father would be
wide awake after the birth. I would generally have had both Mother and Father present. I would introduce myself and tell the parents what was happening with their baby. At this point they would be separated from their baby as the baby would have been taken down to the neonatal unit. The parents therefore would be very fraught. I would explain what they would see when they went to see their baby. For example, I would tell them about the lines that would be used on their baby so they weren’t shocked when they saw them. I would explain to the parents how well their baby was and tell them about any particular problems.”

Is that correct?
A That is correct.

Q So the scenario: child born prematurely, dealt with by paediatricians, rushed to special care baby unit, parents remain in room where the delivery had taken place. Is that a common scenario?
A That would be a common scenario.

Q You would not hang around with low Apgar scores or difficulties with respiration, seeking consent to set up lines, drips or whatever other support was needed for life from the parents prior to taking a very sick, premature baby to the special care baby unit?
A The first thing is you have to get the infant stable before you could really…apart from anything else, before you would have anything to report back to the parents and before it would be safe to actually leave the baby and go back to see the parents. You needed to make sure that baby was safe before you did that.

Q In treating neonates in this way, you have been asked about NIRS, Dopplers, ultrasounds – you said, helpfully, in your statement that the query on the flowchart we are all now familiar with indicated that ultrasounds may or may not be done prior to entering CNEP – the absolute priority, I suggest, was to save the baby’s life and establish some kind of respiratory function?
A Absolutely.

Q So you would have been most upset, would you not, if somebody was trying to do a near infrared study in an unstable neonate?
A I do not recall the situation ever remotely occurring. This was the sort of thing that would be done after an infant was stabilised and effectively safe.

Q And safety was the priority?
A Absolutely.

Q You have said you would labour the point that it was a trial but you recollect that the use of the word “new” often seemed to impact upon parents the most?
A That is the way it seemed to me certainly.

Q Would you agree that during the process of consenting, either for this trial or generally in medicine, that your experience is that there might be certain buzz words or phrases that seem to remain in the memory and recollection of parents to the exclusion of
other important information that you give them?
A  I think that is probably true of life.

Q  You recall the A4 sheet of paper which you say was left with patients?
A  As I recall, I think we had a supply on the unit and we would take one of these sheets up with the consent form when we went to see the parents.

B  Would you be careful to ensure in your own mind that the parent or parents were giving informed consent?
A  To the extent that that was possible. I would certainly endeavour to give as much information as I was able to do.

Q  Would you be careful to stress the fact that consent to the CNEP trial did not mean that the child automatically went into CNEP?
A  Yes. As I say, I had this fear (that may have been over-reaction) that they would come down and find their baby had been randomised to conventional treatment and wonder why they were not getting the new treatment, so that was one point I do remember driving home.

Q  Did you nevertheless on occasions feel that although you had explained the process of randomisation the parental expectation was that the child would receive “the new treatment”, whatever that was?
A  I certainly felt that that would have been the parental expectation though I do not recall anybody actually complaining, so it may well have just been my own anxiety.

Q  You were asked about scans and ultrasounds despite the fact that you were not working in the hospital at the relevant time; can I just ask you this? In your statement you say I do not think you had been shown the scan reports, which I am not going to take you to:

“Whilst these results should have been mentioned to the parents they do not show any severe abnormality. Scanning is carried out fairly regularly on the unit and the parents would usually be aware of scanning being carried out.”

Mrs Henshall told us, I think, she was present during one of the scans.

“If I was communicating those results I would have been very careful to do so in a reassuring way. That level of bleed is not uncommon and is not generally associated with disability.”

I will just complete your statement:

“Whilst it would be reasonable for there to be a general assumption amongst parents that a brain bleed is bad news, that need not necessarily be the case.”

Do you stand by those comments?
A  I think the only qualification I would make would be serious disability, especially
in the light of research that has been subsequently carried out.

Q At the time though, back in 1992, would you see any difficulty with somebody communicating the result of that scan, and you have told us – and we have no idea at this distance in time, I am afraid – it could have been a registrar, it could have been a consultant on the ward, but communicating it in this way, either the ultrasound changes could be considered virtually normal and would not be associated with an increased risk of handicap or alternatively that it is a minor abnormality which they should not be concerned about. Would you have a problem with those scans being communicated to the parents in that way?
A I am going to give one qualification because I do not actually do this in my day job now and have not done so for over a decade but---

Q At the time, I am asking you about?
A At the time that would seem quite reasonable to me.

MR FORDE: Thank you very much. I have no further questions for you.

Cross-examined by MISS O’ROURKE

Q Dr Wheatley, I ask questions on behalf of Dr Southall and I have only got a few for you. First, can I read you this from your statement? You say in paragraph 5 that you were a supervising registrar on a separate CNEP trial in older children with bronchiolitis?
A That is correct.

Q You say in the same paragraph in respect of that:

“`We noticed in the bronchiolitis trial that when a child was placed in the CNEP tank their need for oxygen reduced dramatically.”`

A That is correct.

Q So you presumably would have thought that CNEP was a good thing, certainly for bronchiolitis patients?
A In terms of reducing their oxygen requirements it certainly worked in those terms.

Q And in those terms it was a safe and effective treatment?
A It was effective in reducing their oxygen requirement and it appeared quite safe from the experience that I had had and the fact that similar mechanisms of ventilation had been used previously and at one time had almost been the norm.

Q Because you also say in your statement, when you were talking about the potential neck problems, you identify that somebody said – in your statement you identify it as Professor Southall and you said today you cannot remember, but somebody had certainly said – if an endotracheal tube causes harm then this is inside the body and it could be more critical as it could endanger the breathing?
A Absolutely.

Q That was, of course, part of the thinking behind introducing CNEP for neonates
with RDS?
A  I believe it was part of the thinking, yes.

Q Just a few other questions then about information and training. You mention in your statement a Theresa Wright who was very involved in the trial?
A  Yes.

B Q  And you remember her?
A  Yes.

Q You say in your statement:

“She was extremely capable as a research co-ordinator. She would make sure that all of the paperwork that accompanied the trial was complete.”

A  Yes.

Q You were asked questions about a booklet – you were shown it in the file at page 341. In front of you on the desk you will see a red folder. I want to ask you if you actually recognise that and suggest to you that was a folder kept at the nurses’ station put together by Theresa Wright and Katy Lockyear and it was available for doctors to show to parents to explain the tanks and the conventional treatment; it had photographs and copy consent forms – that sort of thing. Do you recognise it?
A  Yes, it looks familiar. That is all I can say.

Q In terms of Dr Southall, you left Stoke in, I think, October 1992?
A  That is correct.

E Q  And he had only come a short while beforehand?
A  That is correct.

Q So in fact you only worked with him, if at all, for a very short period of time?
A  I believe it was a month.

F Q  But you do remember him coming, you think, to do a training session at some stage or to be involved?
A  I certainly have a recollection that the department had a relationship with the Brompton and with Professor Southall, much of it around this research. I have a vague recollection of him coming up to the department before then. We were certainly very aware of him.

G Q  But you were aware of him being available, were you not, at the end of the phone to answer any questions that you had?
A  Yes, and principally at the end of the phone when I rang for randomisation.

Q That is what I was about to ask you about next. In your statement you deal with that and you say that you have a recollection, in fact you say:
“I am sure that they asked questions as to whether consent had been taken, whether the exclusion criteria had been considered and they did it in a checklist style fashion.”

That is correct, and you generally got the impression they were riffling through a box looking for the---

That was the next thing I was about to ask you. You said they had a box of envelopes and they would open one to see which treatment the baby was to receive?

They were available, Dr Southall and Dr Samuels as well, to answer any questions about the trial?

They were, yes.

You, presumably, were aware that they had both been involved in using CNEP before in older patients with bronchiolitis?

I was certainly aware that they had been involved in using CNEP before.

You also said in your statement you personally disliked the CNEP tank because it was extra work for nurses and indeed doctors?

More because it was extra work for me.

So there would be no incentive for you to persuade someone to go into the trial; if anything, the incentive would be the other way round?

I think the incentive was the other way round, certainly.

So there would be no question of forging anybody’s consent or overdoing it and not providing enough information in order to persuade a parent to go in the trial?

I cannot imagine why I would want to.

Finally in respect of this: you now work, I think, in another field as a community paediatrician?

That is correct.

So although you have not worked with Dr Southall other than a month, you think, at Stoke, you in fact know him for his other work because of the work you do?

I certainly know him from other work that has come out and from meetings and conferences, yes.

And your impression of him?

He seems a very keen, very hard-working, passionately committed to the work that he does.

Thank you. I have no further questions.

I represent Dr Samuels and I have just a couple of questions. The randomisation:
the impression might have been given to the Panel at some stage that at the stage of
randomisation there was some detailed discussion about the clinical aspects of the case
between the person ringing up and Dr Samuels or Dr Southall. That is completely wrong,
is it not?
A  As I recall, there were certain things that had to be done and one was about
consent and the other certainly that we did have to look at were the exclusion criteria and
I think it was a case of “You have made sure that you have checked these, haven’t you?”,
as far as I recall.

Q  As far as consent was concerned, you would not be making the telephone call if
you had not obtained consent; that is right, is it not?
A  No, it would not, but I suppose it does not do any harm to check these things.

Q  All that Dr Samuels or Dr Southall would do was rip open an envelope and say
“CNEP” or “No CNEP”?
A  We were simply told which arm they were to go into.

Q  The consent process generally: it is part of a doctor’s everyday life, is it not,
taking consent in various contexts?
A  Yes.

Q  It is something you are introduced to from your first day as a medical student?
A  Yes.

Q  While, of course, in the context of consent within a trial you have to know what
the trial is about and be able to explain it, there is no particular magic, is there, in the
process of consent when it comes to a clinical trial?
A  Not particularly.

MR FOSTER: Thank you very much.

Re-examined by MS SULLIVAN

Q  Are there concepts that you need to explain to parents in a trial such as this in any
way more complicated or not than what you would have to explain in other consenting
processes?
A  I think the one thing that differs from normal consenting processes is the aspect of
randomisation because you are effectively – there are two potential different avenues and
you cannot say which one they will go down should they consent.

Q  Dr Wheatley, you mentioned the bronchiolitis trial and your role within that.
When did that start in comparison with this CNEP trial in neonatal respiratory failure?
Which was first?
A  Looking at the dates you have presented me with here then I would have to say
that the premature infant trial must have been first.

MS SULLIVAN: Thank you.

THE CHAIRMAN: Dr Wheatley, it seems the Panel have no questions for you so that
completes your evidence. It just remains for me to thank you very much for coming this afternoon and for the assistance you have given to the Panel. Thank you very much.

(The witness withdrew)

THE CHAIRMAN: Anything else to be raised before we finish for the day?

MS SULLIVAN: Not that I am aware of, sir.

MISS O’ROURKE: Sir, the only question is this, whether the Panel wanted at this stage to see the red folder or whether you want to wait until Ms Morris has made enquiries of somebody, the Director of Human Resources. I am simply concerned that somebody look after it because it is obviously an important document. I wonder whether---

THE CHAIRMAN: Would you like to give it to the custody of Mrs Khan.

MISS O’ROURKE: And possibly the randomisation log as well.

THE CHAIRMAN: I am sure Mrs Khan will look after both carefully. I think before we look at them in any detail or at all we will wait until the provenance question has been addressed.

Thank you very much. We will finish for the day now and meet again tomorrow at 9.30, when Dr Palmer will be here.

MS SULLIVAN: Dr Palmer is our only witness tomorrow.

THE CHAIRMAN: Thank you.

(The Panel adjourned until 9.30 a.m. on Friday, 6 June 2008)
GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council’s Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988)

On:
Friday, 6 June 2008

Held at:
St James’s Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

STEPHEN ANDREW SPENCER BM BS 1976 University of Nottingham
Registration No: 2305893

DAVID PATRICK SOUTHALL MB BS 1971 University of London
Registration No: 1491739

MARTIN PHILIP SAMUELS MB BS 1981 University of London
Registration No: 2732178
(Day Nineteen)

Panel Members:
Mr D Kyle (Chairman)
Mrs V Brickley
Mrs S Hollingworth
Dr T Okitikpi
Dr M Sheldon
Mr A Forrest (Legal Assessor)

MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hempsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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THE CHAIRMAN: Good morning, everyone. We continue with the case of Dr Spencer, Dr Southall and Dr Samuels. Ms Sullivan.

MS SULLIVAN: Dr Palmer, please.

KATHERINE SARAH PALMER, sworn
Examined by MS SULLIVAN

Q Good morning, Dr Palmer. Would you tell us your full names to begin with?
A It is Katherine Sarah Palmer.

Q Dr Palmer, what are your qualifications?
A I qualified from Nottingham with Bachelor of Medicine, Bachelor of Surgery in 1985. I obtained MRCP in 1999, a Doctorate of Medicine from the University of Nottingham in 1994 and Fellowship of the Royal College of Paediatricians in 1997.

Q What is your current appointment?
A It is consultant paediatrician with a special interest in neonatology, University Hospital of North Staffordshire.

Q Dr Palmer, you told us you qualified in 1985. Were you then, I think, first at another hospital before being appointed to a surgical position at North Staffordshire?
A Yes, that is correct.

Q Did you then spend two years on a paediatric rotation?
A Yes, I did, yes.

Q Was that as a senior house officer?
A Yes.

Q Then you went elsewhere and then in February 1991 did you return to North Staffordshire as a research registrar?
A I did, yes.

Q In that capacity did you work on the neonatal unit caring clinically for the babies?
A I did clinical duties on call, which was every Tuesday night.

Q Did you also join Dr Spencer in his clinic?
A Yes, on a Wednesday morning. My project was a clinically based project so I was around on the neonatal unit but those were my sort of exclusively clinical times.

Q Yes, but apart from that, as you say, you were around on the neonatal unit because in fact I think you were involved in a particular trial called Near Infrared Spectroscopy. Is that correct?
A Yes I was, yes.

Q I want to in fact ask you about another trial, the CNEP trial. Was that a separate trial from your Near Infrared Spectroscopy trial?
A Yes, it was but some of the patients overlapped, but it was an entirely separate
trial.

Q Some of the babies who were receiving CNEP or, indeed, were part of the CNEP trial, full stop, would they be also part of your research on occasions?
A Some of them were, yes.

Q So we can understanding the timing of when you were there, when did you actually start your research project for NIRS?

Q For how long did you continue it?
A I was there until the end of June 1993 with a period of maternity leave between September 1992 and I went back in February 1993, so I had four and a half months of maternity leave in that time.

Q So four and a half months off between September 1992 and February 1993?
A Yes.

Q You leave, I think, in June 199---
A That project. There was then a three week gap and I did another six month project with a separate grant on the same unit. That took me to December 1993.

Q Yes. The project that I want to ask you about, or the trial I want to ask you about, is not your NIRS trial but the CNEP trial, because that is what this Panel is concerned with, so when you came to work on the unit first of all, which was in February of…

Q …1991, at that stage was the CNEP trial under way?
A Yes.

Q Had you any prior experience of CNEP?
A I was aware of it because it had been written up, a large experience of clinical cases, in the British Medical Journal and when I was working in Birmingham we had brought a baby up with severe chronic lung disease who had come to Stoke for CNEP treatment.

Q So when you start the trial is already under way. From whom did you find out about the trial and the protocol and how the babies would be eligible for it?
A The information was freely available on the unit. I was taught by the consultants on the unit. Teresa Wright, who at that time was the nurse running the trial, was extremely helpful, had lots of information, did lots of teaching in sessions and the nurses were very knowledgeable and there were folders freely available on the unit with both details of the trial protocol, technical details of CNEP and the information was everywhere, basically.

Q What involvement did Teresa Wright have in any training? How did that compare, say, with others, with the doctors on the unit? Who was doing the training?
A In terms of the hands-on practicalities of how to put a baby in CNEP, say, Teresa was teaching that but by the time I was there the nurses knew how to do that so she was...
more involved in explaining it to the doctors and supporting nurses. The trial was, the terms of the trial, was discussed on ward rounds and the like so it whenever it came up it was discussed, basically, whenever it was needed to be.

Q Yes. How would you go about assessing a baby’s eligibility for the trial?
A The protocols were available on the unit. If a baby required, I think it was 40% oxygen at the age of two hours, they were likely to be eligible for the CNEP trial, but they were not entered into the trial until the age of four hours, so at two hours you could assess eligibility and think about asking parents but they were not entered into the trial until four hours if they still had those requirements at four hours.

Q At what stage would the parents’ consent then be sought?
A Two hours – if the baby at two hours was in 40% oxygen or needing more support than that, then that would be a time when you could start talking to the parents about it and gaining consent but the child would not be entered into the trial at that point.

Q No, the child would need to be entered into the trial at what point?
A At the age of four hours if they still met the criteria at four hours and you had got consent.

Q So between two and four hours consent would need to be obtained?
A Yes.

Q Had you been involved in trials before this and obtaining consent for them or not?
A Not for trials but I had done a lot of consent for surgical procedures and the like because in those days it was the junior doctor’s role.

Q In terms of obtaining consent for this trial, how did you go about deciding how to do that? Was there any training at all?
A Yes. I had been taught about consent as a junior doctor. It was very clearly explained to us what the criteria were, that it was a randomised controlled trial and how to go through it and there was lots of information available in the books that were around in the unit.

Q In terms of how often you took consent for the trial, what is your recollection of that, just in general terms? Did you consent often or not?
A Fairly often, yes, if I was around yes, I did.

Q If you would just have a look at a bundle for us – file 1 tab 3. If we look at page 367 to begin with. I do not know whether you have seen this before, Dr Palmer. You may not have done because I am not suggesting it is in your writing in any way. It is the log of the patients who were entered into the trial in Stoke?
A Yes.

Q We do not see your name, obviously, to begin with because you were not there…
A I was not there then.

Q …you told us until February of 1991. Is that right?
A That is right, yes.
Q So if we turn over to page 369?
A Yes, my name is there.

Q That is where we see your name for the first time. Is that right?
A Yes.

Q 9 March 1991, I think the second or third entry from the bottom there, there is your name?
A Yes, that is made 21 March, I am also there.

Q Also 21 March yes, that is you and it looks as if it might be you on 3 April as well?
A Yes.

Q You were a registrar at that stage?
A Yes, as a research registrar, honorary NHS contract.

Q Then as we go over the page, Dr Palmer, I think we see your name more frequently now as we go through page 370. We see it a little on page 371?
A Yes.

Q And so on as we go through for the times when you would have been actually there. When did you say you went on maternity leave?

Q Yes.
A The beginning of September, yes.

Q So, for example, then we obviously do not see your name appearing at that sort of stage. Does that give you an indication of when you would have consented…
A Yes.

Q …and how frequently it would have been. Obviously you have had a lot of experience since but I want you to think back to the time when you would have been taking consent for this trial and just help the Panel as to how you would approach parents in order to obtain consent for the CNEP trial.
A I would talk to them, both parents if they were available. I would take along with me the consent form and the parent information leaflet and after a while when I was there I put together some photographs of CNEP and conventional treatment to show parents.

Q Do you remember at what stage you put those together?
A I think it was fairly soon after I started because I did some for my Near Infrared Studies as well and found them helpful so I did some for the CNEP and I think other people used them as well because they were found to be helpful.

Q So what was it that you put together?
A I had four photographs and I had one of these sort of plastic folders that an A4 sheet goes in and I just mounted them, photographs about this big and I just mounted the
four of them on a bit of paper and put it in there with just a caption under each one what it was. They were useful to help to explain to parents what a CNEP tank looked like and what conventional ventilation looked like when you are talking about it.

Q  Yes, I see. You have those four photographs?
A  Yes.

Q  What else did you have?
A  The parent information leaflet and the consent form.

Q  You say that you would talk to both parents. Would there be occasions when that was not feasible?
A  Yes there was and there were also occasions when I know that there was only a mother who had had a Caesarean section and was still very sleepy and I chose not to get consent on those occasions, not to try, because I felt that mother was not in a state to have a conversation.

Q  Yes. All right, so going back to the process that you went through, you had your photographs, your information sheet and a consent form and what would you explain to the parents with the aid of those documents?
A  It would take a little while to explain because of the numbers of concepts that you wanted to get over but I want to explain that their child was premature and some of the problems of being born premature and one of the issues was that we knew that premature babies often had difficulty with their breathing and, indeed, that their baby was having difficulty with breathing which is why I was talking to them.

I would explain that when neonatal intensive care was first being developed there were really two ways of helping babies with their breathing – one was where you put a tube down that baby’s throat and blew air into the lungs, which was called positive pressure ventilation, and the other was when you basically put a baby in a tank and sucked on the chest so that you drew the chest out and drew air into the lungs and that was called negative pressure ventilation. Initially both techniques had been used but as time went by the positive pressure techniques became better refined and that became the more normal mode of helping, although the negative pressure ventilation was still used in special treatments, in special cases, and I would liken that to iron lungs used for polio because I found that was something that parents were aware of.

Then I would say that Dr Southall and his team at the Brompton had been looking at negative pressure ventilation again and had got round quite a few of the problems that had previously been there, particularly the problems with the neck seal which had caused problems in the past, and that they had tried it out in a number of situations and found it to be very helpful, they felt that it was working, that this had been published in the British Medical Journal.

I then go on to try and explain the trial by saying that having thought this treatment worked, they wanted to find out if it was as good as or better or not as good as the current treatment and that the way you tried to do that was to get two groups of patients who were very similar and give one the standard treatment and one the new treatment and then look at how they did and see whether one group did better than the other and if the groups
were otherwise similar, then you would say it was the difference in the treatment that had made the difference.

This is what we were doing at North Staffordshire Hospital, along with some other hospitals and we were asking parents if their babies could be involved in doing this. I would explain that we would get babies of similar – match them for how premature they were and how much help they were needing with their breathing and the time of going into the trial and that on the basis of that they would be randomly allocated by somebody other than us into either the group that got the standard treatment or a group that got the CNEP but in all other ways, the baby would be dealt with entirely the same.

Q How easy was it to get across that concept of randomisation?
A I think if you took your time with it and allowed people to think about it and ask questions, I think most people did – I would not have gone on with asking if I thought people did not understand. I find you needed to give people time and certainly when I talked to them I would let them think it over and go back and ask any questions because I think if you say, “Have you got any questions?” straightaway people have not had time to think, so I would always go back and answer any questions.

Q Yes, so you would begin this process at two hours, or round about, so how long would the whole process taken, including you going back?
A It would probably take towards the two hours, I suppose, because you would leave them and then go back to them and I would explain, I would go through the patient information leaflet as I went through that and I would also explain that it was entirely voluntary, their children going in the trial, and that should they not wish their child to go in it would not affect their treatment in any way and also if they went in they could change their mind at any time without it affecting the treatment for their baby.

Q I wonder if you could just look in that same file again at tab 3 page 336, because you have mentioned a parental information leaflet?
A Is that the one that is also 330 and 45?

Q It does, I am afraid, yes. Do you recognise that at all?
A It looks like a parent information sheet, similar to those that we used in the CNEP trial. I could not say it is the exact one it is such a long time ago.

Q I do not know whether you can help us with the one at the next page, page 337? Does that relate to your other trial?
A It is not one that I used for the trial. The consenting things were set up for the trial I did before I started and this is not an information leaflet I used but I imagine it might have been written in preparation before the trial had been finalised. I am not aware of that one actually having been used. It was not used by me.

Q Thank you. The one on the previous page I think relates just to CNEP?
A Yes.

Q You are not sure whether that is the one or not?
A That is basically – I cannot remember exactly what the form looked like but that is what was in – from what I recall that is what the leaflet said, though I could not tell you
what the exact words of the leaflet were after nearly 20 years. It was a form that looked like that and had that sort of content in it.

Q Yes. You have told us in the course of the explanation that you have given to the Panel about the consenting process, that you would mention that there had been a problem with the neck seal. What problems were you aware of that there had been, Dr Palmer?

A I think there had been difficulties, when CNEP was first used I think the neck seal was quite crude and could give sore necks but by the time that the CNEP trial was in Stoke there was three layers to the next seal and that was not a problem any more.

Q Were you aware of there having been a problem with a specific problem with the neck seal at Queen Charlotte’s rather than Stoke?

