

Professor Southall did not appeal against the Committee's decision, therefore the Condition took effect on 7 September 2004 for a period of 3 years. CHRE appealed the decision and on 3-4 March 2005 in the High Court Judgement handed down on 14 April 2005 by Mr Justice Collins the appeal was allowed to a limited extent. Collins J ruled that the PCC's decision to impose conditions on Southall's registration was not unduly lenient. However, the PCC was unduly lenient in failing to direct that a resumed hearing would take place at the end of 3 years. In addition, the conditions imposed were not tightly enough drawn to prevent any involvement by Professor Southall in child protection work, and were therefore unduly lenient. An Order has been agreed between the parties which will be substituted for the PCC's original decision. The principle terms are that: The PCC's condition is still in force from 7/9/04 for 3 years. In addition, Professor Southall must report any concerns on child protection issues (whether arising from NHS or non NHS, medical or non medical work) to a child protection doctor working for his employer/ the Trust immediately not take any further steps or have any involvement whatsoever in relation to such concerns or initiate any communications with, or seek to influence in any way that child protection doctor/other person/body in relation to such concerns. Provide details of any cases where he has reported his concerns to the GMC every 6 months. Notify any employer of the existence of the conditions. There will be a resumed hearing at the end of the 3 year period.

Date of Professional Conduct Committee Hearing: 7-15 June + 5-6 August 2004

Name of respondent doctor: David Patrick SOUTHALL

Registered qualifications: MB BS 1971 Lond

Registered address: Staffordshire

Registration number: 1491739

Panel: Prof D McDevitt - Chairman

Ms F Bremner

Mr S Gurjar

Ms C Langridge

Rev J Philpott

Legal Assessor: Mr David Mason

Committee Secretary: Mrs Zaheda Khan

Type of Case: New Conduct

Representation:

GMC:

Mr Richard Tyson (Counsel), instructed by Field Fisher Waterhouse Solicitors, represents the GMC and Mr A.

Doctor:

Professor Southall was present and was represented by Mr Kierran Coonan QC, instructed by Hempsons Solicitors.

Charge:

"That, being registered under the Medical Act,

'1. In November 1999 Ms A was convicted of the murder of two of her children, Master B and Master C; Admitted and Found Proved

'2. On about 27 April 2000 you watched the "n0÷Àó "programme about Ms A's case that was broadcast on Channel 4 television that night; Admitted and Found Proved

'3. As a result of information gleaned during your watching of the programme, on the next day you contacted the Child Protection Unit of the Staffordshire Police to voice your concerns about how the abuse to Master B and Master C had in fact occurred;

Admitted and Found Proved

'4. As a result of such contact, on 2 June 2000 you met Detective Inspector G of the Cheshire Constabulary, the senior investigating officer into the deaths of Master B and Master C, and in effect told him that, as a result of watching the programme, you considered that

a. Mr A, Ms A's husband, had deliberately suffocated his son Master B at a hotel prior to his eventual death, Admitted and Found Proved

b. Mr A was thus implicated in the deaths of both Master B and Master C, Admitted and Found Proved

c. there was thus concern over Mr A's access to, and the safety of, family A's third child, Child A; Admitted and Found Proved

'5. At the time of meeting Detective Inspector G, you

a. were not connected with the case,

Admitted and Found Proved

b. made it clear that you were acting in your capacity as a consultant paediatrician with considerable experience of life threatening child abuse, Admitted and Found Proved

c. were suspended from your duties by your employers, the North Staffordshire Hospital NHS Trust ("pTrust"),

Admitted and Found Proved

d. knew that it was an agreed term of the Trust's enquiries that led to such suspension that you would not undertake new outside child protection work without prior permission of the Acting Medical Director of the Trust, Admitted and Found Proved

e. had not sought permission of the Acting Medical Director prior to contacting the Child Protection Unit of the Staffordshire Police and /or meeting with Detective Inspector G,

Admitted and Found Proved

f. relied on the contents of the "television programme as the principal factual source for your concerns,

Admitted and Found Proved

g. had a theory about the case, as set out in Head 4 above, that you presented as fact as underpinned by your own research;

Found Proved

'6. Your actions as described in Heads 3 and/or 4 and/or 5 were

~ precipitate, Found Proved in relation to Heads 3 and 5

Found Not Proved in relation to Head 4

~ irresponsible, Found Proved in relation to Head 5

Found Not Proved in relation to Heads 3 and 4

~ an abuse of your professional position; Found Not Proved in relation to Heads 3, 4 and 5

'7. On 30 August 2000 you produced a report on the A family at the request of Solicitors Admitted and Found Proved

~ At the time that you produced your report you

i. did not have any access to the case papers, including any medical records, laboratory investigations, post-mortem records, medical reports or x-rays,

Admitted and Found Proved

ii. had not interviewed either Mr A or Ms A,

Admitted and Found Proved

~ Your report concluded that

i. it was extremely likely if not certain that Mr A had suffocated Master B in the hotel room,

Admitted and Found Proved

ii. you remained convinced the third child of the A family, Child A, was unsafe in the hands of Mr A,

Admitted and Found Proved

~ Your report implied that Mr A was responsible for the deaths of his two eldest children Master B and Master C ,

Admitted and Found Proved

~ Your report was thus based on a theory that you had about the case that you presented as fact as underpinned by your own research, Found Proved

~ Your report declared that its contents were true and may be used in a court of law whereas it contained matters the truth of which you could not have known or did not know, Found Proved

~ Your report contained no caveat to the effect that its conclusions were based upon very limited information about the case held by you, Admitted and Found Proved

~ When given the opportunity to place such a caveat in your report you declined, by faxed email dated 11 September 2000, on the basis that even without all the evidence being made available to you it was likely beyond reasonable doubt that Mr A was responsible for the deaths of his two other children;

Admitted and Found Proved

'8. Your actions as described in Head 7 above were individually and/or collectively

~ inappropriate, Found Proved

~ irresponsible, Found Proved

~ misleading and, Found Proved

~ an abuse of your professional position. Found Proved

"óthat in relation to the facts alleged you have been guilty of serious professional misconduct. "Guilty of Serious Professional Misconduct

Determination:

"b óxSouthall:

In November 1999 Ms A was convicted of the murder of her two children, Master B and Master C. On or about 27 April 2000 you watched the "ñ0÷Àó" programme about Ms A's case that was broadcast on Channel 4 television that night. As a result of information gleaned during your watching of the programme, on the next day you contacted the Child Protection Unit of the Staffordshire Police to voice concerns about how the abuse to Master B and Master C had in fact occurred. Following this contact, on 2 June 2000 you met Detective Inspector G of the Cheshire Constabulary, the senior investigating officer into the deaths of Master B and Master C, and in effect told him that, as a result of watching the programme, you considered that Mr A, Ms A's husband, had deliberately suffocated his son Master B at a hotel prior to his eventual death. Mr A was thus implicated in the deaths of both Master B and

Master C. Based on this opinion, you raised concern about Mr A's access to, and the safety of, their third child, Child A.

At time of meeting Detective Inspector G, you were not connected with the case. You made it clear that you were acting in your capacity as a consultant paediatrician with considerable experience of life threatening child abuse and that you were suspended from your duties by your employers, the North Staffordshire Hospital NHS Trust ("pTrust"). You knew that it was an agreed term of the Trust's enquiries that led to your suspension that you would not undertake any new outside child protection work without the prior permission of the Acting Medical Director of the Trust. Despite this, you had not sought permission of the Acting Medical Director prior to contacting the Child Protection Unit of the Staffordshire Police and meeting with Detective Inspector Gardner. You relied on the contents of the "n0÷Àó" television programme as the principal factual source for your concerns. You had a theory about the case that you presented as fact as underpinned by your own research. The Committee found your actions in contacting the child protection unit of the Staffordshire Police to be precipitate and by not seeking the permission of the Acting Medical Director of the Trust before meeting D I Gardner to be precipitate and irresponsible.

On 30 August 2000 you produced a report on the Clark family at the request of Solicitors. At the time that you produced your report you did not have any access to the case papers, including any medical records, laboratory investigations, post-mortem records, medical reports or x-rays. You had not interviewed either Mr A or Ms A. Your report concluded that it was extremely likely if not certain that Mr A had suffocated Master B in the hotel room. You remained convinced that the third child of the family, Child A, was unsafe in the hands of Mr A. Your report implied that Mr A was responsible for the deaths of his two eldest children Master B and Master C. This was based on a theory that you had about the case that you presented as fact, as underpinned by your own research. Your report declared that its contents were true and may be used in a court of law whereas it contained matters the truth of which you could not have known or did not know. Your report contained no caveat to the effect that its conclusions were based upon the very limited information about the case known to you.

When given the opportunity to place such a caveat in your report you declined, by faxed email dated 11 September 2000, stating that even without all the evidence being made available to you it was likely beyond reasonable doubt that Mr A was responsible for the deaths of his two other children. The Committee have found your actions as described above to be individually and collectively inappropriate, irresponsible, misleading and an abuse of your professional position.

The Committee are extremely concerned by the facts of this case. The Committee have heard that a formal complaint was made against you in January 1999. The Trust placed a limitation on your work preventing you from undertaking any category 2 work (work that is commissioned by an external agency) pending the outcome of their investigations. You agreed to the Trust's request. Due to the seriousness of their concerns in November 1999 the Trust suspended you for the duration of their inquiry and you were therefore prevented from undertaking any child protection work.

The Committee have heard that you had been following Ms A's case with interest as a proportion of your clinical and research work involved the sudden and unexpected deaths of infants and on 27 April 2000 you watched the Channel 4 Dispatches programme which featured an interview with Mr A. As a result of viewing the programme, you formed the definite view that Mr A had murdered both Master B and Master C and that accordingly not only had the wrong person been convicted but that the life of the remaining child (child A) was in danger by virtue of the fact that he was being cared for by Mr A. You were so convinced of your opinion that you contacted the local child protection team, and subsequently met with Detective Inspector G, the police officer in charge of the case. The matter was reported to Social Services and subsequently there was a meeting between yourself, Social Services and the Guardian of child A. This in turn led to Social Services convening a Child Protection Planning meeting. The result of this meeting was that you were asked to produce a report and the matter was investigated further. You did produce such a report, dated 30 August 2000, in which you concluded that Mr A was responsible for the deaths of both Master B and Master C and that their third child was unsafe in his care.

The Committee are extremely concerned that you came to this view without ever meeting or interviewing Mr or Mrs A, without seeing any of the medical reports, post mortem reports and without knowledge of the discussions between the experts or witnesses involved with Ms A's case. You did not put yourself in a position to give a meaningful explanation. Your view was a theory, which was however not presented as a theory but as a near certainty. Your hypothesis, based on your research, was that the nosebleed that Master B suffered in the hotel room whilst alone with Mr A was a result of an assault. Your view is that a bilateral nose bleed in an infant in the absence an identifiable disease or accident, was virtually always the consequence of life threatening child abuse, usually an attempted smothering. We heard from Professor D, the GMC expert witness that in order to come to such a firm view, one must explore all the potential causal explanations for the nose bleed and detail this process in the findings. In your evidence you stated you did not do this, as it was known to all the recipients of the report that you did not have access to any other documentation. However you have accepted that it would have been good practice to have detailed the diagnostic process in your report.

The Committee have been directed to the guidance entitled 'Expert Witnesses in Children Act Cases' produced by Mr Justice Wall, which you have acknowledged as good guidance. However, it appears that you did not follow this guidance in the circumstances of this case. Paragraph 5.4 states that 'You should be very cautious when advising a judge that in your opinion a particular event occurred. You should do this only if you feel you have all the relevant information.' You accepted the fact that you should have made it clear in your report that you did not have access to any documents and that the views expressed were based solely on watching the Dispatches programme. The guidance further states at paragraph 10.5 'What the court is anxious to prevent is any unrecorded informal discussions between particular experts which are either influential in, or determinative of, their views and to which the parties to the proceedings do not have access.' You further conceded the fact that you should have disclosed the involvement of

Professor E and Professor F who you stated helped confirm your theory on the case. Your reason for this omission was out of concern for them as they had given evidence at the trial of Ms A.

As a potential Expert Witness, you had a duty to list in your report the limitations of either the method you used to come to your conclusion or the results. The Committee were concerned by the fact that when given the opportunity to add a caveat to your report to state that your views were based solely on your viewing of the TV programme and not on any other evidence, you refused to do so. In fact your opinion was put in more concrete terms by using the words 'beyond all reasonable doubt'.

The Committee accept that as a Consultant Paediatrician you had a duty to report any concerns that you may have regarding child safety with other professionals, but as you were prevented from undertaking any new child protection work due to the suspension imposed on you, you should have contacted Dr G, Medical Director as the terms of your suspension required, prior to taking any action.

The Committee also accept that the nature of child protection is such that sometimes concerns are raised which prove to be unfounded. However, despite this, there is a duty of care to raise such concerns in order to ensure the protection of children.

Taking into account the facts found proved against you including inappropriate and irresponsible behaviour and an abuse of your professional position, the Committee consider your conduct amounts to a serious departure from the standards expected from a registered medical practitioner. The GMC's guidance Good Medical Practice (July 1998) states that 'Good clinical care must include an adequate assessment of the patient's condition, based on the history, and clinical signs and if necessary an appropriate examination'. In providing care you must 'recognise and work within the limits of your professional competence', 'be competent when making diagnoses and when giving or arranging treatment.' You did not adhere to this guidance when you involved yourself in this case. You must also 'respond constructively to assessments and appraisals of your professional competence and performance'. GMP further states under the heading 'If things go wrong' that 'If a patient under your care has suffered serious harm, you should act immediately to put things right. When appropriate you should offer an apology'. GMP further states that 'Registered medical practitioners have the authority to sign a variety of documents, on the assumption that they will only sign statements they believe to be true. This means that you must take reasonable steps to verify any statement before you sign a document'. The Committee do not believe that you did take reasonable steps before you signed the report on the Mr A's case. Your failure to adhere to these principles resulted in substantial stress to Mr A and his family at a time when they were most vulnerable and could have resulted in Child A being taken back into care unnecessarily and Mr A's prosecution as a result of your false allegation. The Committee are concerned that at no time during these proceedings have you seen fit to withdraw these allegations or to offer any apology.

Taking all these matters into account, the Committee find you guilty of serious professional misconduct.

