EXHIBITS

Fitness To Practise Panel (PCC)
Dr Stephen Andrew SPENCER,
Dr David Patrick SOUTHALL and
Dr Martin Philip SAMUELS
8 May – 4 July 2008

GMC EXHIBITS:-

C1 – GMC Skeleton Argument on Abuse of Process Applications
C2 – Chronology
C3 – Case of R v Smolinski (2004)
C4 – Case of Henshalls v GMC (2005)
C5 – Case of Henshalls v GMC (2006)
C6 – Submissions on behalf of Drs Spencer + Samuels in the Court of Appeal
C7 – Panel Bundle 1
C8 – Panel Bundle 2
C9 – Panel Bundle 3
C10 – Panel Bundle 4
C11 – Panel Bundle 5
C12 – Pre- Op Care Checklist
C13 – [redacted] CV
C14 – [redacted] CV
C15 – [redacted] CV
C16 – Guidelines to aid Ethical Committees considering Research involving children
C17 – [redacted] CV
C18 – [redacted]
C19 – Head Scans and the CNEP Trial

DEFENCE EXHIBITS:-

D1 – Skeleton Argument on behalf of Dr Spencer - abuse of process and delay
D1A – Bundle of documents to support (Spencer) application
D1B – Bundle – (Spencer) correspondence
D1C – Bundle of letters from GMC to Dr Spencer
D1D – GMC Minutes – Case of Dr John Rogers
D2 – skeleton Argument on behalf of Dr Samuels – abuse of process
D2A – Bundle of documents to support (Samuels) application
D2B – Bundle – correspondence from GMC to Dr Samuels
D3 – Defendant's Summary of Grounds for Contesting the Claim
D4 – 5 Photos of CNEP Tank
D5 – [redacted]
D6 – Extract from BMJ – 19 Sept 1998
D7 – Nursing Notes
D8 – Patient Consent Form [redacted]
D9 – Letter to Trust from Staffordshire Police
D10 – High Court Henshall Judgement (2001)
D11 – [redacted] Medical Record
D12 – [redacted]

D13 – Controlled Trial of Continuous Negative External Pressure in the treatment of severe respiratory distress syndrome
D14 – Negative extrathoracic pressure in the treatment of respiratory failure in infants and young children
D15 – Continuous negative extrathoracic pressure in the treatment of bronchopulmonary dysplesia
D16 – Pulse oximeter and trancuteneous arterial oxygen measurements in neo-natal and paediatric intensive care
D17 – [redacted]
D18 – [redacted]
D19 – The Lancet Articles
D20 – 1986 Guidance – Research Ethics Committees
D21 – Dept of Health – Supervision of the Ethics of clinical research Investigations and Fetal Research
D22 – Doncaster Material

R. v SMOLINSKI

COURT OF APPEAL (The Lord Chief Justice (Lord Woolf), Mr Justice Aikens and Mr Justice Fulford): May 4, 2004

[2004] EWCA Crim. 1270; [2004] 2 Cr App R 40

Abuse of process; Appeals against conviction; Delay; Indecent assault; Stay of proceedings

H1 ABUSE OF PROCESS

Delay in prosecution

Guidance as to whether and when to make applications to have cases stayed on the basis of abuse of process where there has been delay

H2 The appellant was charged, *inter alia*, with offences of indecent assault upon two females aged six and seven. The offences were first reported to the police some 20 years later. The appellant denied that he had been guilty of the conduct alleged and an application was made on his behalf to stay the proceedings for abuse of process, the submission being that he could not receive a fair trial as a result of delay and that he would be prejudiced by lack of memory because of the time that had elapsed. The trial judge came to the conclusion that on the balance of probabilities it had not been shown that a fair trial was impossible. The appellant was convicted by a majority verdict of 10:2 on count 1 but the jury were unable to reach a verdict on counts 2–4, which were ordered to remain on the file. The appellant appealed.

H3 **Held,** allowing the appeal and quashing the conviction, that applications to stay proceedings based on abuse of process where there had been delay had become prevalent but should be discouraged. In cases of alleged sexual offences it was sometimes very difficult for young children to speak about such matters and therefore it was only many years later that the offences came to light. However, when a long time had elapsed, the court would expect that careful consideration would be given by the prosecution as to whether it was right to bring the prosecution at all. If, having considered the evidence to be called, and the witnesses having been interviewed on behalf of the prosecution, a decision was reached that the case should proceed, then in the normal way it was better not to make an application based on abuse of process. Unless the case was exceptional, the application would be unsuccessful. If an application were to be made to a judge, the best time for doing so was after any evidence had been called and for the judge then, having scrutinised the evidence with particular care, to come to a conclusion whether or not it was safe for the matter to be left to the jury. That was a particularly helpful course if there was a danger of

inconsistencies between the witnesses of the sort that; it was common ground, had occurred in this case. In relation to one girl the jury came to the conclusion that they were satisfied that the case had been made out; but in relation to the other girl they were not satisfied that the case had been made out in respect of the second count of the indictment. This was significant because the two girls had agreed that the appellant behaved in exactly the same way in relation to the subject matter of the first and the second count on the indictment in respect of each. In this case the Recorder had properly left the case to the jury and had properly summed up to the jury. It would not be right for the court to lay down the principle that where a particular period had elapsed (in this case 20 years), even though the complainant had given a reason for the delay, it was inevitably the case that the conviction would be unsafe. However, if there was an appeal where there had been a long period of delay and where the complainants were young the court would scrutinise the situation with particular care. Looking at this matter as a whole, bearing in mind that there were discrepancies and that the elder sister, until reminded by her younger sister, was apparently oblivious of what was alleged to have happened earlier, and also bearing in mind the conclusion which the jury reached on the first count but were unable to reach on the second count, this was a case where the appellant's conviction was unsafe.

H4 *Attorney General's Reference (No 1 of 1990)* (1992) 95 Cr.App.R. 296, [1992] Q.B. 630, CA, followed.

H5 (For abuse of process owing to delay, see *Archbold* 2004, paras 4–64a to 4–71 and 16–73.)

Appeal against conviction

H6 On June 27, 2003, in the Crown Court at Swindon (Mr Recorder Powles) the appellant, Mark Paul Smolinski, was convicted by a majority verdict of 10:2 of indecent assault upon a female (count 1). The jury were unable to reach a verdict on count 2, indecent assault upon a female and counts 3 and 4, gross indecency with a child. They were therefore discharged from delivering a verdict on those counts and the matters were ordered to remain on the file. The appellant was subsequently sentenced to a Community Rehabilitation Order for three years.

H7 The facts and grounds of appeal appear in the judgment of the Court.

H8 *Henry James* (assigned by the Registrar of Criminal Appeals) for the appellant. *Paul Grumbar* (instructed by the Crown Prosecution Service) Chippenham, for the Crown.

Lord Woolf C.J. delivered the judgment of the Court.

1 On June 27, 2003 in the Crown Court at Swindon, before Mr Recorder Powles, the appellant was convicted by a majority verdict of 10:2 of indecent assault upon a female (count 1). The jury were unable to reach a verdict on counts 2–4. They were therefore discharged from delivering a verdict on those counts and the mat-

ters were ordered to remain on the file. The appellant was subsequently sentenced to a Community Rehabilitation Order for three years. As he was convicted of a sexual offence to which Pt 1 of the Sex Offenders Act 1997 applies, the appellant was required to comply with s.2 of the Act: notification to the police for a period of five years. The appellant now appeals against conviction by leave of the single judge.

2 We have no transcripts available to us of the evidence which was given by the two complainants who were sisters, and who were respectively aged six and seven at the relevant time, but we have been assisted by the fact that counsel who appear before us today were the counsel who appeared at the trial.

3 The offences were alleged to have occurred some time between 1981 and 1983, but they were first reported to the police 20 years later, in September 2002. The appellant at the time of the offence was 16 years old. He baby-sat for the two girls, C and M, at their house on between three and six occasions over a period of a few months.

4 It was the prosecution's case, supported by both girls, that on one such occasion the appellant sat between them when they were wearing nightdresses and simultaneously played with their vaginas (count 1 in respect of C and count 2 in respect of M). The girls could not recall if they had underwear on beneath their nightdresses. There was no suggestion of any digital penetration.

5 The appellant's case was that the allegations were untrue. He denied that he had been guilty of the conduct alleged. However, when he was interviewed by the police he was not as adamant about his not having done anything of this nature as might be expected, notwithstanding the period of time which had elapsed.

6 An application was made by Mr James on behalf of the appellant to stay the proceedings for abuse of process. It was submitted that the appellant could not receive a fair trial as a result of delay and that he would be prejudiced by lack of memory because of the time that had elapsed.

7 The judge perfectly correctly, as is accepted, approached the matter in accordance with the decision of *Attorney General's Reference (No 1 of 1990)* (1992) 95 Cr.App.R. 296. He came to the conclusion that on the balance of probabilities it had not been shown that a fair trial was impossible.

8 The making of applications to have cases stayed where there has been delay on the basis of abuse of process has become prevalent. In making his application Mr James followed what has become the usual practice in cases of this nature. This Court does not criticise him for doing so. However, the Court questions whether it is helpful to make applications in relation to abuse of process before any evidence has been given by the complainants in a case of this nature. Clearly, having regard to the period of time which has elapsed, the court expects that careful consideration has been given by the prosecution as to whether it is right to bring the prosecution at all. If, having considered the evidence to be called, and the witnesses having been interviewed on behalf of the prosecution, a decision is reached that the case should proceed, then in the normal way we would suggest that it is better not to make an application based on abuse of process. It will take up the court's time unnecessarily. Unless the case is exceptional, the application will be unsuccessful. That was indicated by this Court in *R. v B* [2003] EWCA

Crim 319, [2003] 2 Cr.App.R. 197, which is also referred to in the current edition of Archbold. In that case this Court referred to the earlier decision, including *Attorney General's Reference (No 1 of 1990)* (1992) 95 Cr.App.R. 296, and suggested that the approach of Lord Lane C.J. in that case indicated the general position.

9 If an application is to be made to a judge, the best time for doing so is after any evidence has been called. That means that on the one hand the court has had an opportunity of seeing the witnesses, and, on the other hand the complainants have had to go through the ordeal of giving evidence. However, despite the latter point, which obviously is one of importance, it seems to us that on the whole it is preferable for the evidence to be called and for a judge then to make his decision as to whether the trial should proceed or whether the evidence is such that it would not be safe for a jury to convict. That is a particularly helpful course if there is a danger of inconsistencies between the witnesses — inconsistencies of the sort that it is common ground occurred here. However, as is pointed out by Mr Grumbar on behalf of the Crown, the Recorder who tried this case was very experienced. He gave an immaculate summing-up. He dealt with the application to which we have made reference in a perfectly appropriate manner. It is likely that if he thought this case was not one which it was safe for the jury to consider, he would have withdrawn it from them.