A I was aware that before it had started in Stoke there had been a problem, but I think the neck seal had been changed since then. Certainly my experience in Stoke was there was not any problem with the neck seal. I mean it was something we were aware of and nurses regularly looked to check the neck, but I do not recall a baby having a problem with a sore neck.

Q What steps were taken to ensure that the neck became less sore and did have that ---

A There was a very detailed standardised way of doing the neck seal, which was very clearly explained in the information booklet with diagrams. The first layer of the neck seal was a layer of foam, I think it was called Spenco foam, and it was a rectangle about this big which was laid across the neck where the neck seal would go. The baby was then put in a little vest made of stockinette, which was sort of like a knitted tube and it was folded over about four times and then arm holes cut in it so it was like a little polar neck jumper that came to about here and went up over the neck. There were diagrams in the book of how that is made up. Then the rubber seal that was used, there was a hole cut in the centre that went over the baby’s head and there were different sizes of seal for different sizes of baby, so you made sure you got the right size seal for the baby.

Q You have referred to an information booklet?

A Yes.

Q For whom was that?

A It was for all the staff on the unit, for the nurses and medical staff. It was generally the nurses that put the babies in, but obviously the information was there for the doctors as well as the nurses.

Q You have described how you would explain the randomisation process to parents. In terms of describing what was happening, we know it was a trial. Would you use that term or would you use any other term to describe it when talking to parents?

A I do not know, I think generally these things are either called trials or studies and I think the two words tend to be used interchangeably.

Q Yes, I think we see it says “study” on the leaflet that we see there?

A Yes.
At some point was a questionnaire given to a sample of parents?

Yes, Theresa Wright was the nurse initially involved and then another nurse, Kate Lockyear, as she was then, assisted her and eventually took over when Theresa left. I think Kate was doing some higher nursing diploma and as part of that she did a questionnaire about bonding for the CNEP study, because one of the things was because it was different to a standard incubator where the parents felt different about it, so she did a questionnaire which I think was given to a small number of parents in CNEP and a similar number of parents with the standard treatment.

Q Obviously you have told us that the purpose of that was to see whether parents bonded with the baby. Were any questions asked at all about their understanding of the trial?

A The first question was, “Did you understand that it was a trial?”

Q Do you know what the purpose of asking that question was? Why was that included?

A I do not know because it was not my questionnaire. It was very much done by Kate. I presume it was just sort of getting a feel of the parent’s understanding of what was going on.

Q Then, of course, having obtained consent on the occasions that you did, Dr Palmer, we now know that contact was made I think by telephone either with Dr Southall or Dr Samuels?

A Yes, that is correct.

Q It was either one or the other who would then be involved in the randomisation process. Can I ask you then about scans? Were scans done before children were entered into a trial?

A Not routinely, no.

Q And afterwards?

A They were done - I mean, these babies would have met the criteria clinically for having cranial ultrasound scans because they were premature and sick.

Q I do not think I have anything further to ask, except perhaps to clarify your last answer there. What about if a baby died, were scans done then?

A I think on some occasions, but scanning then was a lot less sophisticated. It would depend on the availability of Dr Egginton, who was the radiologist who did the scans. She was the only paediatric radiologist, so she was busy a lot of the time so sometimes scans were done I think.

MS SULLIVAN: Thank you. If you wait there, there will be some more questions.

Cross-examined by MR FORDE

Q Good morning, Dr Palmer. I am asking some questions on behalf of Dr Spencer. Could I just ask you about the last point? You were talking about availability of the radiologist and I want, if I can, to try and place your work in a sort of real world, real time perspective. If children were born late in the evening, in the early hours of the
morning, would you have had radiological support?
A No, no, Dr Egginton would not have been available then.

Q Can we take it that in terms of scanning prior to entry into the trial that you would have to have available to you a radiologist or somebody capable of doing a scan within normal sort of working hours, let us say 8.30, nine until six o’clock in the evening?
A Sorry, I do not quite ...

Q If you wanted to do a scan prior to entry of any neonate into the trial, you would probably have to hope that the child was born within the sort of normal working day. Is that fair?
A Yes, yes.

Q It does not necessarily mean there was not a scan done ultimately, but we know that the protocol had a query, I think, the flow chart, about doing a pre-entry scan, but that was obviously going to be, to some extent, dictated by the availability of the relevant member of staff?
A Yes, I think you would say it would be a good thing to do if you could, but it would not be an essential.

Q I wanted to ask you about the two trials, if I could. You have very helpfully told the Panel that you were interested in doing the near infrared study?
A Yes.

Q We know that you did not arrive until February 1991. Really, this is the first opportunity the Panel have to try and understand what it was. I am going to try and deal with it in simplistic lay terms. If I get it wrong, then please do not hesitate to correct me. I think what you were trying to do was to identify any disturbances in the cerebral circulation, in other words the blood flow within the brain. Is that right?
A Yes, it is, yes.

Q Were you doing that in all neonates or only in those that were receiving CNEP? In other words, was it being done in standard treatment and CNEP or just CNEP?
A It was babies who were receiving assistance with their breathing, so some babies who were on standard positive pressure ventilation and also babies who were in CNEP.

Q What was thought to be the potential value of that study from your perspective because you were the research registrar?
A We know that babies who are born prematurely are at risk of brain damage. It has long been thought that disturbances in the blood flow around the brain are significant in causing that. It was trying to understand more about how that may affect things. There was already work suggesting that positive pressure ventilation can affect brain blood flow as well as whether negative pressure ventilation did as well in a similar way or a different way.

Q Was it thought that the positive pressure ventilation had the potential to affect brain blood flow in a way that was adverse to the neonate? Was that one of the things that you were looking at or did you simply not know?
A Potentially, yes. I mean I think the typical baby who needed ventilated is a high
risk for a number of factors, but that was a significant additional factor certainly considered.

Q Would you agree with me that the primary aim, regardless of any study, whether it be CNEP or near infrared, was to attempt to stabilise the baby?
A Yes.

Q That would be the case whether receiving standard treatment or CNEP?
A Yes, the near infrared study was very much an observational study observing things during changes.

Q Would it be fair, again in lay terms, in a sense describing it as a sort of added extra? If you had a baby stabilised either within standard treatment or CNEP, then you would attempt the NIRS, but it would not be something that you would do in an unstable child?
A You could not do it in an unstable child because earlier research, some of it carried out in the same hospital, had shown that if babies had disturbances in their breathing and their levels of oxygen changed, if their heart rate changed, that caused significant changes on the NIRS traces and therefore I could not do the study on an unstable baby because I would not then know whether the changes are breathing or something else had happened to cause any changes I saw. So the patient had to be stable in order for me to study them.

Q Would you think that any doctor with a medical qualification, for instance, as part of an Ethics Committee, would know that your study could not be undertaken in an unstable child? I mean, is this basic physiology?
A I do not know. It would have to be stated as part of your application details of the study that you would say that it would not work. The near infrared spectroscopy is a new technique and they work looking at the apnoea, pauses in breathing and bradycardia. The slow heart rate had been done by Dr Livera, my predecessor, and that had been published I think about a year. She had done the work before I started; it was published round about the time I started.

Q But before your time - and I am not going to show you the document because it was before your time - there had been an application within the context of CNEP for a near infrared study to be done. Were you aware that that had gone in before you started ---
A Yes, because the ethical (inaudible) study had already been done. I know there had been some talk initially as to whether it would be possible to put the near infrared spectroscopy on the baby and monitor the baby as it went into CNEP, but this unit(?) had not any experience in near infrared spectroscopy, that was clearly not possible because it was extremely insensitive to move them to artefact and you could not get a baby - you could not get the probes on the baby’s head and you could not put a baby in a CNEP without removing the probes. That is the other thing; there was a big issue where if a baby wriggled you got big changes from that, so again the baby had to be quiet and stable.

Q Is it your understanding that the difficulties with doing both were appreciated after the initial application went in? So there was a refining, if you like, of the process?
A I think so. It certainly was not part of the process when I started.
Q By the time you came along, you needed a baby stable in CNEP or in standard treatment?
A Yes, I do not think the babies in the CNEP trial had been studied with near infrared until I came along; there was a different group of babies that were being studied prior to that.

Q I do not think there is any suggestion, is there, that near infrared study was harmful to a child?
A No, it was when I got consent for that I would make it very clear to parents that as far as I was aware there were no risks associated with the study, but there were likely to be no benefits in terms of direct alteration of the baby’s care either. It was really something we were doing to learn more and develop intensive care for the future.

Q Again, can you help the Panel in terms of dealing with the potential possibility they may have with any harm. You have told us there was not any. How did it actually work? I am going to make a suggestion - and, again, please correct me - you were shining a sort of light through the baby’s head. Is that a simplistic way of explaining it?
A That is right.

Q I think there was one probe that transmitted the light and one that picked up the reading on the other side of the head?
A Yes.

Q And you taped it to the baby’s head?
A There is little self-adhesive sticky rings that you use, yes, and put it under a bonnet to help put it in place.

Q The child could not feel the light?
A No, we use a very similar technique, pulse oximetry is used, standardised in all types of medical care, which again uses light. It is often put on a baby on a finger and you shine the light through. That is visible light. This is near infrared light that the near infrared spectroscopy uses. Basically the same technique, you shine light through and you know how much has gone through and you measure the absorbance.

Q You were hoping that by detecting the amount of absorbance you could work out what was happening within the cerebral circulation?
A Because oxygenated and deoxygenated haemoglobin absorbs light at different wave lengths, you could detect the changes. I would see this work initially in cerebral blood volume and changes in the volume of the oxygenated and deoxygenated blood.

Q By the time you were involved in that study, were you consenting parents along the same lines as you have described CNEP? In particular, I want to ask you about this: were you giving them the option of going into the trial first of all? They could join the NIRS trial or they could not, was it optional?
A Absolutely, yes. Definitely, yes.

Q Were you also informing them of the fact that if at any stage they wished to draw their child from the trial, they could?
A Yes, mine was more just a case of going along and doing a study on a baby, rather than being an on-going trial with data being collected over a long time like the CNEP trial.

Q You were shown a form at page 337. I think as far as you were concerned that was not the one...
A I did not use that form.

B ... you actually used?
A No, I did not use that form.

Q Can I just show you - and we can have copied if necessary - two information sheets? Dr Spencer has been trying to see if he could find one that was actually used. I just want to see if this jogs your memory. If you cannot remember, then please do say.
A Yes.

C Does that look as if it was either the form or very similar to it?
A Yes, the form I used was based on the form that Dr Livera used, which I modified slightly and put my name on the bottom of it.

D Again, there are many issues which do not necessarily involve you around the issue of consent. The 337 form appears to be a form which attempts to get consent for CNEP and near infrared at the same time?
A Yes.

Q The form I have just shown you is dedicated to NIRS?
A Yes.

Q Do you recall a time when it was thought it was too complicated to give information about both? So you would actually consent for near infrared in a simplistic way and consent if you could for CNEP, in a more simplistic way?
A The babies went into CNEP trial at the age of four hours. The near infrared studies would have come later, so it would not have been appropriate to consent for near infrared at the time because you did not know whether the babies would be suitable to study and I was studying them later in their illness.

Q Again, just help us about that because it may be of importance. You have said that at round about two hours you would begin to discuss the CNEP option with parents. You knew they had to be in the study by four hours?
A Yes.

G Was there any specific time period by which you wished to commence the NIRS study?
A These studies I did were done at the time the babies were getting better and about to discontinue their ventilated support, so that could be several days after they had gone into the CNEP trial.

Q Or possibly weeks?
A Possibly, yes, however long they had been in it ---

Q So there was not, from your perspective, the same impetus in terms of NIRS that there was with CNEP?
A No, because the babies when they were acutely ill going to CNEP would have been unwell and unstable and not suitable for near infrared studies. I would not have even thought about near infrared at the time they were going to the CNEP trial.

B Q As you have indicated, sometimes these neonates could be stable in lower percentages of oxygen with good saturation levels within 24/48 hours but other times it might take considerably longer?
A Yes.

C Q There is certainly no question, in those circumstances, of consenting for the near infrared spectroscopy dealing with parents that were under the influence of anaesthetic, for instance? The mother would have given birth many hours before ---
A No, it was completely separate. It was always quite a while after birth. Never did it with the CNEP trial, not unless they did it straight after the birth because you needed time to know if the patients were going to be suitable for a near infrared, so you would not have known that if you went and they were only an hour or two old.

D Q Can I just ask you about some more general topics? The Panel will appreciate that I asked one of your colleagues, Dr Morgan, about some of these areas yesterday. You have very helpfully explained to Ms Sullivan about the process of consent and you have explained that it is something which is fundamental to medical training. As a junior doctor you would initially, I think, have witnessed more senior doctors consenting and then you would have been consenting yourself for surgical procedures?
A Yes.

E Q Were you satisfied in your own mind, in terms of any consents you took for CNEP, that you had the ability to gain informed consent?
A I would not have done it if I thought otherwise. There had been an issue in a previous job when I had felt less comfortable and we had actually - the juniors raised that with the hospital.

F Q In this trial you felt competent to gain informed consent from parents?
A Yes.

G Q Was that as a result of training that you had had as far as CNEP was concerned? Were you comfortable with the amount of information first of all you had been given as a medical practitioner?
A Yes, I was.

H Q We believe that available to you would have been protocols and training information about CNEP, is that correct?
A Yes, it was. Yes.

Q I think they were, as you have described, available to the nursing staff protocols, diagrams, relating to the neck seal, for instance?
A Yes. There was an A4 ring binder, a sort of royal blue colour, which had a lot of information about the trial and there was also a book, spirally bound book, with a lot of information. There was also information for the parents; a book with information specifically for the parents.

Q I think also there was technical information?
A There was another manual with technical information, yes.

Q If the tank broke down the technicians, I think, had circuit board information---
A They did, yes. There was a manual for that as well.

Q My suggestion to you is across the board technical staff, nursing staff, junior doctors, registrars, consultants, had a wealth of information available to them about how CNEP worked?
A Yes.

Q Is that fair?
A Yes.

Q If you or your colleagues had felt in any way unable to explain the technical detail to parents, would you have sought the assistance of senior colleagues?
A Yes.

Q Were those senior colleagues, from your perspective, interested and approachable so far as the trial was concerned?
A Extremely, yes.

Q As far as the consenting process is concerned Ms Sullivan asked you about randomisation and you gave a very detailed explanation as to how you would try and explain that process. Dr Morgan was telling us yesterday that he felt that sometimes the use of the word “new” meant that parents had expressed a particular enthusiasm for anything that was new but that he was very careful to explain that he could not predict which arm of the trial any neonate would go into. Was that something that you were aware of?
A That was very important, that you need to say that if they were agreeing to their child going in the trial then there was a 50-50 chance they would get the CNEP or the conventional treatments. So they were agreeing for the trial, they were not agreeing to having CNEP.

Q Was there any occasion where you were guaranteeing that a child would go into CNEP prior to the call that had to be made about randomisation?
A No, you could not.

Q Did you see from the point of view of the validity of the trial the importance of the person who was consenting, not knowing which arm of the trial the child would go into?
A Yes.

Q Can you just help the Panel and the rest of us as to why that was important?
A I think the randomisation had to be done by somebody who was not involved with
the clinical aspects of the trial and was not involved in the clinical care, and it was done by phoning Dr Samuels or Dr Southall, who were based in London.

Q Did you see that as a check and a balance to make sure that if a doctor were particularly enthusiastic about one method that they were not pushing it?
A Yes. Well, you would not want bias that you thought, you know, you wanted to pick the patient you thought were going to go best going to CNEP. That could not possibly happen with the way the randomisation was done, but if you did not have that then it was potentially open to that risk.

Q Is this correct from your perspective, as others have told us, that in fact in some ways CNEP, in terms of the practical care in particular, was a much more awkward situation for a neonate to be in than the standard treatment?
A I think we were less familiar with it because it was not a standard – I mean, we were all familiar with doing things with babies in incubators. CNEP tanks, whilst they looked like incubators, were slightly different. For instance, when you put your arm through the portholes they looked like an incubator porthole. There was an elastic cuff that went round to maintain the seal, which was a little bit sort of different to get used to but you got used to that. If you were new to it, then there was a learning curve for learning how to use the equipment.

Q I just want to explore with you whether there is any particular magic in it being a trial. As far as we understand – and if I have got this wrong please correct me – the basic monitoring of a neonate with breathing difficulties was the same whether it was somebody in a CNEP tank or receiving standard treatment, is that correct?
A Yes.

Q So you would be looking at vital signs?
A Yes.

Q When surfactant was introduced can you confirm it was introduced for all the neonates who have the proper clinical indications for it?
A Yes, I was involved in writing the protocol for that. It came in when the region agreed to fund surfactant, and obviously we had babies in the CNEP so we wrote the criteria of that, which basically took account of the fact that when you put a baby into CNEP if they had been on positive pressure ventilation you lowered the peak pressure by the amount you were putting the CNEP in. So when we gave surfactant we had a peak pressure level for positive pressure ventilation and a different one for the CNEP that took account of that.

Q Does it come to this? It could be argued it would have been unethical, once the region was prepared to fund surfactant, not to offer it to those within the CNEP trial?
A Absolutely, that is why all the babies got it. If they met the criteria they got it whether they were in CNEP or not. The adjustment in ventilation was just to make sure they got it at the same level of respiratory support as the conventional pressure babies.

Q Another question I wanted to ask you about in relation to training was this. You have indicated that you felt competent to consent. Were there dedicated educational sessions so far as you can recall about CNEP, run by Theresa Wright or any other---
A Theresa did a lot of teaching for it and she was always available. She used to do teaching sessions in a seminar room. She was always available to discuss things and there was always information. There was support there if you needed it – it was always available.

Q Were you encouraged to be inquisitive about the evidence base for CNEP by your senior consultant colleagues? Was it something that was seen as having an important educational role?
A Yes, and it was discussed on ward rounds if baby was on CNEP and things like that – it was talked about all the time.

Q In terms of the working rota I think, and correct me if I am wrong, you were suggesting that you were aware that Dr Spencer had a clinic on a Wednesday afternoon?
A Wednesday morning.

Q And also on a Wednesday morning?
A Yes, and Tuesday afternoon.

Q And a Tuesday afternoon?
A Yes.

Q Can you just help us with what the clinic was on a Tuesday afternoon? I had it in front of me but---
A That was the renal clinic.

Q Then on a Wednesday morning?
A Was the general paediatric clinic.

Q As his registrar would you be involved in those clinics?
A I went to the general paediatric clinic but not the renal one.

Q We know there were two consultants, Dr Brookfield and Dr Spencer?
A Yes.

Q Was it the case if one was doing a clinic that the other was available to the junior staff?
A Yes.

Q We know Dr Brookfield was also the Clinical Director?
A Yes.

Q So would it be fair to say that as long as there were not unnecessary complications this was very much a registrar and nurse-led service that you were offering to the neonates?
A Yes, there were consultant ward rounds. Dr Spencer’s were on a Monday and a Thursday and Dr Brookfield went round on a Tuesday. Their offices were on the neonatal unit and their doors were always open and they were always available whenever anybody needed any support. They were always available.
Q Did you find the nursing staff to be competent in the administration of the trial?
A Extremely competent, yes.

Q Did you ever doubt their ability to monitor vital signs, make appropriate notes and, for instance, detect hypoxia?
A No, the nursing staff were extremely skilled.

Q Just dealing with that last point, regardless of whether there is a trial or not would you agree with me that the state of the neonate’s respiratory drive and the oxygenation of a neonate is something which is absolutely fundamental to the adequate nursing of a child in that condition?
A Yes.

Q As far as you could tell, were the nursing staff acutely aware of that?
A Yes, and the welfare of the baby took priority over any other research or trial or anything else.

Q Could I just ask you to take up our bundle 2, and I want to look behind tab 5. I just want to ask you about some values. There should be a separate page 84, if it has not been placed into the bundle, available to you.
A Is that that sheet?

Q Yes. It is a blood gas result sheet. Would this usually be filled in by nursing staff or might it be doctors?
A It could be either.

Q I think this chart starts in the early hours of the morning and the better copy you can see some “A”s about four or five entries down?
A Yes.

Q Would you surmise that where one has an “A” it is an arterial sample but where there is not an “A” it is probably capillary?
A I would, yes. If you look at the four or five results before you get to the “A”s and the ones with the “A”s, you can see that the pH and CO2 in the base excess are fairly similar but there is a marked increase in the pO2 values when it comes to “A” for artery, which is what you would expect.

Q Again, just contrasting the pO2 values with the “A”s as against what you surmise to be the capillary samples, would you agree that in terms of looking at the amount of oxygenation a capillary sample is not really giving you a true pO2?
A I would use a capillary gas for the pH and the CO2 in the base excess only; I would not make a judgement on pO2 for a capillary gas.

Q Again, when we are looking at these values, because the 7.23 has been alighted upon as being potentially indicative of hypoxia, would you agree with me that that is probably contraindicated because of the other values that we have there, in particular the base excess does not appear to be consistent with hypoxia?
A Yes, and also if you look across it the baby was a 40 per cent headbox on a saturation of 96 per cent at the time that gas was done, which again would not be
consistent with hypoxia.

Q So we look at the FiO$_2$ column, 40 per cent---
A And the saturation should be what the monitor was reading, was reading 96 per cent.

Q SAO$_2$ 96?
A Yes.

Q So would you agree with me that it is highly unlikely that a child whose pH is 7.23 but nevertheless has a 96 per cent saturation in 40 per cent oxygen is hypoxic?
A Yes, particularly with the base excess on that as well. Yes, I would.

Q Again, for those of us who do not understand what a base excess is, could you just explain in simple terms what a base excess is?
A When you measure a blood gas the carbon dioxide and oxygen levels are measured directly by the machine. The machine also measures the bicarbonate, which is the HCO$_3^-$ – the right-hand of the blood gas results column – but the result that you get for the bicarbonate depends upon the pH of the sample. So what the machine does is it calculates a figure called base excess, which is giving you a value for correcting for a normal pH for the bicarbonate, because we look at the base excess as representing the pH from the circulatory metabolic side as opposed to the CO$_2$ which gives you the respiratory side. So a normal base excess would be around zero but in these sort of babies anything from sort of minus 6/minus 7 to zero would be normal. Anything more than minus 10 you would think was significant and you may consider treating more than minus 10.

Q We can see, can we not, for instance, when it got to 9.4, the base excess, at 1600, which is an arterial sample, the oxygen percentage is at 65 per cent and increased to 69?
A Yes.

Q Is this right, that when one is looking at pH you are looking at how alkaline or how acidic the blood is?
A Yes.

Q When your respiratory drive is low and you are not driving off the carbon dioxide you become more acidic?
A Yes. The pH, the value that you get, depends upon what is happening on the metabolic side, which is like circulation and other factors, which is reflected by the pH, and the more minus the pH the more acidic you are. The respiratory side also affects the pH because carbon dioxide is a weak acid so the higher your CO$_2$ the lower your pH, more acidic your pH will be as well. So you look at a baby and they are going to have either, due to a respiratory problem, a metabolic problem or both. I think if you look at that blood gas the pH is 7.31 so the overall pH of this baby is absolutely fine.

Q Again, I just want to place this in context because we will have to ask others about this. In a child who is suffering from respiratory distress syndrome with immature lungs as a result of prematurity, you would not regard, would you, a value of 7.23 with the base excess we see at 5.1 as sinister or indicative of hypoxia?
A No, I would be satisfied. If it was a capillary gas I would be quite happy with that gas.

Q As you have said, you have got your saturation monitor showing 96 per cent, which may be higher than the value that some of us have got in this room. Is that correct?
A Yes. I mean, it is a normal level, yes.

B Q Could I then ask you to look – and the numbering is a little difficult but there is a page 125, and this is during a period where it has been suggested this baby was hypoxic. It is at 1930 crossed out in the left-hand margin and then there is---
A Could I just go to the page?

Q Yes. You may find 126 easier to see, or 124 in fact.
A Is that the page you are talking about?

C Q It is and if you look at 1900 crossed out 30, and we have an O₂ percentage of 24 per cent, the saturation of 95?
A Yes.

Q And then the temperature of 36.6, I think, and 36.5?
A Yes.

D Q Then there is a signature?
A Yes.

Q First of all, would this chart conventionally be filled in by nurses, because I think we recognise this is a Lythgoe signature?
A Yes, this is the standard nursing chart for a baby that was not in intensive care. It is an observations chart.