In considering whether to take action in relation to your registration, the Committee have considered the issue of proportionality and have balanced

the interests of the public against your own. The Committee have given careful consideration to the submissions made on your behalf and on behalf of the GMC and Mr A. It has also considered carefully the GMC's Indicative Sanctions Document. The Committee have been extremely impressed by the vast number of and the quality of testimonials that have been put before them. It is clear from the testimonials that you are held in the highest esteem by your professional colleagues both in the United Kingdom and internationally. They all testify to your outstanding clinical skills and unparalleled commitment to the welfare of children all over the world. In particular we have noted the comments of Professor Sir H, President of the Royal College of Paediatrics and Child Health (RCPCH) who states that there has been no doubt that you have been an academic leader and that you have undertaken extremely important ground breaking research which 'has greatly influenced the way that babies and children have been managed all over the world.' The testimonials dealt with not only your research work, but also your work in paediatrics and child protection. There are many references to your unstinting involvement in the care of seriously ill children both within your own Trust and wider afield. Your colleagues have testified of your willingness to help them when faced with difficult cases no matter the personal cost to yourself. The Committee have also heard and have been impressed by the fact that you set up Child Advocacy International, a charitable organization which helps and promotes the welfare of sick children in less privileged parts of the world. The Committee notes that prior to this hearing you have more than 30 years of unblemished medical practice.

The Committee have taken into account the evidence of Dr G, Medical Director who appeared before the Committee to give an oral testimony on your behalf. Dr G stated that since your return to work in October 2001, you have only worked in the area of general paediatrics and that you no longer involve yourself in paediatric intensive care or indeed in child protection work. The Committee nevertheless concluded that the findings against you reflect a serious breach of the principles of Good Medical Practice and the standards of conduct, which the public are entitled to expect from registered medical practitioners and the Committee therefore feel obliged to take action in the public interest. In reaching this conclusion the Committee have borne in mind the Privy Council judgement in the case of Dr Gupta (Privy Council Appeal No. 44 of 2001) which states that:

"reputation of the profession is more important than the fortunes of any individual member. Membership of a profession brings many benefits, but that is part of the price."

In considering what action to take against your registration, the Committee recognise that taking no action and concluding this case with a reprimand would be wholly inappropriate.

In the circumstances, the Committee have concluded that in your own and the public interest it must take action regarding your registration. Based on the findings on facts in this case and your apparent lack of insight the Committee have decided that it would be inappropriate for you to continue with child protection work for the foreseeable future. Therefore, the Committee have decided to impose the following condition on your registration for a period of 3 years:-

~ You must not engage in any aspect of Child Protection work either within the NHS (Category I) or outside it (Category II).

The effect of the foregoing direction is that unless you exercise your right of appeal, your registration will become subject to the specified condition 28 days after the date when written notice of the direction is deemed to have been served upon you." Confirmed

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Signed Date

Date of Fitness to Practise Panel:~ 23 July 2007

(applying the GMC's PPC and PCC (Procedure) Rules 1988)

Name of respondent doctor: ~~~~~~ Dr David Patrick

SOUTHALL

Registration number: ~~~~~~ 1491739

Registered qualifications:~ ~~~~~~ Mb BS 1971 Lond;

MRCS Eng

Registered address: ~~~~~~ Staffordshire

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Panel:~~~~~

~~~~~ Dr F Wilson, Chairman (Medical)

~~~~~

~~~~~ Mr S Burton (Lay)

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~~~~~ Dr G Hanlon (Medical)

Legal Assessor:~ ~~~~~~ Ms

Esther Cunningham

Panel Secretary: ~~~~~~ Miss

Jackie Kramer

Type of Case:~~~~~

Resumed case of conduct

Representation:

GMC:Mr Richard Tyson, Counsel, instructed by Field Fisher Waterhouse
Solicitors.

Doctor:Present and represented by Ms Alison Foster, QC, instructed by
Hempsons Solicitors

Determination

Dr Southall~

The Professional Conduct Committee(PCC) on 6 August 2004 found you guilty of serious professional misconduct and determined to impose one condition on your registration for a period of three years. The condition imposed was that you must not engage in any aspect of Child Protection work either within the NHS (Category I) or outside it (Category II). You did not lodge an appeal against this decision and the condition took effect on 7 September 2004.

CRHP appealed the decision of the PCC and on 14 April 2005 the High Court handed down the judgement of Mr Justice Collins in your case, which was to allow the appeal to a limited extent. Mr Justice Collins ruled that the PCC's decision to impose conditions on your registration was not unduly lenient. However, the PCC was unduly lenient in failing to direct that a resumed hearing would take place at the end of three years. In addition, the condition imposed was not tightly enough drawn to prevent any involvement by you in child protection work. An Order, which was agreed between the parties, was substituted for the PCC's original decision. The principal terms are that: the PCC's condition is still in force from 7 September 2004 for a period of three years; in addition, you must report any concerns on child protection issues (whether within or outside the NHS and whether clinical, research based or otherwise) to the most senior child protection doctor working for your

employer/ the relevant local primary care trust as soon as possible, not take any further steps or have any involvement whatsoever in relation to such concerns or initiate any communications with, or seek to influence in any way that child protection doctor/other person/body in relation to such concerns; you must, every six months, provide to the GMC details of any cases where you have reported your concerns; you must inform any employer of the existence and terms of the conditions. It was directed that your case should be resumed at the end of the three year period of conditional registration.

At your PCC hearing on 6 August 2004, the Committee found that in November 1999 D was convicted of the murder of two of her children, B and C. On or about 27 April 2000 you watched the "Ñó÷Áó" programme about the D case and as a result, contacted the Child Protection Unit of the Staffordshire Police to voice concerns about how the abuse to B and C had occurred. On 2 June 2000 you met Detective Inspector E of the Cheshire Constabulary, the senior investigating officer into the deaths of B and C, and told him that you considered that F, D's husband, had deliberately suffocated B prior to his eventual death. You raised concerns about F's access to, and the safety of, the third child, Child A.

At that time, you were not connected with the case but made it clear that you were acting in your capacity of a consultant paediatrician with considerable experience of life threatening child abuse and that you were suspended from your duties by your employers, the North Staffordshire Hospital NHS Trust. You knew that it was an agreed term of the Trust's enquiries that you would not undertake any new outside child protection work without the prior permission of the Acting Medical Director of the Trust. You had not obtained this permission prior to contacting the Child Protection Unit of the Staffordshire Police or to meeting Detective Inspector E.

You relied on the contents of the television programme "Ñó÷Áó" as the principal factual source for your concerns and you presented as fact a theory about the case underpinned by your own research. Your actions in doing so were precipitate and irresponsible.

On 30 August 2000 you produced a report on the family at the request of Forshaws Solicitors, representing Child A. At the time, you did not have any access to the case papers, medical records, laboratory investigations, post-mortem records, medical reports or x-rays. You had not interviewed either F or D. Your report concluded that it was extremely likely if not certain that F had suffocated B and you remained convinced that Child A was unsafe in the hands of F. Further, your report implied that F was responsible for the deaths of B and C. Your report declared that its contents were true and may be used in a court of law whereas it contained matters the truth of which you could not have known or did not know. It contained no caveat to the effect that its conclusions were based upon the very limited information about the case known to you. You declined an opportunity to place such a caveat in your report, stating that it was likely beyond reasonable doubt that F was responsible for the deaths of B and C. The PCC found that your actions were individually and/or collectively inappropriate, irresponsible, misleading and an abuse of your professional position.

The PCC expressed extreme concern that you came to the view that F was responsible for the deaths of B and C without ever having met F or D or viewing the medical evidence. The Committee noted that you did not follow

the guidance entitled 'Expert Witnesses in Children Act Cases' produced by Mr Justice Wall.

The Committee noted that your failure to adhere to the principles contained within the GMC's guidance 'Good Medical Practice' resulted in substantial stress to F and his family at a time when they were most vulnerable and could have resulted in Child A being taken back into care unnecessarily. It was concerned that at no time during those proceedings did you see fit to withdraw your allegations or to offer any apology. Further, it considered that your conduct amounted to a serious breach of the principles of Good Medical Practice and the standards of conduct which the public are entitled to expect from registered medical practitioners.

The Panel today has also noted the contents of the High Court judgement handed down by Mr Justice Collins on 14 April 2005. In Justice Collins' view, your refusal to change your mind, despite circumstances which should tell a reasonable person that his view is wrong is a serious weakness which can lead to a risk to patients and others in the same way as a lack of insight. He further stated that absence of remorse and contrition is likely to be indicative of a lack of insight or of maintenance of unreasonable views. In either event, it may show that a risk of repetition exists. Justice Collins noted that the PCC had stated that it would be inappropriate for you to continue with child protection work 'for the foreseeable future' and imposed the maximum period of conditions, namely three years which, he stated, is hardly the foreseeable future.

In his submissions before it today, Mr Tyson, on behalf of the GMC, informed the Panel that you currently face further misconduct allegations at the GMC which are unrelated to the matters being considered by this Panel today. It noted the advice of the Legal Assessor who stated that these matters are not relevant to this Panel's decision.

Mr Tyson informed the Panel that the Attorney General has made a statement in the House of Lords about medical records kept by you, known as 'Special Cases Files'. The Attorney General has announced that these files will be investigated and the findings will be announced to Parliament.

Mr Tyson told the Panel that the South Wales Police are currently investigating a matter in which you may be involved, relating to a child and events which occurred in 1993.

The Panel notes that none of these matters are material to its decision today.

The Panel today has first had to consider whether you have complied with the conditions imposed on your registration in August 2004, and added to by the High Court in April 2005. It notes that you have regularly updated the GMC with regard to patients where child protection may be an issue and that you have referred each of these cases on to your colleagues in child protection work. It has noted the contents of the references provided by you for the purposes of today's hearing from your colleagues at the University Hospital of North Staffordshire, which verify that you have complied with the conditions imposed on your registration. It further notes the submissions of Mr Tyson that the GMC is satisfied that you have not failed to comply with the conditions. The Panel has determined that you have complied with all of the conditions imposed on your registration.

In accordance with Rule 42(2)(a) and (b) the Panel went on to consider whether to revoke the conditions, vary them, make no further direction or whether to impose a further period of conditional registration.

It notes that the position of both Mr Tyson and Ms Foster, your representative, is that the current conditions imposed on your registration should remain in place for a further period of 12 months, to be reviewed before the expiry of those conditions.

In determining what action to take with regard to the conditions currently imposed on your registration, the Panel has applied the principle of proportionality, weighing the public interest with your own interests. The Panel has a duty to protect the public interest. This includes the protection of patients, the maintenance of public confidence in the medical profession, and the promotion of proper standards of conduct and behaviour as set out in the GMC's document 'Good Medical Practice'. The Panel recognises that the purpose of sanctions is not to be punitive, although they may have a punitive effect.

Although the Panel did not hear evidence from you, or submissions from Ms Foster on this point, it noted the submission of Mr Tyson that there has been no substantial change in your position in respect of the allegations you made against F.

The Panel has considered the calibre and content of the references from your professional colleagues and notes that you are held in very high esteem and that your work is considered to be of the very highest quality. It further notes that in the opinion of your colleagues at the University Hospital of North Staffordshire, the conditions imposed on your registration are practicable and workable.

The Panel notes that you currently work in paediatrics at the University Hospital of North Staffordshire for approximately one week per month and spend the remainder of your time in paediatric work for charitable organisations and the WHO.

The Panel's attention has been drawn to the GMC's 'Indicative Sanctions Guidance' (April 2005). The Panel appreciates that the guidance is intended for the Fitness to Practise Panel operating under the General Medical Council (Fitness to Practise) Rules 2004, however it considers its contents are relevant in this case. This guidance states the circumstances in which conditions may be appropriate.

The Panel also notes the contents of 'Indicative Sanctions Guidance' in respect of review hearings. The guidance states that it is important that no

doctor should be allowed to resume unrestricted practice following a period of conditional registration or suspension unless the Panel can be certain that he or she is safe to do so. It further states that in all cases where conditions have been imposed the Panel will need to be reassured that the doctor is fit to resume practice either unrestricted or with conditions or further conditions. The Panel considers that this case is very serious. It notes the views of the PCC and Justice Collins, that the conditions currently imposed should remain in place for the foreseeable future. It also notes that the conditions are workable and that you have fully complied with them during the period in which they have been imposed on your registration. It also notes the submissions made on your behalf by Ms Foster that it would be in your own interests for these conditions to remain in place for a further 12 months. In all the circumstances, the Panel has determined that the period of conditional registration be extended for a period of twelve months. The conditions imposed are as follows:

- 1.~~~~~ You must not engage in any aspect of Child Protection work either within the NHS (Category I) or outside it (Category II).
- 2.~~~~~ If, during the course of your medical practice (whether within or outside the NHS and whether clinical or research-based) or otherwise, you form any concerns on child protection issues in relation to a particular child or children (whether or not your patient and whether deriving from any formal or informal approach to you concerning child protection issues) you must~~~~~a.~~~~~ Report those concerns as soon as possible to the most senior child protection doctor working for your employer (or to the person responsible for child protection at the relevant local primary care trust) who is on call at the relevant time (the "child protection doctor"), and
b.~~~~~ Not take any further steps or have any involvement whatsoever in relation to any consideration, steps or actions in any way connected to such concerns or initiate any communications with, or seek to influence in any way whatsoever, that child protection doctor or any other person or body in relation to such concerns.
- 3.~~~~~ For the remaining duration of these conditions, at intervals of six months, you must provide to the GMC full details of any cases (whether involving an individual or individuals) in respect of which you have reported concerns in accordance with condition 2 above or, alternatively, confirm that there have been no such cases during that interval.
- 4.~~~~~ You must inform your current employer and any subsequent employer (or relevant local primary care trust) of the existence and terms of conditions 1, 2 and 3 above.

The Panel will resume consideration of your case at a meeting to be held before the end of the period of conditional registration. It will then consider whether it should take further action in relation to your registration. You will be informed of the date of that meeting, which you will be expected to attend. Before that date you will be asked to furnish the Council with names of professional colleagues and other persons of standing to whom the Council may apply for information, as to their knowledge of your conduct since the hearing of this case.~ Please note at the next resumed hearing your case will be heard by a Fitness to Practise Panel applying the General Medical Council (Fitness to Practise) Rules 2004.~The effect of the foregoing direction is that,

unless you exercise your right of appeal, your registration will be subject to these conditions for a period of 12 months beginning 28 days from the date on which notice of this decision is deemed to have been served upon you.~ The previous order of conditional registration will remain in place until the new direction takes effect.

That concludes this hearing.

Confirmed

23 July 2007 ~~~~~

Chairman

~~~~~  
~~~~~ 5 November – 4 December 2007

Name of respondent doctor: ~~~~~

SOUTHALL, D

Registered qualifications: ~~~~~ MB BS
1971 Lond;

MRCS End LRCP Lond 1971 SR

Reference number:

~~~~~ 1491739

Type of Case:

~~~~~  
New case of conduct

Panel: ~~~~~

~~~~~ Dr J Mitton, Chairman (Lay)

~~~~~ Mrs L Lloyd

(Lay) ~~~~~

~~~~~ Mr A McFarlane

(Medical) ~~~~~

~~~~~ Mr A Simanowitz (Lay) ~~~~~

Legal Assessor:

~~~~~ Mr Robin

Hay

Secretary to the Panel: ~~~~~

Mrs Nilla Varsani

Representation:

Mr Richard Tyson, Counsel, instructed by Field Fisher Waterhouse,  
represented the Complainant's

Dr Southall was present and was represented by Mr Kieran Coonan QC,  
instructed by Hempsons.