10 Although this was not stressed by Mr James, the matter that has weighed heaviest with this court in considering this appeal is the fact that in relation to one girl the jury came to the conclusion that they were satisfied that the case had been made out; but in relation to the other girl they were not satisfied that the case had been made out in respect of the second count of the indictment. This is significant because the one thing upon which the two girls were agreed was that the appellant behaved in exactly the same way in relation to the subject matter of the first and the second count on the indictment in respect of each. We find it difficult to see, if the jury accepted, for example, C's evidence, who was apparently the most adamant about the matter in relation to the count affecting her, and they were satisfied as to her, why they should not be satisfied with regard to her sister as well, particularly in view of the description which C gave. It is true with regard to counts 3 and 4, which alleged acts of gross indecency, that the girls' accounts differed, but in relation to counts 1 and 2 they were the same.

11 Looking at this case as a whole, we see the position as follows. We consider that it was proper for the Recorder to leave the case to the jury. He properly summed up to the jury. Questions as to whether witnesses are to be believed or not are essentially matters for the jury. If it had not been for the matter of the verdicts, to which we have referred, we would have found it difficult to interfere with the conviction which took place in this case. We do not think it is right for this Court to lay down the principle that because of the period which has elapsed (20 years) when the complainant has given a reason for the delay, it is inevitably the case that the convictions will be unsafe. However, where there has been a long period of delay such as existed in this case, and where the complainants are young, as they were here (six and seven respectively at the time matters happened), this Court should scrutinise convictions with particular care. Likewise, we consider

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that trial judges should scrutinise the evidence with particular care and come to a conclusion whether or not it is safe for the matter to be left to the jury.

12 In this case, looking at the matter as a whole, bearing in mind there are discrepancies, bearing in mind that the elder sister, until reminded by her younger sister, was apparently oblivious of what was alleged to have happened earlier, bearing in mind the conclusion which the jury came to on the first count but were unable to come to the same conclusion on the second count, that this is a case where the conviction is unsafe. Accordingly, we will therefore allow the appeal.

13 We hope we have made clear two things in the course of hearing this appeal. One is that we discourage applications based on abuse in cases of this sort. Secondly, where evidence is given after so many years, the court should exercise very careful scrutiny at the end of the evidence to see whether or not the case is safe to be left to jury. If there is an appeal, then this court will scrutinise the situation with care. We are certainly not indicating that it is not right to bring prosecutions in the appropriate circumstances merely because of the period that has elapsed. As this Court appreciates, it is sometimes very difficult for young children to speak about these matters and therefore it is only many years later that they come to light. Justice must be done of course to a defendant, but the court must also be mindful of the position of the alleged victims.

Appeal allowed.
Conviction quashed.

[2005] All ER (D) 190 (Dec)

R (on the application of Henshall) v General Medical Council

[2005] EWCA Civ 1520

C4

Court of Appeal, Civil Division

Auld, Sedley and Jonathan Parker LJJ

13 December 2005

Medical practitioner – Disciplinary proceedings – Preliminary Proceedings Committee of the General Medical Council – Whether committee entitled to refuse to place complaint before Professional Conduct Committee – General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988, SI 1988/2255, rr 11(2), 16.

Rule 11(2) of the of the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988, SI 1988/2255 provides, so far as is material 'When referring a case to the Professional Conduct Committee the Preliminary Proceedings Committee shall indicate the convictions, or the matters which in their opinion appear to raise a question whether the practitioner has committed serious professional misconduct, to be so referred and to form the basis of the charge or charges ... ' Rule 16 provides: 'Where the Committee have decided not to refer a case for inquiry no complainant, informant or practitioner shall have any right of access to any documents relating to the case submitted to the Council by any other person, nor shall the Committee be required by a complainant, informant, or practitioner to state reasons for their decision.'

In the early 1990s the three interested parties, DS, AS and MS, who were all registered medical practitioners, had been involved in a clinical trial of a treatment for premature babies with breathing difficulties, known as Continuous Negative Extrathorasic Pressure Ventilation (CNEP). The claimant had two premature babies, both of whom were included in the CNEP trial. The first child died 60 hours after her birth, and the second child was subsequently found to have cerebral palsy. The claimant complained to the General Medical Council (**GMC**) about the integrity of the trial and about the supervision and conduct of it at the hospital, alleging that each of the three doctors had been guilty of serious professional misconduct. The matter went before the **GMC's** Preliminary Proceedings Committee (PPC), whose role was to consider whether to refer the matter the Professional Conduct Committee (PCC) as appearing to raise a question whether the doctors had committed serious professional misconduct. The PPC did not have before it a report, the G report, on the design of various trials including the CNEP trial, but had an article published in the British Medical Journal (BMJ) which was highly critical of the G report. It also had a confidential report commissioned by the hospital, the H report, into 12 research programmes conducted by DS to determine whether any disciplinary action should be taken against him which, whilst expressing some concerns, was generally supportive of his and his colleagues' work. All three doctors responded to the complaints, but DS did so only on condition that his responses would not be disclosed to the claimant. The PPC refused disclosure to the claimant of DS's response because of his failure to give his consent, relying on r 16 of the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988. Having considered all the material before it, the PPC concluded that none of the complaints should be put before the PCC. The claimant sought permission to apply for **judicial review** of the PPC's decision but her application was refused. She appealed.

She submitted, inter alia, that the PPC's conduct had been unfair to her in refusing to disclose DS's response to their complaints; and that the PPC had uncritically accepted the views in the article in the BMJ without considering or considering adequately the G report.

The appeal would be allowed (Auld LJ dissenting).

(1) It was completely unacceptable to derive by implication from r 16 a general inhibition which, by enabling a practitioner to put in potentially contentious material in response and to deny sight of it to the complainant, was capable of stifling the individual's right to bring a tenable complaint to the attention of the PCC of the **GMC.** Somehow, therefore, the PPC had to operate r 16 fairly. The only way to do so was to recognise that there were two competing imperatives: the fact that r 16 would become ineffective to the extent (not necessarily a large one) that documents were disclosed by the PPC in the course of its work, and the fact that the PPC could not do its work fairly or therefore lawfully if significant material were able to be put in by practitioners and kept from the knowledge of complainants. The solution was to consider in each case what the practitioner had put in; to decide whether in fairness it was something the complainant should be able to respond to; and, if it was, to tell the practitioner that unless he or she agreed to the disclosure of the material it would be ignored by the PPC. In the instant case the PPC had erred in law in failing to appreciate that it

should take that approach to DS's response.

(3) The PPC had erred in accepting and giving weight to the article in the BMJ, and had gone beyond the limits of its function as laid down in r 11(2).

It was one thing to evaluate the available evidential material in order to determine whether in its opinion such material appeared to raise a question whether the practitioner had committed serious professional misconduct, but quite another to purport to resolve disputed factual issues. In so doing the PPC had trespassed on an area which was properly the province of the PCC, should the case be referred to it.

The only fair outcome was that the PPC should be reconstituted in order to do the job it had so far failed to do. It should make it clear first of all that, unless DS agreed to let the claimant see his submissions, if necessary on suitable undertakings, the submissions would be put aside. Secondly, it should act on the published literature only if, having considered the BMJ article alongside the G report, the H report and any other relevant material placed before it, it was satisfied that there was in sum no evidence capable of raising a question within s 11(2). It was not the PPC's task to evaluate conflicting professional views of issues raised by the complaint. Its final task was to apply, with whatever exegetic help it found useful, the test set by r 11 (2): whether the material advanced for and against the complaint raised a question whether one or more of the practitioners had committed serious professional misconduct.

R v The General Medical Council, ex p Toth and another [2000] All ER (D) 865 applied.

Philip Havers QC and Ian Wise (instructed by Irwin Mitchell) for the claimant.
Mark Shaw QC (instructed by Field Fisher Waterhouse) for the **GMC.**
Andrew Kennedy (instructed by Hempsons) for DS.
Mary O'Rourke (instructed by Radcliffes Le Brasseur) for AS and MS.

Kate O'Hanlon Barrister.

Judgment

[2005] EWCA Civ 1520

COURT OF APPEAL, CIVIL DIVISION

13 DECEMBER 2005

LORD JUSTICE AULD, LORD JUSTICE SEDLEY and LORD JUSTICE JONATHAN PARKER

JUDGMENT: APPROVED BY THE COURT FOR HANDING DOWN (SUBJECT TO EDITORIAL CORRECTIONS)

LORD JUSTICE AULD:

Introduction

1. This is an appeal and substantive hearing of an application by permission of Laws LJ of the appeal of Deborah Henshall against the refusal on 15th December 2004 by Pitchford J. of her application to claim **judicial review.**

2. *The application concerns complaints made by Mrs Henshall and her husband to the General Medical Council* ("the **GMC**") against three doctors in 1997 alleging serious professional misconduct by them in 1992. At all material times the disciplinary procedures governing such complaints were contained in a statutory scheme prescribed by the Medical Act 1983 ("the 1983 Act") and the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules 1988 ("the 1988 Rules"). Under that scheme, there were two preliminary stages to the consideration of a complaint, an initial check by a **GMC** "screener", largely as to formalities, and a second, somewhat more rigorous check, by the Preliminary Proceedings Committee ("the PPC"), as to whether they ought to refer the complaint referred to them by the screener to the Professional Conduct Committee ("the PCC"), for determination of the complaint. In November 2004 that three tier scheme was replaced by a two tier scheme by the General Medical Council (Fitness to Practise) Rules Order of Council 2004 ("the 2004 Order"). Since the decision under challenge in this case was made in February 2004, the old, not the new, scheme, governs it.

3. Mrs Henshall challenges a decision of the PPC of 26th February 2004, communicated to her and her

husband by letter of 12th March 2004, not to refer her complaints against three registered medical practitioners, Professor David Southall, Dr Martin Samuels and Dr Andrew Spencer to the PCC. If successful in that challenge she seeks referral of the matter straight to the PCC or remittal to the PPC or its nearest successor under the **GMC's** new statutory scheme.

4. In the early 1990s those doctors had been involved in a clinical trial of a treatment for premature babies with breathing difficulties at the North Staffordshire Maternity Hospital in Stoke ("the Hospital"). The treatment was known as Continuous Negative Extrathorasic Pressure Ventilation or 'CNEP'. Mrs Henshall had two premature babies both of whom were included in the CNEP trial. The first, Stacey, died 60 hours after her birth and the second, Sofie, was subsequently found to have cerebral palsy.

5. Mrs Henshall complains about the integrity of the CNEP trial, which was designed and established by Professor Southall and Dr Martin Samuels, and about the supervision and conduct of it at the hospital, for which Dr Spencer was responsible. She and her husband first complained in 1997, but the PPC did not make its decision until, as I have said, early 2004. In summary, the PPC concluded: 1) that the majority of the *complaints were unsupported by any evidence*; 2) *that the remainder had some evidential support, but* insufficient to indicate a real prospect of establishing them factually or of the emergence of further sufficient evidence to do so; and/or 3) that, such allegations that might be provable by existing or further evidence had no real prospect of amounting to serious professional misconduct.