E Q What we see if we go from 1930 to 2330 that the percentage of oxygen is increasing from 24 per cent to 50?
A Yes.

F Q There is the saturations are fluctuating between 94 and 97, and then if you go over to the next page, which takes us into the following morning – we have got some timings which are obscured – again we have got a percentage of O₂ of between 45 per cent and 50 per cent?
A Yes.

G Q Would you agree with me that although there is a TcpO₂ which is normally the monitoring by probe, the initials CNEP and the minus figures suggest that that is the negative pressure that is being recorded?
A Definitely. You could not have a negative TcpO₂ and it is not on the previous chart, it is when the baby has gone to CNEP.

H Q So this is when the baby commences CNEP. We have then got values in terms of saturation levels, I think at between 95 and 100?
A Yes.
Q Just looking at that overall clinical picture as recorded – and I think we see the nursing signatures on the right-hand side – would you agree with me that this child is not demonstrating during this period of time hypoxia?
A Yes.

Q Then I just wanted to ask if you could go back in the bundle with me – we were looking at page 84; I just want to ask you about pages 85, 86, 87 and 88 very briefly. First of all, do you recognise this type of chart?
A Yes, I do.

Q Can you just help the Panel? What kind of chart is this?
A These were the intensive care charts, so this would be the chart that would be used to record the observations on an intensive care baby and it would also include what they were having in terms of assisted ventilation, what pressures were being used, what intravenous and arterial infusions were going through and any results of anything like that. Things like when they had physiotherapy suction. Everything that happened to the baby would be on this chart.

Q Would this be on the end of the bed?
A Yes, it would be.

Q Who would fill this chart in?
A It would be the nursing staff. They would fill in observations every hour. They would take those every hour. The babies are monitored the whole time and every hour they would be filled in on the chart.

Q If we look at page 85 by way of example, we have got timings obviously against the “Time” column?
A Yes.

Q Then we have a column which is “PAP CMS H₂O” and somebody has written “CNEP”?
A Yes.

Q Are the negative values an indication of the negative pressure?
A Yes, they are.

Q Then when we go down to “Headbox O₂ is that the percentage of oxygen being delivered via the headbox?
A It is, yes.

Q We see two 23s and then two “A”s – what does that denote?
A Air.

Q So that is a child who is not receiving any support by way of oxygenation?
A No additional oxygen.

Q So this is a child breathing in air?
A  Yes.

Q  Then we have got the saturation levels at O₂ SAT?
A  Yes.

Q  And we see those starting at 92, 94, 96?
A  Yes.

Q  Then we have got the arterial pO₂/TCPO₂ and we think that that word is “Searle”?
A  Yes, I would agree.

Q  Can you just help the Panel? What does that mean?
A  If a baby received intensive care then you would – a significant amount of
oxygen, you want to monitor arterial blood rather than capillary blood because you could
measure oxygen level on that. The first choice you would do that would be to put in an
umbilical arterial catheter to sample blood and at that time we had catheters with a probe
called a Searle probe on a tip, and this was an indwelling probe which would give you a
continuous read out of the pO₂ in the artery, so you could have that continuously read out
and then you would intermittently sample blood gases and you would calibrate the Searle
each time you took the blood gases.

Q  So would that give you some digital display that you could glance at to make sure
that the baby was properly oxygenated?
A  Yes, it had like a dial on it; sort of the arrow went up and down point to it – a bit
like a speedo on a car – as to what the level was.

Q  Would you have the saturation levels, the pO₂, monitored by a pulse oximeter?
A  Yes.

Q  A clip on the finger?
A  On the finger or the toe or across the arm in a small baby, yes.

Q  Was there any independent monitoring of blood pressure via either of those? We
do not have them recorded, which is a deficiency which has been pointed out, but as far
as you are aware, would there have been any continuous monitoring of blood pressure
either via the transducers or the catheters or the pulse oximeter?
A  You can put a transducer on to an intra arterial line.

Q  Would you agree with me that it was probably the responsibility of the nursing
staff to fill in the blood pressure mean part of this chart?
A  Yes, the nurses filled these charts in, yes.

Q  If there are missing readings in the early hours of the morning or late in the
evening, would you agree that that is likely to have been a deficiency that occurred when
you did not have a consultant on the ward?
A  Yes.

Q  Because to your recollection, what sort of time did Dr Spencer depart in the
evenings leaving the junior staff to cope with being on call?
A I would think early evening, sort of normal working day, sort of five, six o’clock, that sort of time.

Q If he was not doing a ward round when would you tend to see him in the neonatal unit in the mornings?
A I suppose half eight, nine, that sort of time in the morning, depending on if he had other commitments.

Q If he was doing a clinic in the morning would you see him in the mornings or would he tend to appear after his clinic? If you cannot remember---
A I do not know because he may be around in the office and not in the unit.

Q You have said if there was a problem, an apnoea or a bradycardia or any kind of suggestion of a collapse during the normal working hours, the consultants were available?
A The consultant would be available any time. The nurses would be with the babies, monitoring the babies continuously, doctors would be around, if there was a problem they would call the junior doctor, the registrar, and if the registrar needed help they would call the consultants and they would be available whatever time of the day or night. Obviously at night time they would not be sitting on the unit if there was not anything for them to do.

Q No, but you could call them?
A Any time, yes.

Q If there was an absolute crisis they would attend?
A Yes, absolutely, yes and if you wanted telephone advice there was no problem getting that either.

E Mr Foster - who is maintaining for the main part a dignified silence in these proceedings - and I have alighted upon an area I should have asked you about earlier and I apologise. It is about the consenting process. I just want to ask you about your experience of the consenting process. You obviously have your initial discussion with the parents about the trial?
A Yes.

Q Once babies had entered the trial did you find that parents sometimes questioned you about matters which you had previously explained to them?
A Yes, I think this always happens with these babies because they have been through such a lot and there is such a lot happening that people often come back and ask further questions later.

Q Is it your experience, or has it been your experience, that it would appear, for understandable reasons, that that parents do not always retain everything you told them about at the time of the consenting process. It is a continuous process?
A Yes. I would agree with that.

Q That is something that doctors are well used to?
A Very aware of, yes.
MR FORDE: Thank you very much, doctor.

Cross-examined by MISS O’ROURKE:

Q Dr Palmer, I ask questions on behalf of Dr Southall. I have only got a few. The first is this. You were shown a randomisation log. It is in file number 1 at page 380, you will remember, and Ms Sullivan took you through it and said these seemed to be the occasion when you consented. What I wanted to suggest to you is, in fact, they may not necessarily represent when you consented as opposed to when you called Dr Southall or Dr Samuels because sometimes it may be that somebody else took the consent and you were the one who made the phone call?
A Yes, very much, it did not have to be the same person doing the consent and the randomisation.

Q Indeed. I am going to suggest that is in fact the case that we see in respect of a patient that we are calling Patient number 7 and it is on 14 January 1992. You made the call but in fact we know from the consent form that it was not you who took the consent?
A 12 November?

Q I am sorry, February 1992. 12 February 1992. It is a patient we are calling Patient 7 but you will recognise her surname?
A Yes.

Q The record in the log here shows that you made the call. We have a consent form for that child signed by the father and the consent form is signed by a male doctor, Dr Arumugam – in other words not by you?
A Yes.

Q You have made the call. Why would that happen, that you made the randomisation call?
A Because randomisation was not done until consent had been obtained but once it had been obtained, then you just needed to get which arm of the trial the child was going in and then if I was around and then if I was around and free and the doctor who had got the consent was busy with the baby, then I would just do that to help.

Q Indeed.
A It did not matter, as long as you knew the number to ring and the details of the baby that you had give, it did not matter who did that.

Q Therefore the number of occasions that Ms Sullivan took you to and said, “This is you, you and you”, all that means is that you made the call; it does not mean you took consent on all those occasions?
A This is “name of caller” - it would be that I phoned on that occasion, yes.

Q The same would apply to others as well, so we cannot take that as being a list of those who took consent?
A No, on some occasions it would be but other occasions it might be somebody
different.

Q Next I wanted to just check with you about the bonding questionnaire. If you can look on page 378 in the same folder, file number 1. I think you will see the letter that was going out with the bonding questionnaire. You told us it was Kate Lockyear but if you look at the letter does that jog your memory?
A I have not seen that letter before.

Q What I am going to suggest to you is it was Teresa Wright was behind the bonding questionnaire and the letter seems to confirm it?
A That would suggest that. I know I discussed this questionnaire with Kate but I do not know who wrote the letter and sent that out. I have not seen that letter before.

Q Right. The third thing is this. You talked about information available for parents and in particular about photographs. Can I ask if you can be given a red folder that we have got here and see if this jogs your memory? (Same handed) Do you want to take a minute to look at that and see if you recognise that? (Pause) I am going to suggest to you that that is a folder put together by Teresa Wright and Kate Lockyear at the beginning of 1992 and it was available at the nurses’ station for doctors to take and show to parents and containing photographs of ordinary standard treatment…
A Yes.

Q …CNEP treatment and it also had in it consent forms and parent information leaflets?
A Yes.

Q That is a folder that you would have used or could have used?
A Yes, I think it was a development because I had put the rather Heath Robinson pictures and this was a sort of – it was found useful so this was a more formal way of doing the same thing.

Q Right, so it was developed and evolved over a period of time because you had started doing photos and then Teresa said, “This is a good idea”?
A Yes.

Q And the folder was prepared?
A Yes. There was information before that but I think this folder was made at the time, yes.

Q About that time?
A Yes.

Q You do recognise the folder?
A Yes, I do. Yes.

Q Finally this. You yourself were the subject, were you not, of a complaint by the Henshalls to the General Medical Council?
A Yes, I was.
Q That complaint continued until a hearing before the Court of Appeal in June 2005?
A Yes.

MISS O’ROURKE: Thank you.

MR FOSTER: No questions, sir.

Re-examined by MS SULLIVAN

Q Just a few matters if you would not mind, Dr Palmer. We know that you were a research registrar – that is what you have told us. In terms of consent taking from parents, was there any hierarchy as to who would take consent, or would it just be a question of who was available at the time?

MR FORDE: First of all I am not sure that that question arises out of cross-examination. If my learned friend thinks she should have asked it first time round I am not going to object.

MS SULLIVAN: Maybe Mr Forde is right but he is not objecting is the upshot, so perhaps I can ask it.

THE WITNESS: Consent was generally taken by the registrars, as they were the more experienced doctors around on the unit, but not always.

MS SULLIVAN: So generally by registrars. Was there any preference between the types of registrar?
A There was really only one type of registrar at that time. What do you mean by “types of registrar”?

Q I am thinking you are a research registrar whereas another registrar might be involved in clinical care?
A I did consent when I was doing clinical care and sometimes if they were very busy then I would lend a hand with the clinical care if there was, say, an emergency or a problem and then it would, I suppose, be discussed with the doctors at the time who was the most suitable person to do something.

Q You did say when questioned by Mr Forde that you had raised concerns about consent. Is that right?
A Yes.

Q With the hospital. Was it this hospital or a different one?
A No, it was in Manchester.

Q Just what was the nature of the concerns that you had at that time?
A I was one of three SHOs working in paediatric surgery and we worked for a number of surgeons, one of whom was an eye surgeon who only came to the hospital on Friday, went to theatre and we had never seen and we were getting consent for eye operations that we did not really feel that we knew in detail what these operations were,
so we raised the issue with other surgeons that we felt we did not feel were getting fully informed consent because we did not really understand the operations ourselves and could we speak to this surgeon because we had never met him, we never saw him the whole four months we were there. We were spoken to by the Medical Director for the hospital who told us that if we did not understand we should go away and read it in a book and not to cause trouble.

Q Right, I am not going to ask you anything more about that, Dr Palmer. You mentioned that scans were not essential in relation to the trial?
A Doing scans before the babies went into CNEP, yes.

Q Before the babies went into CNEP, but what about after and if a baby died?
A These babies would have met the criteria for being head scanned, having head scans done as part of routine clinical care whether they were in a trial or not because they were premature and sick.

Q So if a baby died would a head scan be done? That is what I am trying to ascertain, or should it be done?
A It might have already had a head scan done before the baby died.

MS SULLIVAN: I wonder if you would just look at these documents, which have been disclosed to my learned friends. (Same handed to Defence counsel) It is unused.

MR FORDE: Before any question is asked, I wonder if Ms Sullivan and I could have a very quick word at the back of the room about where we are going with this? I do not think it relates to any charge but it may be that I am not seeing a point.

MS SULLIVAN: I am happy to explain the relevance of it.

MR FORDE: I do not think we need to leave the room. (Mr Forde and Ms Sullivan conferred)

MR FORDE: We have resolved that, sir. I am very happy for the question to be asked.

MS SULLIVAN: Dr Palmer, as no-one else has a copy of that for the moment perhaps you would just have a look at it and see whether you recognise it as I think a typed document that has your name at the bottom and a hand-written document?
A Yes.

Q Can you just explain what those documents are saying?
A I know this is a modification to what was being done, was a suggestion that babies who had died should have a head scan and there was a scanner on the unit which people could use to get some pictures, obviously not as good as you would get with a skilled radiologist but this is saying that if babies died then it would be helpful to have a head scan and it is a message written by myself saying that if I was available then I would do such a scan, but it is limited by the fact that the baby needs to be available on the unit and the bodies did not remain, obviously they had to go to the mortuary and did not remain on the unit for long, but if the body was there and I was available I would do a head scan.
Q Yes, and the purpose of that was?
A Because it was felt it would give additional information towards the trial. If a baby had not had a scan then it was a way of trying to get some information but it would not be done on every baby because sometimes the babies would have gone to the mortuary and would not be available to do this.

Q Thank you. If you just let us have those back we will copy those documents so that the Panel can have them.

You were asked about the red folder. Do you still have it there?
A Yes.

Q Does it have a date on the bottom right-hand corner?

Q “Published February 1992, on shelf in neonatal unit.” Does that accord with where you think it was kept?
A That is where all the information was kept, yes. Now you have seen this, I remember this was what was subsequently used, it was put together so when you went to get the consent you took this with you to show the parents the photographs of CNEP and standard conventional treatment.

Q You were asked about surfactant and its introduction. I wonder if you could just take up a moment file 1 tab 1 pages 22 and 23 – that is the top right-hand corner. You might have to look for 23 and then go back for 22 because it is covered up.
A Yes.

Q Pages 22 and 23, which I think bear a date at the bottom of 22 July 1991?
A Yes.

Q Is that the protocol that you were referring to as having drafted in relation to the use of artificial surfactant?
A It is, yes.

Q Then if I could just ask you to---
A It is not the protocol itself. This was a discussion when we were going to introduce surfactant and Dr Spencer asked me to look at how we would do that in relation to babies in CNEP, which other hospitals in the region did not have and this was my discussion paper with my proposed solution for it. There was a separate document that just gave the protocol that was put out and started and had all the discussion bit at the beginning with it.

Q Yes. I think in fact page 22 refers to various items and then suggested protocols?
A Yes, that would be the protocol that would be shared with the staff.

Q Page 23?
A Yes.
Then could I just ask you to take up a moment that separate sheet of paper with the blood gas results, page 84? I think that is all I need to ask you to look at for these purposes.

Yes.

You have already indicated that the saturation levels that you looked at were normal, being between 94% and 99%, not here but on the document you looked at before?

Yes.

Can I just ask you about the other levels that are shown here? In terms of the pO$_2$ level, would 4.5 to 4.7 be a low level or not?

Those are on capillary gases so you could not draw an opinion on that.

In terms of pH level, would you agree that a level between 7.23 and 7.28, certainly 7.23, would be an indication of acidosis?

Not on that gas, no, I would not.

Then in terms of the pCO$_2$ level, 6.3, we see, and 7.4, were those raised levels?

They are a little bit raised than normal, which is to be expected in a baby with respiratory distress syndrome and it is why they are being monitored. I think what would be reassuring clinically would be to see that the 6.3, that it went up and came down again. If it was consistently raised, along with other factors, that might be one of the factors making you indicate a decision to escalate treatment, but not on a single value of that if the rest of everything else about the baby was okay.

Yes, so it would be a question of monitoring the baby?

It is slightly above normal, so you would want to keep on monitoring it, which is clearly what happened here, because there are a number of more gases after those.

Thank you. I have no further questions.

There were a couple of matters which arose in re-examination which did not strictly arise out of I think cross-examination. Does anybody want to ask anymore about it? No.

Dr Palmer, that completes the questions which the lawyers have for you. As I indicated at the outset, now is an opportunity for Panel members to ask questions, if any have.

Good morning. As you were trained at Nottingham, I am sure you had very good communication skills by the time you qualified. On a ward such as this, clearly communication skills with the parents were vital?

Yes.

Did you come across any problems on this unit with those sort of communication skills?

No, not at all. I always felt people communicated very well and that the nurses
and the medical staff had a very relaxed and friendly relationship with the parents on the unit.

**Q** Were the nurses better at communicating than the doctors?
**A** That is a loaded question. I think they communicated differently about different things. I think often a nurse sitting by a baby will have a more sort of low key general conversation about the baby and other things. Medical communications may be if there was something more important to say or news that you had to impart, so you would be communicating differently, I think, in a different way.

**Q** Both nurses and doctors were encouraged to communicate frequently with the parents?
**A** Absolutely, yes. If the parents were there, if you go and do a blood gas and the parents were there you would speak to them.

**THE CHAIRMAN:** Dr Palmer, I think, going right back to the beginning of your evidence, we know that you were the research registrar in North Stafford from February 1991 onwards?
**A** Yes.

**Q** I think you described yourself during that period as being on neonatal unit clinical duties on an on-call basis?
**A** I had an honorary NHS contract and I was paid to be as an NHS person on-call on a Tuesday night.

**Q** Yes, but notwithstanding that, you were clearly on the unit ---
**A** I was around the unit all the time because that is where my work was based.

**Q** Because we can see from the log that you were making randomisation calls during the day?
**A** Yes.

**Q** You clearly had an opportunity, or frequent opportunity, to be talking with the staff on the unit, both presumably about your own NIRS study and the CNEP study?
**A** Yes.

**Q** You were talking to us about your Manchester experience where you had concerns about consent. During the time that you were at Stoke and on the neonatal unit in the way you have described, could you recall any situation where any of the staff on the unit expressed to you concerns of a type which you had at Manchester?
**A** No.

**THE CHAIRMAN:** Thank you very much indeed. Any questions arising out of Panel questions? No. Dr Palmer, that completes your evidence this morning. It just remains for me to thank you very much for coming this morning and the assistance you have been able to give the Panel. Thank you very much.

*(The witness withdrew)*

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MS SULLIVAN: Dr Palmer is the only witness, sir, that I wish to call. I do not know if there are any other matters to deal with or not.

MR FOSTER: Sir, can I say this: I mentioned that there would be an application to exclude the evidence of Dr Nicholson. There has been a good deal of discussion between counsel on this side about the way to approach that issue. It has been decided that the relevant issues can be canvassed in cross-examination of Dr Nicholson and subsequent submissions. Therefore, there will not be an application before Dr Nicholson is called.

THE CHAIRMAN: Thank you very much. Is that a common position, is it?

MR FORDE: It is, sir, and hopefully will lighten your decision-making load.

Can I just indicate I think we are due to have Dr Stimmler on Monday. I know that Miss O'Rourke is very keen that Dr Raine gives evidence before Professor Hutton and we have now arranged that. I am more than happy to deal - if it is a problem with timetable - with the clinical issues that only affect my client with Dr Stimmler once he has given all his evidence in-chief. In that way we are hoping that we will have a seamless week rather than any gaps.

MISS O'ROURKE: Sir, I think it is because I had indicated on the record the other day that I was concerned that Dr Stimmler, when I saw his latest report, deals with scoring systems and that I felt as the only witness that the Panel was going to hear from in the GMC’s case who could possibly deal with scoring systems is Dr Raine, who is a factual witness, that I felt it was appropriate that Dr Raine should give evidence before Dr Stimmler.

In fact, I subsequently spoke to Ms Sullivan and indicated that rather than disarrange the timetable, that I was happy for Dr Stimmler to give his evidence and I would cross-examine him on it. The only thing it means is that I will have to put to him that which will be said, I anticipate, about scoring systems because he will not yet have heard it. But rather than have Dr Stimmler give evidence, be cross-examined on other matters and not scoring systems and have to come back after Dr Raine, I think that it is possible to do it, but it will involve me having to say to him, “And if in fact the purpose was A, B, C, D”, and therefore anticipate the evidence of Dr Raine, but indeed the evidence of these witnesses should it come to the defence side of the case.

So it is nothing abnormal and so I think I indicated I am content for Dr Stimmler to be called on Monday, but I would still insist on Dr Raine being called before Professor Hutton, because Professor Hutton only deals with scoring systems and statistics and therefore she should hear, or at least be advised of what is said on the transcript by Dr Raine in that respect.

THE CHAIRMAN: That is a helpful indication, Miss O’Rourke, because if I understand what you are saying correctly, that means that we will be following essentially the pattern of witnesses as set out in the schedule, and recognising that this may mean that some of the questions which you ask of Dr Stimmler may be somewhat lengthier than they would have been had Dr Raine given evidence first. Clearly, that is something which can be accommodated. We will be starting with Dr Stimmler on Monday, then there will be
Dr Raine and then Professor Hutton. That is how the week will progress, followed by Dr Nicholson later on.

Very well. In that case we will adjourn now, unless there is anything else, and meet again at 9.30 on Monday morning.

(The Panel adjourned until 9.30 a.m. on Monday, 9 June 2008)
GENERAL MEDICAL COUNCIL

FITNESS TO PRACTISE PANEL
(applying the General Medical Council’s Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988)

On:
Monday, 9 June 2008

Held at:
St James’s Buildings
79 Oxford Street
Manchester M1 6FQ

Case of:

STEPHEN ANDREW SPENCER BM BS 1976 University of Nottingham
Registration No: 2305893

DAVID PATRICK SOUTHALL MB BS 1971 University of London
Registration No: 1491739

MARTIN PHILIP SAMUELS MB BS 1981 University of London
Registration No: 2732178

(Day Twenty)

Panel Members:
Mr D Kyle (Chairman)
Mrs V Brickley
Mrs S Hollingworth
Dr T Okitikpi
Dr M Sheldon
Mr A Forrest (Legal Assessor)

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MR M FORDE, Queen’s Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Spencer.

MISS M O’ROURKE, Counsel, instructed by Hempsons, Solicitors, appeared on behalf of Dr Southall.

MR C FOSTER, Counsel, instructed by RadcliffesLeBrasseur, Solicitors, appeared on behalf of Dr Samuels.

MS J SULLIVAN, Counsel, instructed by Eversheds, Solicitors, appeared on behalf of the General Medical Council and the Complainants, Mr and Mrs C Henshall.

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THE CHAIRMAN: Good morning, everyone. We continue with the case of Dr Spencer, Dr Southall and Dr Samuels. Ms Sullivan.

MS SULLIVAN: Sir, the next witness is Dr Stimmler who is here.

**Leo STIMMLER, affirmed**

Examined by MS SULLIVAN

Q Dr Stimmler, would you mind starting with your full names, please?
A Leo Stimmler.

Q Dr Stimmler, you supplied us with a curriculum vitae. I am going to ask that that be handed out to the Panel. My learned friends already have a copy of it. Perhaps you would like a copy in front of you as well.

THE CHAIRMAN: That will be C13.

MS SULLIVAN: Thank you. (Same handed) Dr Stimmler, we have that in front of us now so if we could just go through, first of all, your qualifications, please. When did you qualify?
A 1954.

Q You have set out there your initial qualifications of Bachelor of Medicine and Bachelor of Surgery?
A Yes.

Q You have then set out thereafter various further qualifications, MRCS?
A I did that before actually but, yes.

Q So tell us what your further qualifications were?
A MRCS, LRCP is an alternative to MB BS. It is an initial qualification which used to be called the Conjoint Exam.

Q When did you become a consultant?
A 1966.

Q What type of consultant did you become?
A Consultant in paediatrics, neonatology and paediatric endocrinology.

Q For how long did you continue with your substantive post as a consultant?
A I retired in October 1995 but continuing doing a locum for about another nine months.