Charge:

That being registered under the Medical Act 1983,

1. ~~~~~ From 1982 you were a senior lecturer and subsequently also a  
consultant paediatrician based at the Royal Brompton Hospital,  
London; Admitted and Found Proved

2. ~~~~~ From 1992 and at all material times you have been professor of  
paediatrics at the University of Keele and also a consultant paediatrician at  
the North Staffordshire Hospital, Stoke on Trent; Admitted and Found Proved  
(as amended)

3. ~~~~~ a. ~~~~~ In January 1998 you were contacted by social  
workers from a local authority who had concerns about Child M2, and in  
particular about similarities between current events in Child M2's life  
(including apparent suicide threats) and those in his elder brother, Child M1's,  
life shortly before Child M1's death by hanging in June 1996, when aged  
10, ~~~~~ the Royal Brompton Hospital, London; Admitted and Found  
Proved

1. You gave the social workers certain advice, and on 29 January 1998  
Child M2 was removed from home under an Emergency Protection Order,  
Admitted and Found Proved

c.~~~~~ Your advice was put into writing in a preliminary report dated 2 February 1998,Admitted and Found Proved

d.~~~~~ On 3 February 1998 the local authority applied for an Interim Care Order in respect of Child M2;Admitted and Found Proved

4.~~~~~ On 17 March 1998 you were instructed by the local authority to prepare an assessment/report for them in the care proceedings. Such report was to cover both Child M2 and his family;Admitted and Found Proved

5.~~~~~ a.~~~~~ For the purpose of preparing your assessment/report you interviewed Mrs M on 27 April 1998,~~~~~ Admitted and Found Proved

b.~~~~~ During the course of such interview you accused Mrs M of drugging and then murdering Child M1 by hanging him;Found Proved

6.~~~~~ Your actions as set out in 5.b. above,

a.~~~~~ Were inappropriate,Found Proved

b.~~~~~ Added to the distress of a bereaved person,Found Proved

c.~~~~~ Were an abuse of your professional position;Found Proved

7.~~~~~ a.~~~~~ In March 1989 Child H was referred to you at the Royal Brompton Hospital by Dr D of Great Ormond Street Hospital for investigation and advice,Admitted and Found Proved

b.~~~~~ Child H was admitted to the Royal Brompton Hospital, where his breathing was monitored, in September 1989 and again in March 1990,Admitted and Found Proved

c.~~~~~ On about 22 March 1990 Child H's parents informed you that they no longer wanted you to be involved in the management of Child H's care;Admitted and Found Proved

8.~~~~~ a.~~~~~ On 22 March 1990 you wrote to Dr D stating that,~~~~~ i.~~~~~ Child H's parents were not acting in Child H's best long term interests,~~~~~ Admitted and Found Proved

ii.~~~~~ you were suspicious of their motives,Admitted and Found Proved

iii.~~~~~ you viewed Child H's long term prognosis with great concern,Admitted and Found Proved

b.~~~~~ You copied the letter mentioned at 8.a. to an unnamed Consultant Paediatrician at the Royal Gwent Hospital even though no one there was involved in Child H's care,Found Proved

c.~~~~~ You did not seek, nor obtain, Child H's parents' consent,

i.~~~~~ to the fact of involving a local paediatrician in Child H's care, orFound Proved

ii.~~~~~ to any letter being sent to an unnamed local paediatrician, orFound Proved

iii.~~~~~ to the letter mentioned in 8.a., and in those terms, being sent to an unnamed local paediatrician;Admitted and Found Proved

9.~~~~~ Your actions as set out in 8.b. and 8.c. above, or either of them, were,

a.~~~~~ Inappropriate,Found Proved in relation to 8b  
Found Not Proved in relation to 8c(i)  
Not considered in relation to 8c(ii) and 8c(iii)

b.~~~~~ In breach of Child H's, and his parents', confidentiality;Found Proved in relation to 8b  
Found Not Proved in relation to 8c(i), 8c(ii) and 8c(iii)



- 10.~~~~~ In the cases listed in Appendix 1,  
a.~~~~~ You created, or caused to be created, an "/C "File wherein certain original medical hospital records relating to the child were then placed by you or on your behalf, (as amended)  
Found Proved in relation to Child D and Child H  
Found Not Proved in relation Child A and Child B  
b.~~~~~ The cited medical record is not elsewhere in the child's hospital medical records;Found Proved in relation to Child B, Child D and Child H  
Found Not Proved in relation Child A  
In the light of the Panel's findings in Head 10a, in relation to Child A and Child B, the Panel made no findings under Heads 11 and 12 in respect of~ Child A and Child B
- 11.~~~~~ The placing, or causing to be placed by you or on your behalf, of such cited original medical records in a "/C "File,(as amended)  
a.~~~~~ Damaged the integrity of Amounted to tampering with the child's hospital medical records,Found Proved (as amended)  
b.~~~~~ Caused any such item to be inaccessible to others involved in the medical care of the child at that time or in the future;Found Proved
- 12.~~~~~ Your actions as set out in 10. and 11. above were,  
a.~~~~~ Not in the best interests of the child concerned,Found Proved  
b.~~~~~ Inappropriate,Found Proved  
c.~~~~~ An abuse of your professional position;Found Proved  
In the light of the Panel's findings in Head 10a and 10b, in relation to Child A, the Panel made no findings under Heads 13 and 14 in respect of~ Child A
- 13.~~~~~ a.~~~~~ You treated both Child A and Child H at the Royal Brompton Hospital, and there created an "/C "file for each child,Admitted and Found Proved  
b.~~~~~ Each such "/C "file contained original Royal Brompton Hospital medical records,Admitted and Found Proved  
c.~~~~~ You took, or caused to be taken, the "/C "Files relating to both Child A and Child H away from the Royal Brompton Hospital and to the North Staffordshire Hospital;Admitted and Found Proved
- 14.~~~~~ Your actions as set out in 13.b. and 13.c. above were,  
a.~~~~~ Not in the best interests of the child concerned,Found Proved  
b.~~~~~ Inappropriate,Found Proved  
c.~~~~~ An abuse of your professional position;Found Proved
- 15.~~~~~ a.~~~~~ On the computer system held at the Academic Department of Paediatrics, North Staffordshire Hospital you maintained, or caused to be maintained, the medical records set out in Appendix 2,Admitted and Found Proved  
b.~~~~~ These computer medical records are not contained in children's hospital medical records at either the Royal Brompton Hospital (for Child A and Child H) or the North Staffordshire Hospital (for Child D and Child B),Found Not Proved~ (as amended)
- c.~~~~~ Neither Child A nor Child H were treated at the North Staffordshire Hospital, but only at the Royal Brompton Hospital;Admitted and Found Proved
- 16.~~~~~ Your actions as set out in paragraph 15. above,

- a.~~~~~ Were not in the best interests of the individual children,Found Not Proved
- b.~~~~~ Amounted to keeping secret medical records on them,Found Not Proved
- c.~~~~~ Were inappropriate,Found Not Proved
- d.~~~~~ Were an abuse of your professional position;Found Not Proved
- 17.~~~~~ In the cases set out in Appendix 3 you failed to treat the respective children's mothers in the ways set out below, or any of them,
- a.~~~~~ Politely and considerately,Found Proved in relation to Mrs M, in that Dr Southall questioned Mrs M in an accusatorial and intimidating manner Found Not Proved in relation to Mrs D
- b.~~~~~ In a way they could understand,In relation to Mrs M, this allegation is not applicable in relation to the particulars, as set out in Appendix 3 Found Not Proved in relation to Mrs D
- c.~~~~~ Respecting their privacy and dignity; Found Proved in relation to Mrs M, in that Dr Southall failed to respect Mrs M's dignity by reason of the accusatorial and intimidating manner in which he questioned her
- In the light of the Panel's determination in relation to the Rule 27 (1)(e)(i) submission the Panel did not consider this sub-head in respect of Mrs D.
- 18.~~~~~ Your failure/s in these respects under paragraph 17,(as amended)
- a.~~~~~ Were inappropriate,Found Proved in relation to Mrs M Found Not Proved in relation to Mrs D
- b.~~~~~ Were in breach of your duty to establish and maintain trust between yourself and the children's mothers while they were acting with parental responsibility,Found Not Proved in relation to Mrs M Found Not Proved in relation to Mrs D
- c.~~~~~ Caused distress to each individual woman;Found Proved in relation to Mrs M Found Not Proved in relation to Mrs D
- "óthat in relation to the facts alleged you have been guilty of serious professional misconduct. "Guilty of Serious Professional Misconduct

Determination on the facts:

Dr Southall:

The Panel has given detailed consideration to all the oral and documentary evidence adduced in this case and has taken into account the submissions made by both Mr Tyson and Mr Coonan.

The Panel has borne in mind that the burden of proof rests on the Complainants and that the standard of proof required is that the Panel has to be satisfied so that it is sure that each of the allegations has been proved. It has considered each head and sub-head of charge including, where relevant, the items in the three appendices separately.

In setting out this determination the Panel has grouped certain Heads of Charge where they are related.

The Panel has made the following findings on the facts:

Head 1 has been admitted and found proved.

Head 2 as amended to read 'From 1992 and at all material times you have been professor of paediatrics at the University of Keele and also a consultant paediatrician at the North Staffordshire Hospital, Stoke on Trent,' has been admitted and found proved.

Mrs M

Heads 3a, 3b, 3c and 3d have been admitted and found proved.

Head 4 has been admitted and found proved.

Head 5a has been admitted and found proved. Head 5b has been found proved.

The Panel found Mrs M to be a clear, honest and credible witness.

You accused her of drugging and then murdering M1 by hanging. This is supported in the notes written shortly after the interview, by Dr C on 28 April 1998 and Mrs P, Mrs M's solicitor, on 29 April 1998. Dr C's handwritten note includes the verbatim statement that she says was made by Mrs M 'they didn't do toxicology quite possible you drugged him first'. Also the Panel notes your report where you describe Mrs M as 'categorically' denying asphyxiating M1. As to Miss S, in many respects the Panel did not find her evidence to be wholly convincing. ~Head 6a has been found proved. Head 6b has been found proved. Head 6c has been found proved.

You were a registered medical practitioner and in that capacity you were instructed by Shropshire County Council to provide an independent expert report to the court. Although Mrs M was not your patient, your action in accusing her of drugging and then murdering Child M1 by hanging him was inappropriate, added to her distress and was in the circumstances an abuse of your professional position.

Head 17a has been found proved.

The Panel has found that during the interview on 27 April 1998 you questioned Mrs M in an accusatorial and intimidating manner. The Panel found your report dated 20 May 1998 to be significant in that it is supportive of Mrs M's evidence.

The Panel has determined that Head 17b is not applicable in relation to the particulars, as set out in Appendix 3 and has therefore found it not proved.

Head 17c has been found proved in that you failed to respect Mrs M's dignity by reason of the accusatorial and intimidating manner in which you questioned her.

The stem of Head 18 was amended to read 'Your failure/s under paragraph 17' and in relation to Mrs M,

Head 18a has been found proved. Head 18b has been found not proved.

The Panel was not satisfied that there was a duty to establish and maintain trust between you and Mrs M. She was not your patient. You were instructed by Shropshire County Council to prepare an independent expert report for the court.

Head 18c has been found proved.

Dr D letter dated 22 March 1990

Heads 7a, 7b and 7c have been admitted and found proved.

Heads 8a (i), 8a (ii) and 8a (iii) have been admitted and found proved. Head 8b has been found proved.

The Panel is satisfied that the letter addressed to Dr D, dated 22 March 1990, was copied and then sent to Dr W and an unnamed consultant paediatrician at the Royal Gwent Hospital. It is written on both the file copy and the original letter that it was so copied. Moreover Dr D and Dr W received the letter. ~Head 8c(i) has been found proved.

The chronology of events is apparent from the documentary evidence. Your report of 27 June 1991 indicates that the decision to involve a paediatrician local to the child's home was made after Mrs H had indicated that she no longer wished to be involved with the ~ Royal Brompton Hospital. Despite the inconsistencies between Mrs H's oral evidence and her affidavit, the Panel is satisfied that Mrs H did not give her consent to the involvement of a local paediatrician. Even if Mrs H had previously given her consent the Panel is further satisfied that it would have been withdrawn when Mrs H telephoned you and informed you that she was rejecting your proposed treatment regime. Head 8c(ii) has been found proved. Head 8c (iii) has been admitted and found proved.

Heads 9a and 9b have been found proved in relation to 8b.

The Panel has found that it was inappropriate to send a letter containing sensitive information relating to a child to an unnamed paediatrician at a hospital where that child was not being and had not been treated.

Head 9a has been found not proved in relation to 8c(i).

Professor D's evidence confirms that the needs of the child are paramount.

This case included alleged child protection issues. Dr W, a local paediatrician had previously been involved in the case. Therefore it was appropriate not to seek the consent of Mrs H when involving a local paediatrician.

Head 9a was not considered in relation to 8c(ii) and 8c(iii) as it cannot be appropriate to seek consent to the sending of a letter to an unnamed local paediatrician where that action has itself been found to be inappropriate.

Head 9b has been found not proved in relation to 8c(i). Head 9b has been found not proved in relation to 8c(ii). Head 9b has been found not proved in relation to 8c(iii).