The issues

6. The application raises the following issues:

> i) whether the PPC identified and applied the correct legal test in deciding not to refer Mr and Mrs Henshall's complaints to the PCC;
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> ii) whether the PPC wrongly declined to disclose to Mr and Mrs Henshall written responses to their complaints of Professor Southall communicated to the PPC; and
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> iii) whether the PPC wrongly relied in reaching its decision on an article in the British Medical Journal ("BMJ") by Dr Edmund Hey and Sir Iain Chalmers ("the *Hey & Chalmers Article*"), highly critical of a report commissioned by the NHS Executive by a panel headed by Professor Rob Griffiths ("the Griffiths Report").

The facts

7. In 1992 Mrs Henshall gave birth to her two daughters, Stacey and Sofie, at the North Staffordshire Royal Infirmary, Stacy on 12th February 1992, and Sofie, on 14th December 1992.

8. Both babies were born prematurely and received CNEP treatment as part of the clinical trial designed and overseen by Professor Southall, a consultant paediatrician. Dr Samuels, also a consultant paediatrician, had worked with Professor Southall on a protocol for the trial. Dr Spencer was the consultant paediatricial/neonatologist with clinical responsibility for children recruited to the CNEP trial in North Staffordshire and was also lead researcher at the North Staffordshire Maternity Hospital. The trial had been put before and approved by the local ethics committee.

9. Mr and Mrs Henshall claimed not to have known that their daughters had been given CNEP treatment until told a long time afterwards, in December 1996. As a result of that information, in May 1997 they complained to the **GMC** about the three doctors' involvement in and/or conduct of the trial treatment, alleging, in each case, serious professional misconduct. They maintained that the doctors should not have undertaken it, that they and other parents whose babies had been similarly treated had not had an opportunity to make an informed choice about it, in particular, they had not been told of the risks associated with it.

10. Mr and Mrs Henshall's complaints, which have been helpfully summarised by Mr Mark Shaw QC, counsel for the **GMC,** and Mr Andrew Kennedy, for Professor Southall, consisted of the following:

> 1) deception of the local ethics committee about the benefits and safety of the CNEP technique in order to secure approval and funding for the trial;
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> 2) performing unnecessary caesarean sections specifically in order to ensure an adequate supply of premature neonatal babies for the trial;

3) forging Mrs Henshall's signature on the consent forms for entering her daughters into the trial, her consent not having been given;

4) in the alternative to 3), entering Mrs Henshall's daughters into the trial without having obtained her informed consent, in particular without having provided her with an information leaflet or informing her of the risks, benefit, efficacy and experimental nature of the treatment;

5) entering Stacey into the trial notwithstanding her ineligibility for it according to the trial criteria;

6) inadequate clinical care of Sofie;

7) knowing failure to follow the trial protocol;

8) employment of doctors and nursing staff unsuitably qualified and/or trained to develop or conduct the trial;

9) fraudulent misrepresentation of the results of the trial in order to further their personal financial interests in the development of CNEP equipment; and

10) conspiracy to misreport post-mortem results with a view to preventing any death being attributable to the trial.

Save for the first complaint of deception of the local ethics committee and the ninth of misrepresentation of the results of the trial, which were alleged against Professor Southall personally, the remaining summarised complaints insofar as they related to him, were, in the main, of a failure of supervision.

11. There was considerable delay on the part of the **GMC** in responding to Mr and Mrs Henshall's complaints. Instead of proceeding to investigate the complaint through its established machinery, it decided to await the publication of the Griffiths Report, commissioned by the NHS Executive in February 1999. The panel's terms of reference were "to look into the general framework for both the approval and monitoring of clinical research projects in North Staffordshire", that is, to examine the design of trials, including the CNEP trial, as distinct from clinical issues arising from them. In relation to the CNEP trial, the main conclusion in the Griffiths Report, which was published on 8th May 2000 (some ten years after the local ethics committee had approved it) was that its design did not match what would, at the time of publication, be considered best practice. Professor Griffiths also made it clear in the Report that the panel had not sought to determine the truth of allegations of poor practice, or to apportion blame if practice could have been better, or to determine whether any actions taken at the end of the trial were wrong.

12. The main findings and recommendations of the Griffiths Report included the following:

(a) research governance, including practice and policies in individual trials, as well as in the North Staffordshire Trust generally, in the relevant period did not match what would, in 2000, be considered best practice;

(b) although the use of CNEP had been in routine use in the North Staffordshire Trust as a technique for respiratory support for children with bronchiolitis, the panel had not been able to identify a substantial evidential base to support it.

(c) some parents had alleged serious side effects from CNEP and, in two cases, the panel had heard claims that children had suffered serious brain damage or had died. The Trust, after examination of those claims, believed that the children had some signs of brain damage before undergoing the treatment.

(d) It was impossible for the panel to tell after such passage of time whether CNEP was the cause or made it worse, but it recommended that there should be "a substantial audit" of the Hospital "to see if claims of significant benefit or damage ... [could] be substantiated".

13. Although Mrs Henshall placed much reliance on the Griffiths Report in her application before Pitchford J, it had only been indirectly before the PPC as the subject of considerable criticism in the *Hey & Chalmers Article* published in the BMJ in September 2000, a well documented and peer reviewed analysis. The Article contained a review of the Griffiths Report with the benefit of contemporaneous material that had not been

before the Griffiths Panel and also information provided by the three doctors, in particular Professor Southall in his written response to the Griffiths Report. The first paragraph of the summary at the front of the Article gives the flavour of its authors' conclusions over-all:

> "We believe that almost every statement made about the design, conduct and reporting of the neonatal ... [CNEP] trial in the Griffiths report was ill-informed, misguided or factually wrong."

14. In addition to a detailed criticism of the conclusions in the Griffiths Report, in particular as to the lack of foundation for many of them, and a reminder of the Griffiths panel's disclaimer of having sought to determine whether allegations of poor practice were true, Hey and Chalmers expressed the following view about the CNEP trial:

> "... one can still form a view as to whether the research in question was properly conducted. The [Griffiths] panel seem to have concluded that it was not. We do not agree.
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> "... the conduct of the CNEP trial was exemplary. It was certainly up to the standard of most neonatal trials that were recruiting patients in Britain in the early 1990s;"
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> and
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> "... we found clear documentary evidence that the staff in Stoke went to unusual lengths to ensure that families were as informed as possible about the nature of the care on offer, both before and after entry to the study. The role of the nursing staff in this regard was particularly praiseworthy."

15. In a letter written by Dr Hey to Mr and Mrs Henshall of 26th September 2000, in response to a letter from them about the *Hey & Chalmers Article*, he wrote:

> "... We think you have missed the point of our article. This was not to say whether the CNEP trial was well conducted, but whether the Griffiths Inquiry was well conducted. Had it been, the report of the Inquiry would not contain the factual errors is does contain. ...
>
> We have not concluded that there were no irregularities in the way the CNEP study was undertaken. We could not possibly reach such a conclusion without even knowing what criticisms some families raised with the panel, or examining relevant papers to which we have not had access. We have seen documents that you have not seen, you have seen documents that we have not seen. What remains extraordinary is that the Griffiths panel apparently never sought, let alone examined, much of the relevant contemporaneous documentation."

16. In the same edition of the BMJ as that in which the *Hey & Chalmers Article* was published, there appeared a reply by Professor Griffiths, which, also was not directly before the PPC. In it, he wrote that the most important conclusion in his panel's report was of the need for a new research governance framework. He also referred to having received submissions from several expert witnesses of eminence that the North Staffordshire CNEP was probably no different from that in many other trusts at the time, namely in the early 1990s. He added that any criticism, real or imagined, in the Griffiths Report had nothing to do with the instigation of Mrs Henshall's complaints to the **GMC,** which had preceded the publication of the Report.

17. The Hospital then commissioned a confidential review by Professor Sir David Hull, assisted by a small team, to "inform its employment procedures". In effect this exercise became an enquiry into twelve research programmes conducted by Professor Southall, including the CNEP trial, during his time at the North Staffordshire Trust, to determine whether any disciplinary action should be taken against him. Among the material at which Professor Hull looked, was a North Staffordshire consent audit and a Midland Health Consultancy Network Report, both of which were favourable to Professor Southall and, indirectly, to Drs Samuel and Spencer. In December 2000 Professor Hull produced a report ("the Hull Report"), which, while expressing some concerns, was generally supportive of Professor Southall's and his colleagues' work. As a result, Professor Southall, who had been suspended as a result of Mr and Mrs Henshall's complaints to the **GMC,** was reinstated. (Given the confidentiality that the Hospital attributed to the Hull Report, Mrs Henshall did not see it until it was disclosed in these **judicial review** proceedings.)

18. Meanwhile, the **GMC** had yet to consider Mr and Mrs Henshall's complaints.

19. As I have said, under the 1983 Act and the 1988 Rules then governing the **GMC's** disciplinary procedures,

:h re was a three tier system, an initial check largely as to formalities by a "screener", a second somewhat more rigorous check by the PPC as to whether they ought to refer a complaint for inquiry and determination by the PCC, and finally, if the PPC referred the matter to the PCC, the PCC's determination whether the complaint of serious professional misconduct was established.

20. In this case, the screener decided initially not to refer Mr and Mrs Henshall's complaints to the PPC. Following a threat by Mrs Henshall of a claim for **judicial review** arising out of his failure to take account of a large quantity of documentation that she and her husband had provided to the **GMC,** he decided in September 2002 to reconsider the complaints. In the course of his reconsideration he invited and received further written responses from the three doctors. In January 2004 he referred the complaints to the PPC.

21. All three doctors responded to the complaints, Drs Samuels and Spencer had first responded to the complaints in May 2001. Professor Southall had responded by letters from his solicitors in January and June 2002. But, unlike Drs Samuels and Spencer, he had done so, on condition that his responses would not be disclosed to Mr and Mrs Henshall. He provided a further response in February 2004 on the same condition. His reason, as set out in his solicitors' letters, was that he believed that Mr and Mrs Henshall would use the content of his responses to further a long-standing campaign against him by an action group, some of whom were associated with the **Henshalls,** opposed to his involvement in child protection work. He was specifically concerned that, in breach of an injunction, Mr and Mrs Henshall had sent to the **GMC** papers that had been stolen from his office. He maintained his refusal of consent to disclosure despite their offer to undertake not to use any information derived from his responses save for the purpose of their complaints to the **GMC;** he maintained that, because of their behaviour, he had no confidence that they would comply with any such undertaking. It looks from the way in which the **GMC** has pleaded its case in paragraph 10(4) of its summary grounds for resisting the application for permission to claim **judicial review** (see paragraph 54 below), that the screener felt bound to comply with his refusal.

22. The PPC considered the complaints and the doctors' responses to them and representations made on their behalf, the *Hey & Chalmers Article*, the Hull Report, and many other documents - over 3,600 pages in all. The PPC also refused disclosure to Mr and Mrs Henshall of Professor Southall's responses because of his refusal of consent to their disclosure. Having considered all that material, the PPC concluded that none of the complaints should be put before the PCC. The PPC's view in all three cases was that there was "no real prospect" of their proving the factual basis of their complaints and that even where there might have been, there was "no real prospect" of them proving that any of it amounted to "serious professional misconduct".