Q You were in practise as a consultant at the period with which this Panel is concerned from 1990 through until 1993?
A That is correct.

Q It makes clear from your CV that you were a consultant paediatrician at Guy's Hospital in London?
A Yes.
Q Then following your retirement you say that you carried on as a locum for a while. Did you continue with medico-legal work, as we see from your CV?
A Throughout my consultant career and ever since.

Q Throughout your career and are you still doing such work now?
A I am, yes.

Q You have set out on the second page of the CV for us that you prepare 40 to 60 reports a year, is that correct?
A Yes.

Q For both sides, so to speak?
A Yes.

Q The type of cases in which you have been involved; medical negligence cases and also criminal cases as well?
A That is correct.

Q Over the course of your career you have indicated that you have written between 900 and 1,300 reports?
A That is an estimate.

Q And attended court as an expert witness on over 100 occasions?
A At least.

Q You are a member of the Academy of Expert Witnesses and a member of the Institute of Expert Witnesses. You have attached here a list of publications?
A Yes.

Q Could I ask you also this, do you have experience in the course of your career in research trials?
A Not the sort of this one. The researches I have done have tended to be investigational researches. I measured calcium phosphate levels in babies. So there was not two alternatives. Anybody who consented to have the test done we did. It is much easier than comparing two groups. I have not, that I am aware of, ever been in a trial involving two separate groups, controls in children having --- babies having new treatments.

Q So you have not been involved in a trial involving randomisation?
A No.

Q I wonder if you would mind pulling the microphone slightly towards you. It is quite a large room. For the purposes of this case, Dr Stimmler, you have prepared a report dated 12 March 2008. Do you have a copy of that in front of you?
A I have, yes.
Q Did you also
A at the request of Eversheds Solicitors prepare a further addendum report dated 28 May 2008?
A Yes, I did.

Q Do you have a copy of that available to you as well?
A Yes.

Q I just ask you to bear in mind, Dr Stimmler, that although you and counsel have copies of the reports the Panel do not. Have you set out in your report the material to which you were given access in order to prepare your initial report?
A Yes.

Q Have you since been sent and read transcripts of the evidence that has been called so far in this case?
A I believe I have. I am not one hundred per cent sure whether I got the transcripts for last Friday or not. I probably have but I got them by post on Saturday. It was very clever to have got them to me and so fast.

Q We hope you have, indeed, had the transcripts from last Friday which were sent but those that you have received have you read through, Dr Stimmler?
A I have.

Q Now you know that this Panel is concerned with the CNEP trial, as we have been calling it, which received Ethics Committee approval in North Staffordshire on 10 January 1990. The way in which I intend to take you through your evidence so that everyone can hopefully follow it is by reference to those heads of charge about which you have the expertise to express an opinion.
A Yes. Is it the second report?

Q No, if you put that report to one side you will find a yellow sheet of paper, that is it. It is the charge that relates to Dr Spencer as that is the fullest. It might help everyone just to have it to hand. I am going to ask you to turn over to the first heads of charge. It is page 3 in the bottom right-hand corner, Dr Stimmler. Do you have that?
A No.

Q It is in the bottom right-hand corner.
A Labelled 8?

Q Yes, that is head of charge 8. The page numbers are in the bottom right-hand corner. Do you have them there?
A Yes.

Q If you just keep that to hand, it would be helpful. I want to ask you first of all about head 6 of the charge, which is on that page. Do you see it?
A Yes.

Q That relates to an incident of neck trauma?
A Yes.

Q In about February 1990, at Queen Charlotte’s Hospital in London, which was another centre for the trial, a baby experienced neck trauma, and I wonder if you might
just be given file 3, please? *(Same handed to the witness)* This is C9. If we go behind tab 8 to pages 152 first, then 153 ---

Q Yes, just in front of 153. Do you have it there, Dr Stimmler?
A Yes.

Q It is just in front of 153, which is marked in the top right-hand corner. Do you have that, Dr Stimmler?
A I have, yes.

Q This is a photograph of neck trauma to a baby at Queen Charlotte's Hospital, and if we turn over to page 153, the next page, we can see that this baby was born on 30 January 1990 and died on 2 February 1990. Do you see that?
A I cannot see the date of death.

Q It is number 1 on the death certificate.
A Yes, I can see it now.

Q I may well come back to this at a later stage, but what I want to ask you for these purposes, please, Dr Stimmler, because you have been asked about this in your report, is whether neck trauma of the type that we can see at page 152 would be described as an adverse event?
A Yes.

Q As far as an adverse event such as this is concerned, how serious would it be?
A This was serious.

Q In 1990, because that is the time with which this Panel is concerned, would you have expected the trial investigators to have reported this incident to the respective Ethics Committee?
A I would think not. It is the sort of problem that arises in general neonatal care, even in children that are not on a trial. Intravenous drips can tissue and cause lesions not dissimilar from this, and injections that have been given intravenously can be given intramuscularly. These are all problems that do occur anyway, and this I would put as one of those, except that in this case it was produced by the ring round the baby’s neck, which probably interfered with the blood flow.

Q So would you have expected that to have been reported at all?
A I think that everybody in the study should have been told about it, and I think there is good evidence that they were. I do not know what the rules of the Ethics Committee were at that time, but I would not have thought that they would be expected to be informed of that sort of detail.

Q What is your rationale for that?
A Because the management of patients depends on the clinicians, not on the Ethics Committees. The only thing the Ethics Committee could really do would be to stop the trial, and I cannot imagine an Ethics Committee that would stop the trial because of one misadventure like that.
Q Would you have expected any changes to have been made as a result of this particular adverse incident?
A Yes, I would.

Q Of what sort of type?
A To make sure that the ring round the neck – it is not actually a ring; I do not know what you would call it – was never that tight, that the blood flow through the skin around it should be monitored, and that an alternative adhesive or whatever, or something, put round the neck to prevent it happening; and, as far as I can gather from the report, this was done. They developed or used a sort of gel to put inside the seal, and that seems to have been very successful.

Q I now want to ask you to look at the yellow sheet of paper again, Dr Stimmler, and at the paragraphs, or heads as we call them, numbered 7, 8 and 9. Do you see those?
A Yes.

Q Those relate to various amendments to the trial protocol. Head 7 relates to two changes to the scoring system in May 1990. Do you see that?
A I see that two changes were made. It does not say… I cannot remember what they were, those two changes.

Q We can look at those, if you would like. If you put that existing bundle to one side for a moment and look at file number 1 and go to tab 1, page 19 in the top right-hand corner, we can see that this is Dr Raine writing to Dr Spencer to notify him of two changes to the CNEP protocol. The first was the plan to perform the overall scoring on the patients at 56 days of age rather than at discharge home?
A Yes.

Q The second modification is referred to in the second paragraph of the letter. It is to exclude retinopathy of prematurity from the scoring system?
A Yes.

Q So those were the changes that were proposed at that stage on 15 May in head 7?
A Yes.

Q In head 8 of the charge, if you look at the yellow sheet again, we can see that what is being introduced now, in about July or August 1991, was artificial surfactant as a treatment option for patients?
A Yes.

Q If you look at head 9 of the charge, going over the page, what is being suggested here is the amendment of the exclusion criteria to include patients who were born following prolonged ruptured membranes, provided that they were of not more than seven days’ duration?
A Yes.

Q In relation to those changes to the scoring system, should those changes have been reported to the Ethics Committee, Dr Stimmler?
I think that the two on 15 May were logical, made sense, and did not affect the trial in any way, other than making it more sensible to have a finishing time, which I think was a good idea. The second one about not including retinopathy (retrolental fibroplasia), the eye problems, is also sensible because there were no cases anyway.

You say that those were sensible changes, but my question was: should they have been reported to the Ethics Committee?

It depends on what rules the Ethics Committee made with regards to being informed. I would not have thought that it made much sense that they should have been informed about every tiny item if it did not materially affect the type of study that they were doing.

So it was not necessary to report every tiny item?

I would have thought not, unless the Ethics Committee in that case said, “We need to know every tiny change that you make”, and then you go by the rules of that Ethics Committee.

What about the introduction of artificial surfactant? First of all, tell us what artificial surfactant is, if you would not mind, in lay terms?

The cause of respiratory distress syndrome in premature babies – sometimes frequently called hyaline membrane disease – is due to the absence of a chemical produced in the air sacs to the lungs, the alveoli, which lowers the surface tension of the fluid inside it, and it has been shown many years ago that in the absence of surfactant, it requires something like 15 times the force to expand the lungs than would be required if surfactant was present. So, over the years companies worked and developed the chemicals that had the effect of the surfactant – a chemical called diparmotile lecithin at one time, though I expect that it has much more complex names by now – and it worked extremely well. No, that is an exaggeration; it worked well. That is a problem when you introduce something like that in the middle of a trial, because you have a different sort of baseline. Now I think that may have been an occasion when the Ethics Committee might have been informed.

You think that the introduction of artificial surfactant was something that the Ethics Committee might or should have been informed of?

It depends on the rules of the Ethics Committee at that time, but it was a major change in the trial.

If you just want to look at tab 1, page 21, in the large bundle, the one that you have in front of you just to your left, page 21 in the top right-hand corner, we see that it is obviously proposed from the second paragraph of this letter, or hoped anyway, to commence artificial surfactant on 1 August of 1991. You have said that that was a more major amendment to the trial, the introduction of surfactant?

Yes.

Why was that? Why would that have more impact on the trial than, for example, the other amendments that we were looking at earlier?

Because surfactant had the marked effect of making infants better. I think it is the use of surfactant and the way it has been elaborated since it was first introduced has allowed the survival of these tiny infants which we are now hearing about. In the absence
of surfactant availability, it is very unlikely that any infant of less than 25 weeks would stand a great deal of chance of surviving, certainly not less than 24 weeks. Now they get survivals even younger than that. It was certainly noted to be very helpful in my experience on the babies we used it on. We used it, of course, on the older babies to begin with.

Q Yes, so would the introduction of surfactant have had any effect on the trial?
A I think there was no question, but it had to be used. When it became available it would have been grossly unethical not to give the babies surfactant. What the difficulty is, the conundrum, is they were only allowed to use it in certain situations. I can remember that very clearly for two reasons. One is they were not sure whether it worked outside the particular parameters that were used. Secondly, it was very expensive and they only wanted to use it where they knew it was effective. The trial that had decided that surfactant was good for premature babies only did it within certain limits.

Q Yes, my question really to you was this: would the introduction of surfactant have had any effect on the CNEP trial that was being conducted in North Staffordshire?
A I think so because some children were eligible for surfactant under the rules and regulations that had been decided. Others were not. I do not know who got surfactant and who not, except that there were 30 per cent in each of the group but they were not well, it does not say whether they were given to each pair. I think they should have been, irrespective of the regulations at the time, but it may not have been possible to have achieved that. All I am pointing out is the difficulties that the introduction of surfactant made to the proper pairing of these babies if one baby in a pair had surfactant and the other baby did not.

Q Yes, so if one baby in a pair had surfactant and the other did not, what potential effect did that have on the trial?
A The one who did not might be worse off than the one that did for virtue of not having surfactant. It could go against the final results or in some instances might have advanced the final results. For example, if a baby that was doing quite nicely did not need surfactant, might have done much better if they had had surfactant and vice versa.

Q Yes, so that is the introduction of surfactant. Can we come then to the exclusion criteria and the amendment to that, which is referred to in head 9 of the charge? Do you see that?
A In some respects it follows the same ideas as in paragraph 7. It is a sort of thing which on the surface at least seemed reasonable, you just gave - it just allowed you to include more babies in the trial.

Q Yes ---
A But it would also have an impact on the pairing process. You know, it is the sort of thing that did not strike me when I first went through the notes, it struck me because I had so much time to think about this trial now. So that a baby that has been losing liquor is not in quite the same position as one who is not. Babies who have been losing liquor for four days may have problems associated with poor lung function because of that. Whether four days would make any difference or not I really do not know, but it is that sort of worry. Ideally, a baby who has been losing liquor for four days should be paired with another baby who had been losing liquor for a similar period of time.
Q Yes, so it is a question of comparing like with like. Is what you are saying?
A Yes.

Q Is that right?
A Yes.

Q In terms of any amendments to the trial protocol?
A Yes.

Q Can I just go back a moment a minute to the question of the neck trauma, Dr Stimmmer?
A Yes.

Q You told us that you would not have expected that incident that occurred in February of 1990 to have been reported to the Ethics Committee?
A Right.

Q Had there been any further incidents of neck trauma, what would your answer be as to whether it would be necessary to go back to the Ethics Committee?
A There was in fact another, was there not? There were two cases of neck trauma, which I have forgotten about when I wrote my report. They occurred, I would imagine, fairly close together. It is really having two at that time dealt with eventually by the use of the gel foam would not have been a situation to throw the trial into doubt. I think if there had been any more after then perhaps one should have considered this was serious enough not to continue, but I think I would accept the first two.

Q As you have indicated, whether any particular amendments ought to be reported to the Ethics Committee depends also on what the Ethics Committee says should be reported?
A That is right.

Q If there had been amendments made of the type that we see here, would there have needed to have been any amendments to the trial protocol made by an Ethics Committee?
A I think it would have been very useful to have discussed the problem of surfactant. I would, if I had been on it - of course I had no chance of being on anything like that because I have no knowledge of ethics - I would have preferred, from a scientific point of view, if both babies on the trial received surfactant; if one needed it, then the other one should have been given it, whether it followed the criteria or not. I can see why that would not have happened because of the difficulties there were regarding the use of surfactant.

Q So far as ethics is concerned, I think you said that that was not something with which you were ---
A Everybody has their own views on ethics and I would have said it would have been grossly unethical not to give surfactant. I think it would have been unreasonable to stop the trial because of the difficulties that I have suggested. I would expect the trial to have continued in spite of it. The only proviso I might have made is that when the final calculation was done, because of the difficulties of not being paired for surfactant,
perhaps one should look at doing the calculation without the babies that had surfactant and those that had surfactant separately and see whether it made any dramatic difference. It was probably done and probably found not to make any difference, but I do not know.

Q I would like you to look now, please, at number 11, head 11 on the charge, which relates to the issue of consent.
A Yes.

Q Have you read the evidence of the various parents who have come to give evidence to this Panel, Dr Stimmmer?
A I have.

Q And also the evidence of the doctors who have come?
A Yes.

Q Can you help, first of all, about the numbers of staff involved in the consenting process? It might just help a moment if we all take up file 3 again. That will be handed to you, Dr Stimmmer. If you go behind tab 8, just straight behind tab 8, pages 1 to 3 there, which was an audit of consent carried out by Professor Southall. Do you see it?
A Yes.

Q If you turn to the second page, please - the number is in the top right-hand corner - you will see there that he found, in relation to North Staffordshire, that a total of 34 professionals were responsible for seeking consent?
A Yes.

Q Twelve registrars, one research fellow, 18 senior house officers, two consultants and one clinical nurse specialist?
A Yes.

Q He says that obviously he did not seek consent. You will be aware that in relation to the part of the trial being conducted in Queen Charlotte’s Hospital, Dr Raine did most of the consenting, except of course when he was away or on holiday or such like?
A Yes.

Q Can you help as to what your experience is of that number of staff being involved in consenting for a process such as this?
A Dr Raine was doing his MD thesis and there is nothing like an MD thesis that makes you get up all hours of the day and night and see everybody yourself personally and so on. You cannot apply the same rules in a busy hospital where everybody had to work all day and on duty at night. There was no alternative but to teach everybody involved in the consenting process, or make sure that everybody in the consenting process knew precisely how to obtain consent, matters that they should discuss with the parents and so on. I do not think you could - it is over a period - you are obviously going to have changes of staff in that time as well giving you this large number.

Q Can you help us as well about the type of training you would expect for doctors involved in the consenting process? You have read again the transcripts of what they have had to say. How does that compare with the type of training you would have
expected doctors to have received prior to a consenting for a trial at this period of time, so in the early 1990s?
A I think they had to know everything about the trial: what the aim is, what the apparatus was like, how it would be applied. They had to know how the children would be chosen for the trial. This is the difficulty, they had to know how to communicate that to the parents.

B I am sorry to say that I think the vast majority of us do not communicate with parents as well as we should. That is the nature of being a doctor and dealing with people who do not have the same understanding of medical things as you do, but it has to be done that way.

I was sent a whole series of papers on consenting random trial and in all of them there were a proportion of the parents who had been talked to who first of all did not understand what they had been told and a good many of them did not remember that this had been discussed with them, even if there was good evidence there in those trials, as in this one, that people had taken the trouble to attempt to explain it to them.

Q How easy a process is it to explain the concepts involved?
A I think very difficult. I explained to you about surfactant and I do not know if the lay people on the Panel understood what I was saying, not with ease, I suspect, and that is a fairly simple thing to explain I think compared to explaining a complex issue like positive pressure and negative pressure, how it might affect the airway and so on.

Q What level of doctor would you expect to be involved in consenting given those difficulties.
A Senior house officer. Ideally a consultant first, registrar second and SHO third, but I would definitely include SHOs. People before they are accepted for medicine have to have a high level of intelligence and ability to learn. They would have been shown about consenting from the time they first qualified, that is ordinary consent that you get when a patient has to have a procedure like surgery, and they would have been told exactly about this sort of trial and I think anybody who has reached the stage of working in a paediatric department would have the ability to understand the trial and explain it to the parents. The longer you have been at it perhaps the more difficult it is to explain things to people, but even then I used to have an outpatient sister sit in on my clinic for years and after I had seen the patient she then took the trouble to explain to the patient what I had said. I always thought I spoke reasonably plainly and I thought people would understand me, but how wrong can you be?

I think where you have got a situation like a trial with really sick babies and lots of them are going to die anyway and you are trying your best to improve things, how you can get this concept through to parents who are distressed and not in a perceptive mood for anything I do not know and I am not at all surprised that a fair number of them cannot remember having been consented.

Q Because we know that consent had to be obtained by four hours after birth.
A I know and you cannot change that because otherwise the trial becomes worthless.

Q What should the approach have been where a mother had had, for example, a
caesarean section?
A I think you have got to decide whether she is following what you are saying and hope you have got it right. It is instant judgment and the interesting thing is that some of the trials I have been leading over the weekend where the trial was planned well before they were going to do anything, treatment for malignant disease, where there is plenty of time, parents were fully aware what was going to happen beforehand.

Q This was a different trial.
A A different trial, nothing to do with that, and even in that trial there were a proportion of mothers who could not remember having been asked about it.

Q What should the approach be if a mother has, for example, had a general anaesthetic or perhaps medication for pain following an epidural?
A I doubt these factors made a great deal of difference compared to the other trials and I think when mothers are distressed, even if they are fully conscious, they have a habit of not quite taking it all in.

Q Bearing those factors in mind, Dr Stimmler, should parents have been given time to consider the decision?
A Yes.

Q What sort of time would you envisage being necessary for them to take on board what they were being asked to consent to?
A Ideally you would come back to them and ask them about it, set a little question, give the parents a little questionnaire and make sure that they understood what you were saying, but again it is not only the parents who are under stress, sometimes the doctors themselves are under stress. For example, at two in the morning, you are the houseman or registrar, you are asking about consenting. You have got to do it all within a time scale. You then go away and then have to come back again and you may be called to another case in the meantime. It cannot be done ideally in every case.

Q Should the parents who were being asked for consent have been given a copy of any information?
A Yes, they should and I believe there was a leaflet giving them the information and it should have been handed to them.

Q For them to keep?
A To keep.

Q Again, if you just look in file 1 again, tab 3, page 336. It is the first page behind tab 3. You have seen that before, Dr Stimmler.
A I have.

Q It is described as information for parents about neonatal ventilation study.
A Yes.

Q How does that compare with the type of information leaflet you say should have been given to parents?
A I think this is very good, but whether they would understand it is another matter.
Q How do you ensure they have understood it?
A The only way is you have enough time to tell them about it, get them to read this and then come back and set a series of questions as to whether they understood it or not, but that would be very, very difficult in practice.

Q Before I come on to something else about that leaflet, could I just go back to the question of surfactant a moment, Dr Stimmler.
A Yes.

Q We know as far as the CNEP protocol was concerned surfactant would have been given at least four hours because that is when the children entered CNEP.
A Yes.

Q Are you aware of when children would otherwise have received surfactant?
A They may not have fulfilled the criteria at that time, but if they then fulfil the criteria on another day or two later they would have been eligible to have it, yes.

Q Once surfactant was introduced for children at what stage would it have been administered to them?
A As soon as they fulfil the criteria established for the use of surfactant.

Q Which would have been when?
A I have forgotten. That they could only be kept going by a certain concentration of oxygen, that they were given positive pressure ventilation, the amount of pressure they had to have to keep them going and so on and there was a formula we used to use which I have long forgotten and we applied this formula.

MR FORDE: If it helps my learned friend, and Dr Palmer dealt with this, if you go to pages 22 and 23 behind tab 1 of bundle 1 it may help Dr Stimmler. Those were the criteria which she devised which are referred to. It is the suggested protocol on page 21.

MS SULLIVAN: Yes, do you want to just go to that a moment. I am grateful to Mr Forde for that.

MR FORDE: It is a little hard, doctor, to read the numbers but you were taken to a letter on page 21 dated 23 July 1991.
A I have found it.

Q Then if you look, doctor, three paragraphs down on page 21 it says:

"On the second page Kate has suggested a protocol".

That is Dr Palmer.
A Yes.

Q Then the suggested protocol with the local criteria you should find on pages 22 which is obscured top right unhelpfully and then 23 you can see about half of the next page.
A Yes. It is 22 we are looking at, is it not?

MS SULLIVAN: If you look at 23 I think that might help you in relation to the protocol for surfactant and the timing. Obviously there are weights, pressures etc, but the baby needs to be at least four hours old.

A Yes.

B Q Really my question was this. Leaving aside the trial a moment, once surfactant was introduced as a treatment when would a baby receive it?
A When it fulfilled the criteria that are here. Obviously the weight will not change, but they say it has to have an x-ray done first at that time and the FiO2, which is the proportion of oxygen used in the ventilator, of 0.6 means that 60% of the inspired air from the ventilator is oxygen.

Q This relates to when babies in the trial would receive surfactant.
A Yes.

Q Babies generally, when would they be eligible for surfactant?
A I think they would be very similar to this, if I remember. We did not to begin with using it on very small babies, it was thought it might not work. I do not know if it does or does not. They made these strictures because that had been the study that had been performed at the time which covered the parameters.

Q If you do not mind, Dr Stimmler, if we could just go back to the information leaflet. I am sorry, I went back to the question of surfactant to ask you some questions.
A Can you remind me what page that is on?

Q Tab 3 in the same file, the very first page behind tab 3, we were looking at the information leaflet.
A Yes.

Q I just wanted to draw your attention to the third paragraph on that leaflet. Do you see where the reference is made to this:

“Although the technique has been shown to be safe and effective we now need to find out whether it is better than the usual treatment”.

Do you see that?
A Yes.

Q I want to ask you this. Had the technique been shown to be safe in the management of premature babies?
A The studies that were quoted I think by Professor Southall were mainly bronchiolitis, it was used for bronchiolitis, and some of the children had been premature and some of them may have been premature at the time that they were using it, I am not sure, but they were very young babies and it seemed to work well. You then had to extrapolate from data of very small babies to even smaller babies and in general it is not an unreasonable thing to do.
Q That was my next question, is whether it is permissible to extrapolate the effects you may observe in one group to another.
A I think there is always going to be a risk with that and that is one reason for doing the trial.

Q Yes. So can it at this stage be said that the technique had been shown to be safe for premature babies?
A There were some premature babies in their study, not enough I suspect to be sure that it was always safe.

Q Should any disadvantages, for example, we looked earlier about the baby with the trauma to the neck?
A Yes.

Q Should any disadvantages, for example, potential problems with the neck seal have been mentioned to parents at the time of this trial in the early 1990s?
A It happened no more after these first two. It would not occur to me if I were doing the trial to have mentioned it, particularly something that has only happened twice and had stopped happening and for which you had thought you had found a good solution.

Q I want to turn now, Dr Stimmler, and ask you about the scoring about the babies for the trial.