Special Case Files

Head 10a, as amended to read 'You created, or caused to be created, an "/C "File wherein certain original medical hospital records relating to the child were then placed by you or on your behalf,' has been found proved in relation to Child D and Child H.

Child A

The Panel is satisfied that the 'MRI report' is an original medical hospital record. However, there is evidence that the 'MRI report' may have been put in the S/C file by mistake and the Panel could not be satisfied that the 'MRI report' was placed in the S/C file by you or on your behalf.

Child B

The Panel is satisfied that the 'Crawley referral letter' is an original medical hospital record. However, there is evidence that the S/C file may have been tampered with when not under your control and the Panel therefore could not be satisfied that the 'Crawley referral letter' was placed in the S/C file by you or on your behalf.

Child D

The Panel is satisfied that all documents referred to in Appendix 1 are original medical hospital records and that they were filed in the S/C file pursuant to your policy.

Child H

The Panel is satisfied that all documents referred to in Appendix 1 are original medical hospital records. In regard to Dr S's manuscript note, this was compiled following his meeting with the parents of child H. It is signed and contains certain data which cannot be found elsewhere in the child's medical records. The Panel accepts Professor D's opinion that the document is a detailed summary outline of the case. The Panel found that the manuscript note is an original medical hospital record. The Panel is also satisfied that all the documents were filed in the S/C file pursuant to your policy.

Head 10b has been found proved in relation to Child B, Child D and Child H. In respect of Child B the Panel noted the use of the present tense in this head of charge. It is undisputed that the 'Crawley referral letter' is not currently in the child's hospital medical records.

In the light of the Panel's findings in Head 10a, in relation to Child A and Child B, the Panel made no findings under Heads 11 and 12, in respect of Child A and Child B.

In relation to Child D and Child H

The stem of Head 11 was amended to read 'The placing, or causing to be placed by you or on your behalf, of such cited original medical records in a "/C "File'.

Head 11a as amended to read 'Damaged the integrity of the child's hospital medical records,' has been found proved.

Head 11b has been found proved.

The Panel has found that the setting up of S/C Files, was not in itself damaging provided that there was sufficient internal signposting, knowledge by the clinical staff looking after the children and that the information within the S/C Files was readily accessible. The Panel was not satisfied that you had systems in place to ensure that there was sufficient internal signposting.

There is also evidence that, if such a system existed, it was not adhered to nor was there sufficient knowledge on the part of the people who should have known of either the system or the existence of the S/C Files.

The Panel accepted that the difficulties experienced by the families of Child D and Child H in obtaining the S/C Files may have been a result of the then current practice as to disclosure of medical records for litigation purposes.

Head 12a has been found proved. Head 12b has been found proved. Head 12c has been found proved.

You have a responsibility and duty as a doctor to ensure that medical records are readily available to colleagues as and when required. You were in a position where you could and did make decisions in regard to patients. Your actions were therefore an abuse of your position as the treating doctor.

Child A and Child H – Transfer of S/C Files

In the light of the Panel's decision in respect of Head 10a and 10b, in relation to Child A, the Panel makes no finding under this head of charge in relation to Child A.

Heads 13a, 13b and 13c have been admitted and found proved.

Head 14a has been found proved. Head 14b has been found proved. Head 14c has been found proved.

The Panel has already found that having the documents in the S/C Files at the hospital damaged the integrity of the child's hospital medical records. The damage caused was compounded by the transfer of the records to a hospital at which the child was not being and had not been treated.

Computer medical records

Head 15a has been admitted and found proved.

Head 15b as amended to read 'These computer medical records are not contained in children's hospital medical records at either the Royal Brompton Hospital (for Child A and Child H) or the North Staffordshire Hospital (for Child D and Child B),' has been found not proved.

The Panel has interpreted 'computer medical records' as the data held in the computer rather than the documents or the format of the documents that were produced from the computer. The Panel found that all the data held on the computer was available in the children's hospital medical records. ~Head 15c has been admitted and found proved.

Head 16a has been found not proved.

The Panel is not satisfied that the transfer of the computer medical records or anything contained with them was detrimental to the individual children.

Head 16b has been found not proved.

The Panel is satisfied that the keeping of this data in the computer did not amount to the keeping of secret medical records as there is evidence that the IT department members, the relevant clinical team and the nurses inputting the data were aware of the existence of the computer and that others had direct access to the computer. You have provided evidence that you wrote to the Business Manager in 1993 raising the issue of registration of the data on the computers for the purposes of the Data Protection Act 1984. Head 16c has been found not proved. Head 16d has been found not proved.

Mrs D

Head 17a has been found not proved.

Head 17b has been found not proved.

In light of the Panel's earlier determination in relation to the Rule 27 submission the Panel has not considered Head 17c in respect of Mrs D.

The Panel believed Mrs D's evidence that some incident occurred in the corridor. It could not, however, be satisfied that this allegation was proved.

There is no evidence to corroborate Mrs D's account and she made no complaint about this incident until 2004.

The stem of Head 18 was amended to read 'Your failure/s under paragraph 17', Head 18 in its entirety has been found not proved.

Having reached its findings on the facts, the Panel then considered whether the facts found proved would be insufficient to support a finding of serious professional misconduct. The Panel has found that the facts proved would not be insufficient.

For the benefit of the public, I should explain that the Panel will now invite Mr Tyson to adduce evidence, if he wishes to do so, as to the circumstances leading up to the facts which have been found proved, the extent to which those facts indicate serious professional misconduct on your part and as to your character and previous history.~ After that, the Panel will invite Mr Coonan to address them on those matters and also to adduce evidence in mitigation, if he wishes to do so.~ Both Counsel are reminded that they should refer to the Indicative Sanctions Guidance when making submissions on sanction.

The Panel will then proceed to consider whether you have been guilty of serious professional misconduct in respect of those facts that have been found proved against you, and, if so, they will go on to consider whether or not they should make any direction regarding your registration.

Determination on Serious Professional Misconduct and Sanction:

Dr Southall:

The Panel has considered this case in accordance with the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988.

The Panel has heard that from 1982 you were a senior lecturer and subsequently a consultant paediatrician based at the Royal Brompton Hospital, London. From 1992 you were professor of paediatrics at the University of Keele and also a consultant paediatrician at the North Staffordshire Hospital, Stoke on Trent.

In January 1998 you were contacted by local authority social workers who had concerns about the welfare of Child M2. You were told that there were similarities between current events in Child M2's life (including apparent suicide threats) and events in the life of his elder brother, Child M1, who in

June 1996, when aged 10, had died by hanging. You gave the social workers certain advice. On 29 January 1998 the court made an emergency protection order. As a consequence Child M2 was removed from his parents' care. On 2 February 1998 you wrote what you described as a preliminary report, following which on 3 February 1998 the local authority applied for an Interim Care Order. On 17 March 1998 you were instructed by the local authority to prepare a report for the care proceedings. Your report was to cover both Child M2 and his family. For the purpose of preparing your report you interviewed Mrs M on 27 April 1998. The Panel has found proved that during the course of this interview you accused Mrs M of drugging Child M1 and then murdering him by hanging. This was done in an accusatorial and intimidating manner. The possibility of M1 being the victim of murder had not been raised until you became involved. At the inquest the coroner had recorded in his verdict that he had considered suicide and accident but in the event he returned an open verdict. It is apparent that no evidence was presented at the inquest to suggest that murder was a possibility. Despite the verdict, you formed the belief that the circumstances of M1's death needed to be investigated by you. The Panel is extremely concerned by these facts. You are a registered medical practitioner and in that capacity you were instructed by Shropshire County Council to write an expert report for the court in care proceedings based on the papers that had been provided to you. The letter of instruction made it clear that it was important that the parties had confidence in your independent status.

Your action in accusing Mrs M of murdering Child M1 was inappropriate, added to her distress as a bereaved person and was, in the circumstances, an abuse of your professional position. By acting in an accusatorial and intimidating manner you failed to treat Mrs M politely and considerately and did not respect her dignity. This~ behaviour was also inappropriate and caused distress to Mrs M.

In some situations doctors have responsibilities not only to patients but also to third parties. Although Mrs M was not your patient you interviewed her in your capacity as a registered medical practitioner and you had a clear obligation to treat her as you should treat a patient, that is politely and considerately and respecting her dignity. The manner in which you conducted the interview, questioned~ and directly accused Mrs M was incompatible with your position as a doctor. The Panel regards your behaviour towards Mrs M as a very serious instance of misconduct.

In March 1989 Dr D, a consultant paediatrician at Great Ormond Street Hospital, referred Child H to you for investigation and advice. In September 1989 and again in March 1990 Child H was admitted to the Royal Brompton Hospital where his breathing was monitored. In March 1990 you proposed to the parents a home monitoring and care regime. However, on about 22 March 1990 Child H's parents informed you that they no longer wanted you to be involved in the management of Child H's care.

On 22 March 1990 you wrote to Dr D to the effect that the parents were not acting in Child H's best long term interests, that they liked the idea of him having a rare illness, that you were suspicious of their motives and that you viewed the long term prognosis with great concern. You copied and sent this letter to an unnamed Consultant Paediatrician at the Royal Gwent Hospital even though no one there was currently involved in Child H's care or had



been involved in the past. The letter contained sensitive and confidential information. Your action was inappropriate and in breach of the confidentiality owed by you to Child H and his parents.

In the General Medical Council's Guidance, Professional Conduct and Discipline: Fitness to Practise (March 1989), which was in force at that time, paragraphs 79-82 cover the subject of professional confidence. It is a doctor's duty, subject to the exceptions listed in Paragraph 81, to strictly observe the rule of professional secrecy by refraining from disclosing voluntarily to any third party information about a patient which he has learnt directly or indirectly in his professional capacity. None of the exceptions applied in this case because the letter was sent to an unidentified recipient.

In relation to Child D and Child H, you created, or caused to be created, an "/C "File for each child wherein certain original medical hospital records relating to the children were then placed by you or on your behalf. These medical records are not elsewhere in the children's hospital medical records. The placing of the original medical records in "/C "Files damaged the integrity of the children's hospital medical records and caused the items concerned to be inaccessible to others involved in the medical care of the children at that time or in the future.

You have a responsibility and duty as a doctor to ensure that medical records are readily available to colleagues as and when required. Failure to do so can result in serious consequences. Your action in this respect was not in the best interests of either Child D or Child H. It was inappropriate and an abuse of your professional position.

You treated Child H at the Royal Brompton Hospital, and there created an "/C "file for the child. The "/C " file contained original Royal Brompton Hospital medical records relating to Child H. When you moved to the North Staffordshire Hospital in 1992 you took, or caused to be taken from the Royal Brompton Hospital, the "/C "File relating to Child H.~ Your action was not in the best interests of Child H. It was inappropriate and an abuse of your professional position.

The damage to the integrity to the child's hospital medical records was compounded by transferring them to a hospital at which the child was not being and had not been treated.

The Panel takes a serious view of your conduct in relation to the "/C "files over a considerable period of time.

In 2004 the Professional Conduct Committee (PCC) found you guilty of serious professional misconduct in relation to the 'Clark case' and placed a condition on your registration for a period of three years. The events in that case took place in 2000 and also concerned child protection issues. The Council for the Regulation of Health Care Professionals appealed the decision of the PCC. In his judgment given on 14 April 2005 Mr Justice Collins held that that the PCC's decision to impose conditions was not unduly lenient but that the condition imposed was not sufficient to prevent any involvement by you in child protection work. Moreover, the PCC should have directed that a resumed hearing take place towards the end of the three year term. He substituted more tightly drawn conditions for that originally ordered. A Fitness to Practise Panel reviewed the case on 23 July 2007 and determined that you had complied with the conditions. It directed that the period of conditional registration should be extended for a further period of twelve months.

The events that gave rise to the Clark case occurred after the matters before this Panel. These events and the consequent finding of serious professional misconduct have been disregarded by this Panel when considering the question of serious professional misconduct before it.

In February 2007 the Attorney General set in hand a review of cases in which you had acted as a prosecution witness. This was with particular reference to the S/C Files. The report is yet to be published. The Panel has also heard that the South Wales police are investigating the treatment of Mrs H's son.

The Panel has concluded that any police investigation and the Attorney General's review are not relevant to its consideration of the question of serious professional misconduct, nor indeed to any sanction.

It has been accepted on your behalf that, in the light of the findings of fact there is evidence before the Panel from which it could conclude that you are guilty of serious professional misconduct.

The Panel has found that your conduct has fallen well below the standard expected of a registered medical practitioner in a number of respects. It therefore finds you guilty of serious professional misconduct.

The Panel next considered what action, if any, to take in relation to your registration.

The Panel has borne in mind throughout its deliberations that any sanction imposed must be proportionate and appropriate, and that the purpose of sanctions is not to be punitive, but to protect patients and the public interest. The public interest includes not only the protection of patients, but also the maintenance of public confidence in the profession and the declaring and upholding of proper standards of conduct and behaviour. The public interest can also include a doctor's return to safe practice.

The Panel has balanced the public interest against your own interests. It has taken into account the Indicative Sanctions Guidance published by the General Medical Council. The Panel is aware that the question of what, if any, sanction to impose is a matter for the Panel, exercising its own independent judgment.~

The Panel has given consideration to the submissions made by both Counsel. Mr Tyson, on behalf of the Complainants has submitted that the only appropriate sanction in this case is that of erasure. Mr Coonan, on your behalf, has submitted that an order placing tight restrictions on your registration would be sufficient.~

The Panel is in no doubt that it is necessary to take action against your registration and that the sanction imposed must mark strong disapproval of your behaviour. Given the serious nature of your misconduct the Panel has determined that to conclude this case without making any direction in respect of your registration or to issue a reprimand would not be sufficient.

The Panel next considered whether it would be sufficient to impose conditions on your registration.

The Panel is aware that you are a paediatrician of international renown and that you have contributed significantly to the field of paediatrics and child protection.