23. Mrs Henshall then applied for permission to claim **judicial review** in respect of the PPC's decision not to refer her and her husband's complaints against all three doctors to the PCC. She relied upon three main grounds, which I set out in a different order from that given to them in argument at the hearing and by the Judge in his judgment:

> i) that the PPC, in their "filtering" role to determine whether to refer the complaints to the PCC, had acted irrationally or otherwise unlawfully in adopting too rigorous a test in considering whether her allegations of serious professional misconduct had "a real prospect of success", when they should have considered whether there was "a real as opposed to fanciful prospect of success";
>
> ii) that the PPC's conduct of their filtering role was unfair to her and her husband in not disclosing to them Professor Southall's response to their complaints; and
>
> iii) that the PPC had uncritically accepted the views in the *Hey and Chalmers Article* in support of the CNEP trial and without considering or considering adequately the Griffiths Report.

24. As I have said, Pitchford J refused Mrs Henshall's application. He did so because he was of the view that: i) the PPC, in considering whether the complaints had a "real prospect of success", applied the correct test; ii) the statutory scheme did not require disclosure of Professor Southall's responses at the PPC stage and that they had properly exercised their discretion not to disclose them in the light of his refusal of consent to such disclosure; and iii) the PPC were entitled to have regard to the criticisms in the *Hey and Chalmers Article* of the Griffiths Report as part of the material tending to undermine the complaints.

The statutory scheme

25. Before I consider each of the three issues, the Judge's rulings on them and the challenges to those rulings, I should say a little more about the statutory scheme then provided by the 1983 Act for the **GMC's** investigation and consideration of complaints of serious professional misconduct.[1] By section 1(3) of the Act, the **GMC** was required to have a number of committees, including the PPC and the PCC and a Health

committee. By section 36 of the Act, the PCC could cause a medical practitioner's name to be removed from the register if found guilty of a criminal offence or guilty of serious professional misconduct. But, by section 42 of the Act, all complaints had first to be referred to the PPC for their decision whether such matter "ought to be referred for inquiry" by the PCC or the Health Committee.

26. By section 43 and paragraph 5 of schedule 4 to the 1983 Act, the **GMC** could make rules for the PPC as to how they were to discharge their function. At the material time, as I have said, the operative rules were the 1988 Rules, and they provided for a three tier system for consideration and determination of complaints. The first, the screener, was bound to refer the matter to the PPC after satisfaction of certain formalities unless it appeared to him "that the matter need not proceed further". Then there was the PPC whose role was to consider whether to refer the matter to the PCC, and to do so where it "appear[ed] to raise a question whether the practitioner ha[d] committed serious professional misconduct" or, as the courts, taking their lead from Lightman J's judgment in *R v **GMC**, ex p Toth* [2000] 1 WLR 2209, at para 14(5) (see paragraph 49 below), have interpreted that test, whether there was a "real prospect" of establishing such misconduct. And, finally there was the PCC whose role was to determine whether such conduct was established.

27. The initial consideration of cases by a "screener", for which Rule 6 provided, was clearly of a fairly basic or 'narrow" kind, as Lightman J described it in *Toth*, at para 14(4), in which the issue was the extent of the screener's role. But, as was apparent from the requirement in Rule 6(3) to inform the practitioner of matters in the complaint "which appear[ed] to him to raise a question whether the practitioner ha[d] committed serious professional misconduct", he was expected to give at least some cursory consideration to that question. How far the screener had to go to be satisfied that the complaint "appear[ed] to raise" such a question may have some bearing on the PPC's determination of the same question, which was presumably intended to be more rigorous. This is how Lightman J attempted to contrast the two roles in *Toth*, at para 14 (4):

> "The role of the screener is a narrow one. It is to filter out from formally correct complaints, not those which in his view ought not to proceed further, but those which he is satisfied (for some sufficient and substantial reason) need not proceed further. For this purpose he must be satisfied of a negative, namely that the normal course of the complaint proceeding to the PPC need not be followed. ... The absence of 'need', of which the screener must be satisfied before he can halt the normal course of the complaint to the PCC, connotes the absence of any practical reason for the complaint so proceeding and that for the complaint to proceed to the PCC would serve no useful purpose. There may be no need because there is nothing which amounts to a complaint; because the formal verification is lacking; because the matters complained of (even if established) cannot amount to serious professional misconduct; because the complainant withdraws the complaint; or because the practitioner has already ceased to be registered. Wider questions, as to the *prospects of success* of the complaint, as to whether the complainant is acting oppressively or as to the justice of the investigation proceeding further do not lie within the screener's remit. So far as they may go to the issue whether complaint ought to proceed, they fall within the remit of the PPC. It is not for the screener to arrogate to himself the role of the PPC and decide whether the complaint ought to proceed further, still less to arrogate to himself the role of the PPC and weigh up conflicting evidence or judge the prospects of success. He must respect the role assigned by the Rules to the PPC (for which the PPC is armed with investigative powers) and recognise that his duty is only to act as preliminary filter before the more substantive role as filter is exercised by the PPC." (my italics)

28. The more substantial "filtering" role of the PPC was governed by Section 42(2) of the 1983 Act, which required them to consider any case referred to them by the screener and to determine whether it "ought to be referred" to the PCC for an inquiry. Given the judicial gloss placed by Lightman J in *Toth* on the test indicated by Rule 11(2) of the 1983 Rules for making that decision, I should set out the material part of the Rule:

> "When referring a case to the Professional Conduct Committee the Preliminary Proceedings Committee shall indicate the convictions, or the matters which in their opinion *appear to raise a question* whether the practitioner has committed serious professional misconduct ..." [my italics]

29. As I have indicated, Lightman J's gloss in *Toth*, which was in paragraph 14(5) of his judgment, was that the PPC's task was to determine whether there was a "real prospect" of the complaint being established before the PCC.

30. In the light of that judgment, the **GMC** provided guidance to PCC members in the form of an aide memoire prepared for them by counsel ("the Aide Memoire"). It was expressly approved by Burton J in *Woods v **GMC*** [2002] EWHC 1484 Admin, at para 14(ii), and included the following:

"1. In conduct cases the PPC's task is to decide whether, in its opinion, there is a real prospect of serious professional misconduct being established before the PCC. Serious professional misconduct may be considered in the context of conduct so grave as potentially to call into question a practitioner's registration whether indefinitely, temporarily or conditionally.

2. The "real prospect" test applies to both the factual allegations and the question whether, if established, the facts would amount to serious professional misconduct. It reflects not a probability but rather a genuine (not remote or fanciful) possibility. It is in no-one's interest for cases to be referred to the PCC when they are bound to fail, and the PPC may properly decline to refer such cases. On the other hand, cases which raise a genuine issue of serious professional misconduct are for the PPC to decide.

3. ... in performing its task the PPC:

(1) should bear in mind that the standard of proof before the PCC will be the criminal standard (beyond reasonable doubt);

(2) is entitled to assess the weight of the evidence;

(3) should not, however, normally seek to resolve substantial conflicts of evidence;

(4) should proceed with caution (given that, among other considerations, it is working from documents alone and does not generally have the benefit of [a] complainant's response to any reply to the complaint submitted on behalf of the practitioner);

(5) should proceed with particular caution in reaching a decision to halt a complaint when the decision may be perceived as inconsistent with a decision made by another public body with medical personnel or input (for example, an NHS body, a Coroner or an Ombudsman) in relation to the same or substantially the same facts and if it does reach such a decision, should give reasons for any apparent inconsistency;

(6) should be slower to halt a complaint against a practitioner who continues to practise than against one who does not;

(7) if in doubt, should consider invoking Rule 13 of the Procedure Rules and in any event should lean in favour of allowing the complaint to proceed to the PCC; and

(8) should bear in mind that, whilst there is a public interest in medical practitioners not being harassed by unfounded complaints, there is also a public interest in the ventilation before the PCC in public of complaints which do have a real prospect of establishing serious professional misconduct."

31. Lightman J's and the **GMC's** test of a "real prospect" of establishment of a complaint has been approved and applied in a series of recent High Court judgments, namely: *R (Richards) v* ***GMC*** [2001] Lloyds Med Rep 47, per Sullivan J at para 58, subject to two qualifications not affecting the fundamental nature of the tests (see paragraph 49 below); *R v* ***GMC,*** *ex p McNicholas* [2001] EWHC 279 Admin, per Sullivan J at para 12; and, as I have noted, *R (Woods) v* ***GMC***, per Burton J at para 14(ii). It was also seemingly approved by Jonathan Parker LJ, with whom Laws and Keene LJJ agreed, in *R (Holmes) v* ***GMC*** [2002] All ER (D) 412, CA, at para 74.

32. Where the PPC decide not to refer a complaint to the PCC, Rule 11(5) required them to inform the complainant and the practitioner of their decision "in such terms as the Committee direct[ed]". Rule 13(1) empowered the PPC, before making their decision, to cause further investigations to be made and/or to seek legal advice and assistance. Rule 13(2) enabled them where, inter alia, they considered that further investigations were desirable, provisionally to refer the matter to the PCC. And Rule 16 provided, as Rule 10 (4)(a) provided for the screening stage, that where the PPC decided not to refer a complaint to the PCC the complainant should not have a right of access to documents submitted to the **GMC.**

33. It is only at the PCC stage that the matter assumed the character of the traditional forensic process, with sequential mutual disclosure of documents, a public hearing which began by the reading and putting of the "charges" to the accused, a hearing in which the **GMC** and the accused doctors could be represented by lawyers, where evidence was prepared and given in traditional form, orally and/or in writing, and where the

:vidence of witnesses on each side could be tested in cross-examination.

:ssue 1 -The PPC's "Filtering" Role

34. As I have indicated, Pitchford J rejected the submission of Mr Ian Wise on Mrs Henshall's behalf that the PPC had acted irrationally or otherwise unlawfully in deciding not to refer the matter to the PCC. That submission had two parts to it. The first was that the PPC's threshold for referral, namely "a real prospect of success" was too high and that, in applying that test, they should have added to it so that it read "a realistic prospect as opposed to a fanciful prospect of success". The second was that, whatever the precise formulation of the test, the PPC had usurped the role of the PCC by resolving issues of fact.

35. It is instructive to consider the PPC's decision letter of 12th March 2004 to see how they approached their task and whether there is any life in the same complaint that Mr Philip Havers QC makes on Mrs Henshall's behalf before this Court. I can deal with this relatively briefly, as the Judge, with the same exercise in mind, has set out, in paragraphs 43 to 45 of his judgment, extensive passages from their reasoning in the case of each practitioner.

36. First, the PPC, not only consistently stated and applied the *Toth* test of a "real prospect" of establishing the complaints against the doctors before the PPC, they also made specific reference to the Aide Memoire by way of preface to their individual treatment of the complaints against each doctor.