MR FORDE: If that is about to be done because it is rather a dense area I know for me to follow, I do not know about anybody else in the room, Dr Stimmler has been giving evidence for about an hour and my client wishes to discuss with me some aspects of the evidence he has given thus far. I wonder whether it would be permissible, sir, I know it is a little early and I know we started late, just to have a short-ish break so I can marshall those points and then perhaps move on to the issue of scoring which we are going to hear about in detail for the first time. I do not know if that is acceptable?

THE CHAIRMAN: That probably is sensible. Probably if you are moving to a different topic, each time this happens if those representing the doctors wish to discuss with their clients the aspects of what has just gone then it is sensible to do that, I think.

MS SULLIVAN: I have no problem with that, sir, at all.

THE CHAIRMAN: Let us have our normal quarter of an hour break and come back at twenty past eleven.

MR FORDE: Thank you very much, sir.

(The Panel adjourned for a short time)

THE CHAIRMAN: Yes, Ms Sullivan.

MS SULLIVAN: Sir, I was about to turn to the scoring system, Dr Stimmler. So if we could deal with that, please. First of all, I just want to establish this, is it right that you were asked to look at a sample of medical notes?
A I was, yes.

Q And to see whether the data recorded in the data collection sheets for the trial corresponded with the findings in the notes?
A I thought they were.

B Q Was that what you were asked to do?
A Yes.

Q I want to go through the individual patients with which you were concerned and see how those scores compared. I wonder if you could just first of all have file 3, please. You will find, Dr Stimmler, behind tab 6 are the notes for a patient whom we have called Patient 14. If we all just turn to tab 2 behind tab 6 in file 3 we will see just at the top of the page there that this patient has been anonymised as Patient 14. Can you see that?
A Yes.

Q I am going to ask everyone to take up another file as well so that we can just identify who Patient 14 is, that is file number 4. There is an index at the front of file 4 and then if you go behind that to pages 1 to 6 that is a spreadsheet that has been copied. Can you see that?
A On page 6? No. Page 7?

Q Pages 1 to 6 are a spreadsheet.
A Yes, yes.

Q Do you have that there? If you look at page 4 you will see in the far right-hand column, second from the bottom of the page, Dr Stimmler, a number, it is not very clear but that is number 14. Do you see?
A The one that reads 184.5?

Q That is it. So number 14 is the number that we have given this patient. We see the total score for the patient is 184.5, we see the patient was born on 9 May 1993. Do you see that?
A Yes.

Q Also if you just go over you will see that the trial number for the patient is 226?
A Yes.

Q So if we go back to the other file a moment, so back to file 3, page 119. There we can match up the Patient 14 with a trial number. Do you have that, Dr Stimmler?
A Yes.

Q If we could then go forward again to page 141 we will see the scoring sheets for that child which go through from 131 to 135?
A Yes.

Q On page 135 we see there the total score, 184.5?
A Yes.

Q I am going to use this particular patient as an example of how the scoring system
appears to have worked, Dr Stimmler. As far as your consideration of the notes of this patient was concerned, this is Patient 14, you indicated in your report that you could find no record of an ultrasound of the skull in the patient records?

A That is true that I did not find it.

Q You can see that from your report and we know that this child scored 184.5. Was that a high score? How did the scoring system work? Let us go through the sheets a moment from page 132 and see how the scoring system---

MISS O'ROURKE: Sir, can I indicate on this before my learned friend starts to take Dr Stimmler through this, I would be very grateful that she does not lead him on this. This is the point that I made to you last week when I indicated that really we should be hearing Dr Raine before we hear Dr Stimmler. My learned friend has not set up the basis on which or what is the basis of Dr Stimmler's understanding of scoring, in other words what he has read or what he knows about it. Bearing in mind the answer he gave us about not previously himself being involved in a randomised trial I would be grateful if my learned friend asked him first of the basis of his understanding and then was very careful not to lead him because I know my learned friend has read a lot more, she has obviously read the evidence of Joe Raine and other stuff but I am very concerned if this witness is going to give evidence about scoring it should not be led information. He should volunteer what he knows or understands because it may be that there are deficiencies in his understanding and he is not the appropriate expert, certainly that may be my case once I have heard him.

MS SULLIVAN: I have no problem with that, sir.

THE CHAIRMAN: Thank you.

MS SULLIVAN: Looking at this particular scoring sheet can you help, first of all, as to your understanding, Dr Stimmler, of how the scoring system worked?

A I assume at the time that the child was discharged or had died the details of patients were sent to either Dr Samuels or Dr Southall and I believe that they were responsible for the scoring. That was my understanding anyway. So it was done only by these two doctors. They had to weight it depending on what they reckoned were the important bits of the scoring system, and by and large I think it is reasonable.

Q Just explain your understanding of how it worked by reference to the scoring sheets?

A If the child survived, that gave them 50 points.

Q For example, on page 132 we can see that this child received 50 points for surviving. That is question 1 on the form. Is that right?

A Yes. If the child never had any intermittent positive pressure ventilation, they scored 35.

Q Which this child did, we can see from the answer to question 2?

A Yes, and various scores lower than that depending on how many days that it required intermittent positive pressure.
Q Then what is your understanding of the position in relation to question 3?
A The highest level of pressure in the ventilator that was used at any time.

Q When you say “the highest level”, what is it recording?
A The pressure at which the ventilator was administering the oxygen to the baby.

Q So for what would a high score be allotted?
A Where it was very low.

Q So we see a high score allotted in the case of this baby?
A Because the pressure was less than 20.

Q Because a pressure of less than 20 was needed?
A Yes.

Q What is your understanding of the maximum inspired oxygen requirement and how that was scored?
A Depending on the age of the infant, a score was given if the amount of oxygen required, the proportion of oxygen required, to keep the baby’s blood oxygen at a reasonable level, and if it required less than 60 per cent, for example, it scored 6; if they had to use more than 80 per cent, it scored 2 in the first 24 hours; and then the scores went down depending on how old the baby is, so between eight days and 27 days it would score 2 for less than 60 per cent and zero it required 80 per cent even at that age.

Q So the less oxygen required under a level of 60 per cent produced the highest scores?
A Yes.

Q That was for a 27-day period, we see?
A Yes.

Q How was the oxygen requirement at 28 days scored, which is question 5?
A Well, it was simple. If it did not require oxygen at all, they were given 30 points; if they required oxygen from 28 to 56 days, 15 points; and if they still needed oxygen at 56 days, they scored zero.

Q So again this baby has received a high score of 30 for requiring no oxygen at 28 days?
A Yes.

Q We are just using this as an example to show the Panel how the form worked. Now question 6 relates to pneumothorases. First of all, just in layman’s terms, what is that, Dr Stimmler?
A When there has been a rupture of the lung and air has escaped from the lung into the space between the lung and the chest wall.

Q I think this one is clear, but how was a pneumothorax scored?
A Ten if there was not one; five if there was a pneumothorax on one side; and if there was a pneumothorax on two sides, the score was zero.
Q This child again scored the maximum of ten?
A Yes.

Q We come to the next category of scoring, patent ductus arteriosus. Again just in a sentence or two, what is that?
A The foetus has a connection between the main artery on the heart, the aorta, to the pulmonary artery, the artery taking blood to the lungs, and the baby does not need its lungs before it is born and therefore this is a shortcut for the blood to go. From the left ventricle it will go straight into the lungs; from the lungs it goes into the left atrium into the left ventricle and back to the lungs again. The venous blood, which goes into the right atrium, will go into the right ventricle, and from the right ventricle... In fact, in the foetus it is always that way round. From the right ventricle it goes into the pulmonary artery, and from the pulmonary artery it goes into the aorta. In fact, this is the way it goes round in the foetus.

Q All right, I do not think we need to understand the detail of it too much ---
A It gets more complicated.

Q It is complicated but ---
A I am sorry, I was going to go on. Soon after birth, from a number of hours to a few days, this ductus closes, so that you have the normal infant circulation, which is the same as the adult circulation.

Q So, looking at question 7 here, how did the scoring work here, on your understanding?
A If there was no patent ductus arteriosus, at any time I assume that means, it got ten points. If there was a patent ductus which required some fluid restriction to close it, it got 7.5. If it needed some medication which is known to close ductuses, indomethocin, which I think is a non-steroidal analgesic mostly but in this case is used as a prostaglandin... I do not know; I have forgotten. Anyway it affects the prostaglandin and that closes the ductus, so that scored five for that. If it required no treatment at all – sorry, if it required surgical treatment, then it scored zero.

Q Help us, please, with question 8. What was that intended to record?
A Whether there was abnormality produced in the brain either with a hydrocephalous or haemorrhage, or other serious condition called periventricular leukomalacia.

Q What is that, in a sentence?
A Damage to the neurones round the ventricle.

Q Likewise if there were certain types of cyst, it would appear?
A If none of these, then it would get 20. If there were some of these, the score would diminish progressively.

Q At what stage was that to be assessed and how?
A Fifty-six days of age, or plus or minus four days on the last scan preceding death.
Q In terms of any abnormal appearance, what is the maximum score, in your understanding, that should have been given?
A Twenty if there was nothing, and then very little if any of the other things had happened, particularly haemorrhage into the substance of the brain; nothing if there were cysts present and cortical atrophy.

Q If there were problems with either side of the brain, what is your understanding of what the score should be, the maximum score?
A I think it was an average, was it not? Well, they say “summate”. It would have brought it up to 40. I think they meant average. You would give the lowest single score for each side and summate. You see, Patient 14 would then have had 20 for none on one side and 20 for the other. I think the authors implied the average of the two.

Q The average of the two?
A Yes. That is how it was used in this case.

Q If we just turn the page to number 9, which is the last of the scoring outcomes, can you just explain that to us?
A Necrotizing enterocolitis was a condition which no one understood when I was still working. I do not think anyone has discovered very much since, but I may be wrong about that. It is devastating when it occurs. You get an escape of air from the lumen of the bowel into the tissues of the bowel wall, and quite often perforation all the way through, so it is frequently associated with peritonitis.

Q If a baby had no necrotizing enterocolitis, the score would be…?
A Five.

Q If “yes”…?
A Nothing.

Q A score of nil?
A Yes.

Q Do we then see below, Dr Stimmler, the scores being added up, the individual scores?
A Yes.

Q We see that this baby got 184.5?
A Yes.

Q You have indicated that there was no ultrasound that you saw in this baby’s notes?
A No, but it could have been done. I assume that it was done and was normal, but I could not find it in the notes. I mean it could have dropped out of the notes.

Q If the baby had not had a scan, how would that have affected the scoring at all?
A That is the difficulty. You would have to score it as zero, but it is not very satisfactory because it is obviously a well baby.

Q Scoring what as zero?
A The ultrasound.

Q So the answer to question 8, if there had been no ultrasound, would have been zero?
A Well, I do not know how you could tackle that, quite honestly. Zero could have been rather punitive for a child who was well.

B But would the score have been as high as 20 if there had been no ultrasound?
A If there had absolutely been none, then I think you would have to give one of the lower scores.

Q Which would have affected the total, obviously?
A Yes, would have lost 15 points.

C Now that we have hopefully explained how the scoring worked – and I am not going to go through the detail of this myself – just prior to the scoring sheets in the bundle there, Dr Stimmmer, do we see the record sheets for this child?
A Yes.

Q So that the Panel understand how the system worked, was data collected and then transferred on to the record sheets?
A I believe so.

Q I am going to leave it at that, because I now want to turn to a particular patient again, some of whose notes we have, and that is Patient 41. If you keep in the same file and turn on to tab 7, please, and page 1 behind tab 7, this is out Patient 41 whose trial number is 119. Do you see that there?
A Mm-hm.

Q We see that this child was born on 21 September 1991. Do you see that?
A I cannot, actually.

Q Page 1 behind tab 7?
A Oh yes, 21 September.

Q If you would not mind please, Dr Stimmmer, just turning on to page 12 in the top right-hand corner, do you see there an autopsy report on this child?
A Yes.

Q Do we see that this child died on 22 September 1991?
A Yes.

Q At 1.05 hours?
A Yes.

Q So this child lived for 24 hours?
A Well, possibly less, because I am not quite sure what ---

Q Yes, possibly less, you are quite right. Then do we see further down, on internal
examination, that there was a little fresh haemorrhage in the left lateral ventricle?
A  Sorry, there was an extensive ---
Q  An extensive fresh haemorrhage within the tissues of the left side of the skull?
A  Yes. It says:

“Intracranial vessels are extremely congested and there is a little fresh haemorrhage to the left lateral ventricle and in the subarachnoid space around the cerebellum. The appearances are consistent with hypoxia and prematurity”.

Q  Yes. I now want to look at the scoring sheets for this child. You have had a look at these and it may help you to have open page 22 of your report as well as the scoring sheet there. At page 22 of your report you deal with this patient. Do you see that, Patient 41?
A  Yes.

Q  I want to ask you about the scoring for this child who died. Could we just have a look, please, at the scoring sheets behind tab 7, page 2 in the top right-hand corner, which is where the treatment outcome scores start?
A  Yes.

Q  As I said, it may help you to have your report to hand. We know, as we have just established, that this child died within 24 hours?
A  Yes.

Q  So what do you have to say, first of all, about the score that was given for the child’s death?
A  It was given 25, because it was said that it did not die of a respiratory cause, but the post-mortem result, if I can find it ---

Q  The post-mortem result that we were looking at previously, the autopsy report, begins at page 12. My question is this, Dr Stimmler: should this baby have been given, in your opinion, a score of 25 for death from a non-respiratory cause?
A  The lungs and pulmonary vessel bits of this sheet are missing, but my memory of it was that it showed hyaline membrane disease and atelecstasis, but that is cut off from this sheet.

Q  Cut off at the bottom?
A  Yes.

Q  We will just see if we can get you a better copy there. On the basis of what you have indicated about hyaline membrane disease, what should the cause of death have been in your opinion?
A  I think a combination of intraventricular haemorrhage and respiratory failure.

Q  So what score should it have received according to the score sheet?
A  Well, when there are two causes of death they do not state, but I think it should have scored 0.
Q: Can we look then at the second question in relation to this baby, which is the case of intermittent positive pressure ventilation?
A: Yes.

Q: We see that this baby scored 15 for needing IPPV for less than four days?
A: Yes.

Q: Is that an appropriate score in your opinion?
A: No.

Q: What should the score have been?
A: 0.

Q: Just going back to you saying that something had been cut off the bottom of the page ---
A: Of the death certificate?

Q: Yes, of the autopsy report, if you look at page 14, does that make reference to hyaline membranes?
A: Yes, wide spread collapse with hyaline membranes, the lungs.

Q: I am sorry. We just, I think, have been looking at IPPV and you indicated that for less than four days the baby should have scored 0?
A: 0 because it was dead by then.

Q: What about peak and inspiratory pressures used, question 3, is that an appropriate score?
A: For the time it lived that was the maximum pressure they had used, which was 25 to 29 cm of water, so that is reasonable.

Q: So that is a reasonable score, 7.5. What about question 4, maximum inspired oxygen requirement?
A: Between 24 and three days of age it was dead, therefore, it could not have scored anything for that at all.

Q: Likewise, question 5, oxygen requirement at 28 days, what do you have to say about that?
A: The same applies really. The baby was dead at 28 days and the score of 30 was not relevant.

Q: What should it have scored?
A: 0.

Q: What about pneumothoraces?
A: The baby could have developed a pneumothorax in the first two hours of life, but pneumothoraces in this context was the pneumothorax had occurred at any time after birth. If this baby had lived he may well have developed pneumothoraces. The fact that he did not live, did not really have time - he did have some time to develop them but he may not have developed them until a day or two later. Again, I would say 0.
Q And number 7, patent ductus arteriosus?
A You very rarely - it is very unusual to be able to diagnose a patent ductus arteriosus in the first few hours of life because there usually is not a murmur until they are quite a few days old. So the fact they did not find a patent ductus does not mean - there might not have been.

Q What should the score have been there?
A Here you have the post mortem. I wonder if they mention anything about it in this. In all fairness, they do say normal, so presumably post mortem there was not an obvious patent ductus. I would say they probably deserved to score that one.

Q So deserved to score 10?
A Yes.

Q In terms of cerebral ultrasound appearances at 56 days of age?
A Which is number?

Q Number 8, question 8 on page 4.
A Yes.

Q We know from the autopsy that page 13 - do you have that?
A Yes.

Q The cause of death we see is shown as 1(a) intraventricular haemorrhage?
A Yes.

Q And (b) prematurity 29 weeks?
A Yes.

Q What should the score have been for this baby in answer to question 8?
A 0. It is interesting, they do give 20 for each hemisphere.

Q Yes, we know in fact that was corrected at a later stage, which I think you may have seen, Dr Stimmler, to show 20 in total.
A Yes.

Q On this it shows 20 plus 20?
A It should have been 0 anyway.

Q It should have been 0 in any event?
A Yes.

Q As far as you were concerned - sorry, I have not quite finished. If you just go on to number 9, question 9 what should the score have been for the baby?
A Again, I would have said 0 because it died so young before the baby was ever fed. It is very unusual to get a necrotizing enterocolitis by that age anyway.

Q We see at the bottom there the scores are totalled and this baby is given 154.5?
A

Yes.

Q But from the scores that you have indicated you will have allocated this baby - in other words the scores in answer to questions 3 and 7 - that would have totalled 17.5?
A I had not taken account of the post mortem report showing normal blood vessels, therefore I should have given it another 10, so it comes to 27.5.

B

Q Just help us as to where you get your other ---
A When I made my estimate, I did it on what I would expect that you cannot diagnose a patent ductus arteriosus on day one, but there was none shown at post mortem.

Q Yes, so therefore you would have given it 10?
A Yes, there was another 10.

C

Q You would have given, in answer to question 3, 7.5?
A Sorry? Yes.

Q Would you have given any other scores for this child?
A No.

D

Q In the light of what is said in the post mortem report about intraventricular haemorrhage, did this baby have any ultrasound abnormality?
A I do not think so. I am not sure that ultrasound was done.

Q Yes, I think if I can ask the question in this way, whether or not ultrasound was done, was that an abnormality?
A Yes.

MISS O’ROURKE: I am sorry; I do not think that is the right question. If you are dealing with scoring sheets and ultrasound abnormalities, then it has to be a question of whether it would have shown up in an ultrasound. It is not the same question to say is that an abnormality. I wonder if my learned friend might want to think again about that because the witness did answer to the question ultrasound abnormality, “No, I do not think so”.

MS SULLIVAN: I think the issue with this child is in fact whether the score should have been given at all. Let us leave it at that for the moment, Dr Stimmler. You have indicated that the score should be 0 there. Let us go on, if we may, to the question of infants who died, as this one does here.

A Sorry?

Q The question of infants who died as this one did here, Dr Stimmler - and we are going to come to another example shortly - what is your concern, if you can articulate it, please, as to scoring these babies once they had died?
A I think it is a difficult one. My own knee jerk response to that was if they are dead they are dead and they should score nothing because that is the worst possible outcome for the trial. On the other hand, where you are specifically - I can see why they were scored because if you are specifically looking for what their lungs had been like before they died as an effect of positive pressure versus CNEP, you would need to take into...
account what was going on before they died, so that I can understand why it would not perhaps be reasonable to give them all 0. I do not think you can give them scores for anything that happened after they were dead.

Q  What is your rationale for that?
A  How can you give - I do not know how you can possibly give a score to someone who is not alive if they were not having any oxygen seven weeks later.

Q  Here, as you know, these infants were in matched pairs?
A  Yes.

Q  Therefore, within a pair both babies may live, both may die, but you may get a situation where one lives and one dies?
A  That is so, yes.

Q  In terms of scoring the dead babies in this way, have you any concerns about what would happen if a dead baby was scored in this way and scored possibly a higher score than a live baby?
A  Yes, I do. I think that would, as far as that case was concerned, distort the value of that particular line of treatment they were on.

Q  Again, can you just explain why? It may be obvious but just explain why?
A  Because the idea of the scoring system was to be able to judge which group were doing better than the other. On that, the researchers were going to decide as to how long the trial should continue. Therefore, the scoring had to be accurate if that decision was made.

The scoring system, as far as I understand, was not used in coming up to their final conclusions. As it happened, they had done the 122 pairs - which is a lot of work - and they came up with a positive answer which showed that CNEP seemed to be a good method of treating these babies. They could have done that without any of the scoring system altogether. If they had totally ignored scoring and they had not scored any babies at all, they would have come up with the same answer as it happens because the situation where the trial was stopped early did not occur. I do not think there would have been a case for carrying on longer because you have got a good result as it was. There would be no justification.

I mean, looking at the results, for example, I think it is 56 days of age in the published paper. There were 20 children who were still requiring oxygen than those who had had positive pressure ventilation and only ten if they were on CNEP. You know, you have stopped - you can argue from that that you have prevented bronchopulmonary dysplasia, cut it by half. I think that is a very good result.

Q  Yes, my ---
A  That would have been the same result if they had not bothered with any of the scores whatsoever. At least that is my understanding.

Q  My question really related to the dead babies potentially scoring more than the live babies.
A There were 50 babies that died altogether ---

Q That is right, it was 50 who died.
A 50 altogether, 28 in the CNEP group and 22 in the other and I believe there were five infants where the dead babies scored more ...

B Yes.
A ... than the live ones. I do not think that would have made much of an impact.

Q In fact?
A Yes, I understand from the statistician that ---

Q You referred to the statistician in relation to the significance of the statistics ...
A Of course.

Q ... as they actually were. Can we turn then, please, to Patient 7, whose identity I think you already know, Dr Stimmler, but it is on that piece of paper that may be buried there somewhere now. It is just coming back to you. (Same handed)
A Yes.

Q Let us take up, if we may, file 2 and tab 4. (Same handed) We can see that this baby was born on 12 February 1992, Dr Stimmler. She died on 14 February 1992 after a collapse, which we see reference to in page 15 of the notes and you have looked at these notes before?
A Yes.

Q I think we can just summarise it in this way, Dr Stimmler: you indicated in your report that you are not critical of the care of this baby?
A That is correct.

Q What I want to do is again to look at the scores that this baby received. We will see the scoring sheets. We have them in a number of places, but let us stay in the same file. Turn on, please, to page 68. I just want to show you where you have this in your report, Dr Stimmler, your analysis of the scoring for this baby, Patient 7. If you just want to get that, it starts at page 15 I think. Do you have that there?
A Yes.

Q I wonder if we could just go through the way in which this baby was scored and to see whether or not you agree with the total score that she was given at the end of the day of 137.
A Yes.

Q If we can do it in order of the questions, starting at page 69 behind tab 4. Question 1: “Death from a non respiratory cause”.
A Yes. As far as I know, this child did not have an autopsy.

Q That is right.
A Therefore you cannot say what it died of.
Q Therefore, not being able to say whether the death was respiratory or non respiratory, what should the score have been?
A I think it should have been nought.

Q Let us just look, if we may, at page 66. Just go back a few pages. We see a death certificate here for this child.
A Yes.

Q What do you have to say about the cause of death that appears there?
A I think extreme prematurity is a recognised thing you can write on a death certificate. Renal failure is almost certainly due to something else that had happened and from my experience severe hypoxic ischemia.

Q But we also see, as well as it saying “extreme prematurity” it also has next to it RDS.
A Yes, it said RDS, yes, respiratory distress syndrome.

Q In the light of that what would have given for this child?
A Nought and, of course, all the babies that died had RDS because that is the rationale for putting them in the trial in the first place.

Q So as far as this child is concerned, you would have given nought, you say.
A Yes.

Q So that is the first score with which you differ.
A Yes.

Q Help us, please, as to IPPB where we see that she was scored 15 for needing IPPB for less than four days. What do you have to say about that?
A She could not have had it for longer than two days because the child was dead.

Q So how would you have scored her?
A Nought.

Q Again, how would her score compare, for example, with someone who had survived but was requiring IPPB at 28 days?
A She would have scored more as far as that point was concerned.

Q Is that of any concern that she would have scored more?
A Like we discussed with the other case, yes, because it could distort the decision as to which group was doing better.

Q If we go on to page 3, please, the peak pressures, how would you have scored that?
A I think I would have given ten on the same basis as the previous one, that she probably was only ventilated between 20 and 24.

Q The next question, maximum inspired oxygen, where she scored 12, we see, for needing less than 60% oxygen, how much would you have scored her here in the three
separate categories?
A Zero, because she did not live for three days.