The Panel recognises that your misconduct has arisen as a result of the child protection work that you were undertaking at that time and that your actions, although clearly misguided, may have been motivated by a concern to protect children. There is no evidence before the Panel to demonstrate that your

actions have caused direct harm to patients or their families other than in cases involving child protection. Since your reinstatement in 2001, following suspension by your Trust, you have not worked in child protection. You have complied with the conditions to which your registration has been subject. The Panel has been provided with testimonials indicating that you are held in high regard by your professional colleagues. The testimonials highlight your clinical skills and commitment to the welfare of children. They also indicate that you have undertaken important ground-breaking research, which has influenced how the medical care of babies and children has been managed both in the United Kingdom and internationally.~

The Panel has heard oral evidence from Dr P, a consultant paediatrician at the University Hospital of North Staffordshire and from Dr B, a recently retired consultant paediatrician and Chairman of the Trustees of Child Health Advocacy International, a charity founded by you. Dr P has given evidence about your outstanding clinical ability and your compliance with the conditions currently on your registration. He also informed the Panel that numerous letters of support and thanks from your patients have been received. Both witnesses confirmed that they were aware of the findings of fact made by this Panel. Nevertheless they remain confident in your clinical abilities. The Panel has also considered carefully the evidence given by Dr E, Medical Director at the time, to the Professional Conduct Committee in August 2004 and her testimonial dated 16 November 2006. She holds in high regard your clinical skills and the contribution you have been making to the paediatric team at North Staffordshire Hospital.

The Panel has noted the determination of the Professional Conduct Committee in August 2004, the judgment of Mr Justice Collins in April 2005 and the determination of the Fitness to Practise Panel at the review in July 2007.

The panel has been mindful of Lord Bingham's well known observation in the case of *Bolton v The Law Society*, adopted in the case of Dr Gupta, as noted in the Indicative Sanctions Guidance:~~~~~ "profession's most valuable asset is its collective reputation and the confidence which that inspires..... ..preputation of the profession is more important than the fortunes of an individual member..... ..Membership of a profession brings many benefits, but that is part of the price."~

The Panel also had in mind Lord Hoffman's judgment in *Bijl v General Medical Council* [2002] *Lloyds Med Rep* 60, in which he said:-

"The Committee was rightly concerned with public confidence in the profession and its procedures for dealing with doctors who lapse from professional standards. But this should not be carried to the extent if feeling of necessary to sacrifice the career of an otherwise competent and useful doctor who presents no danger to the public in order to satisfy a demand for blame and punishment....."

Having considered all the evidence that is before it, the Panel accepts that were your registration to be restricted by tightly drawn conditions, patients would be unlikely to be at risk. However, in considering the maintenance of public confidence in the profession and the declaring and upholding of proper standards of conduct and behaviour the Panel has concluded that the imposition of conditions would not reflect the gravity of your misconduct. Your multiple failings over an extended period caused the Panel great concern.

Furthermore, the Panel is influenced by the fact that, although the events in the current case predate those in the Clark case, there are now two instances where without justification you have accused a parent of murdering their child. The Panel has therefore determined that to impose conditions on your registration, no matter how tightly drawn, would not be sufficient to protect the public interest.

The Panel next considered whether a period of suspension would be appropriate. It has carefully balanced the public interest against your own interests. It has taken into account the aggravating features of this case and the mitigation that has been advanced by you. The Panel is particularly concerned by your lack of insight into the multiplicity of your failings over a long period. The Panel is aware that an apparent lack of remorse should not result in a higher sanction but it has noted that notwithstanding the findings of fact you have not either directly or through your counsel offered an apology to any of the Complainants for your actions nor has there been any acknowledgement by you as to your failings.

In all the circumstances the Panel has concluded that you have deep seated attitudinal problems and that your misconduct is so serious that it is fundamentally incompatible with your continuing to be a registered medical practitioner.

The Panel therefore directs that your name be erased from the Medical Register. The Panel is satisfied that this is necessary in the public interest for the maintenance of confidence in the profession and in the interests of declaring and upholding proper standards of professional conduct and behaviour.~

The effect of the foregoing direction is that, unless you exercise your right of appeal, your name will be erased from the register 28 days from the date on which notice of this direction is deemed to have been served upon you.

Having reached a decision that your registration should be erased, the Panel is minded to consider, in accordance with Section 38 of the Medical Act 1983 as amended, whether to direct that your registration be suspended forthwith. The Panel will invite submissions from both Counsel on this matter.~~

Determination on immediate sanction:

Dr Southall:

Having determined that your name should be erased from the Medical Register, the Panel has considered in accordance with Section 38 of the Medical Act 1983 as amended, whether your registration should be suspended forthwith.

Mr Tyson has submitted on behalf of the Complainants that immediate suspension is necessary in the public interest.

Mr Coonan has submitted on your behalf that suspension forthwith is not necessary as patients are not at risk.

The matters identified in the determination, which necessitated the erasure of your name from the Medical Register, are of serious concern. The Panel has therefore determined that it is necessary in the public interest that your registration should be made subject to suspension with immediate effect.

This means that your registration will be suspended from today. The substantive direction for erasure, as already announced, will take effect 28 days from today,

unless you lodge an appeal in the interim. If you appeal, the immediate suspension will remain in force until the substantive direction takes effect. That concludes this case.