37. Secondly, in the case of all three doctors, the PPC reached their decision after setting out the complaints and the issues on them raised in their responses, the *Hey & Chalmers Article* and Professor Griffiths' response to it, the Hull Report and the other documentation. The following summary in their decision letter of their conclusion in relation to the complaints against Professor Southall, though focusing in his case on his responsibility for design and oversight, is typical of their approach to all three:

> "The Committee considered that, as Professor Southall was not involved in any clinical care, any sustainable allegations must relate to the design of the trial and its overall conduct. The Committee was of the view that, in the light of the Hull report, the Hey and Chalmers article, and the fact that the subsequent paper was published in Paediatrics and therefore subject to peer review, the trial had been properly conducted. ...
>
> The Committee carefully considered all the information before it. It decided that the allegations had no real prospect of being proved to the required standard. Moreover, the Committee was of the opinion that where there might be some evidence in support of the allegations, they would not, if proved, reach the threshold for serious professional misconduct."

38. The Judge considered that those conclusions were not the product of a misunderstanding by the PPC of their role, but a proper outcome of a detailed examination of the material before them on which they were entitled to conclude that there was no real prospect of Mr and Mrs Henshall establishing serious professional misconduct before the PCC. In reaching that conclusion, he likened the general issue before the PPC to a prosecution in which the case for the prosecution consisted of Mr and Mrs Henshall's affidavits setting out their complaints, "purportedly supported" by the Griffiths Report, and:

> "The case for the defence, which was to be found in the representations of the doctors ... and in the Hey and Chalmers article, in Professor Griffiths' reply and in the Hull report ... [and] The North Staffordshire consent audit and the Midland Health Consultancy Network Report ... referred to ... in Professor Hull's Report."

39. The Judge's reaction, at paragraph 69 of his judgment, to Mr Wise's addition to Lightman J's test of "real prospect of success", namely that it should be "a realistic prospect of success as opposed to a fanciful prospect of success", was that it seemed to him to be precisely the test described in the Aide Memoire, in particular the final sentence of paragraph 2 of it (see paragraph 30 above). He said:

> "... Paragraph 2 is framed in terms which are, if anything, more favourable to the claimant. Certainly, by the use of the words 'cases which raise a genuine issue of serious professional misconduct are for the PCC to decide', the PPC was given guidance helpful to the complainant about what would constitute a real as opposed to a fanciful prospect of success."

Accordingly, he concluded in paragraph 70 of his judgment that Mr Wise had nothing to complain about in this respect:

"Mr Wise suggests that permission should be granted so as to enable the correct test to be formulated. I am afraid that I regard the application in this respect as misguided. There is nothing to examine. The test is clear and, apart from an exercise in semantics, Mr Wise agrees with it. ..."

40. As to the second part of Mr Wise's contention that the PPC acted irrationally or otherwise unlawfully in its decision not to refer in that it usurped the fact-finding role of the PCC, the Judge identified what he saw as the PPC's task and distinguished it from that of the PCC. He commented on the nature and volume of the "evidence" that had been put before the PPC and described its task and how it went about it thus:

"73. The PPC was not to attempt to resolve the questions raised on both sides, but to consider the materiality and weight of the evidence in particular and in the round. It was then required to pose the question whether so much of that which had a reasonable prospect of proof would raise a real prospect that serious professional misconduct had occurred. The judgment of what might in the context of this case amount to serious professional misconduct was a matter for the expertise of the Committee."

"76. It seems to me that the PPC was entitled to point out to the complainants the nature of the material which tended to undermine the complaints made. It was not necessary, and would have been inappropriate to engage in a line by line recitation of the complaints, but it was appropriate to weigh up the complaints on the one hand and the body of evidence which could, should the matter proceed, be deployed on behalf of the doctors on the other. In reaching their decisions, the PPC of course had to distinguish between those facts which were incontrovertible and those which were controversial, and therefore the subject for the deployment of conflicting evidence. As to conflicting evidence, the PPC were required to consider not the result of the conflict, but the realistic prospects for the result of conflict."

"77. Finally, the PPC had to consider whether that which appeared incontrovertible and that which realistically remained in issue gave rise to a real prospect of a finding of serious professional misconduct. That is the process in which it seems to me the PPC not only said it was engaged, but was in fact engaged, when it expressed itself in its decision letter of 12th March 2004. ..."

Submissions

41. Mr Havers, on behalf of Mrs Henshall, returned to the first part of Mr Wise's submission on this issue to the Judge, that the PPC, in failing to consider the obverse of a real prospect of success, namely a fanciful prospect of success, had adopted the wrong or an incomplete test. He acknowledged that the PPC, in their decision letter, had expressly prefaced their treatment of the complaints against each doctor with a reference to the Aide Memoire, which juxtaposed to and contrasted with the "real prospect" test the expression "not [a] a remote or fanciful" possibility. But, he complained, they should have spelt out the exact terms of that expression when dealing with each doctor. He suggested that the Judge was wrong to dismiss it as a semantic point in the circumstances, because the PPC, whilst referring in their decision letter to the "real prospect" test, did not indicate their understanding that a complaint, to have a "real prospect of success", merely has to be not "fanciful". He argued that a "real not fanciful prospect" test is a significantly lower than the unqualified "real prospect" of success test applied by the PPC.

42. Mr Havers prayed in aid in support of his submission, as Mr Wise had done before the Judge, the criticism of Dame Janet Smith in her Report on the *Shipman Inquiry*, of the general approach of the PPC as too focused on the interests of doctors in contrast with the interests of patients. He suggested that the PPC's failure in this case expressly to balance the "real prospect" test against a fanciful prospect of success showed that they were, on the material before them, too focused on the interests of the doctors in this case, leading them to adopt the wrong test for referral to the PCC.

43. Faced with the responses of counsel for the **GMC** and the doctors that the Judge had rightly dismissed this approach as semantic, Mr Havers turned to what he submitted was a lower test than Lightman J's gloss of "a real prospect of success" to the threshold for referral as set out in Rule 11(2), namely whether the material before the PPC "appear[ed] to raise a question" of serious professional misconduct.

44. Mr Shaw and Mr Kennedy submitted that the PPC and the Judge, in applying the "real prospect" success test, applied the correct test, namely that as precisely identified by Lightman J in *ex p Toth* and followed and approved in the authorities to which I have referred briefly in paragraph 31 above. To contrast that with a fanciful prospect of success, they submitted, neither added anything to the test nor was necessary as a matter of emphasis.

45. Miss Mary O'Rourke, on behalf of Drs Spencer and Samuels, on the other hand, urged the Court to disregard Lightman J's gloss on the statutory scheme and its adoption and elaboration by the PPC in the Aide Memoire, since neither bound this Court. She characterised the seeming acceptance of it by Jonathan Parker J in Holmes, at para 74, as only a passing reference. She submitted that the PPC should have adopted the test for prosecutors in paragraph 5.1 of the Code for Crown Prosecutors, namely whether there was "a realistic prospect of conviction", taking account of criminal rules of evidence and the criminal burden and standard of proof, that is whether the PCC was more likely than not to find that serious professional misconduct had been established. However, she concluded that whether the test was expressed as a matter of possibility, as suggested by the formula in Rule 11(2), or as a balance of probability, to which the *Toth* test inclines, is immaterial in the circumstances of this case because the PPC rightly found that the complaints reach neither threshold.

Conclusion

46. I am not sure whether there is very much between the various formulations of the test for the PPC that have been discussed in this appeal. First, and most obviously, I agree with the Judge that, other than as a matter of emphasis, the words "not a fanciful prospect" of success add nothing to Lightman J's gloss of "a real prospect" of success on the statutory test. As Mr Shaw observed, by reference to an observation of Lord Woolf MR (as he then was) in *Swain v Hillman* [2001] 1 All E R, 91, CA, at 92j, it is self-evident, even if not spelt out, that a fanciful prospect of establishing a case is not a real prospect of doing so.

47. Secondly, although the test as stated in Rule 11(2), whether the complaint "appear[ed] to raise a question" could be said to be lower threshold than "a real prospect of success" and more of a piece with the PPC's characterisation of it in paragraph 2 of the Aide Memoire as a "genuine ... possibility" rather than a probability, I doubt if there was much between the Rule 11(2) formulation and Lightman J's gloss on it as a matter of practical application. It is true, as Sedley LJ observed in argument with reference to Rule 11(2), that the PPC could only refer a matter to the PCC if "in their opinion it appear[ed] to raise a question whether the practitioner ha[d] committed serious professional misconduct", but that it was not for the PPC to answer that question. But to my mind, for the PPC to conclude that a complaint had a real prospect of success, as distinct from a probability or a real probability of success, was just another way of saying that it appeared to them to raise a question that ought to be referred to the PCC for determination. Similarly, I do not consider that the test, "a realistic prospect of conviction" in the Code for Crown Prosecutors, as espoused by Miss O'Rourke is a materially different test, taking into account, the criminal standard of proof for the realisation of such prospect before the PCC and the need to proceed with caution as paragraphs 2 and 3(4) of the PPC Aide Memoire advised. It is interesting in this context to note how Jonathan Parker LJ in his seeming acceptance in *Holmes*, at para 74, of the "real prospect of success" test in *Toth* and *Richards*, equated it with "an arguable case" of serious professional misconduct.

48. It is clear from the PPC's decision letter that, in the case of each of the three doctors, they applied the "real prospect" of success test. And, for what it was worth, they did so, having in mind the contrast drawn in paragraph 2 of their Aide Memoire of a remote or fanciful prospect, and they did so both as to the establishment of any relevant facts in support of each complaint and to the question whether such facts, if established, could amount to serious professional misconduct. Accordingly, in my view, the Judge correctly held that the PPC had applied the correct test and that, even on Mrs Henshall's case before him as to its meaning, she had nothing to complain about. As to the general criticism made by Dame Janet and the possible need for reformulation of the test for referral by the PPC, the Judge rightly observed that whether or not there was a need for such reformulation, it was not his task; he was there to apply the law as it was, not as it might become.