Q Your answer to question 5, Dr Stimmler?
A She was not alive to require oxygen at 28 days.

Q What would you have scored her?
A Nought.

Q Question 6?
A Some babies develop pneumothoraces straight away but because a fair number develop pneumothoraces later it is very difficult to know how you would score that.

Q Would you agree or not with the score of ten there?
A No, but I do not know quite what to put in its place.

Q Question 7. How should that have been scored?
A She may have had a ductus arteriosus or she may not, we will not know, because you often do not hear them in the first day or two of life anyway. If she had had cardiac ultrasound done then you might have been able to spot whether she had one or not, but she did not, nor was it a standard procedure anyway, so again I think you have got to give zero.

Q Question 8, please. She scored 20 in answer to question 8, we see here, for having no cerebral ultrasound appearances at 56 days of age.
A Yes.

Q Plus or minus four days.
A She had a scan before she collapsed though, did she not?

Q I am going to show you what scans she did have, this child, if you look back, please, to pages 55, 56 and 57 which you have looked at before, Dr Stimmler.
A In this file?

Q In the same file. I think you have indicated to us that the dates were confusing on these scans.
A Yes. They were generated by the machine that was doing the ultrasound. That is the only explanation I can think of, because you cannot do an ultrasound before the baby … I have never heard of anyone. It can be done, but it is unlikely to have been done before birth.

Q So these are likely to have been what?
A Before she collapsed? I do not know. If you do not have a date you cannot tell.

Q Then I want you to go to page 14. Do you see there at the top of the page the entry for 12 February 1992, Dr Stimmler?
A Where it says “Randomised for CNEP at 3.05 p.m.”?

Q Yes and then the second point there: “Head scan aged four hours”.

D20/28
A Yes.

Q That says “normal”.
A Normal, yes.

Q Going back, please, if we may, to question 8, the only ultrasound we can be sure that she had was that one at four hours.
A Yes.

Q Help us. On the basis of that was it correct to score her 20 in answer to question 8 or not?
A I think not, because intraventricular haemorrhages can occur for quite a number of days after birth and she had not lived long enough to demonstrate that. The fact that the very first ultrasound scan was normal does not mean that she deserves 20 points.

Q So you would not have given her 20 points there.
A No.

Q Then if you turn over, please, to question 9 what would you have given her here?
A Again, necrotising enterocolitis is relatively unusual in the first day or two of life and if she had lived long enough she might well have developed necrotising enterocolitis so you cannot give any points for that either.

Q You indicated in your report that you would have given her a score of about 30 at most.
A Yes.

Q Do you maintain that, Dr Stimmler, or what is your position?
A Yes, I would maintain that.

Q We see that the score that she received here was 137.
A Yes.

Q If you have still got file 4 to hand, Panel bundle 4, we know that she is trial number 143 which is on page 3 in the top right hand corner. Do you have page 3 there?
A Yes. What number was she?

Q The third column in is trial numbers and it is about half a dozen or so below the second punch hole.
A What number?

Q Do you see no 143 there?
A Yes, I have found it, yes.

Q You see that she was recorded as scoring 137.
A Yes.

Q We can see what the matched pair scored because we know that she is pair 77 and the second of the pair, 77, trial no 154 scored 110.5.
A Yes.

Q So she is an example of the dead child scoring more than its live partner.
A That is correct.

Q In fact I will not ask you to go through these here, but we have identified five such examples in the spreadsheet. I am going to turn now to deal with Patient 6. You can stay in the same file, that is file 2, and just go behind tab 5 a minute.

A Yes.

Q This baby, just to orientate you, as you will see from page 1, the number is now in the bottom right hand corner, Dr Stimmler, was born on 14 December 1992 and discharged on 7 January 1993 and you know who this baby is from the piece of paper that you have there and also the name.
A Yes.

Q I just want to deal with the scoring as far as she is concerned a moment. If you go on in this file to page 340 I think I can summarise it in this way thus far, Dr Stimmler, that except in, I am going to suggest, one respect the scoring sheets do accurately reflect her notes. Is that your position?
A Yes.

Q Here we have the answer in relation to cerebral ultrasound appearances at 56 days of age.
A Yes.

Q We see that this patient, Patient 6, again scores 20 for having no abnormal appearances.
A Yes.

Q Would that be right?
A I believe so. It is very difficult to make out from the ultrasound reports as to what was seen. In the first one there is talk about a clot in one of the ventricles.

Q Yes. Let us just look at that a moment. In the same file if you keep open, please, 340, but if you go back to pages 161 and 162.
A Suspicious of a clot.

Q Yes. We see on 22 December 1992 a report that:

“There is increased density on the left suspicious of clot attached to the choroid plexus and in association with mild lateral ventricular dilatation”.

Then a further scan on 29 December 1992 on the following page indicating:

“There is mild symmetrical dilatation of the lateral ventricles consistent with haemorrhage although no clot is definitely identified within the ventricular system.”
Q My question is, going back to page 340, please, is the answer to question 8 correct or not?
A It probably is, because in the scoring system it talks about pairing chymal haemorrhage; that is, haemorrhage into the tissues of the brain outside the ventricles. Here the finding was that there might possibly be haemorrhage in the ventricles, so if you grade these things, and I have long since forgotten how they are graded, I believe that would be grade 1, so this would be relatively minor in appearance.

Q That ultrasound, we know, was done at 14 days of age.
A Yes.

Q Should any ultrasound have been done at a later stage?
A I think so. The idea was that they would do it before they went home and it should have been done.

Q Prior to discharge it should have been done?
A Yes.

Q I will be coming on now to Patient 6’s care which I am happy to deal with. I now need to deal with the care of Patient 6, the same patient, and if you just have to hand, please, and I would ask that everybody else does as well a charge faced by Dr Spencer and heads 16(a) to (g).
A Yes.

Q Dr Stimmler, you have seen the records for this patient, Patient 6, is that right?
A Yes.

Q Have you now also seen the originals of the records?
A Yes.

Q Have you read the transcripts of the evidence of Dr Brookfield?
A Yes.

Q And also the evidence of Drs Morgan and Palmer?
A I have.

Q Have you also had sight of, and perhaps you ought to have it in front of you now, it is there somewhere, the clearer page 84. (Same handed) First of all if we just go back to the doctor’s notes a minute at page 23 behind tab 5.
A Yes.

Q So we see that Patient 6 is seen on 15 December 1992?
A Yes.

Q We heard that it was Dr Brookfield who saw her then. What was her condition at this stage?
At 12.30 p.m?

No. The first entry on the page.

“CNEP -4”

that is four centimetres of water negative pressure:

“40% oxygen. [Respiratory rate] 90 [per minute]
? [umbilical arterial catheter] later this morning
[Diagnosis] RDS
Cont present support - hopefully will not require ventilation.”

Then we see on 15 December 1992 at 12.30 p.m. there is an entry which we know is Dr Ayra’s indicating prolonged bradycardia and apnoea?

That is correct.

Then we see a UAC is inserted and Patient 6 is ventilated?

Yes.

We know from the charge that the Panel have and can you just have that in front of you?

Yes.

Number 16, that you were critical of the period between 00.03 on 15 December 1992 and 12.30, so the time we see that there at page 23, on 15 December 1992?

Yes.

Was that on the basis of any particular document within Patient 6’s medical notes?

There are two points. First of all, the photocopy I got had the date and some of the times missing and I saw nothing else except the times. Secondly, I realised reading the transcripts that there were recording pO₂s obtained from capillary blood. I had not anticipated that they would do that because it is well known that capillary pO₂s are worthless. They are both inaccurate and unreliable and I would not have thought, I did not consider that in a study of this nature that they would take the trouble to record them and this is what misled me into believing she was hypoxic at the time. I mentioned in my report that whatever my views were this would be argued about and it was and I have now discovered the answer why those pO₂s were different from the saturations.

Let us examine this a moment. Are you maintaining, Dr Stimmler, or not that this patient was hypoxic?

I am not maintaining that any longer.

The reason for that, as I understand it, is because the pO₂ levels you realise from page 84 and from the transcript?

Yes.

Were capillary samples?

Yes, yes. In my view they should never have been put on to her sheet.
Q I understand that---
A They should have left a gap.

Q But as far as capillary samples are concerned, so that we can follow through the logic of this, are capillary samples reliable in assessing pO\textsubscript{2} levels?
A No.

Q So, therefore, are you able to maintain in head 16(a) of the charge, in the light of the fact that these are capillary samples, that these were at low levels?
A No. Sorry, I cannot maintain.

Q Cannot maintain that?
A Yes.

Q Therefore, what does the oxygen saturation level of between 94 and 99\% indicate in the light of the fact that you cannot rely on the pO\textsubscript{2} levels as being low?
A Oxygen saturation monitors are usually very good and are likely to give the correct result. Like all electronic instruments they may not always function perfectly or properly. In this situation where it is the only information we have and I think it is perfectly reasonable. They are normal.

Q Are you able to maintain the allegation in head 16(e) that the combination of results suggests that the monitor was faulty?
A No.

Q Just so that we understand the position, with regard to the PH levels referred to in head 16 as being between 7.23 and 7.28 how bad or not are they?
A Clearly the baby is acidic but that could be for a number of reasons. It could be due to hypoxia but there is no evidence for that. It could be due to a too high level of carbon dioxide and the carbon dioxide levels are high-ish, or it could be due to metabolic reasons which we do not fully understand.

Q Although it indicates that she was acidic it could be due to a number of reasons?
A One would normally find that sort of PH in premature babies of that age.

Q What about the pCO\textsubscript{2} levels?
A They are not as unreliable as the pO\textsubscript{2} but even so I would be very doubtful about accepting a capillary pCO\textsubscript{2} either.

Q So are you able to maintain that those are raised levels in the light of the fact that they were capillary?
A I cannot do that.

Q Can I turn then to the question of blood pressure. We have earlier indicated in the light of what you have said in your later report, Dr Stimmmer, that the period in which the blood pressure check should have been made was when Patient 6 was being ventilated?
A Yes.
Q Is that the position; blood pressure should be taken at that stage during ventilation?
A The protocol for the study was that the babies would have their blood pressure measured. From that respect they should be measured throughout because blood pressure can be very important. If blood pressure falls it can be a sign that baby is in serious trouble.

Q Have you found any blood pressure measurements in the notes at all?
A No.

Q We know that on 15 December 1992 from Dr Ayra’s note that a UAC was inserted?
A Yes.

Q Did that enable blood pressure to be taken, or could it have enabled blood pressure to be taken?
A If a requisite transducer was put into the artery it could have been but may not have been.

Q But whether or not it was done do we find any record in the notes at all of it being recorded?
A I could not find any.

Q Who would you have expected it to have been recorded by?
A The nurses usually. If you have got a little --- to measure your blood pressures for you then it is read out from the screen and the nurses write it down.

Q Would the doctors have had sight of those observation sheets?
A Yes.

Q In terms of ultrasound scans, we looked at those before?
A Yes.

Q At tab 5, pages 161 and 162. My question is did each of those show an abnormality?
A Yes.

Q Should the parents have been informed of any such abnormality?
A Yes, I think they should have been.

Q You have already indicated that a further scan should have been done prior to discharge on 7 January 1993?
A I think that would have been wise.

Q As far as the monitoring of Patient 6 is concerned you have described to us how you cannot say that she was hypoxic on the basis of those being capillary samples?
A That is correct.

Q Was it appropriate to monitor by way of capillary samples or not?
A It is really only useful for PH. It is worth it if you cannot get anything else because you have not got an arterial line in then it probably is a good idea to measure the PH from time to time by capillary samples.

Q How should the baby have been monitored?
A I would have thought once every four hours, perhaps twice a day.

B Q By what method?
A Blood by capillary sample. If you have no intra-arterial line there is nothing else you can do. You can measure pO\(_2\) and pCO\(_2\) by transcutaneous monitors which were available at that time but apart from misleading me I do not think that they would have been necessary because I think if I were looking after that baby I would be quite content if there were a good functioning oximeter measuring blood situations I would have been quite content with that.

C Q Are you critical of the monitoring in any way?
A No.

Ms Sullivan: If you wait there, there will be some more questions at some point.

D The Chairman: I would think this is probably a good moment to adjourn for lunch.

Miss O’Rourke: I can do ten minutes if you want to have lunch at one. I just want to ask some very general matters, if that is acceptable to you?

The Chairman: Yes, let us get the general matters.

Cross-examined by Mr Forde

Q Dr Stimmler, I represent Dr Spencer and you can imagine he is relieved by the concessions that you have just made?
A I did not have any choice.

Q I will come back to those matters. I just wanted to understand a little about your practise and background and a little bit about the development of medicine during your lengthy time as a consultant. You have told us that you qualified in 1954. Looking at your curriculum vitae it looks as if your particular interest was in endocrinology. Is that fair?
A I had three responsibilities. When I retired I was replaced by three people but it did it all in my time, yes.

Q I am not suggesting that you are not well qualified in the field of paediatrics and neonatology but I was just trying to understand what your working pattern was in about 1989, 1990? What was it that you were actually doing?
A I was the only consultant in neonatology at Guy’s at that time. When I was appointed in 1966 they had no neonatologists, in fact, they had an obstetrician there who refused to allow a paediatrician onto his ward. So it was a first. I looked after the newborn all the way through until I retired and I did a locum because the new neonatologist could not start until about July and I would spend --- I would have formal rounds, I cannot remember exactly but I would say two or three times a week.
Q With your registrars?
A Yes. On the other days there would be hardly a day when I would not go into the neonatal unit.

Q So you have a very clear understanding of the pressures that exist within a neonatal department? It is a busy, pressured environment?
A Very much so.

Q You have to deal constantly with parents who are distressed?
A Yes.

Q And you would expect, would you not, anybody working within a neonatal department, and I include nursing staff, to develop relatively rapidly the skills needed to communicate reasonably well with parents in that situation?
A Yes, they did, I mean, we were lucky because we did not have a big turn over and therefore the nurses were very good indeed in my unit.

Q But the doctors also will soon be discovered, will they not? If they are poor communicators the interaction between parents in particular and the nurses is such that they practically, if their children are very premature, live on the unit and form relatively close relationships with nursing staff and, indeed, other parents?
A Yes, I would say that---

Q Is that fair?
A Yes.

Q I want to suggest to you so that the Panel, because you will understand that many of us in this room are lay people, this is not as impersonal as perhaps a day case orthopaedic ward. You will often have babies there until term that are maybe there for two or three months at a time?
A Yes.

Q Would you accept that during that period of time the nursing staff and the junior staff and, indeed, the consultants tend to form relatively good relationships with the parents who are on the unit?
A We get to know them. We do not necessarily become bosom pals. We get to know them very well.

Q You must have been very visible during your working life?
A Yes.

Q Every parent would get to come to know you were Dr Stimmler?
A You are occasionally having a drink in a pub and someone comes up to you, ‘Oh, 14 years ago you looked after my baby’. ‘How is he now?’ ‘Well, he’s still got his cerebral palsy’ and you cringe a bit but you carry on.

Q But presumably you will also have situations where they will introduce you to a six foot two, strapping 16 or 17 year old?
A A very pleasant experience.

Q Can I just ask you a bit about research because again I want to make sure I am not taking an unfair point. The research documentation publications that I have read again tend to centre around endocrinology as well?
A Yes.

B Q So is it fair to suggest to you that you whilst, of course, you have to have an interest in respiratory disease because it is very common in neonates, have not published anything in the area? Or have you?
A No, I have published. It will be in there somewhere. My work on calcium metabolism phosphate related to renal function was on newborn not premature babies and I did a study with giving sodium to premature babies but that was my only premature baby study.

C Q Would you say that was specific to respiration?
A No, I have not published anything related to respiratory disease.

Q Again, I just wanted to explore this with you briefly, if I may. Was I right in understanding that you have never been involved in a randomised trial of this sort?
A No. You are right, sorry.

D Q Does that mean, again, it is not clear from your CV, have you ever had to make an application for any sort of trial to a hospital ethics committee?
A I have not been in a trial for a number of years, as you realise.

Q Yes.
A Before that I had given up research, the last proper research I did was 1970s. What it consisted of in those days, they had a person in charge of ethics, you phoned them up, told them what you were doing and that was an end of it. Things have change a great deal. So the answer to your question is, no, I have not.

Q I just wanted to ask you this because it is obviously a developing field. Would you agree that it is quite difficult to at this distance in time reconstruct the attitudes to ethical research 16 or 17 years ago?
A I think Ethical Committees have evolved but even though we are not ethicists we all have our own idea as to what is ethical or what is not. We do not make pronouncements. We do not decide as a paediatrician that this is okay, we will do that or not, and I do not think that has changed at all. We now know that you have to go to the Ethical Committee and get all your facts right as to what you are going to do, to say what you are going to do and stick to it.

F Q But do you accept that, as you have said, in the middle 70s – and we will perhaps show you the paper after lunch – a very few paragraphs were published by the Department of Health, which basically said, “Make sure that you have an Ethics Committee consisting of doctors and a layperson”? That was about as much as it said on the topic?
A Yes, I can sort of remember that.
Q In about 1991, so after this trial started – and we have this document in the bundle and I shall take you to it – there was not even a description of an adverse event or any definition of it?
A I am sorry, I missed the question?

Q Even in the early 1990s there was not even a recognised description of an adverse event or the need to report it?
A For this trial?

Q No, in all trials, there was no general guidance in the early 90s to clinicians?
A Yes, I can believe that.

Q What we have seen, looking through the paperwork – and we will develop this with another witness – is that from about 1996, and certainly by 2000 – and we were told this by a witness Mrs Canning; I do not know if you read her evidence – things became a lot more formal in terms of application and feedback from the Ethics Committee, saying “We would like annual reporting or we would like changes to be informed to us”. Do you recall that happening about then?
A No, I cannot.

MR FORDE: All right. Dr Stimmler, that is all I have on the general matters. Sir, I wonder whether that would be a convenient time for us to break for lunch.

THE CHAIRMAN: Yes. We will break until 2 o’clock.

(The Panel adjourned for lunch)

MR FORDE: Good afternoon, Dr Stimmler. Could I ask you to take up for me bundle 1, first of all, please? I want to go just behind tab 1. What we have here on 29 November 1989 is a letter from Dr Spencer to the chairman of the Ethical Committee. He is writing that the MAC Office… Do you know what the initials MAC stand for, or stood for then?
A No.

Q It is Medical Advisory Committee. He is saying that they intend to use their consent form, so there was a standard document, which you will see has been filled in… I am sorry, just let me make sure that I have got that right. Yes, we then have the agenda document, which is page 2 through to page 4, to start with, and you can see that the title of the project is “Randomised Controlled Trial of Continuous Subatmospheric Negative Extrathoracic Pressure in Neonatal Respiratory Failure”. That is at the top of page 2. If you go over the page to page 3, you can see that it was going to depend on sequential analysis and that the thinking was about 50 patients, but we know that the trial involved, I think you have told us, 122 pairs. If you then go to the top of page 4, you can see this, which is what I want to ask you about: “Describe the exact procedures which will be applied to each patient”. Do you have that?
A Well, it says “Procedures” on the top of it, yes.

Q Then it says, “Babies are randomised”, which happened. Do you agree?
A Yes.
Q "The head is exposed and a seal round the neck is made with very soft Latex which does not cause venous occlusion or neck soreness"?
A Yes.

Q So there was an appreciation, I suggest to you, of the fact that that may have occurred elsewhere. Does that seem a reasonable inference to you to draw?
A What may have occurred elsewhere?

Q Neck soreness?
A It did occur, I thought, in Queen Charlotte's.

Q Yes, but it never occurred in Stoke?
A As far as I know, no.

Q Then there is also a suggestion that some near infrared spectroscopy will be done?
A Yes.

Q I just want to ask you this: would you expect the medical members of the Ethics Committee to understand and appreciate that the primary study was in relation to respiration and that it was only once a child was stable from the perspective of respiration that one would begin or might think of starting the near infrared spectroscopy?
A Can I read this paragraph?

Q Yes, of course. (Pause)
A I could not tell.

Q You cannot tell from that?
A Which one was a priority.

Q Do you not get a clue first of all from the title of the trial?
A I accept that. I was aware from the beginning that this was a trial on CNEP, but from that particular paragraph you would not be able to tell.

Q In fairness to you, if you look at the title of the project on page 2 and then look at the procedures, and then perhaps more importantly what accompanied this application was the information sheet on page 5, and if you go over the page you will see that, you think you describe that as an excellent information sheet. I am just suggesting that any medically qualified member of the Ethics Committee – and I think we agreed that back in these days you would have, I think the advice was, four medically qualified and at least one lay – that it would be obvious that the primary study was for CNEP and that no other trial would be attempted until a child was stabilised from a respiratory point of view?
A It is not obvious from that paragraph but that is how it turned out in practice.

Q Yes, but do you think that overall, taking the documents in conjunction, it is obvious that the CNEP trial is the primary trial and that the NIRS trial is an add-on where appropriate?
A Yes.

Q Looking at page 5, one of the other criticisms that is made of these doctors is in
describing in the patient information sheet – and it is the third paragraph, Dr Stimmmer, and you may want to read it to yourself – the technique as having been shown to be safe and effective, and I just wanted to explore your views in relation to that, if I may. Do you recall that this is an issue in the case?

A I think the argument was whether it was safe.

Q I beg your pardon?

A I thought the argument was whether it was safe.

Q Whether it was correct to describe it as safe and effective?

A Well, as far as anybody knew at that time, yes.

Q I am looking at page 4 of your first report and I am just going to read it into the transcript. You said this in the third paragraph from the top: (Document not supplied to shorthand writers)

“It is my view that the leaflets explain the procedure to which the infant was to be subjected. The parental information leaflet was the essential document to be provided to the parents. The booklet would have been helpful but not essential. Continuous negative extrathoracic pressure had been used in infants with severe respiratory disease without any demonstrable side effects. In these infants the method had been shown to be safe and effective.”

You then say:

“There was clearly no way of knowing whether that would be the case with premature infants.”

I want to come back to that, if I may, because later in your report you were to express the view that you thought it was reasonable – and if I cannot find it, it may in fact be in your second report – for those who had experience of CNEP to extrapolate from the older children?

A Yes.

Q I just wanted to explore that with you, if I could, for a moment. Have you read the evidence of Dr Brookfield?

A I have, yes.

Q Again I can take you to it in detail if I need to, but he explained that within Stoke, which was a large, busy unit, I think 6,000 live births per year, they had used CNEP in neonates, perhaps 30/31 weeks?

A That is premature.

Q Yes.

A Yes, I thought they had.

Q That was not just in the context of the trial but they had done so before?

A This was for respiratory disease?
Q: For bronchiolitis, I think. I am sorry, they had used it for broncho-pulmonary dysplasia?
A: Yes.

Q: Therefore, I want to suggest to you that if their experience was that it was safe and effective and had not caused positive harm in 30/31-weekers, it was reasonable to regard it as safe and effective for the purposes of this trial?
A: Yes, I think that is true. What had not been done, as far as I know, was that the small babies were less than a kilogram, and that is all. I think it was a reasonable trial and I think it was reasonable, so far as they knew, to state that it was safe and effective.

Q: I do not think you are aware of any evidence that CNEP was causative of any damage to children prior to this study. It certainly was not the experience of the investigators?
A: No, I am not aware of that point.

Q: I should have read on. You said:

“All the time during research it is essential to extrapolate the effects which have been observed in one group to another.”

You qualify that by saying:

“There might well have been an unknown hazard when CNEP was applied to premature infants. It may have been a good idea to have included in the leaflet a comment that this is a study that was breaking new ground, which may show there are significant advantages in using this technique.”

The information sheet did say that it was a new technique, in the first paragraph?
A: Yes.

Q: So it would be my suggestion that it did indicate to parents that it was a new technique, and you may recall that I think Dr Morgan said that he thought that lots of the parents took away with it new, thinking that it was going to be mandatory rather than understanding that it was randomised?
A: That could well be, yes.

Q: But you went on to say “I am not aware of any research project of this kind that would have included such possibilities” – in other words, an unknown factor that might come to light that was potentially hazardous – “in the leaflet to parents in 1990”?
A: I am sure that is right. I think the first time people were aware of this was in the Northwick Hospital disaster.