Confirmed

~

4 December

2007 ~~~~~  
~~~~~ Chairman

Date of Fitness to Practise Panel Hearing: 8 May – 4 July 2008

Name of respondent doctor: SOUTHALL, David Patrick

Registered qualifications: MB BS 1971 Lond;
MRCS End LRCP Lond 1971 SR

Registered address: Staffordshire

Reference number: 1491739

Type of Case: New case of conduct

Panel: Mr David Kyle, Chairman (Lay)
Mrs V Brickley (Lay)
Dr M Sheldon (Medical)
Dr T Okitiki (Lay)
Mrs S Hollingworth (Lay)

Legal Assessor: Mr Alastair Forrest

Secretary to the Panel: Mrs Zaheda Khan

Representation:

Ms Jane Sullivan, Counsel, instructed by Eversheds Solicitors, represented the Complainant's and the General Medical Council.

Dr Southall was present and was represented by Ms Mary O'Rourke, Counsel, instructed by Hempsons Solicitors.

Charge:

"p÷being registered under the Medical Act;

1. At all material times you were practising as a Consultant Paediatrician, namely at the Royal Brompton until June 1992 and thereafter at North Staffordshire Hospital; Admitted and Found Proved

2. On 29 November 1989, you applied to the Ethics Committee of the North Staffordshire Royal Infirmary ("pEthics Committee") for approval of a trial entitled "randomised controlled trial of continuous sub-atmospheric (negative) extra thoracic pressure (CNEP) in neonatal respiratory failure. "("pCNEP trial");

3. The application inaccurately described
a. the procedures that would be applied to each Patient,
Deleted Following a Rule 27 (1)(e)(i) Submission

b. the number of patients that would be required for the trial;

Withdrawn by the GMC

4. The design of the trial was such that it did not sufficiently minimise the possibility of bias; Withdrawn by the GMC
5. The trial received Ethics Committee approval on 10 January 1990; Admitted and Found Proved
6. In or around February 1990, at Queen Charlottes Hospital, a trial patient was found to have experienced neck trauma
 - a. This was an adverse event which should have been reported to the Ethics Committees of both Queen Charlottes and North Staffordshire Hospitals,
Deleted Following a Rule 27 (1)(e)(i) Submission
 - b. You failed to report the matter to the Ethics Committee of North Staffordshire Hospital;
Deleted Following a Rule 27 (1)(e)(i) Submission
7. On 15 May 1990, two changes were made to the scoring system,
 - a. These were changes to the Trial Protocol which should have been reported to the Ethics Committee,
Deleted Following a Rule 27 (1)(e)(i) Submission
 - b. You failed to report the matter to the Ethics Committee;
Deleted Following a Rule 27 (1)(e)(i) Submission
8. In or around July or August 1991, artificial surfactant was introduced as a treatment option for some patients in the trial Admitted and Found Proved
 - a. This was a change to the Trial Protocol which should have been reported to the Ethics Committee,
Deleted Following a Rule 27 (1)(e)(i) Submission
 - b. You failed to report the matter to the Ethics Committee;
Deleted Following a Rule 27 (1)(e)(i) Submission
9. On 11 September 1991, the exclusion criteria were amended to include patients who were born following prolonged ruptured membranes, providing this was of not more than 7 days duration Admitted and Found Proved
 - a. This was an amendment to the Trial Protocol which should have been reported to the Ethics Committee,
Deleted Following a Rule 27 (1)(e)(i) Submission
 - b. You failed to report the matter to the Ethics Committee;
Deleted Following a Rule 27 (1)(e)(i) Submission

10. By the time that 100 patients from North Staffordshire had participated in the trial, it was apparent that substantially more patients from North Staffordshire would be required to participate Withdrawn by the GMC

a. This was a change to the Trial Protocol which should have been reported to the Ethics Committee, Withdrawn by the GMC

b. You failed to report the matter to the Ethics Committee;
Withdrawn by the GMC

11. In your role as a responsible investigator in the conduct of the CNEP trial you failed to ensure that appropriate procedures were in place to obtain informed parental consent to the patients' participation in the CNEP trial, in particular Deleted Following a Rule 27 (1)(e)(i) Submission

a. You inappropriately delegated the task of taking consent to too many different medical and nursing staff,
Deleted Following a Rule 27 (1)(e)(i) Submission

b. You failed to provide adequate training to those taking consent for the trial, Deleted Following a Rule 27 (1)(e)(i) Submission

c. You misrepresented within the parental information leaflet that the technique had been shown to be safe,
Deleted Following a Rule 27 (1)(e)(i) Submission

d. You failed to ensure that every parent had a copy of the parental information leaflet; Deleted Following a Rule 27 (1)(e)(i) Submission

12. In your role as a responsible investigator in the conduct of the CNEP trial

a. You used a scoring system that was not validated,
Withdrawn by the GMC

b. You failed to ensure that the scores were allocated correctly,
Deleted Following a Rule 27 (1)(e)(i) Submission

c. You failed to ensure that the scores were calculated correctly,
Withdrawn by the GMC

d. You failed to ensure that there was an appropriate method of scoring,
Deleted Following a Rule 27 (1)(e)(i) Submission

e. You thereby failed to produce valid results from the trial;
Withdrawn by the GMC

13. You co-authored a paper entitled "Continuous Negative Extrathoracic Pressure in Neonatal Respiratory Failure "published in Paediatrics on 6 December 1996 ("pPaediatrics Paper") Withdrawn by the GMC

- a. The abstract states "The overall outcome score showed an overall significant benefit for CNEP", Withdrawn by the GMC
- b. This statement should not have been made in view of the defects in the scoring system referred to in Head 12 above;
Withdrawn by the GMC

14. Your actions as outlined above were

- a. inappropriate,
Deleted Following a Rule 27 (1)(e)(i) Submission
- b. inadequate,
Deleted Following a Rule 27 (1)(e)(i) Submission
- c. not in the patients' best interests,
Deleted Following a Rule 27 (1)(e)(i) Submission
- d. likely to bring the medical profession into disrepute;
Deleted Following a Rule 27 (1)(e)(i) Submission

And that in relation to the facts alleged you have been guilty of serious professional misconduct. "Not Guilty of Serious Professional Misconduct

Determination on Rule 27 (1)(e) (i) and (ii) Application:
The Panel would at the outset announce that Dr Southall is Not Guilty of Serious Professional Misconduct.

Ms O'Rourke: The Panel has given detailed consideration to your submissions made on behalf of Dr Southall under Rule 27 (1)(e)(i) and (ii) of The General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988. It has accepted the advice given by the Legal Assessor.

The Panel notes that you have already admitted the following allegations on behalf of Dr Southall: 1, 5, the stem of 8 (as amended) and the stem of 9. The Panel has recorded that these are admitted and found proved.

Ms Sullivan, on behalf of the General Medical Council and the Complainants (hereafter referred to collectively as the 'GMC') withdrew allegations 3b, 4, 10 in its entirety, 12a, 12c, 12e and 13 in its entirety. These have now been deleted.

THE LEGAL TEST

You referred the Panel to the case of R v Galbraith 73 Cr App R 124.

"1. If there is no evidence that the crime alleged has been committed by the defendant, there is no difficulty. The judge will of course stop the case.

2. The difficulty arises where there is some evidence but it is of a tenuous character, for example, because of inherent weakness or vagueness or because it is inconsistent with other evidence.

a) Where the judge comes to the conclusion that the prosecution evidence, taken at its highest, is such that a jury properly directed could not properly convict upon it, it is his duty, upon a submission being made, to stop the case.

b) Where however the prosecution evidence is such that its strength or weakness depends on the view to be taken of a witness's reliability, or other matters which are generally speaking within the province of the jury and where, on one possible view of the facts, there is evidence upon which a jury can properly come to the conclusion that the defendant is guilty, then the judge should allow the matter to be tried by the jury."

The Panel was also referred to the case of *R v Shippey* [1988] Crim LR 767, where Turner J held that the requirement to take the prosecution evidence at its highest did not mean "aÅsout all the plums and leaving the duff behind." It was submitted that, in considering any particular allegation against Dr Southall, the Panel must take account of all the relevant evidence presented and not just those elements that go to support the GMC case. In this context you have invited the Panel to have regard to a variety of factors which you submit should affect its evaluation of evidence given by Mr and Mrs A, Dr B, Professor C and Dr D.

Central to the submissions which have been made to the Panel is that the events giving rise to the allegations against Dr Southall occurred between 1989 and 1993 in the context of a research study into the effectiveness of Continuous Negative Extra-Thoracic Pressure (CNEP) in the treatment of premature babies with respiratory distress syndrome. Given the lapse of time, it is submitted, first, that the Panel is entitled to regard contemporaneous documents, compiled at a time when proceedings were not contemplated, as more reliable than recollection many years after the event. Secondly, most, if not all, witnesses have struggled to recollect the fine detail of this case or the state of medical practice at the relevant time. Thirdly, the Panel must also recognise that there will have been at that time considerable variance in practice regarding randomised trials and acceptable standards. The advice and guidance to Ethics Committees were in the process of developing and there has been an assimilation of improvements in research practice over the last twenty years. It is further submitted that there is a real danger that these practitioners might be judged by the standards of 2008 rather than by the standards of the time.

LEGAL ADVICE

The Legal Assessor advised that the correct test at this stage is not whether the Panel itself believes the witnesses but only whether they are capable of belief.

He advised the Panel to consider in respect of each witness who had been called as an expert whether the evidence which he or she gave was within their relevant area of expertise and whether the witness had complied with the duties of an expert.

The Legal Assessor reminded the Panel of the passage from the oft-cited case of *The Ikarian Reefer*, [1993] 2 Lloyd's Rep 68, which is itself mirrored in various rules in both criminal and civil procedure that:

“prole of an expert is to provide independent assistance to the court by way of objective unbiased opinion in relation to matters within his expertise. An expert witness in the High Court should never assume the role of an advocate”.

He also drew attention to the decision of the High Court in the case of *Liverpool Roman Catholic Archdiocesan Trust v David Goldberg QC* [2001] EWHC Ch 396, in which the proposed expert was a good friend of the defendant, on whose behalf he gave evidence. The witness admitted that “ppersonal sympathies are engaged to a greater degree than would probably be normal with an expert witness” and the judge decided that this admission rendered the evidence unacceptable as the evidence of an expert on the ground of public policy that justice must be seen to be done as well as done. In light of the challenge to Dr D’s independence and objectivity, the Legal Assessor advised that, even if the Panel took an adverse view of him in this respect, it should not simply ignore his evidence. It might however find some guidance from that case as to the weight which it should attach to his evidence.

He also advised the Panel to consider whether those who were called to give expert evidence had applied the correct standard. He made clear that the standard to be applied is the standard which prevailed at the time of the relevant events.

THE PANEL'S APPROACH

Before turning to address the specific allegations against Dr Southall, the Panel wishes to make a number of general comments about its approach to your submission.

5. This hearing has involved allegations not only against Dr Southall, but also against Dr Andrew Spencer and Dr Martin Samuels based on their joint involvement in the CNEP Trial. Whilst the Panel has considered the case of each doctor separately, it has taken into account, so far as relevant to Dr Southall, both your submissions and those made on behalf of the other two doctors.

6. At the start of the hearing, the Panel rejected applications by Dr Spencer and Dr Samuels that the proceedings should be stayed as an abuse of process on the ground of delay. The Panel determined that it remained possible to have a fair hearing notwithstanding the lapse of time because of the inherent safeguards in the process, including the right to make an application under Rule 27 1(e)(i) of the 1988 Rules. The Panel has recognised throughout the hearing and its evaluation of the submissions the possible impact of the lapse of time on the reliability of witness recollection. It also recognises that, over the years, there have been opportunities for relevant documents to have gone missing. An example of the potential for prejudice in this respect was the chance discovery at a late stage in the proceedings of a red plastic folder with documents relevant to the training of medical staff engaged in taking consent from parents.

7. The evidence adduced by the GMC included evidence from factual witnesses, namely parents of babies involved in the trial and some of the medical staff on the neonatal unit at the relevant time. In assessing the evidence of all these witnesses, the Panel has taken account of reliability of recollection and availability of documents referred to above. Amongst the parents who gave evidence were the complainants, Mr and Mrs A. You invited the Panel to conclude that Mr and Mrs A have both consistently told lies over the course of many years and in their evidence to the Panel. In her response, Ms Sullivan submitted that, whatever the Panel makes of the evidence of Mr and Mrs A, there can be no doubt that their motivation stems from an entirely natural and understandable need to know what happened to their two daughters, both of whom received CNEP treatment in the course of the trial and one of whom died, while the other now suffers from cerebral palsy. Mr and Mrs A have always believed, and may well continue to believe, that CNEP was the cause. Whilst the Panel understands the depth of their feelings in relation to what happened to their two children, the cause is no part of the allegations in this case. What has emerged from their extensive cross-examination by you is evidence that, over many years, they have been active in bringing the CNEP trial and what they see as its dangerous shortcomings to public attention. They have courted media attention and had contact with representatives of various pressure groups. They have participated in earlier inquiries and, significantly, they have sought to acquire a great deal of knowledge about the treatment of premature babies and the CNEP treatment. Insofar as they have given evidence about events at the time of the births of

their children, particularly as to their lack of knowledge of the trial and lack of informed consent, the possible impact of lapse of time and after-acquired knowledge is something which the Panel is bound to take into account when assessing the reliability of their recollections. The Panel is not however able to conclude on the evidence it has heard that either of them is dishonest.

8. The GMC has adduced evidence from three witnesses presented as experts, namely Dr B, Emeritus Consultant Paediatrician, Professor C, an academic medical statistician and Dr D, whose evidence related to medical ethics.

In relation to the evidence of the expert witnesses, Ms Sullivan acknowledged that there was conflicting evidence. She submitted however that this does not prevent the Panel from finding that there is a case to answer. She referred the Panel to the Judicial Studies Board direction on expert evidence, 'it is for the Panel to decide whose evidence and whose opinions, if any, it accepts. Indeed it does not even have to accept expert evidence.'

In the circumstances, the Panel thinks it right to record its impression of each of these witnesses. In relation to Dr B and Professor C, the Panel has no doubts about their independence. The Panel has been assisted by Dr B's obvious expertise in clinical matters, taking due account of his lack of experience in conducting randomised trials, to which you referred, and by Professor C's obvious expertise in statistics.

As to Dr D, the Panel does not think any reasonable Panel could safely rely on his opinion evidence, firstly because of considerable reservations whether he qualified as an expert due to the limited expertise he can demonstrate. He has little or no formal training in medical ethics. He is no longer registered as a medical practitioner and is subject to no form of professional regulation. Whilst he has published and broadcast extensively, little of this material has been subjected to peer review. Secondly, there are considerable reservations about his independence and objectivity. As he conceded in cross-examination, he has in the past seen and conducted himself as a supporter of the As, having been prepared to accept their version of events without challenge. Furthermore, he has until recently published articles in his Bulletin of Medical Ethics and been quoted in the media such as to demonstrate a deep animosity towards Dr Southall and, by association, towards the other doctors involved in these proceedings. A typical example can be found in the March 1999 edition of the Bulletin in which he wrote 'what would paediatric consultants in North Staffordshire have to do before the local NHS Trust would think it necessary to suspend them?' Insofar as Dr D was able to identify relevant national and international guidelines on conducting research trials, the Panel has taken these into account as appropriate.

5. Although it appears from the evidence that Dr Southall was at the Royal Brompton Hospital in London up until June 1992, it also appears from the evidence that he was the person who took the initiative for proposing this research trial into CNEP. He is named as a Responsible Investigator on the application which was submitted to the North Staffordshire Ethics Committee by Dr Spencer. The Panel considers there is evidence on which a Panel could

reasonably conclude that Dr Southall assumed the duties of a Responsible Investigator to which he was subject even though he was not based at North Staffordshire Hospital until June 1992.

THE ALLEGATIONS

In the light of your submissions, the Panel has considered the evidence that has been placed before it and, bearing in mind that the burden of proof ultimately rests on the GMC, has determined whether there is sufficient evidence in respect of each allegation on which a reasonable Panel could find that allegation proved to the required standard.

Allegation 2 – That Dr Southall applied to the North Staffordshire Ethics Committee for approval for the CNEP Trial

In relation to allegation 2, you submitted that there is no oral or documentary evidence to support the fact that Dr Southall applied to the Ethics Committee of North Staffordshire for approval of this particular trial. The application was made by Dr Spencer and signed by him. He submitted it as he was employed by North Staffordshire Hospital. You further submitted that the approval of the application was notified to Dr Spencer. You submitted that there is no evidence that Dr Southall saw the form or that he authorised his name to be put on it.

In the Panel's view, there is, as already stated, evidence on which a Panel could conclude that Dr Southall was the instigator of this research trial. From this, the Panel further considers there is evidence on which a Panel could conclude that he was a party to, and therefore shared responsibility for the application. In that respect, he could be said to have 'applied' for approval.

Allegation 3a – That the Application to the Ethics Committee for the CNEP Trial inaccurately described the procedures that would be applied to each patient.

In support of this allegation, the GMC rely on the application to the Ethics Committee signed by Dr Spencer as a Responsible Investigator in which the procedures to be applied are stated at paragraph 12 to include near infra-red spectroscopy (NIRS), intracranial pressure monitoring and Doppler ultrasound. It is contended that these were not used as part of the CNEP trial and that accordingly the application inaccurately described the procedures to be applied. Evidence was adduced that NIRS was a separate trial which commenced in February 1991 and was the subject of a separate application to the Ethics Committee. It is further contended that paragraph 13 is inaccurate because, if the procedures described in paragraph 12 were to be used, this would involve more instrumentation and not less as asserted in paragraph 13.

It has been submitted that the application was perfectly proper and that no doctor should be criticised for applying simply for permission to carry out proposed research only where clinically indicated. It has been suggested that

the medical members of the Ethics Committee would have appreciated that the proposed adjuncts to the study would occur only where clinically indicated.

The Panel notes that the only oral evidence came from Dr D who said that, if it was not designed to mislead then it was just "q€p". The Panel considers however, that the issue to be addressed is whether the application form was inaccurate at the time of submission. So far as paragraph 13 is concerned, the reference to 'less instrumentation' is clearly limited to the CNEP procedure and, taken on its own, there is evidence that this would involve less instrumentation than positive pressure ventilation. There is no evidence on the basis of which, even if the other procedures described in paragraph 12 were used, a Panel could find that the level of discomfort would be other than 'minimal'. The Panel has concluded that there is insufficient evidence on which an inaccuracy in paragraph 13 could be found proved. As to paragraph 12, the Panel does not think the mere fact that these procedures were not used when the trial started in April 1990 could justify an inference that there had been no intention to use them when the application was submitted in November 1989. For example, there is evidence to suggest the reason intracranial pressure monitoring was not done was that the probe could not be made to work.