49. As to the more focused way in which Mr Havers put it to this Court, perhaps a re-framing of a further submission that Mr Wise made to the Judge, namely that the PPC usurped the role of the PCC by resolving issues of fact, it is necessary to keep in mind the different functions and procedures of the PPC and PCC. Whilst the former was to act as a "filter" for the latter before referring to it complaints of serious professional misconduct, and the latter was to decide on evidence put before it whether such complaints were established, the filtering was clearly intended to take a more rigorous form than that conducted by the screener, though not so rigorous as the determinative and forensic role of the PCC. In particular, it was not adjudicative in the sense of considering oral and written evidence and its adequacy, presented in the event of referral for the first time to the PCC and tested in its inquiry by a forensic process and after full mutual disclosure. The latter was the sole function of the PCC as Lightman J's comparative analysis in *Toth*, at para 14(5) and paragraphs 3 (1), (2) and (3) of the Aide Memoire make plain, the former reading:

> "... The PPC's role is to decide whether the complaint ought to proceed. This language must be read in the context of a scheme under which the complainant has no right to the practitioner's comments

on the complaint or other material put before the PPC, and a scheme in which the central feature is the investigation of complaints by the PCC before whom alone there is full disclosure of documents and evidence and a form of hearing where the complainant (and public) can see, and be reassured by seeing, the proper examination of the merits of the complaint. The PPC may examine whether the complaint has any real prospect of being established, and may themselves conduct an investigation into its prospects, and may refuse to refer if satisfied that the real prospect is not present, but they must do so with the *utmost caution* bearing in mind the one-sided nature of their procedures under the Rules, which provide that that, whilst the practitioner is afforded access to the complaint and able to respond to it, the complainant has no right of access to or to make an informed reply to that response, and the limited material likely to be available before the PPC compared to that available before the PCC. It is not their role to resolve conflicts of evidence. ... the PPC must bear in mind their limited (filtering) role and must balance regard for the interests of the practitioner against the interests of the complainant and the public and bear in mind the need for the reassurance of the complainant and the public that complaints are fully and properly investigated and that there is no cover-up. In the case of the PPC ... any doubt should be resolved in favour of the investigation proceeding." (my emphasis)

50. However, although the respective roles of the PPC and PCC may be contrasted in the manner indicated, there remains a question of how light a touch the PPC should exercise in determining whether to refer a complaint to the PCC. The Judge clearly had this problem much in mind in paragraphs 73, 76 and 77 of his judgment (see paragraph 40 above), as did Sullivan J in *Richards*, at paragraph 58, where he endorsed Lightman J's analysis, subject to two matters of what he described as "emphasis". The first was to question the need for utmost caution in every case before deciding not to refer, particularly given the Rule 11(2) test whether the matters "appear to raise a question" whether the practitioner has committed serious professional misconduct, and in circumstances where the complaint stems from a finding of another medical body. The second was as to Lightman J's general proposition that it was not the PPC's role "to resolve conflicts of evidence", which Sullivan J qualified:

> "I would prefer to say that it should not *normally* seek to resolve substantial conflicts of evidence. To do so would be to go beyond its screening role and to usurp the function of the PCC. Although section 42 of the Act appears to confer a very broad discretion upon the PPC, its proper role is as described by Lightman J. ..." (my italics)

51. It is plain that it was not the job of the PPC to conduct an inquiry in the full or evidential sense. Its role was not to consider "evidence"; that was for the PCC's consideration if the matter reached it, evidence that could be forensically tested and with the benefit of mutual disclosure. The PPC's role was to consider whether material put before it on paper raised a question as to serious professional misconduct that "ought to be" the subject for evidential presentation to an inquiry by the PCC. If there was to be a gloss on the statutory test, it seems to me that the expression "whether there is cogent indication of a question to be answered" comes closer, as a matter of contextual interpretation and of public policy, to identifying the PPC's role than that of a "real prospect of success". It cannot have been sufficient simply to raise a question for this purpose for there to be some conflict or indication of conflict in the respective accounts put before the PCC, regardless of the materiality of the conflict or of the relative cogency and weight of the material on one side and the absence or paucity of it on the other. Following Sullivan J's train of thought in his second qualification to Lightman J's formulation of the PCC's role, if there was no material and cogent information before the PPC to set against overwhelming information in favour of the doctors' responses to Mr and Mrs Henshall's complaints, it was plainly open to them, if they were to act as an effective filter, to make a value-judgment to that effect and decide, on that account, not to refer.

52. Whatever shade of the test was appropriate, I agree with Miss O'Rourke's submission, and with the Judge's reasoning that the material before the PPC fell short of the threshold for reference to the PCC. On the one side, apart from the **Henshalls'** representations, the only expert material of substance was the Griffiths Report which was concerned with how such trials should be devised and conducted some ten years after the events in question. On the other, there were the peer-reviewed and far better documented *Hey & Chalmers Article* highly critical of the Griffiths Report so far as it went, Professor Griffiths' own response to the Article, disclaiming any criticism of the doctors' design and conduct of the trial according to the standards at the time when it was undertaken, and the Hull Report, including its references to two other investigations, all generally supportive of the doctors' conduct of the trial. In the circumstances, it was plainly, and as a matter of common-sense, open to the PPC to identify and give effect to the significant disparity in relevance, cogency or weight of the material relied upon respectively by Mr and Mrs Henshall in support of their complaints and that relied upon by the doctors. This was how the Judge saw it, correctly so, in my view, in paragraphs 72, 74 and 75 of his judgment:

"72. ... the case for the prosecution, as it were, was comprised in Mr and Mrs Henshall's affidavits and documents, purportedly supported, including the Griffiths report. The case for the defence was to be found in the representations of the doctors who made them and in the Hey and Chalmers article, in Professor Griffiths' reply and in the Hull report. The North Staffordshire consent audit and the Midland Health Consultancy Network Report were referred to, particularly in Professor Hull's Report.

74. ... One of the reasons why I have referred to the evidence in more detail than otherwise I would, is to demonstrate its significance to the deliberations performed by the Committee. Professor Griffiths made it clear that the purpose of his inquiry was not to make a judgment upon the professional competence and behaviour of the doctors by the standards of the time, but '... to look into general framework for both the approval and monitoring of clinical research projects in North Staffordshire'. He revealed, as I have read from his response to Hey and Chalmers that he had received submissions from several expert witnesses of eminence that the trial conducted by the doctors was probably no different from that in many other trusts at the time. He was looking to the question whether, in the light of experience, a national framework was required.

75. It was abundantly clear that, in any event, for one reason or another, Professor Griffiths had not been provided with all the material required to make an informed judgment about the CNEP trial in North Staffordshire. The material was described by Hey and Chalmers and listed in the appendices to their article. Professor Hull also had the advantage of access to documents not seen by others, which caused him not to share those others' misgivings, as he put it."

53. Accordingly, I reject the complaints constituting the first ground of appeal that the PPC applied the wrong test in law or misapplied the correct test on the material before them.

Issue 2 - Disclosure

54. This issue relates only to the complaints against Professor Southall. It is whether the PPC's decision not to disclose to Mr and Mrs Henshall his three responses to their complaints breached common law rules of fairness. The starting point for discussion is rule 16 of the 1988 Rules, to the substance of which I have already referred and which, verbatim, provided:

"Where the Committee have decided not to refer a case for inquiry no complainant, informant or practitioner shall have any right of access to any documents relating to the case submitted to the Council by any other person, nor shall the Committee be required by a complainant, informant or practitioner to state reasons for their decision."

It should be noted that, as to a complainant's entitlement to disclosure, the application of the Rule fell only for consideration by the PPC at the end of their deliberations and when they had decided not to refer the matter to the PCC.

55. The PPC, like the screener, appear to have declined to disclose Professor Southall's responses to Mrs Henshall because they considered his refusal of consent to be an absolute bar to disclosure, the first of two alternative arguments relied upon by Mr Shaw on behalf of the **GMC** before the Judge and this Court. As I have said, that appears from paragraph 10(4) of the **GMC's** summary grounds for resisting the application for permission to claim **judicial review:**

"(4) The Act and Procedure Rules do not, of course, preclude the voluntary disclosure of doctors' responses to complainants.

a) But, as Mr Justice Lightman also noted in *Toth* ... the doctor must consent to such disclosure. It is, after all, his document/information which would be revealed.

b) In the present case, it was made clear to the **GMC** (explicitly, firmly and consistently) by Professor Southall's solicitors that he did not consent to the disclosure of any of his responses to the Claimant (or any other claimant).

(5) In those circumstances, the **GMC** was neither required nor entitled to give the disclosure sought by the Claimant."

56. Pitchford J rejected Mrs Henshall's challenge to the PPC's decision on this issue on two related grounds, first, that the statutory scheme, in particular Rule 16, did not require such disclosure and, secondly, because

ıe considered that the PPC had properly exercised the discretion they had to refuse it. Unlike the PPC, he did ıot act on Mr Shaw's primary argument on the second ground that a doctor's refusal of consent, for whatever e;son, operated as an absolute bar to disclosure.

;7. As the Judge noted, this aspect of the statutory scheme was considered by Lightman J in his judgment in *'oth*, at paras 15 and 16, in which he held that, though the Rules did not entitle a complainant to see material nade available to the screener or to the PPC, they gave them discretion in the matter. Lightman J also eferred to the adoption by the **GMC** of a "new practice" from 1st July 2000 under which, in the absence of exceptional circumstances", the screener should copy to the complainant the doctor's responses to the :omplaint. That practice expressly recognised as an exceptional circumstance for this purpose, one where lisclosure could cause substantial harm to the doctor and/or to a third party, for example by the disclosure of :onfidential medical material. In such a circumstance, the practice expressly acknowledged that the screener night exercise his discretion to allow it against an undertaking from the complainant as to confidentiality ınd/or to allow partial or edited disclosure.

;8. Lightman J, having considered that development at screener level, concluded, at paragraph 16 of his udgment:

> "Whilst the **GMC** is not bound to make such disclosure to a complainant of material put before the screener, it is not precluded by the Rules from doing so and accordingly it is free to do so, at any rate unless precluded from doing so by a confidentiality obligation owed to the party supplying the material. The issue raised is whether, as a condition of voluntarily making disclosure to Mr Toth of confidential medical evidence relating to the health of ...[the respondent doctor], and accordingly of material which ...[the doctor] has every reasonable ground to wish should remain confidential, the **GMC** can insist on Mr Toth providing an undertaking of confidentiality. ... if the **GMC** voluntarily in accordance with the principles of fairness decides that in principle disclosure should be made, it is entirely free to impose conditions which likewise accord with the principles of fairness. In my view, in insisting on respect being afforded by Mr. Toth for the confidentiality of the medical evidence relating to the ... doctor's health, the **GMC** is acting entirely properly. To do otherwise would be calculated to discourage practitioners from submitting relevant, but confidential, material to the **GMC** for consideration by the screener. ..."

59. We are told that this had always been the practice in respect of sought disclosure against the PPC. It is illustrated in the following passage from a letter of 19th September 2002 from the **GMC** in its letter of 19th September 2002 to the solicitors for Drs Spencer and Samuels:

> "... in the interests of fairness to all parties, any comments which you submit concerning material relevant to ... the **Henshalls'** ... complaint, should be disclosed to the complainants by the **GMC.** This is in accordance with our procedures, which make provision for both the complainant(s) and the doctor(s) to be informed of each other's representations, thus enabling both 'sides' to comment upon the other's representations. You have so far prevented this process from happening since you have not provided consent to the disclosure of your submission to complainants. I would ask you to reconsider this decision and if necessary submit an amended version of the original submission, which you agree to the **GMC** disclosing to the complainants."

60. Pitchford J, at paragraph 57 of his judgment, acknowledged that approach as a permissible exercise of discretion in the application of rule 16 and adopted Lightman J's analysis for the purpose, saying:

> "... The Rules do not contemplate the disclosure of the doctor's response at the PPC stage. However, Rule 16 reposes a discretion in the PPC, and the policy to which Lightman J referred states the circumstances in which that discretion will be exercised to withhold disclosure."