Q: What year was that?
A: I cannot remember. It was only two or three years ago.

Q: Two or three years ago?
A: I think so.
Q: The form makes it clear:

“Should you decide that you do not wish your baby to be studied, it is perfectly all right and your baby will receive the usual form of treatment for his or her condition.”

B: That was an appropriate comment to make, was it not?
A: Yes.

Q: Also, you will be aware that the form allowed the parents to withdraw their consent to the study at any time?
A: Yes.

Q: That would be appropriate?
A: Yes.

Q: Can I just then ask you about the evidence that you gave in relation to the neck? You were shown some very graphic photographs, post-mortem photographs?
A: Yes.

D: Would you agree with me that the post-mortem appearance is likely to be far more dramatic than that which appeared in life?
A: I think it would have looked very dramatic in life as well. It would look a bit different. The trouble is with any of these accidents that I was mentioning, the science is that you have got a problem that is remarkably subtle. For example, if a vein has gone into the tissues, all you may see is a bit of pallor, then 24 hours later you have got all the skin and muscles and everything...

E: Exposed?
A: ...being destroyed.

Q: So the initial signs can be fairly insignificant?
A: Yes.

F: But you went on to explain in your evidence that this was not something that you thought in 1990 or 1991 would have been reported as a matter of course to an Ethics Committee?
A: I would have thought not, no.

G: You gave a number of reasons for that. The first was that, in your view, certainly those at Stoke had not experienced it?
A: That is right.

Q: We heard from a Mrs Cannings that even as late as 1994 she did not think that untoward events would be reported to an Ethics Committee unless they happened within the local hospital. In other words, a Queen Charlotte's Hospital problem would not be reported to Stoke’s Ethics Committee?
A: I think that is a more difficult problem. It may not have been. Unless the Ethical
Committee demanded it, I would not have thought that people would have found a problem which they then had solved, that they would report this.

Q I think you were impressed by the fact that it was quite clear from the documentation and leaflets that you have seen, and the Panel have seen them, that a great deal of care was taken in respect of the neck?
A Yes.

Q They had special Latex and they made these roll-neck ---
A Yes, all the various documents who were consenting were aware of it.

Q But, more importantly perhaps, the nursing staff were also aware?
A I should think they are the most important people to be aware.

Q I will come back to surfactant in a moment, if I can, but I think you were also of the view that an amendment to the exclusion criteria to allow a prolonged rupture of membranes was again not something that would necessarily be reported to an Ethics Committee in 1991. That is as I understood your evidence?
A Yes. I mean there are problems with that, as I have mentioned.

Q The problem as it seems to me is not so much around the ethics but whether you feel that you will have your matched pair?
A Yes.

Q You have said something, if I may say so, very important on a number of occasions. You have said that much would depend on the rules of the Ethics Committee?
A I believe so, yes.

Q Do you agree with me that you would expect the Ethics Committee to set a framework for clinicians as to the kinds of things that they want reported and the kinds of changes that they want reported?
A Yes.

Q Was that common in the 1990s?
A I do not know, but I would doubt it.

Q If I suggest to you that certainly the experience of Dr Spencer – and you will recall that the approval, which, if you want to see it, is behind tab 1 in that bundle, page 18 at the top – was a line and a half:

"Dear Dr Spencer,

The study was considered by the Ethical Committee on 10 January and was approved."

A Yes.

Q Nothing about reporting every six months, every nine months, adverse incidents?
A No.
Q Nothing at all?
A Nothing at all.

Q Can I then go back to surfactant? Again it seemed to me – and please, doctor, correct me if I am wrong – that you did not see the addition of surfactant as invalidating the trial or being a reason ---
A It made difficulties from a scientific point of view.

Q I understand that, but you did not see it from an ethical perspective, did you, as something which first of all the Ethics Committee would be concerned about and, secondly, that was duty bound to be considered by the doctors as a change? That is not how I understood your evidence.
A Surfactant had to be given. It had been shown to be a successful way of treating hyaline membrane disease. It would have been very unethical if they did not treat patients that needed it, so it had to be given. The problem lay in the difficulty of the pairing.

Q What Dr Spencer instructs me, and I want to see whether you agree with this, is that if there had been a change to a better incubator, they would have had to have done that. If they had decided to look at fluid balance in a different way, it would ---
A If they changed to a better incubator, they would have been paired automatically. You would not have half in a rotten incubator and half in a good incubator.

Q I understand that, but they are changes that were brought in – and I will explore this with you through the documentation – across the region, which these doctors felt mandated the use of surfactant based on local criteria?
A Yes, I think they had to.

Q I just want to explore that with you for a moment. We can trace this through the documentation. You were taken to page 21 behind tab 1. That is a letter of 23 July 1991. Just to orientate you, if you keep your finger in page 21 and go to page 23, you can see a suggested protocol that was drafted by Dr Palmer, and that is dated 22 July 1991?
A Yes.

Q So back to the 23rd, it is a letter from Dr Spencer to Dr Southall:

“Dear David, thank you for visiting our Department yesterday. We enjoyed having the opportunity to show you round and are now taking the necessary steps to try and secure both temporary and long term permanent accommodation for your Department.

With regard to the introduction of artificial surfactant, we would hope to commence this on 1 August. I enclose a document prepared by Kate Palmer. Under 1 she has listed the criteria that have been issued by the region for the distribution of surfactant to regional and sub-regional units. We had the opportunity to comment and suggested that the mean airway pressures were not relevant but unfortunately this wasn’t fully accepted. However you will see from
Kate’s notes that the peak pressures are going to be rather high.”

Of course, the whole idea of CNEP was to try and reduce peak pressures, was it not?
A Yes.

“On the second page Kate has suggested a protocol for using artificial surfactant on our Unit. She has based the criteria on peak pressures and I would welcome your comments as to whether you feel these are appropriate.”

So that is for the standard treatment. Then it goes on:

“In babies in the trial do you feel it would be in order to give them surfactant prior to randomisation if they meet all the criteria at 2 hours. It is unlikely that any baby would recover sufficiently to avoid randomisation as any baby who is receiving IPPV will be eligible for the trial.”

So the real decision was around pressures. If you go over the page, you can see the first page, 22, which is slightly obscured ---
A Sorry? That says page 44 here. No, no, I have found it.

Q 22 at the top. It is very obscure.
A I have 23. It is the page before that?

E Q It is the page before, yes. You can see the local criteria as set out at section 1?
A Yes.

Q Then people have tried to look how to apply to the CNEP trial and whether the CNEP included the calculation of the mean airway pressure, that stands for?
A Yes.

F Q Then suggested solutions. Then over the page is the protocol that was to be used in standard treatment ...
A Yes.

Q ... with varying birth weights and pressures. This was also for babies in CNEP receiving standard treatment?
A Yes.

Q Next page, 24, a response from Dr Southall:

“Dear Andy”

- this is 29 July, so six days later -

D20/45
“Thank you very much indeed for your suggested protocol for the use of artificial surfactant in infants with RDS. Martin and I both looked carefully at this and feel the suggestions on page 2 of your protocol are fine.”

Then there is a discussion about pressures.

“We would like to suggest that surfactant is not given until infants have been randomised and perhaps, an hour after randomisation - giving time for CNEP to be applied.”

Then there is the hope that CNEP will reduce the peak pressures.

“If the pressure still remain above the threshold then that will be a good time to administer the surfactant. Of course, if the infant deteriorates and the pressures increase despite CNEP, again the baby could be treated with surfactant. We agree with you completely that we should not add in the negative component to the peak pressure when CNEP is in use.”

And then a discussion to take place with the statistician. Careful consideration has been given to this, clearly, by those involved in the investigation. Would you agree?

A Yes.

Q Does it appear that they have attempted in this correspondence to take on board the mandatory use of surfactant across the region in appropriate cases ...

A Yes.

Q ... and look together to see how, if at all, that might affect the study?

A They have looked, yes.

Q Would you agree that you cannot really expect clinicians to do a great deal more than that in these circumstances?

A I was not there and I was not in a position to mention it, but I would have thought that you could add the positive pressure that you might be applying to the negative pressure on the basis that this was not a question - the amount of pressure you used was one of their criterion as to how sick the baby was, so if it was plus five on one and minus ten on the other, it is reasonable to suppose that if it was not for CNEP it would have had 15, for example.

Q But that is an approach?

A Yes. It was not one they chose but certainly a lot was thought about it.

Q Yes, but there are going to be - I suspect if you had 20 paediatricians in a room they might all have a different idea of how this would alter things, if at all. One thing we do know is that from August I think it is 1991, the surfactant was given to all babies who met the regional criteria?

A Correct.
Q So between 1991 and 1993 at least that is what occurred in North Staffordshire?
A Yes.

Q Whilst I understand your concern about matching, do you think this represents a reasonable attempt on the part of the practitioners, from their stand point at least, to take into account the use of surfactant?
A I think they had to do it that way.

Q But it is ---
A The ideal, which would have been to have given both pairs - which I think would have been the most logical from a scientific point of view - was not available to them because it was not allowed, or they would have to find the money from somewhere else. It was a lot of money.

Q Yes. I think that is a very fair answer, but you will appreciate that the reason that these doctors are here is because it is suggested that these are culpable failures and serious criticisms. The charge is serious professional misconduct. Would you agree with me that this perceived deficiency on your part in terms of the matched pairs - others may have a different way of approach and I will leave them to develop it - could not be suggested to be a serious deficiency on the part of these ---
A Not remotely.

Q Not remotely? Thank you. Could I then return to the question of consent? You had some interesting things to say about this in your report. You very careful went through the witness statements of the various doctors at North Staffordshire. You make reference to Dr Newell (now Stanley), whom we have heard from, Dr Palmer, Dr Arya, Dr Wheatley, Dr Barbara Lay(?), whom we have not heard from, Dr Wildig, Dr Morgan, Dr Livera and Dr Brookfield. The conclusion that you reached is at page 9 of your report and you said this:

“In my opinion the information given to parents would be adequate. The question always arises as to whether the parents understood it”

- but you have explained that is always an issue -

“There was the importance of leaving time for them to consider what was being said and to ask questions before signing their consent form”

and you have explained that. I think when you were asked to consider the competence of the staff, you were quite happy that when you read their witness statements that they appeared to be well trained and competent because of the similarities between the statements?
A Yes.

Q Have you read the transcripts of the evidence of those who gave evidence?
A I have.

Q Can you confirm that that confirmed in your mind the fact that these were
conscientious, able practitioners who were doing their best in difficult circumstances to seek fully informed consent?

A    I would agree with that.

Q    Thank you. One of the issues that has arisen in relation to Mrs Henshall in particular is the extent to which she could give valid consent following her Caesarean section in relation to Patient 6. You have opined on this subject in at least two places in your report. I would just like to ask you about that which you said. Dr Stimmler, it is page 17 of your report. You asked yourself this question:

"Would it have been appropriate for a consent form to have been signed by Mrs Henshall following a Caesarean section?

Please consider from Mrs Henshall’s notes the type of anaesthesia pain relief she received and the time of consent is said to have been taken in [Patient 6]'s notes."

Then you say this, with which I do not disagree:

"Consent should only be obtained from individuals who are mentally competent and sufficiently understanding in making a rational judgment. In my experience most mothers at four hours after a Caesarean section would be competent to sign a consent form."

Can I ask you a preliminary question? Is that four hours after even a general anaesthetic rather than a spinal anaesthetic?

A    It does vary and you have to gauge it, whether how far round she is and how deep the anaesthesia was.

Q    But is it your experience that you suggested there when you talk about “most mothers four hours after Caesarean section” you are not distinguishing between a spinal anaesthetic and a general anaesthetic?

A    No.

Q    I wonder whether you would wish to distinguish between the two?

A    Obviously mother is more competent after a spinal anaesthetic.

Q    Is it right to take that sentence as meaning that your experience of mothers who had a Caesarean section under general anaesthetic is that most are competent to sign a consent form four hours after Caesarean?

A    It depends on the anaesthetic. I know an anaesthetist who was so keen to get the Caesarean section finished, he could do it in a few minutes and therefore the anaesthesia would be very light. He would put in a little more and it was sewn up afterwards. Now these mothers were very with it in an hour or two of coming round from that.

Q    What you go on to say on the next page is this, you quote Mr Henshall’s statement:

"He described Deb was drifting in and out of consciousness."
At the bottom of the second full paragraph you say this:

“There were no comments in the notes about Mrs Henshall’s state of consciousness. It could be that she was at that stage just drowsy and was going off to sleep and then waking up again. It is likely that the consent for the CNEP trial had not been requested before Mr Henshall left. Recovery from an anaesthetic is progressive and usually quite rapid. According to Mrs Henshall’s statement there was no mention of her going in and out of consciousness at the time she was approached for consent.”

The doctors who took consent were all asked about this potential problem. I wonder whether you recall, they all felt that they were sufficiently experienced and competent to be able to recognise a mother who clearly could not give consent because her conscious level was affected. Would you expect competent SHOs and registrars to be able to discern whether a mother was understanding instructions and following them?

A It is very rare that anybody does a neonatal job until they have done other previous house jobs of one sort or another. By that time they will have experienced many patients coming out of anaesthesia and would have found when they could first talk to them, so they would know what it is like to talk to a person who has had an anaesthetic. I think these people were competent to decide that.

Q You have experience, as you told us before lunch, of working on a busy neonatal unit I think at one of London’s major teaching hospitals. Would you agree that you, as a matter of necessity, had on occasion to delegate care, clinical care, to your junior staff?

A Very often.

Q That would particularly be the case at night when you were off duty and in the early hours of the morning?

A Yes, I mean at night I was only there if I was called in.

Q Yes, I am sure you were on-call and available?

A Yes.

Q But, conventionally, would you finish early evening, six-ish? Something like that?

A Usually 6.30/7.00.

Q Then you would know that babies would be born later that evening and up until the early hours of the morning?

A Yes.

Q Would you agree with me that unless the junior staff asked for assistance, they are responsible for the clinical care of both mother and baby along with the nursing staff?

A If they are neonatal, they would look after the baby. The obstetric housemen would look after the ---

Q Would look after the mother? I think you can see, given that this was a 43 month
trial and given that babies are born 24 hours a day, why it was that there were up to 34 members of staff involved in the taking of consent?

A Yes.

Q You do not have a problem with that, do you?
A Not at all.

Q I think also in terms of their competence, that which you read suggested to you that they had been adequately trained?
A Yes.

Q I think that you will have read that some of them were prepared to go so far as to say that because they had the parental information leaflet available to them, and because of the dramatic appearance of the CNEP tank - which looks very different to an incubator - they almost had a script to go through with parents. Does that sound feasible to you?
A That sounds likely.

Q In terms of consultant responsibility, if you are secure in the knowledge that you have competent staff, would you agree that it cannot be - not that we think it happened but if it did - a culpable failure on the part of the consultant who may be conducting clinics, or asleep, to fail to ensure that every parent has a copy of the information leaflet? That must be a ---
A It is a complicated question. I agree with you.

Q I will try and break it down. Delegation, you have explained, is a necessity ...
A Yes.

Q ... at certain times?
A It has to be.

Q The staff appear to you to have been competent in the taking of consent?
A Correct.

Q You would not criticise a consultant if it could be demonstrated, if during the consenting process one of his junior doctors whom he believed to be competent had failed to hand out that form?
A That is correct.

Q Thank you. You will be relieved to hear I am not going to ask you about scoring! I just want to check with you a little about Patient 6 and the notes, if I could, which will mean us going into Volume 2. You can put Volume 1 away completely now, doctor.

Sorry, Dr Stimmner, never believe a lawyer when he says he is not going to ask you a question. I have been reminded by Dr Spencer of something, but it does not require you to look at a document. The position as regards the trial was this: Dr Spencer was a local co-ordinator in Stoke and another doctor, Dr Raine, in conjunction with others, had devised, in conjunction with a statistician, a scoring system. Dr Spencer did not get involved in the scoring system, at its inception at least. Do you think it was reasonable of
him to rely upon the competence of those who devised the initial trial alongside the statistician when he came to be a local investigator?
A I would have said that Dr Spencer never scored the babies, therefore, I cannot quite see why he should be involved at all. He was not responsible for the scores that were given.

Q No, he was not, no. Can I then just ask you a bit about Patient 6? You have our better copied page 84.
A Somewhere. I know what was on it though, do not worry.

Q What is suggested to me in terms of monitoring is that whatever you might have been saying about acidity or acidosis, or the pCO$_2$, not only would the medical staff have been comforted by the more reassuring results for the arterial samples, but the base excess was something else which they would have taken into account. Would you agree?
A I think it is enough base excess as an artificial concept as far as I am concerned, you have to measure the bicarbonate for that ---

Q All right. Well, they did that as well I think you will see as well.
A Yes.

Q So we have the bicarbonate as well. Would you regard that as being something which ---
A The bicarbonate was not that much more accurate than the pO$_2$.

Q But what you have said in relation to the saturation levels - and we can go to other records if we need to - is that the pulse oximeter seems to have been recording reassuring saturations?
A There was no question at all in my mind.

Q It is a relatively sophisticated instrument?
A Yes, I was faced with not even considering that these were capillary samples.

Q There is no criticism of you because you did not have, as none of us had until recently ---
A Even if I had, I am not sure that I would have realised what they meant. It was a pity that that got in. I mean, it is a mistake obviously. You should not put down on the records things that were irrelevant. So they should never put those pO$_2$s and possibly not those pCO$_2$s in if they were done by capillary method. I assumed, incorrectly as it turned out, that they were also measuring - either they had an arterial line in, a radial artery or something like that, or they were using transcutaneous monitors.

Q There did come a stage when that was done, as you know.
A Yes.

Q The umbilical arterial catheter suggested by Dr Brookfield would have been giving reassuring measurements …
A Sure.

Q … recorded in relation to true, if we use that phrase, pO$_2$s.
But if those measurements were not there at all I would not have considered that was a bad thing, because I would have been perfectly happy if they had just relied on the oximetry measurement but as they were there and as they looked abnormal to me brought up as a red herring basically.

I understand that. It is not necessarily something which we need to debate at any length, because if you are reassured by the oximeter, but the reason why the pHs were taken as a capillary sample is because the taking of an arterial sample can be rather painful.

If you had to do it intermittently, yes. It depends on the skill of the people you have got around you, but people can get catheters into things like the radial artery, even in tiny babies.

So there is an associated morbidity in unskilled hands.

If you kept on sticking, ever time you stuck it in you are going to get an abnormal result because of the baby’s pain.

The baby actually ironically becomes hypoxic as a response to pain.

It was thought, and I wonder whether you have got any sympathy with this view, by those on duty at the time that it was better to have some kind of marker, albeit capillary, than nothing at all.

I think they should have relied on the pH and nothing else, after all they have got their oxygen level measurements from the oximeter … whatever it is called, the saturation monitor.

I am sorry, when you said they should have relied upon the pH and nothing else, I think you meant they should have relied on the pulse oximeter and nothing else, is that right?

Yes, and the pH.

What should they have done? Just written it down?

I know what happened. You do a blood and you put it into a machine which gives you all these levels and the only one that is really of any worth, in my opinion, is the pH. You could argue a case for the pCO2 but you can certainly never argue a case for the pO2. Therefore, the pO2 levels done in this way should not have got into the records.

I see, all right, but can you understand why those who were on duty at the time might think belt and braces it was a value worth having?

Yes. They may not know what every paediatrician would know, they are not after all consultants, that capillary pO2s are not worth it.

We have been through the notes and the crucial periods are I think 15 and 16 December. The first clinical note that we have, and you were taken to, I think, page 23 of the notes which is Dr Brookfield’s note, that is on the morning of the 15th, then we have got Dr Arya’s note at 12.30 pm, then day three is not my client’s handwriting and it does not appear that he is mentioned either, I think I am right in saying, in the nursing notes or in these notes until page 26 which is day four of life which is 18 December 1992, so that
is page 25, middle of the page, and then if you go over to 26 about two thirds of the way down: “Seen by Dr Spencer”.

A Yes.

Q That is probably a ward round. By this stage the child was out of the CNEP tank in any event, but again it may seem an obvious proposition but if there were, and I do not think you have identified, deficiencies on the part of staff in relation to blood pressure checks, for instance, during this period of time you would not lay those at the door of a clinician who had not seen the child, would you?

A No.

Q Again, from a consultant perspective you are to a great extent in terms of the observations and the noting of observations dependent upon, first of all, your neonatal staff and also your junior staff.

A Yes.

Q Because you will understand and appreciate that Dr Spencer when he was on the ward and not running clinics was being asked to deal with the most urgent, most complicated cases as a consultant.

A Yes.

Q Would this be fair? If we could find the records from when you were last in practice there were probably were periods of time when your nursing staff failed to fill in blood pressures for your patients.

A Yes, of course there would.

Q You would be disappointed.

A Yes.

Q But I do not think you would see that as a culpable failure on your part, would you?

A No.

Q Finally, can I move to the question of scans and the quality of information that has to be given to parents. There are two scans done on 22 and 29 December and we have the reports at least at page 161 and 162, Dr Stimmler. You were explaining about brain bleeds, but this first scan is reported by the radiologist and it may be this one, it may be the one on the next page or it may be both, but Mrs Henshall told us that she thinks she was present during one of the ultrasounds. Can I just ask you this. It has been described, that first appearance, as a mild change of prematurity, would you agree?

A It said mild, yes.

Q It does not say mild on the first one, but I just wonder whether you would agree with the overall description which has been given by others of it being a mild change not inconsistent with prematurity.

A It does not say not consistent with prematurity that I can see.

Q No, not inconsistent. In other words, premature babies sometimes have this post haemorrhagic ventricular dilatation.
Q: Yes, but do you regard that ultrasound appearance as mild?
A: Yes.

Q: If you want some reassurance as to how it was described, if you go to page 193 in March 1993 Dr Doherty, who was the registrar, was describing it as a mild change.
A: Yes.

Q: When we heard Dr Morgan give evidence (he was another registrar) he was also happy to describe it as a mild change.
A: Yes.

Q: By “mild” what is meant by paediatricians is something that is unlikely to be associated with disability.
A: At that time.

Q: At that time.
A: Yes.

Q: The next important issue is the quality of the information that one gives to parents in the presence of that change. Dr Spencer finds it difficult to remember precisely what he said, but could you go to page 212 which is a letter that he wrote in July 1994 and we are really back again to the quality of information that parents retain. He has said this:

“At one stage there was the possibility of a clot attached to the choroid plexus on the left side. These ultrasound changes could be considered virtually normal in a preterm infant and would not, in any event, be associated with an increased risk of handicap”.

Do you agree with that description?
A: Yes.

Q: Can you imagine a situation where if that is said to a parent what they take away and retain many years later is: “We were told the scan was normal”? Is that a circumstance that you could envisage?
A: They would think they had been told it was normal, yes. I thought their complaint was that no one had told them anything.

Q: There is certainly documentation which suggests that their complaint was that they were told it was normal.
A: Ah well, that is a different situation.

Q: The charge is that we did not tell them of an abnormality and Dr Spencer believes, if he spoke to the parents, he may have said something along those lines, “It is virtually normal and it is not associated with an increased risk of handicap”. So it is semantics really as to whether virtually normal is abnormal.
A: The important thing is that he did speak to them about it and in my second report I said I could not find anything in the notes to suggest someone had spoken to them. I did
not say that no one had.

Q No, I quite understand that. It is Mrs Henshall who recalls I think at least one conversation and did so in her evidence and later her complaint was to be to others that she had been told it was normal. Let me see if I can find it. I think it is the Haycock correspondence. Bear with me a moment. (Pause) I am sorry, Dr Stimmler. There is a letter from Dr Haycock to Dr Spencer. (Pause) It is page 210. If you look at about the third sentence:

“Mrs Henshall initiated a lot of discussion about [Patient 6’s] management on the neonatal unit. In particular she was concerned as to why [Patient 6] was ventilated on day 3 rather than day 1 and she was also concerned that although she was present at the time of [Patient 6’s] ultrasound scan of the head she was told this was normal”.

A Yes.

Q “It was then subsequently related to her at an outpatient appointment that the scan had been abnormal”.

So really your concern is that the conversation should take place about the scan.

A Yes and I think it would also have been wise to say, “There is this very slight thing which I think is normal”.