Allegation 6 – Relates to a failure to report an adverse event (neck trauma) to the Ethics Committees

You submit that the expression ">Àtrauma "is incorrect, but whether described as "r * "or "Ú*~", and despite submissions that there is no definition of an adverse event, there is evidence, notably from Dr B and Dr E, on which a Panel could find that the neck damage sustained by a patient in the trial in Queen Charlotte's Hospital in February 1990 could be described as such. The Panel has noted the Royal College of Physicians Guidelines on the Practice of Ethics Committees, which were published in January 1990 and which suggest that Ethics Committees should tell applicants that they should report serious adverse events. It has also noted the Department of Health 'Red Book', (as to which evidence was adduced that it was published in around July 1991), which also suggests that Ethics Committees should require researchers to report any unusual or unexpected results.

It appears to the Panel from such guidance as may have been available at the relevant time that the onus was on Ethics Committees to require the reporting of adverse events and that there is considerable uncertainty from the evidence adduced as to the responsibility on investigators to initiate such reports in the absence of requirement by the Ethics Committee.

No evidence has been adduced that the North Staffordshire Ethics Committee imposed any requirement on Dr Southall to report adverse events.

Ms F, coordinator of the North Staffordshire Ethics Committee, gave evidence that there was no formal requirement for the reporting of serious incidents to

the Ethics Committee even in 1994. Ms F told the Panel how Ethics Committees have changed since the early 1990s.

Dr B stated that he would not have expected this one adverse incident, even though serious, to have been reported to the Ethics Committee. He would however have expected remedial changes to have been made to the equipment, which had been done.

Professor C told the Panel that in her experience adverse incidents at that time were not generally or routinely reported to Ethics Committees.

Dr D told the Panel that this was a serious adverse event which should have been reported to the Ethics Committees at both Hospitals involved in the trial. He further stated that it should have been included as a risk in the information to be given to future parents being consented for the trial. Given the view that the Panel has expressed about Dr D's evidence, it does not consider that his evidence could reasonably prevail over the other evidence so as to be capable of proving this allegation to the requisite standard.

The Panel does not consider that sufficient evidence has been adduced on which it could conclude that there was an obligation on Dr Southall to report this adverse event (allegation 6a) from which it would follow that there could have been no failure on his part to do so (allegation 6b).

Allegation 7 – Relates to two changes to the trial scoring system not having been reported to the Ethics Committee

There is evidence on which the Panel could find that the trial protocol for which Dr Southall had responsibility as a Responsible Investigator was changed through two adjustments to the scoring system, namely scoring patients at 56 days of age rather than at discharge home and excluding retinopathy of prematurity from the scoring system.

It is submitted that the changes made no difference to the length of the trial or its efficacy and that there is no evidence from a member of the Ethics Committee that Dr Southall was in breach of local Ethics Committee guidance.

The Panel notes the evidence of Dr B who stated that, unless the rules of the particular Committee required otherwise, he did not think it was necessary to report back to the Ethics Committee on every single change if it did not materially affect the type of study that was being carried out. His view was that the two changes proposed on 15 May 1990 were logical and did not affect the trial in any way, other than making it more sensible to have a finishing time, which in his opinion was a good idea. Dr B also thought that the second change, about not including retinopathy, was sensible because there were no cases anyway. Notification was only necessary if a major change to the Trial was being proposed.

Dr E also agreed that the changes were minor. On 15 May, he wrote to Dr Spencer notifying him of the changes to the protocol and explaining the reasons for them. He ended his letter by saying 'you may feel that you wish to inform your Ethics Committee of these changes.' Although he could not be certain, Dr E believes that he would have discussed the content of this letter with Dr Southall before sending it to Dr Spencer. It is clear that Dr E did not believe that it was mandatory to report these changes.

Professor C too thought it unnecessary to report every single change back to the Ethics Committee.

Dr D gave evidence that the changes should have been reported to the Ethics Committee, as even in 1990 some Ethics Committees required notice of even minor changes, although others were more relaxed about this. He accepted that the reporting of minor changes was not a universal practice.

No evidence has been adduced that the North Staffordshire Ethics Committee had made any requirement at any stage during the trial that changes should be notified. Ms F gave evidence that, at least by 1994, changes were generally discussed with the Chairman of the Committee who would then decide whether they needed to go to the Committee. No evidence has been adduced, nor after such a length of time could such evidence be reliably adduced, of the existence or lack of such discussion.

No evidence has been adduced that there were any guidelines in operation at the time dealing with reported changes to trial protocols.

Given the uncertainty apparent from the evidence which has been adduced, no Panel could reasonably find proved to the required standard that Dr Southall should have reported these changes to the Ethics Committee (allegation 7a). It follows that there could have been no failure on his part to do so (allegation 7b).

Allegation 8 – Relates to a change to the trial protocol by the introduction of artificial surfactant not being reported to the Ethics Committee

In relation to the introduction of artificial surfactant, Dr B stated that this was a “*h” change in the trial and he had some concern about the possible impact on the matching of babies in the trial. Dr B stated that surfactant had been shown to be a successful way of treating hyaline membrane disease and that it would have been unethical not to give it to babies where it was clinically indicated. His preference would have been to give surfactant to both matched babies even if not clinically indicated for one of them, although he recognised that this would have been outside the regional health authority policy which had mandated the use of surfactant in appropriate cases throughout the West Midlands.

Dr B suggested that this was a change which might properly have been reported to the Ethics Committee, but once again he said that this would depend on the rules of the Ethics Committee at that time.

In relation to surfactant, Dr D stated this should have been reported. He went on to say, “I would have expected it to be reported, but, of course, it would depend on what the ethics committee itself was giving in advice to the investigators”.

In the Panel's view, the evidence of Professor C and Ms F has the same significance as in relation to the previous allegation.

Once again, no evidence has been adduced that the North Staffordshire Ethics Committee had made any requirement at any stage during the trial that changes should be notified. The Panel thinks that this is significant because, although it is unclear whether the Department of Health's Red Book had been published by July/August 1991, the guidance in the Red Book puts the onus on the Committee to require the Investigator to notify significant proposed deviations from the original protocol.

In relation to Ms F's evidence, Ms Sullivan submits that there is no documentation to suggest that there was any communication, either in writing or orally, with the Chairman of the Ethics Committee in relation to this and other changes to the protocol. In the Panel's view, this is a specific example of a situation in which the Panel should have regard to the effect of lapse of time on the fairness of the proceedings. The Panel does not think that it could be fair either to infer, from the absence of documentation many years later, that no such communication occurred or to expect that individuals could remember any such communication.

Given the uncertainty apparent from the evidence which has been adduced, no Panel could reasonably find proved to the required standard that Dr Southall should have reported this change to the Ethics Committee (allegation 8a). It follows that there could have been no failure on his part to do so (allegation 8b).

Allegation 9 – Relates to a change to the trial protocol by amending the exclusion criteria not being reported to the Ethics Committee

For substantially the same reasons as those given in respect of allegations 7 and 8, no Panel could reasonably find proved to the required standard that Dr Southall should have reported this change to the Ethics Committee (allegation 9a). It follows that there could have been no failure on his part to do so (allegation 9b).

Allegation 11 – Relates to the failure to ensure that appropriate procedures were in place to obtain informed parental consent.

There is evidence on which the Panel could find that Dr Southall was a Responsible Investigator and that he had an obligation to ensure that there were appropriate procedures in place to obtain informed parental consent to the participation of their children in the CNEP trial, including responsibility for the content of the Parent Information Leaflet. The Panel accepts that, during the period when he was working in London, he would have had less control than Dr Spencer over the day to day running of the trial. The Panel has been reminded by a number of doctors who gave evidence that obtaining informed consent is an essential element of good medical practice. The process was affected in this case, first because of the complications inherent in explaining a randomised trial and secondly, because the trial required that consent should be sought at a difficult and emotional time for the parents involved. The doctors at the hospital have told the Panel that, at the time, they were working in a well run neonatal unit. They believed themselves to have been well trained and to be well supported by their senior colleagues.

Allegation 11a – Relates to inappropriate delegation of consent-taking to too many different medical and nursing staff.

The Panel notes that the allegation does not suggest that delegation of consent-taking was inappropriate in itself, notwithstanding Dr D's evidence to the contrary based on his understanding of the declarations and guidelines in operation at the time. He particularly based his opinion on the terms of the Nuremberg Code and the 1975 Helsinki Declaration. In addition to the Panel's view of Dr D's evidence, it seems to the Panel that later guidance, for example the Proposed International Guidelines of the World Health Organisation (1982), does contemplate delegation of consent taking to be acceptable in research trials. The Royal College of Physicians report (January 1990) states 'where research activity will be delegated by the Investigator the Ethics Committee should be satisfied that the Investigator will delegate only to individuals who have the necessary skills and experience.'

Dr E told the Panel that he personally did most of the consenting at Queen Charlotte's Hospital. He was given specific training by Dr Southall of a nature suggesting that Dr Southall took the consenting process seriously. Given that Dr E was a full-time Research Fellow who was also intending to submit an MD Thesis based on the CNEP trial, the Panel can understand why he would

have been so involved in taking consent. The Panel does not think however that it could infer from the practice at Queen Charlotte's Hospital a requirement that a single person should have taken consent at North Staffordshire.

Evidence has been adduced, from an audit conducted by Dr Southall, that over the 42 month duration of the trial, 34 members of staff at North Staffordshire were involved in taking consent. These included twelve registrars, one research fellow, 18 senior house officers, two consultants and one clinical nurse specialist (who took consent in one case). At any given time, because of the rotation of staff, it is likely that no more than about half a dozen doctors would have been involved in consent-taking.

Dr B told the Panel that, on a busy neonatal unit dealing with the clinical care of very many sick babies, some delegation of consent-taking would have been inevitable. Recognising that this had to be done responsibly, he said "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."

It appears to the Panel that proof of an allegation that consent-taking had been delegated to too many people would depend on evidence that those to whom the task was delegated were insufficiently trained, with the consequence that there were systemic deficiencies in the consenting process.

As already mentioned, the Panel has heard evidence from a number of doctors who considered that they had been fully trained in all aspects of the CNEP trial, including consent-taking – training in which Dr Spencer, Ms G, Clinical Nurse Specialist, and indeed Dr Southall had been involved. The doctors had an imprecise recollection of how they took consent generally and had no recollection of the specific cases of the parents who gave evidence. However, they variously said that they would have explained the trial appropriately, that they would have taken consent only from people in a fit state to give it, that they were aware of written documentation available for the parents and that they would have told the parents that they were free to withdraw their child from the trial at any stage.

In addition to the evidence of the doctors, the Panel has heard evidence from 13 parents, including Mr and Mrs A, about their experiences of the consent-taking process in relation to nine children. One of these parents has a clear recollection that every aspect of good consent-taking was covered by the doctor concerned. Most of the others initially spoke of some aspects being missed, particularly in relation to the provision of written information. They were aware that their children were involved in a trial, although their understanding of the randomisation process was far from perfect. As to this, the Panel was told by Dr B and Dr P that paediatricians frequently experience situations in which parents quickly forget explanations which they have been given and that the existence of this problem is supported by research. These parents readily conceded in cross-examination that they had difficulty recollecting events so long ago and, on being shown the information leaflet,

conceded that it looked familiar. They also told the Panel that the nurses on the unit were caring, informative and very willing to answer questions.

Mr and Mrs A are however clear in their recollection that they did not give consent to their children participating in the trial. In respect of patient 7, Mr A agrees that he signed a consent form, but he did not read it and did not understand that his child was to be entered into a trial. In respect of patient 6, Mrs A agrees that she was told by a doctor that her child was to be given CNEP treatment, but she did not understand that this was part of a trial and did not sign any consent form for it. When shown the consent form purporting to be signed by her, she told the Panel that she “ñnot know how they did that”. Although, in cross-examination, she accepted the possibility of having forgotten, it is apparent that she does not believe that. To her mind, the position is either that her signature was forged or that she did sign it, but at a time when she was not fit to do so. A third parent also told the Panel that she had not signed a consent form or been told that her child was to be part of a trial. She too raised the possibility of her signature having been forged, although she agreed in evidence that it could be hers and that she may at the time have been “just not in this world” because of the ongoing effect of a general anaesthetic. The Panel notes that forgery, if it occurred, would carry with it the implication that medical and nursing records were later falsified.

The Panel is bound to take into account the impact that the lapse of time may have on the reliability of recollections of the parents whose evidence might support an allegation that they did not give fully informed consent. No Panel could ignore the evidence of the doctors that they would have taken consent in the proper fashion. Given the lapse of time, the difficulties of precise recollection, the stressful circumstances at the time of the premature birth of a baby with respiratory difficulties and the inconsistencies in the available evidence, it could not be proved to the required standard that consent was not properly taken from those parents who suggested otherwise.

Even if it were capable of proof that consent was not properly taken in respect of eight children, the Panel has been advised that it must not speculate as to what evidence might have been adduced in respect of other babies in the trial. Signed consent forms exist for all 224 babies in the trial at Stoke. The Panel is also aware that a number of parents declined to give consent, which may be some indication that an important aspect of consent-taking was in place. Proof that delegation had been extended to too many people would depend on an inference from the available evidence that there was a systemic failure in the management of the consent taking process for which Dr Southall could be held responsible. The Panel does not consider that such an inference could properly be drawn.

Allegation 11b – Relates to the failure to provide adequate training to those taking consent for the Trial.

By the same process of reasoning identified above in relation to allegation 11a, the Panel does not consider that this allegation is capable of proof to the required standard.

Allegation 11c - Relates to misrepresentation in the Parent Information Leaflet.

The alleged misrepresentation is that the CNEP technique had been shown to be safe. It was submitted that misrepresentation is a serious allegation and must denote a reckless or deliberate attempt to mislead, which is shown to be absent in this case because the doctors genuinely believed that CNEP had been shown to be safe. This belief is supported by reference to an earlier trial in which CNEP was used and which had been the subject of research papers, including one published in 1989 by Dr Southall and Dr Samuels. The Panel considers however that the effect on parents who read the leaflets falls to be considered and that an innocent misstatement of the position is capable of being described as a misrepresentation.

Dr B gave evidence that there was nothing in the medical literature that he had read to suggest that CNEP was not a safe and effective treatment. Although correct that most babies in earlier trials had been older, Dr J confirmed that the unit at Stoke had had experience of CNEP before the trial with premature babies as young as 28 weeks. In this context, Dr B said "the studies that were quoted I think by Professor Southall were mainly bronchiolitis ...x.of the children may have been premature at the time they were using it ...óit 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." Ms Sullivan submitted that, although Dr B thought that there was evidence in the papers presented to him that CNEP was safe, the Panel should nonetheless bear in mind that, in most of the previous trials, the babies were bigger and the tank used would not have been the same. She relied on the evidence of Dr E that work done previously by Dr Southall and Dr Samuels, using the modified CNEP chamber, had largely related to older infants and had not itself been part of a controlled trial. Ms Sullivan went on to refer to the incidents of neck trauma at Queen Charlotte's Hospital and submitted that such incidents called into question whether CNEP could continue thereafter to be described as having been shown to be safe. Ms Sullivan also referred the Panel to the 1996 paper, co-authored by all three doctors after the trial with which this Panel is concerned had been completed: 'Further study is warranted to determine the value and safety of CNEP in reducing the incidence of chronic lung disease of prematurity.' She submitted that even at that stage it would have been wrong to say that CNEP had been shown to be safe.

The Panel's attention was drawn to the corresponding written information given to parents at Queen Charlotte's Hospital which said that earlier studies had not shown any harmful effects from the use of CNEP. Insofar as criticism is said to rest on the fact that earlier studies involved older babies, it seems to

the Panel that “to be safe” and “not shown any harmful effects” could be regarded as a distinction without a difference.

The Panel takes the reference to the technique having been shown to be safe as an element of a clinician’s responsibility to inform patients about any risk associated with the procedure to which they are being asked to consent. It recognises that, in the early 1990’s, the accepted standard was for patients to be given less information than they would be given now and the leaflet is to be judged against the standards of the time. ‘Safety’ is not an absolute concept and the interpretation of the word must involve a degree of judgement on the part of both the writer and the reader. There is no evidence that use of the word ‘Safe’ in the leaflet concealed the existence of a known risk. As to whether there was an innocent misrepresentation, the leaflet might nowadays be differently worded. In light of Dr B’s evidence, particularly that concerning the earlier trials, a Panel could not find proved to the requisite standard that it was a misrepresentation to say that the CNEP technique had been shown to be safe.