61. The Judge then referred to Professor Southall's representations through his solicitor and to affidavits submitted on his behalf that he had been concerned that any disclosure of such documents might be used to harass or damage him. The Judge's approach was to consider whether Professor Southall had proper grounds to fear that such disclosure would be used for that purpose, not whether in fact they would be so used, and whether, even so, to withhold disclosure would be unfair to Mr and Mrs Henshall. In the following paragraphs of his judgment, he found that Professor Southall had good grounds to fear harm from the sought disclosure, that to withhold it would not be unfair to them and, notwithstanding the **GMC's** pleaded case, that the PPC had achieved that by exercising a discretion in the matter:

> "59. The issue is not whether the documents would have been used for such a purpose, and the

claimant was prepared to give an undertaking, but whether Professor Southall and the PPC had proper grounds to fear that they would be used for that purpose.

60. ... Unfairness in this context means unfairness to the complainant. There may be circumstances in which the complainant should, notwithstanding, have been given the opportunity to comment upon, for example, an assertion of fact about which she might not otherwise know. I have in mind, by way of further example, that, where an assertion of fact is made to which the complainant is the only one who may be able to provide useful evidence as to the truth or falsity of that factual assertion, considerations of fairness may demand that she has the opportunity comment upon it. However nothing is revealed in the decision letter which indicates that such a situation might have existed here. On the contrary, Professor Southall's defence to the criticism made publicly by the parents in 1997 and since has itself been publicised by the means of the Hey and Chalmers report ...

61. It is clear to me that there is no reasonable prospect that Mrs H[enshall], whose knowledge of the case is encyclopaedic, has been deprived of a meaningful opportunity to present her complaint against Professor Southall.

63. ... it is my view that the discretion has been exercised properly and that, in the result, no unfairness has conceivably resulted. "

Submissions and Conclusions

62. Mr Havers submitted, as Mr Wise had submitted to the Judge, that, regardless of judicial scope for discretion, the bar on a complainant's entitlement to disclosure provided by Rule 16, operated only after a decision by the PPC not to refer the matter to the PCC, not during the course of its consideration whether or not to refer. That rule 16 should be read in this way is clear, he submitted, from its wording and because of its location at the end of the Part, Part III of the Rules dealing with the PPC's procedure. On the premise that the statutory scheme is silent as to a complainant's right to disclosure before the PPC reached a decision one way or the other, he had recourse to Lord Denning MR's solution in *R v Secretary of State for the Environment ex parte Norwich City Council* [1982] QB 808, at 842G, that the common law should fill the lacuna, and to Sedley LJ's articulation in *R v Camden LBC ex p Paddock* CO/2817/92 at page 16 of the principle adumbrated a long time before by Lord Loreburn LC in *Board of Education v Rice* [1911] AC 179, at 182:

> "... that a decision-making body should not see relevant material without giving those affected a chance to comment on it and, if they wish, to controvert it, is fundamental to the principle of law (which governs public administration as much as it does adjudication) that to act in good faith and listen fairly to both sides is 'a duty lying upon everyone who decides anything'" ...

Mr Havers, whilst acknowledging that the requirements of fairness differ according to context, contended that the nature of the present case was such that fairness demanded disclosure of the responses of Professor Southall to Mr and Mrs Henshall's complaints. He submitted that the Judge wrongly distinguished the present case from *Paddock* on the basis that *Paddock* concerned a final determination, whereas decisions of the PPC do not.

63. However, as Mr Shaw and Mr Kennedy observed, it follows as a matter of inexorable logic from the express prohibition in Rule 16 of disclosure where there had been a decision not to refer, that it precluded a right, as such, to disclosure before such decision. Otherwise, the prohibition would have been nugatory. If any further justification were required for that interpretation of Rule 16, it was no doubt to be found in the draftsman's conception of the PPC's role in the statutory scheme as a preliminary and limited form of paper inquiry in the disciplinary process, in contrast with the forensic procedures of the PCC in which mutual disclosure could, for the first time, be directed, and "evidence", both oral and written, presented and tested. Moreover, the draftsman had provided, through Rule 13(1) a means of enabling the PPC to satisfy the demands of fairness by way of further investigations and/or seeking legal advice or assistance. In this case, for instance, they could have exercised that statutory power, if they had considered it necessary or desirable to explore any points raised by Professor Southall not covered in the complaint or with which they considered the complainant should have had an opportunity to deal.

64. As to the finality or otherwise of the PPC's decisions, I agree with Mr Havers that, although their decisions to refer were not final in that they were preliminary to determinations of the PCC, for Mr and Mrs Henshall the PPC's decision not to refer was, subject to challenge by way of **judicial review,** "the end of the road". It was a decision that concluded this matter and prevented a full inquiry. Moreover, given the discretionary overlay to which I have referred, it is via that route - the one already taken by the **GMC** in the adoption of its "new

practice" (see paragraph 57 above) - not the misreading of Rule 16, by which **GMC** and the courts should have recourse to the common law and Lord Loreburn's fundamental principle of fairness.

65. Turning to that discretionary alternative, Mr Havers submitted that the PPC had a discretion voluntarily to disclose and, where fairness demanded it, to exercise it even if that necessitated overriding a doctor's refusal of consent. Mr Shaw, Mr Kennedy and Miss O'Rourke acknowledged that the Rules did not preclude voluntary disclosure by the PPC of a doctor's response to a complaint. But, they maintained, the PPC could only do so if the doctor consented; if he refused, they had no discretion to override his refusal whatever his reason for it. The rationale for such a rule, Mr Kennedy maintained was that, in the context of disciplinary proceedings against a doctor, the latter should be free to put his version of events without fear of attracting further denunciation. Alternatively, they argued, relying by analogy upon Lightman J's reasoning in *Toth*, at para 16, in relation to material before a screener (see paragraph 58 above), if he refused consent on what they considered to be reasonable grounds, they had a discretion whether to refuse disclosure in the interests of fairness or to grant it against an undertaking of confidentiality from the complainant upon which he could rely. Mr Shaw and Mr Kennedy submitted that, here, the PPC refused to disclose on proper grounds, namely that Professor Southall had reasonably refused consent because he had cause to believe that an undertaking of confidentiality would or could be valueless.

66. However, if, as is plain, Rule 16 left room for a discretion in the PPC whether to disclose doctors' responses to complainants, it could only have been a discretion exercisable in the interests of fairness as between both parties. The fact, for example, that a doctor might have had a good or reasonable explanation for refusing consent did not on that account alone necessarily make it fair to withhold his response.

67. Accordingly, I agree with Mr Havers' submission that there is no legal basis upon which a doctor in a response to disciplinary proceedings before the **GMC** had any right to refuse consent to disclosure to the complainant, on the ground of confidentiality or otherwise, so as effectively to remove from the PPC a discretion whether or not to make disclosure in the interest of fairness of both parties. If and to the extent that Lightman J contemplated such a possibility in paragraph 16 of his judgment in *Toth*, I respectfully disagree. However, it looks from his discussion of ways around the problem to enable the **GMC** "voluntarily in accordance with the principles of fairness [to] decide. In principle that disclosure should be made", that he did not regard the doctor as having the final word.

68. Here, the issue was not so much a matter of professional or personal confidentiality, but of concern on the part of Professor Southall that what he regarded as his sound answers to the complaints might be misused by Mr and Mrs Henshall or by others for other purposes. Such a concern was relevant to the PPC in determining whether fairness to both parties demanded disclosure and, if so, on what terms. It is plain that the PPC exercised their discretion in taking the first step towards finding a fair solution, namely by seeking and obtaining an offer of an undertaking from Mr and Mrs Henshall not to use any information derived from Professor Southall's responses other than for the purpose of the disciplinary proceedings.

69. The question is whether the PPC should have taken and did take the next step along that discretionary road of considering what fairness demanded in the light of Professor Southall's continued refusal to disclose because, in the light of his experience of their and others' conduct, he was concerned about their willingness and/or ability to honour such an undertaking. Whilst the PPC may have considered how far such concern went to justify his stance and, if so, whether, nevertheless, fairness as between the parties demanded disclosure, they appear to have been content, according to the **GMC's** pleaded case, to have taken a stand simply on basis of his refusal. For the reason I have given, I do not consider they were entitled to do that. As Sedley LJ observed in the course of counsel's submission, the **GMC** cannot hide behind a doctor's purported veto on disclosure of his responses under a general plea of confidentiality or otherwise.

70. In my view, in the circumstances of this case, the PPC would have been entitled to regard as reasonable Professor Southall's explanation for refusal of disclosure even against an undertaking from Mr and Mrs Henshall to keep it confidential, and as fair between the respective interests of the parties. But, as I have said, the PPC did not refuse disclosure on that basis. Contrary to the Judge's inferential findings in paragraphs 59 to 63 of his judgment (see paragraph 61 above), it is evident from the way in which the **GMC** had pleaded its justification for resisting disclosure (see paragraph 54 above), that the PPC exercised no discretion at all on this aspect of the matter; it had simply acted on Professor Southall's refusal.

71. As the Judge observed in paragraph 60 of his judgment, the issue was ultimately one of fairness and, notwithstanding the reasonableness or otherwise of Professor Southall's stance, there might have been something in his responses upon which, as a matter of fairness the **Henshalls** should have been given the opportunity to comment. But all the signs, as the Judge indicated in his further reasoning in the paragraph, were against it. There was nothing in the PPC's decision letter turning on the truthfulness or accuracy or otherwise of Professor Southall's responses upon which Mr and Mrs Henshall had not already dealt in their

voluminous documentation and which was not also supported in important respects by other material before the PPC and made public in the *Hey & Chalmers Article*.

72. In my view, and contrary to Mr Havers' submissions on the matter, I consider that the Judge was entitled in the circumstances to express the view in paragraph 61 of his judgment that there was no reasonable prospect of Mr and Mrs Henshall having been deprived, by lack of access to Professor Southall's responses, of an adequate opportunity to demonstrate at that stage that they had a reasonable prospect, if there was one, of establishing their complaints of serious professional misconduct against him. In short, on the material before the Court, I am of the view that, even if Professor Southall's representations had been disclosed to Mr and Mrs Henshall, they would not, in the circumstances of this case have made any difference to a proper exercise by the PPC of its discretion, if they had exercised it to the full.

73. Accordingly, I would also reject this ground of appeal.

Issue 3 - Hey & Chalmers Article

74. I have effectively dealt with this ground of appeal, in paragraphs 50 - 52 of this judgment, when dealing with the first and main ground of appeal as to the PPC's test for referral. For the reasons given in those paragraphs, notably those of the Judge with whose reasoning in paragraphs 72, 74 and 75 of his judgment set out in paragraph 52, I there agreed, I am firmly of the view that the PPC were entitled to rely on the *Hey & Chalmers Article* and considerable supporting material in deciding, in the proper exercise of their referral function, not to refer Mr and Mrs Henshall's complaints to the PCC. In summary, and contrary to Mr Havers' submissions:

> 1) the Griffiths Report was effectively before the PPC and its implications if and insofar as they were relevant to Mr and Mrs Henshall's complaints must have been considered by the PPC, since it was the centre-piece of the criticisms in the *Hey & Chalmers Article*;
>
> 2) on the critical issue of the integrity of the design and of the conduct of the CNEP trial according to the standards of the day when it was conducted, there was no substantial conflict between the Griffiths Report and the authors of the *Hey & Chalmers Article* and the other material supporting the latter, as Professor Griffiths himself acknowledged in his reply to the Article; and
>
> 3) the effect of the *Hey & Chalmers Article* and supporting material, to the extent that it bore on any aspect of the Griffiths Report that might have been supportive of Mr and Mrs Henshall's complaints, seriously undermined it; the PPC could not have reasonably failed so to conclude, and, in my view, were entitled to do so as part of their referral role.