Q But you can understand if that had been said that the parents, when they come to recollect later, might well be of the opinion that they were told it was normal, not virtually normal.

A Yes.

Q Secondly, on 29 December, because we are struggling after this distance in time to recall precise conversation and whether it was the 22nd or the 29th, if that scan were done and a registrar or SHO were aware of the result rather than Dr Spencer, would you think it reasonable for them to have a discussion with the parents about the scan?

A Yes.

Q The reason I ask is because, and I do not know whether this was your practice as you were on your own, it is unlikely that Dr Spencer would have been working on 29 December close to new year and the 22nd close to Christmas, so as long as somebody had the conversation, that would be reasonable.

A Yes.

Q Finally, I wanted to ask you about the necessity for a scan on 7 January which is the day of discharge. Can you just help the Panel, first of all, as to why it is you say a scan prior to discharge, given that there had been two within a week, was mandatory, if that is what you are saying?

A It was in the protocol that they should have a scan before they went out or at 56 days, I have forgotten now.
That is certainly in the scoring protocol, is it not?
A Yes.

I think that is where we see it. Maybe I should just check.
A It was in the scoring protocol.

It was not in the main protocol which I am sure we can all look at if need be, but I just want to check. You were asked I think to look at a couple of patients and I just want to see what it says about ultrasounds. Yes. It is question 8 for any patient, sir.

“All infants had cranial ultrasound examination at regular intervals, at least weekly”

which happened here on the 22\textsuperscript{nd} and the 29\textsuperscript{th}.

“In the case of infants discharged home prior to 56 days of age no further ultrasound studies were performed if the scan prior to discharge was normal. If there was an abnormality on the scan prior to discharge the scan was repeated at 56 days”.

So is this right? Because that is contained in the scoring protocol you say it should have been done.
A Yes.

But I do not think you are saying that had these children not been in a trial or had that not been in the scoring protocol that there was a clinical indication for doing so?
A I think there was.

You think there was?
A There were two mildly abnormal scans and therefore it would well be worthwhile to have done another one, but, as I pointed out, it would not have made any difference because there is nothing you can do about it.

No, I think we agree with you as far as that is concerned. The date of discharge was only seven or eight days after the ----
A It need not have been done that day. They could have left it and asked them to come back in a week’s time to have it done.

You see a clinical indication for doing a subsequent one. Do you think that a reasonable body of medical practitioners would not have done so?
A I do not know. I am always asked that question.

Can I then just ask again about delegation. If you go to page 32 behind tab 5, and a lot was happening around this stage, on 5 January two days before: “Home Thursday hopefully” and the nursing notes indicate understandably that this mother of I think seven ---
A I am sorry, where is that?
Q Bottom of page 31: “Home Thursday hopefully”, was anxious to get home. We then have “eye check please” which we believe is Dr Brookfield. Then on the 7th we have a hearing test. So these are all pre discharge tests.

A Yes.

Q Then on the neonatal discharge can you see the stamp?

A Yes.

Q We have got the date, the age, the gestational age, length, how the child is feeding, vaccinations etc. and eye appointment asap and we have heard from the doctor who took this patient’s discharge who was a doctor who was a registrar and was a doctor who told us that she was competent to consent parents in relation to the CNEP trial.

A Yes.

Q Would you agree with me that if a registrar who evidences those competencies is taking this child’s discharge and the protocol requires an ultrasound on the day of discharge that you would expect a competent registrar to organise that?

A Yes, I would have expected her to do it. People forget and I would not think that is a heinous crime.

Q No, we will be possibly addressing this Panel on the basis that if that were a single deficiency on the part of a doctor in a lengthy career, because we now know she has enjoyed a lengthy career, you would not see that as a heinous failure.

A No.

Q But you certainly would not see it as a culpable failure on the part of the consultant who was not there at the time of discharge.

A No.

MR FORDE: Dr Stimmler, thank you very much indeed.

MISS O’ROURKE: Sir, Mr Forde has just asked me about whether I wanted to ask for a break but my understanding is that the Panel is going to rise at 3.30 today so in which case I am working on the basis that you are not therefore intending to have an afternoon break?

THE CHAIRMAN: I was not intending to have an afternoon break.

MISS O’ROURKE: No, I am happy to continue, sir, but simply to say this, Mr Forde did not ask any questions about the scoring system that is because he has very kindly, if that is the right word, left it to me to deal with that. It is going to be quite a long topic. What I would anticipate doing therefore in the half an hour we have got available is ask my questions about the other topics and it may well be if it is twenty five past three I am not going to start dealing with the scoring systems because I anticipate that dealing with that topic may take me well in access of an hour because we are going to need to look at scoring sheets.

Sir, what I was prosing to do now was to ask my various other questions and questions about surfactant and consenting so far as Mr Forde has not asked them and then stop and
then start with the delightful topic of scoring systems in the morning.

THE CHAIRMAN: That seems very sensible, Miss O'Rourke.

Cross-examined by MISS O’ROURKE

Q Dr Stimmler, as you may know, I ask questions of behalf of Dr Southall and I wanted to start with some general questions about you and your curriculum vitae much in the vein that Mr Forde asked you before lunch. Can I start with this. I have looked at your CV and, as Mr Forde put to you before lunch in respect of it, it would appear that as far as your research interest was concerned the main focus of your research work was effectively endocrinology?
A Yes.

Q You very fairly said to Mr Forde that you had not published anything in relation to respiratory disease?
A Not respiratory disease.

Q I am taking it from what you said in answer to questions both to Mr Forde and to Ms Sullivan that you have not yourself got any familiarity with the CNEP technique. Is that fair?
A I have seen it used once.

Q But you have not yourself used it or done any studies in respect of it?
A No.

Q Presumably for the purposes of this hearing and for writing an expert report you have read a number of papers about it?
A Sorry, I missed the question because somebody coughed.

Q I will try and take it slowly. Presumably for the purpose of this hearing and for preparing an expert’s report you have read some papers about it?
A About CNEP?

Q Yes.
A Yes, I have.

Q Can you tell us what? In other words did you read the paper published by these doctors and others?
A The one that interested me the most was the one where they were treating severe respiratory disease in babies with CNEP.

Q I understand that but I want to take in sequence what you have actually read and what material you have had in order to give the evidence that you are giving. You are a very experienced expert witness, I think you say in your CV that you have written in your career something in excess of one thousand expert reports?
A I have no idea really but that was an estimate, yes.

Q That is what you said in your CV?

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Asure, yes.

QYou said in your CV that you had given evidence in various types of medico-legal cases in excess of 100 times?

AYes.

QSo you are an experienced expert witness and you would understand the importance when giving expert evidence on a particular topic to have read around the subject?

AYes.

QIt is not that I am questioning your expertise, and please do not think that I am in terms of being a consultant paediatrician because we have seen your CV and we know the numbers of years you have worked as a consultant paediatrician, but this particular case, as you know, is about two things: it is about the design and the conducting of a clinical trial. Yes?

AYes.

QIt is about CNEP itself?

AYes.

QIn terms of the design and conducting of a clinical trial I think you very fairly said both in answer to questions from Ms Sullivan and when cross-examined by Mr Forde that you yourself had not been involved in any research trials after the 1970s?

AYes, that is correct.

QThat you had never been involved in a randomised clinical trial such as this?

AThat is correct.

QSo you would therefore accept that in looking, as the Panel have to do, for expert assistance on the conduct of a randomised clinical trial at the back end of the 1980s and early 1990s you were perhaps not the best person to be helping them with all aspects of their inquiry. Would you agree?

AIt depends which way you look at it. Whether you want somebody who has done lots of randomised trials or whether you want to get somebody in who has an overview of the paediatrics involved. I would fit the latter but not the former.

QDoes it not then depend on what the specific criticism as contained in the heads of charge are? Would it not depend on that? Let me make it specific. As you know I represent Dr Southall?

AYes.

QDr Southall does not face any heads of charge - you have got the yellow sheet in front of you, he is letter B - in respect of clinical care of any patient?

ARight.

QBecausethe I think you are aware he never treated Patient 6 or Patient 7?

AYes.

QOr, indeed, any other patient at Stoke. Yes?
A  
Q  Yes.
A  
Q  So therefore the heads of charge that he faces relate to getting Ethics Committee approval?  
A  Yes.

B  
Q  There are a number of those charges, it is heads of charge 3, 6, 7, 8, 9 as far as he is concerned.  Yes?
A  Yes.

C  
Q  You very fairly, I think, said back in the 70s when you were doing your research there was not really such a thing as an Ethics Committee.  There may be some guy responsible in the hospital.  You gave them a call and that was it?
A  There was a sort of Committee, yes, one person in charge.  It was very straightforward.  I can remember the time when there were not any Ethical Committees at all.

Q  I think what you said in answer to a question from Mr Forde, if not from Ms Sullivan was that it was not a question of you putting in written applications.  It was that you phoned up somebody who had responsibility, explained what you were going to do and that was the end of it?
A  Yes, that is right.

Q  Some, therefore, if this Panel here has to decide in 1990 and 1991 what sort of things would be reported back to an Ethics Committee you are not able to talk about those things from your own knowledge?
A  Not from my own experience but from my knowledge in so far as I read the journals and so on.

E  
Q  Dr Stimmeler, indeed, but we can all read the journals and construct our knowledge.  What we ask for by way of an expert to assist a Panel that may be lay is somebody who has been there, seen it and done it?
A  Yes.

Q  You were not there, seeing it and doing it at the back of end of the 1980s or early 1990s as far as running trials and reporting back to the Ethics Committees, you were not doing it?
A  That is correct.

Q  I am not decrying your expertise or your amazing CV in terms of work as a paediatrician but in the context of these particular heads of charge that Dr Southall faces if you are going to be fair you would say I am not really the right expert to comment on whether he should or should not have gone back in the 1990s?
A  Sorry, which ones are you talking about?

Q  Heads of charge 3, 6, 7, 8, 9?
A  What I was asked --- 3...

H  
Q  How you described procedures in a written paper?  I think you are looking
possibly at the right wrong page. Dr Southall comes as the second part of that notice of inquiry.

A  I am getting confused.

Q  The first one is Dr Spencer. You will find it numbered 7 at the bottom.

A  On May 15?

Q  Let me put it simply. I am not trying to catch you out, Dr Stimmler. We can probably deal with this quite shortly. What I am suggesting to you is there may well be people who were dealing with Ethics Committees in the late 1980s and early 1990s who were preparing applications and reporting back who would be much better placed than you to assist this Panel as to how it worked in practice?

A  As far as that is concerned.

Q  As opposed to what one might read in a journal?

A  Yes.

Q  Then when we come to, for example, head of charge 12 in respect of Dr Southall - I will deal with this in some detail tomorrow - it relates to a scoring system?

A  Yes.

Q  Again, you have told us that you were not involved in randomised trials at any stage in your career?

A  That is right.

Q  You presumably, therefore, have never devised a scoring system for a trial where you are comparing a control group with a group that is getting specific treatment?

A  That is true.

Q  So you have no experience of sitting down either with other clinical colleagues or with the medical statistician and trying to work out how to devise a standard scoring system?

A  That is true.

Q  It must therefore be very difficult for you when you have never done that to assist this Panel in respect of how it would have been done at the beginning of the 1990s in terms of devising a scoring system that would cover everybody in the trial?

A  Very difficult to do?

A  I would say that is true, yes.

Q  I think that I have seen an attendance note where you were asked by Miss Morris of Eversheds about statistics because you at that stage were recommending that it might be good to approach a medical statistician for advice. Yes?

A  I certainly would not like you to ask me questions on statistics.

Q  I think that is right and you said that to her as well, that you may have done a small amount of statistics as part of some---

A  We all do a bit.

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A  Q ---background in mathematics at some stage but beyond that you had no expertise?
   A We use statistics in all research we use but it is a different sort of statistics.

Q Indeed. You would defer, as Ms Sullivan asked you, to a medical statistician in terms of the expertise that such an individual would have in doing weighting of scores and achieving outcomes?
   A Yes.

B  Q In terms of CNEP, obviously the issues as far as the scoring system will be concerned will depend upon the treatment that you are trying out. Yes?
    A Yes.

Q I think you very fairly said you saw somebody use CNEP on one occasion?
    A Yes.

C  Q Where was that and when was that?
     A That was a child really in extremis from respiratory disease.

Q When was that? 20, 30 years ago? Longer?
    A Professor Southall was involved. Came along with a machine and it was a last chance thing and it did not work. You could not use that as an example at all because we only used it because there was no way we could keep this child oxygenated. This was the time, of course, nowadays you would put on one of these extracorporeal ECMO things.

D  Q The reason I put it to you and, again, it is not to put you down in any way but it is to say that it make it difficult for you to give expert assistance to this Panel when you yourself have not worked with CNEP and have not personally been involved in any work around the use of CNEP. You have seen it on one occasion but you have not personally worked it, taught it, trained your juniors to use it and advised them on the giving of consent. You have done none of that?
     A The questions I answered were ones which I thought I was competent in.

E  Q I am not suggesting you were not in terms of some of the answers - we will come that in a moment. Please understand, Dr Stimmler, this is not a criticism of you. If it is a criticism of anyone it is of the General Medical Council in terms of why they have asked you to give expert evidence as supposed to somebody out there who has been involved in research work of this sort in the 1990s or somebody out there who has been more specifically dealing with CNEP?
     A And who is retired and has the time to spend on it.

F  Q That may well be but, Dr Stimmler, you would presumably agree with me where three consultants are on trial for their medical registration it is important that the Panel which is, you may not know, 80% of the Panel are lay members. It is important that if they have medical expertise and assistance that they get the best assistance available and I am not saying that you are not but I am saying with all due deference this is not your specialist field, CNEP, nor, in fact, is design and conduct of a randomised trial?
     A I was not, as far as I can remember, I was not actually asked those questions.

G  Q Indeed but if you look at the notice of inquiry perhaps you ought to have been.
Would you agree?
A    That is up to my solicitors who asked me.

Q    Indeed.
A    I was set a series of questions which I answered for which you have seen the
    answers.

Q    Indeed I understand that. We will come on to them tomorrow. It is why I asked
    you at the outset of my questioning what material you read given that you have got no
    personal familiarity with CNEP or, indeed, designing scoring systems or conducting
    randomised trials. I am wondering, therefore, given that is what this case is about what
    preparation you did and what work you have read?
A    I was presented with the papers, a few papers that had be written on CNEP which
    I read and to me they looked as if this was a very promising approach to the management
    of respiratory disease in premature babies. It had not been done in premature babies so it
    was a new venture.

Q    Can I just try you out as to, you say, a few papers. That is papers that you were
    given, was it, by Miss Morris at Eversheds or by Eversheds Solicitors?
A    I think those were the actual papers I think used by Professor Southall himself in
    talking to the parents.

Q    Did you go off and do any research of your own? In other words, did you go
    search the *Lancet* or the *BMJ* and read around CNEP or look at the journal called
    *Paediatrics*?
A    No.

Q    Or any of the American literature? No?
A    No.

Q    So, therefore, what you relied upon was the material provided to you with your
    instructions?
A    Yes.

Q    I have got a copy, I think, of what are said to be a summary of the instructions you
    were given. Can I ask you to look at it and if you can confirm that is the document and
    that therefore lists the enclosures that you had available to you? (*Same handed*)
    (The witness read) Does that look familiar?
A    I have seen it. I am reminding myself. This is what I based my report on.

Q    So that is the material that you had. It was articles that were sent to you by
    Miss Morris at Eversheds but you did not go beyond that and look yourself?
A    That is right.

Q    Could I ask you about this, were you aware that there was a follow up done in
    respect of these particular CNEP patients by Professor Neil Marlow and his team at
    Queen’s?
A    This was about the developmental assessment?
Q: Yes.
A: Yes, I did see that.

Q: That is the *Lancet* article in 2006?
A: Yes.

Q: So you saw that in addition, and you presumably saw from that list some of the papers co-authored by Dr Samuels and Dr Southall at the beginning of the 1990s on their earlier CNEP studies?
A: Yes, I did.

Q: I want to turn now to ask you about some of the individual topics that you have dealt with. The first one that I want to ask you about – I think we may fit it in before we have to rise – is the question of neck trauma. In respect of that, I think you said that as far as you were concerned you would not have seen that as the sort of problem that would have needed to be referred back to the Ethics Committee?
A: Yes, that is right.

Q: You will be happy to hear that we agree with you. I just want to put a couple of things to you in respect of that, and in particular in respect of that patient because I am not sure if you fully appreciated this. It is an example of the concern that was caused by that and indeed was followed through in what we say would be a good study. Were you aware that in fact there was a meeting to discuss the outcome so far as that child is concerned, which took place at Queen Charlotte's Hospital – a perinatal mortality meeting?
A: I cannot offhand remember that.

Q: This again is not your fault, Dr Stimmler, but a witness is coming tomorrow, Dr Raine, and I think you have had a copy of his thesis as far as the material ---
A: Some of it, yes.

Q: Some of it?
A: Yes.

Q: I think you also saw his witness statement, or you should have?
A: Yes.

Q: He is coming to give evidence unusually after you simply because of availability, but he is likely to give evidence that there was a perinatal mortality meeting held at Queen Charlotte's Hospital in respect of this particular child of which I think you have seen a photograph – yes?
A: Yes.

Q: Present at that meeting were the pathologist as well as Professors Harvey and Modi from Queen Charlotte's Hospital, and also the consultant neonatologist who was responsible for the care of that child – yes?
A: Well, I take your word for it.

Q: Dr Southall also attended, because it was ---
A I do not think I have seen this meeting, no, but I will take your word for it that they were all there, yes.

Q The difficulty unfortunately, Dr Stimmler, is with the order in which the General Medical Council have had to call their witnesses, so what I want to do is put to you what will be said by Dr Raine, or what I anticipate will be said, so that you have an opportunity to comment on whether it sounds to you as though they were approaching this in the right way and looking at the matter properly, and what I am going to suggest to you happened is that when they had this presentation at the perinatal mortality meeting the conclusion was that this particular baby had died of the complications of his extremely premature birth?
A Yes.

Q Because I think he was born at 25 weeks’ gestation?
A Yes.

Q You will confirm that that is very, very premature?
A It is.

Q Also, that the neck injury was felt by those involved to be secondary to neck oedema and poor skin perfusion, which was secondary to hypotension, hypoxia and hypothermia. In other words, it was not neck trauma as such but because the baby had all these other complications, because the baby in fact had poor skin perfusion?
A Yes, that may well be the case, but the same argument would apply to an area of skin anywhere on the body. The fact that it occurred round the neck suggests that it was the neck seal was the trigger, if you like, or the last straw that broke the camel’s back.

Q I think we would accept the last straw. If you have poorly perfused skin, the baby is going to develop generalised oedema because he has a very poor blood supply because of all his other problems, and then if you have anything touching on that very fragile skin, you are going to be at risk in that area because of the poor blood supply, that you will get generalised oedema and marking of the type that was seen, does not mean, if anyone was going to suggest it, that this baby was strangled by the neck seal or that he died because of the neck trauma, but this is a baby who died because he had serious hypotension, hypoxia, hypothermia and multi-organ failure?
A Yes, I agree with that. If the skin was the only abnormality, it would not have killed the baby.

Q Absolutely. Thank you very much. I am very grateful for that. But what then happened – and I think you have acknowledged this – was that because this was, I am going to suggest to you, a good study and a good trial, they took it seriously and they put two main measures into place: first, the development of this silicone gel seal, which you talked about?
A Yes.

Q Secondly, that they introduced regular checks by the nursing staff of the neck seal to be done at least on a six-hourly basis and more frequently if it was thought appropriate?
A Yes.
Q That was a very good thing to do, but also indicated that this was a well controlled and well run study – in other words, they were watching out for things and they were addressing them as they went along?
A I agree.

Q Indeed one sees that Dr Raine wrote about this in his thesis and indeed exhibited a photograph?
A That is correct.
Q I think you have seen that?
A Yes.
Q Therefore, they were being open and transparent with the clinical staff about what was going on during the trial?
A Yes.
Q That is evidenced by Dr Southall going to this perinatal mortality meeting and by the fact, as I think you have seen from the transcripts, that most of the doctors who gave evidence last week said that they were aware of the neck problem at Queen Charlotte’s?
A That is right.
Q Indeed, I think the *Paediatrics* paper, the paper that is published by these three authors, also makes reference to the neck problem?
A Yes, it does.
Q So this was not a question of them keeping anything hidden. This was a question of them looking and learning and, as you have conceded, the problem never recurred?
A That is right.
Q For that reason, together with others, you would say that there was no need to report it to the Ethics Committee because it was something that they addressed and dealt with?
A I would have said that, yes; I did say that.

MISS O'ROURKE: Sir, I was about to turn to the question of surfactant. I do not know whether you want me to do so now that it is twenty five-past-three.

THE CHAIRMAN: Can you deal with it in five minutes and no more?

MISS O'ROURKE: I think I can probably deal with it in five minutes. I will have a go.

Q You made reference to surfactant and Mr Forde has already asked you some questions about it. You understood, and indeed I suspect that it was the same in your region, that when this was introduced it was introduced in the region, there was a regional policy in respect of it in the West Midlands region?
A There was certainly a policy. I am not sure at what level it came.

Q I think that in the West Midlands and so far as North Staffs is concerned…
A It was dictated to us.
Q ...it was regional?
A Yes.

Q Now what that would mean is this: it would mean that if you met the criteria for its use, it would not be optional but it would be mandatory?
A Absolutely.

Q Therefore, so far as those in the trial were concerned, if they met the criteria, they would have to have it?
A That is correct.

Q The implication of that would be that to deny it to them would be unethical?
A Yes.

Q But, more than that, they were being promised as part of the trial that they were going to have the best treatment? I think you have seen it in the information leaflet. In other words, the trial should not change the way in which they are treated?
A If they did not have the CNEP.

Q Yes.
A Yes, that is right.

Q Even if they did, whether they had CNEP or they were control, they had to have the best in terms of every other aspect of treatment?
A Yes.

Q So once surfactant is introduced, that would have to be surfactant?
A Yes, it would have to be given.

Q Because it is not just the mandatory policy in the region but it would be seen to be of benefit and therefore the children should have it?
A Yes, I agree that it had to be given.

Q Therefore, in terms of the question whether you would go back to the Ethics Committee about it, there would be frankly no point, for this reason: if you had to have it because it was ethical and it was a regional policy, then the Ethics Committee could not say, “No, do not give it”?
A No, they could not.

Q They would have had no right. All the Ethics Committee could have done was say, “Stop the trial”?
A That is correct, which they could not.

Q There would be no basis for stopping a trial for something that was going to apply to children if they met the criteria on either arm of the trial?
A I think the only thing they might have done was to have discussed it with the powers that be, that in a trial like this they should really have given it to both of a pair, which would have meant giving more surfactant than the authority wanted to spend their money on, but I am just suggesting this now.
Q I understand that you are suggesting it, Dr Stimmler, but let me suggest this to you: that what they needed to do was think about it, once surfactant was introduced, that they needed to discuss it among themselves and look at how it would be used, bearing in mind that it was now a mandatory treatment if you met the criteria, and bearing in mind that it was the best treatment and therefore they were going to have to give it, and what they would have been obliged to do was sit down and discuss how to do it within the trial confines?
A Yes.
Q That is what they did?
A That is true.

Q I think you saw that that is what they did by looking at file 1, pages 21, 22 and 23?
A That is right.

Q I do not think you need to turn it up again, but they clearly thought about it, they exchanged letters, they developed a protocol and they gave some time and attention to it?
A Yes.

Q That is an indication again, I am going to suggest to you, that this was a well conducted and well run trial?
A Yes.

Q By good clinicians, giving serious thought to issues as they arose?
A I agree with you.

MISS O'ROURKE: Thank you. Sir, I think I have dealt with it in five minutes.

THE CHAIRMAN: You have. Thank you very much. Dr Stimmler, we are going to break for the day now, so we will look forward to seeing you back here tomorrow morning, please. I have no reason to think that you will but I must ask you not to discuss the case with anyone overnight.

THE WITNESS: I have no one to discuss it with!

THE CHAIRMAN: Very well. Thank you very much, everyone. We will break now and meet again at 9.30 tomorrow morning.

(The Panel adjourned until 9.30 a.m. on Tuesday, 10 June 2008)