The suggestion that the two incidents of neck trauma should have brought about a revision to the information leaflet was put to Dr B for his comment. His view was “it would not occur to me if I was 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.” In the light of this evidence, a Panel could not reasonably conclude that the incidents of neck trauma dictated the need for revision to the information leaflet.

Allegation 12 – relates to the Scoring System

Allegation 12b – That Dr Southall failed to ensure that the scores were allocated correctly

You submit that there is no evidence to support the allegation because the system was that the data sheets were sent from the hospital to a statistician who then entered them onto a graph and into a database. There is no evidence that Dr Southall failed to ensure that they were allocated correctly.

Evidence has been adduced that scores were allocated through completion of a score sheet for each baby in the trial by Ms G, the clinical nurse specialist. Evidence has also been adduced that, on completion, the score sheets were sent directly to Mr H. No evidence has been adduced that Dr Southall either did see or should have seen the score sheets before they were sent to Mr H.

There is evidence on which a Panel could conclude that Dr Southall was a responsible Investigator in the CNEP trial and as such, he had an obligation to ensure that appropriate mechanisms were in place to ensure Ms G would be appropriately instructed in the allocation of scores and the completion of the score sheets.

In support of this allegation, the GMC rely on three strands of evidence:

First, that the score sheets and data collection sheets for patients 7 and 14 record details of ultrasound scans even though there is nothing within the clinical records to indicate that scans had been undertaken. Dr B said in evidence that the scans themselves might have dropped out of the notes, but he would have expected some reference to them in the clinical records. It is a necessary implication that, if scans were not in fact undertaken, Ms G either mistakenly or by design made inaccurate data entries. Taking into account once again the lapse of time and the risk of missing documentation, a Panel could not reasonably conclude that the scans were not in fact done. Even if they were not, a Panel could not then reasonably go on to conclude that this was a managerial failure for which Dr Southall could be held responsible.

Secondly, it is said that patient 6 was allocated 20 points for having no abnormality, an allocation which on the evidence appears to have been made on the basis of ultrasound scans undertaken on 22 and 29 December 1992. No scan appears to have been undertaken on patient 6's discharge from hospital as the trial protocol required. No Panel could reasonably conclude either that this was other than an honest error by Ms G or that it was an error for which Dr Southall could be held responsible.

Thirdly, evidence has been adduced that an error in scoring was made in respect of 25 babies who were allocated 40 points for having no brain abnormality when the maximum score should have been 20. The Panel notes that all these errors were corrected by Mr H who was responsible for collating the data, which is some indication that the scoring system was itself effectively administered. There is accordingly evidence on which a Panel could conclude that Ms G misunderstood how to score those babies with no

brain abnormality. Proof of the allegation in this respect against Dr Southall would depend on evidence that the mechanisms for ensuring that Ms G would be appropriately instructed were inadequate or an inference to that effect. There has been no direct evidence about this. In all other respects, Ms G appears to have allocated scores competently. It is possible that, despite careful instruction, she misunderstood one element of what she had to do. In the circumstances, a Panel could not reasonably draw an inference adverse to Dr Southall.

Allegation 12d – That Dr Southall failed to ensure that there was an appropriate method of scoring

There is evidence on which a Panel could conclude that Dr Southall was a Responsible Investigator, that he participated in the design of the scoring system and that he had a responsibility to ensure that the method of scoring was appropriate.

Dr E told the Panel that the scoring system was developed by six paediatricians, including Dr Southall, and the statistician, Mr H. The Panel has heard evidence that the purpose of the scoring system was to provide information as to when the trial should be stopped. The criticism which is made against the system is that five babies who died were given higher scores than their paired counterparts who lived.

Both Professor C and Dr B expressed their concerns at this; indeed Professor C's description of her concern led to her being challenged in cross-examination by you that she failed to appreciate the clinical reasoning of the doctors, supported by Mr H, for using this scoring system. The Panel notes however that Professor C regards the design of the trial and the scoring system to be good in all other respects, certainly for its time and maybe even by today's standards.

In the Panel's view, the preference which Professor C and Dr B may have for a different method of scoring has limited relevance, because both agreed that the system in place was wholly effective as a tool to ensure that the trial was stopped at the right time. That being the case, there is no evidence on which a Panel could reasonably conclude that the method of scoring was inappropriate to achieve the required statistical outcome.

The essential concern expressed by both Professor C and Dr B was that the system was not appropriate on ethical grounds because the parents of dead babies who had been given higher scores than live ones could be distressed as a result. The Panel's attention was drawn to the Royal College of Physicians Report published in January 1990 which says that 'it is good practice to inform participants of the outcome of research in broad terms...the provisions of the Data Protection Act permit patients to demand to be informed about any information relating to them which is kept in any automated record system.' In the Panel's view, informing participants of the outcome of research in broad terms would not include the provision of raw

data. Furthermore, a Data Protection Act request by one parent would not entitle them to information about their baby's matched pair. The potential for distress was therefore limited or non-existent. For these reasons, a Panel could not reasonably conclude that those responsible in 1990 for ensuring an appropriate method of scoring were in any way at fault on ethical grounds for choosing the system that they did.

Allegation 14

In light of the Panel's determination in respect of allegations 3, 6, 7, 8, 9, 11 and 12, there is no sufficient evidence of any action by Dr Southall which could be found to be inappropriate, inadequate, not in the patients' best interests or likely to bring the medical profession into disrepute.

The Panel has concluded that the GMC has not produced sufficient evidence that would enable it to be satisfied that the allegations contained in allegations 3a, 6a, 6b, 7a, 7b, 8a, 8b, 9a, 9b, the stem of 11, 11a, 11b, 11c, 11d, 12b, 12d, 14a, 14b, 14c and 14d could be proved to the requisite standard. It has therefore determined to accede to your submission under Rule 27 (1)(e)(i) as outlined above and accordingly, those allegations have now been deleted.

SERIOUS PROFESSIONAL MISCONDUCT

The Panel then went on to consider, under Rule 27 (1)(e)(ii), whether in respect of any remaining allegations, the facts of which evidence has been adduced or which have been admitted are insufficient to support a finding of serious professional misconduct.

The Panel notes that the only allegations that remain as admitted or capable of proof contain nothing which could amount to criticism of Dr Southall's role as a Responsible Investigator in the CNEP trial. It follows that your submission under Rule 27 (1)(e)(ii) is upheld.

CONCLUSION

Having upheld your submissions, the Panel finds that Dr Southall is not guilty of serious professional misconduct.

That concludes this case".

FITNESS TO PRACTISE PANEL

11 – 16 AUGUST & 20 – 21 SEPTEMBER 2008

7th Floor, St James's Buildings, 79 Oxford Street, Manchester, M1 6FQ

Name of Respondent Doctor: Dr David SOUTHALL

Registered Qualifications: MRCS 1971 Royal College of Surgeons of
England

Area of Registered Address: Staffordshire

Registration Number: 1491739

Type of Case: Review case of impairment by reason of: misconduct.

Panel Members: Mr A Reid, Chairman (Lay)
Ms V Atkinson (Lay)
Dr L Linton (Medical)

Legal Assessor: Mrs S Breach

Secretary to the Panel: Miss L Meads

Representation:

GMC: Mr R Tyson, Counsel, instructed by Field Fisher Waterhouse Solicitors,
represents the General Medical Council.

Doctor: Dr Southall is present and is represented by Ms M O'Rourke,
Counsel, instructed by Hempsons Solicitors.

Determination on impaired fitness to practise

Dr Southall: At your hearing before the Professional Conduct Committee (PCC) on 6~August 2004, the Committee found that, in November 1999, C was convicted of the murder of two of her children, B and D. On or about 27 April 2000 you watched the "n0÷Àó "programme about the C case and, as a result, contacted the Child Protection Unit of the Staffordshire Police to voice concerns about how the abuse of B and D had occurred. On 2 June 2000 you met Detective Inspector F of the Cheshire Constabulary, the senior investigating officer into the deaths of B and D, and told him that you considered that E, C's husband, had deliberately suffocated B prior to his eventual death and was implicated in the death of D. You raised concerns about E's access to, and the safety of, the third child, Child A.

At that time, you were not connected with the case but made it clear that you were a consultant paediatrician with considerable experience of life threatening child abuse, and that you were suspended from your duties by your employers, the North Staffordshire Hospital NHS Trust.

You relied on the contents of the television programme "n0+Áó "as the principal factual source for your concerns and you presented as fact a theory about the case underpinned by your own research. The PCC found your actions in doing so were precipitate and irresponsible.

On 30 August 2000 you produced a report at the request of Forshaws Solicitors representing Child A. At the time, you did not have any access to the case papers, medical records, laboratory investigations, post-mortem records, medical reports or x-rays. You had not interviewed either E or C. Your report concluded that it was extremely likely, if not certain, that E had suffocated B and you remained convinced that Child A was unsafe in the hands of E. Further, your report implied that E was responsible for the deaths of B and D. It contained no caveat to the effect that its conclusions were based upon the limited information about the case known to you. You declined an opportunity to place such a caveat in your report, stating that it was likely beyond reasonable doubt that E was responsible for the deaths of B and D. The PCC found that your actions were individually and/or collectively inappropriate, irresponsible, misleading and an abuse of your professional position.

The PCC found you guilty of serious professional misconduct and determined to impose one condition on your registration for a period of three years. The condition imposed was that you must not engage in any aspect of Child Protection work either within the NHS (Category I) or outside it (Category II).

The Council for the Regulation of Healthcare Professionals (CRHP) appealed the decision of the PCC and, on 14 April 2005, the High Court allowed the appeal to a limited extent. Collins J ruled that the PCC's decision to impose conditions on your registration was not unduly lenient. However, the PCC was unduly lenient in failing to direct that a resumed hearing would take place at the end of three years. In addition, Collins J ruled that the condition imposed was not tightly enough drawn to prevent any involvement by you in child protection work. An Order, which was agreed between the parties, was substituted for the PCC's original decision. The principle terms were that: the PCC's condition would remain in force from 7~September 2004 for a period of three years. In addition, you were to report any concerns on child protection issues (whether within or outside the NHS and whether clinical, research based or otherwise) to the most senior child protection doctor working for your employer/ the relevant local primary care trust as soon as possible. You were not to take any further steps or have any involvement whatsoever in relation to such concerns or initiate any communications with, or seek to influence in any way that child protection doctor/other person/body in relation to such concerns. You were required, every six months, to provide to the GMC details of any cases where you had reported your concerns. You were also required to inform any employer of the existence and terms of the conditions. It was directed that your case should be resumed at the end of the three year period of conditional registration.

On 23 July 2007 a Fitness to Practise Panel (applying the GMC's PPC and PCC

(Procedure) Rules 1988) resumed and determined that the period of conditional registration should be extended for a period of twelve months.

This Panel has comprehensively reviewed your case under the GMC (Fitness to Practise) Rules 2004. It has recognised that this is a review hearing and not a re-hearing of the original case.

The Panel has considered, under Rule~22~(f) of the Fitness to Practise Rules 2004, whether your fitness to practise is impaired by reason of misconduct and whether you have failed to comply with any requirement imposed on you as a condition of registration. Mr Tyson, on behalf of the General Medical Council (GMC), has stated that you have complied with all of the conditions imposed on your registration. Having received no evidence to the contrary, the Panel has determined that you have complied with all the conditions imposed.

In reaching its decision on impairment, the Panel has considered all the evidence before it including your own evidence. The Panel has had the benefit of hearing evidence from five expert witnesses in the field of child protection called on your behalf. These were:

Mr G, the Assistant Head of Legal Services with Nottinghamshire County Council;

Dr H, a Consultant Paediatrician;

Dr I, a Consultant Paediatrician;

Dr J, a Consultant Paediatrician, and

Dr K, a Consultant Paediatrician.

The Panel has also taken into account the submissions made by Mr Tyson and those made by Ms O'Rourke on your behalf.

Mr Tyson submitted that the seriousness of your conduct has not changed since 2004 and that the Panel should take this into account when considering impairment. At the end of his submissions, however, he stated that the GMC is neutral on the issue of impairment, and reminded the Panel that this decision is entirely a matter for the Panel exercising its own professional judgement.

Ms O'Rourke submitted that your fitness to practise is not impaired, that 8 years have elapsed since the events in question occurred and 4 years since the findings of the PCC, and that developments in paediatric practice since that time have changed perceptions of the seriousness of your actions in 2000.

The Panel has heard that, since the last review, you have resigned from your NHS locum consultant paediatrician post. You have continued to undertake some teaching in the field of child protection. You are now the Honorary Medical Director of Child Health Advocacy International where you work full time. Half of your time is spent in this country and half the time in other countries such as Pakistan, The Gambia, and Zambia. Your work includes writing programmes and developing aid programmes for maternity, neonatal

and child emergencies, and you are an Advanced Life Support Group instructor in paediatrics. You told the Panel that, in future, you hope to work in a supernumerary capacity doing maternity work in an NHS hospital to learn skills to help with your international work.

The Panel has considered the GMC's Indicative Sanctions Guidance (April 2005), in particular, in section 1, paragraph 11 it states:

"Neither the Act nor the Rules define what is meant by impaired fitness to practise but for the reasons explained below, it is clear that the GMC's role in relation to fitness to practise is to consider concerns which are so serious as to raise the question whether the doctor concerned should continue to practise either with restrictions on registration or at all."

Further at paragraph 32, it states:

"It is important that no doctor should be allowed to resume unrestricted practice following a period of conditional registration or suspension unless the panel can be certain that he or she is safe to do so ... in all cases where conditions have been imposed the panel will need to be reassured that the doctor is fit to resume practice either unrestricted or with conditions or further conditions. The panel will also need to satisfy itself that the doctor has fully appreciated the gravity of the offence, has not re-offended, and has maintained his or her skills and knowledge and that patients will not be placed at risk by resumption of practice or by the imposition of conditional registration."

The Panel has also considered the case of *Cohen v GMC* [2008] EWHC 581 (admin) in which Silber J stated

"... must be highly relevant in determining if a doctor's fitness to practise is impaired that first his or her conduct which led to the charge is easily remediable, second that it has been remedied and third that it is highly unlikely to be repeated."

The Panel endorsed the statement of the PCC in 2004 that there is a duty of care to raise child protection concerns in order to ensure the protection of children. In the context of 2008 this duty has been strengthened. As Mr G stated, referring to the case of JD, the current opinion of the Law Lords is

"... and other professionals should not be inhibited from expressing their opinions and putting forward information by some fear that they are going to suffer some complaint by an aggrieved parent."

Current GMC guidance "-18 years: guidance for all doctors" (2007) addresses this issue and states

"... will be able to justify raising a concern, even if it turns out to be groundless, if you have done so honestly, promptly, on the basis of reasonable belief, and through the appropriate channels."

Your first concern must be the safety of children and young people
...must be able to justify a decision not to share such a concern..."

The PCC in 2004 were critical of you for not interviewing E and C before submitting your report. They had heard the view of Professor L that it was important to do so. This Panel has heard from 4 Consultant Paediatricians who say that this is not current practice. Dr J stated

"see it as normal practice that you do not interview parents."
And Dr K stated

"...would be extremely rare to interview the parents where there are child protection concerns. ...It is just not something that is done nor indeed do I believe should be done. ... it is for the investigation authorities, that is police and social services, to do the interviews."

The Panel therefore accepts that your actions in this regard should not now be criticised.

The Panel found your evidence to be clear, cogent and reliable. You have acknowledged that you should have contacted your employer to inform her of your intentions and that, in future, you would also speak to colleagues before reporting your concerns.

The Panel has accepted your evidence that, whilst you were entitled to express your concerns and report your views, the language you used was "s bēa÷", "s ñá€" and "xstrong"; that you were wrong to present your report in the format you did; that you were wrong to use phrases such as "áhwcertain" and "¾h=reasonable doubt"; that you should have made clear the information on which your report was based, and should have indicated your lack of access to certain information. The Panel has noted your recognition that use of injudicious language can damage the message a paediatrician is trying to put across, and your concern and regret that this is what happened in this case. You have also told the Panel that you went further than you should have in reporting your concerns. You stated that in similar circumstances you would now raise your concerns and stop at that.

You have made various other expressions of regret but have not resiled from your view that the events in the hotel room could have indicated non accidental injury. The expert witnesses before this Panel have shared that view. Dr I stated

"would have thought very very strongly that this must be looked into very carefully indeed."

You have acknowledged that you have learnt a lot from these proceedings and that it will impact on all the work you do. You have expressed regret for the impact that the PCC findings have had on the profession, and remorse that your actions have contributed to the fear that now exists amongst paediatricians involved in child protection work.

The Panel considers that you have demonstrated considerable insight into your previous failings.

The Panel is mindful that 4 years have elapsed since the PCC hearing in July 2004 and that 8 years have passed since the events occurred. The Panel has determined that, although the PCC considered your actions serious in 2004, the Panel today, in the light of the evidence given to it by eminent paediatricians and your expressions of regret and remorse, considers that a finding of impairment is not justified.

The Panel is satisfied that you have kept up to date in the field of child protection.

The Panel has determined that your fitness to practise is not impaired.

The present conditions on your registration will expire on 16 December 2008. In the light of the Panel's findings and the submissions made by both Counsel before the hearing adjourned in August, the Panel has determined to revoke the conditions currently imposed on your registration with immediate effect.

That concludes this case.