75. Accordingly, I would also reject this ground of appeal.

76. In consequence, I would dismiss the appeal. I add that, given the considerable lapse of time - 13 years - since the CNEP trial and the considerable body of medical exploration that it has engendered to little or no identifiable advantage to Mr and Mrs Henshall's complaints and to much unjustified professional disruption and personal distress of the doctors, I would, in any event, have been inclined to refuse relief in the exercise of my discretion. In saying that, I have not forgotten the tragedy that Mr and Mrs Henshall have undergone and from which they continue to suffer. All I say is that, I can see no way, certainly by this stage, in which they could establish a grievance in public law in respect of which the law could help them.

LORD JUSTICE SEDLEY :

77. For the purposes of this judgment I adopt with gratitude the full account of the facts and issues contained in the judgment of Auld LJ. My conclusions, however, differ from his. In my judgment, while one cannot necessarily fault the test applied by the PPC, the way in which it applied the test was wrong and the materials to which it applied the test were so weighted against the complainants by unfair procedure as to vitiate its decision.

The correct legal test

78. There is only one legally correct version of the test which the PPC was required to apply in order to decide whether a matter, in the words of s.42, ought to be referred for inquiry by the PCC. It is the test to be found in the delphic language of rule 11(2): does the complaint appear to the PPC to raise a question whether the practitioner has committed serious professional misconduct? The test is self-evidently designed only to eliminate complaints which raise no question capable of resulting in a finding of serious professional misconduct. Such findings must, as Miss O'Rourke submits, be capable of being established beyond

easonable doubt if a complaint is to pass the test. But rule 11(2) does not permit the PPC itself to attempt to nswer any question which is raised by a complaint: that is for the PCC if the complaint otherwise passes uster.

9. All the formulations which appear in the decided cases are paraphrases of the rule. But, as the ubmissions in this appeal have shown, every paraphrase brings further problems of meaning in its wake. ightman J's careful and helpful exegesis in Toth - 'a realistic prospect' - invites the question whether a rospect which is more than fanciful can still be less than realistic. The question cannot be answered from the tatute or the rules, which contain neither phrase, so that to devise an answer is to travel still further from he words of the rule.

0. But this is not to say that the aide-memoire (see paragraph 30 above) was legally wrong or misleading. he want of a clear test in either the Act or the Rules made explanations of this kind inevitable. In many ases, perhaps most, it will have made little or no difference which formula was used. If the present case urned upon it, it would be necessary to make a close analysis of the PPC's decision in order to decide whether t had impermissibly raised the threshold. But, for reasons to which I now turn, the dominant problem with its ecision is not the relatively nice one of the standard to which the PPC evaluated the material before it. It is he much larger one of the material which was included in and excluded from its consideration, and of how far t went in reaching its decision.

The withholding of Professor Southall's response

1. Rule 16 (see paragraph 54 above) was a most peculiar rule. On its face it provided only for the non-isclosure of materials by the PPC following a decision to make no referral. Whatever its purpose (and none is eadily apparent), one of its principal effects was to ensure that the author of a complaint which had been ejected without due process had no way of finding this out unless it appeared on the face of the decision letter. A second effect, germane to this case, was that the rule was ineffective unless the PPC also adopted a policy of non-disclosure prior to its decision on referral. Whoever drafted the rule appears to have been unaware that the common law has always refused to countenance any such policy unless it is unequivocally mandated by Parliament. Yet the overriding of this tenet of the common law was the necessary basis of Mr Shaw's submission that rule 16 by necessary implication forbade disclosure in the absence of consent.

82. Of course not every document which came to the PPC required disclosure. If that had been the case, every complaint would have risked becoming an endless war of words. But it was in my judgment completely unacceptable to derive by implication from rule 16 a general inhibition which, by enabling a practitioner to put in potentially contentious material in response and to deny sight of it to the complainant, was capable of stifling the individual's right to bring a tenable complaint to the attention of the Professional Conduct Committee of the **GMC.** Suppose, for example, that the practitioner were to respond to a complaint by making damaging personal assertions about the complainant which could be refuted but which the practitioner refused to allow to be disclosed. It could make the difference between referral and non-referral of a well-founded complaint.

83. Somehow, therefore, the PPC had to operate rule 16 fairly. In my view the only way to do so was to recognise that there were two competing imperatives: the fact that rule 16 would become ineffective to the extent (not necessarily a large one) that documents were disclosed by the PPC in the course of its work, and the fact that the PPC could not do its work fairly or therefore lawfully if significant material were able to be put in by practitioners and kept from the knowledge of complainants. The solution was to consider in each case what the practitioner had put in; to decide whether in fairness it was something the complainant should be able to respond to; and, if it was, to tell the practitioner that unless he or she agreed to the disclosure of the material it would be ignored by the PPC.

84. The speeches in the House of Lords in *Roberts v Parole Board [2005] UKHL 45*, which were published shortly after the hearing before us, while not immediately in point, contain reasoning which in my present view (for we have not considered it necessary to call for argument on it) supports the conclusion set out above. It is reasoning which might permit non-disclosure of a response which, for instance, placed the practitioner at risk of violence if it were to be disclosed; but the concerns expressed by Professor Southall about the **Henshalls** (who were not members of the action group and whose concerns differed from those of the group) were not in this league and were capable of being met by undertakings.

85. The PPC erred in law in failing to appreciate - no doubt because it had not been advised - that it should take the approach I have outlined to Professor Southall's submission. It has not been submitted to us (it could not logically be) that what Professor Southall wrote was inapt for disclosure. The natural inference is that it was material which, but for its supposed obligation of confidentiality, the PPC would or might well have sought the **Henshalls'** comments on. It follows either that the **Henshalls** have been denied the opportunity to

spond or that the PPC has taken into account material which it should have ignored.

he Hey and Chalmers article

5. The PPC accepted and clearly gave considerable weight to the Hey and Chalmers article. In doing so it red, in my view, in two related ways. First of all, it embarked upon the evaluation of evidence, a task not nfided to it by law. Secondly, it did so upon manifestly partial material. The two issues are related because, the evidence placed before it on a material question were to be substantially all one way, the PPC was ndoubtedly entitled to rely on it in deciding whether the complaint had raised a question of serious rofessional misconduct; while if it were not, and if the conflict required resolution before the statutory uestion could be answered, it was the PCC who had to resolve it.

7. The Griffiths report was neither placed before nor obtained by the PPC. With the greatest respect, I am nable to agree with Auld LJ's formulation that it was effectively before them. What the PPC had was a wingeing attack on Griffiths by two authors, both of whom had correctly and candidly declared an interest of ome significance: that their report had been bespoken (though not paid for) by the doctors' insurance body, he Medical Defence Union. All the PPC knew of Griffiths' findings was what Hey and Chalmers said about hem. The fact that Griffiths, in a measured response, pointed out that his critique had been limited to a nding that the design and conduct of the CNEP trial did not meet the standards of the time, ten years on, of is report, did not amount to an acknowledgement of the justice of Hey and Chalmers' attack on him. And while the authors of the article, in a letter which was sent on by the **Henshalls** to the PPC, disclaimed any opinion as to whether the clinical trial (as opposed to the Griffiths inquiry) had been properly conducted, at east one of the decision letters shows that the PPC relied on their description of the conduct of the trial as exemplary'.

8. The tone and content of the Hey and Chalmers article can be gauged from the first point in its summary:

> "We believe that almost every statement made about the design, conduct, and reporting of the neonatal continuous extrathoracic pressure (CNEP) trial in the Griffiths report was ill informed, misguided or factually wrong."

The Griffiths report, which had been commissioned by the Department of Health, had begun the summary of ts findings thus:

> "4.1.1 The Review Panel was given evidence of individual failures in the way that the research was carried out but as far as the Review Panel can tell the governance systems were broadly in line with Department of Health guidance that existed at the time. That guidance, however, left scope for considerable latitude in the way that individual projects were managed. This in turn left scope for the inadequacies that the Review has identified to go undetected and uncorrected.
>
> 4.1.2 The Review Panel found that research governance, including practice and policies in individual trials, as well as in the Trust generally in the period to which the Review relates did not match what would now be considered best practice. The original complaint made by Mr and Mrs Henshall and which led to the Review has resulted in valuable improvements being made."

In their response, published in the British Medical Journal alongside the Hey and Chalmers article, Professor Griffiths and his collaborators began by saying that Hey and Chalmers.

> "seem to have entirely misunderstood the terms of reference and the main thrust of their report."

89. This is enough to indicate why, in respectful disagreement with Auld LJ, I do not consider that this court can say that the medical literature disposed of any possible question of serious professional misconduct. Nor, however, can I accept Mr Havers' submission that it manifestly required a referral to the PCC. Even to adjudicate on this submission, given the patent conflict of evidence, would risk substituting the court for the PPC.

How the PPC dealt with the evidence

90. I would also hold, in agreement with Jonathan Parker LJ and for the reasons given by him, that by embarking on an evaluation of such evidence as it had, the PPC exceeded its powers.

Conclusion

. In my judgment the only fair outcome is that the PPC should be reconstituted in order to do the jo
far failed to do. It should make it clear first of all that, unless Professor Southall agrees to let the
enshalls see his submissions, if necessary on suitable undertakings, the submissions will be put aside.
condly it should act on the published literature only if, having considered the Hey and Chalmers article
ongside the Griffiths report, the Hull report and any other relevant material placed before it, it is satisfied
at there is in sum no evidence capable of raising a question within s.11(2). It is not the PPC's task to
valuate conflicting professional views of issues raised by the complaint. Its final task is to apply, with
hatever exegetic help it finds useful, the test set by rule 11(2): does the material advanced for and against
e complaint raise a question whether one or more of these practitioners has committed serious professional
isconduct?

2. I would accordingly allow this appeal and, with the co-operation of the parties, make such order as will
oduce the outcome I have indicated.

ORD JUSTICE JONATHAN PARKER:

3. I too am grateful to Auld LJ for his account of the facts and for his exposition of the legal background to
ie appeal. However, like Sedley LJ, I have the misfortune to disagree with his conclusions. I agree with
edley LJ that the appeal should be allowed, and the matter remitted to a reconstituted PPC for
econsideration.

he correct test

4. I agree with the judge, and with my Lords, that the PPC in the instant case identified the correct legal test
s laid down in Rule 11(2) of the 1983 Rules, and as explained by Lightman J in *Toth* and by the **GMC's** Aide-
lemoire dated 31 January 2001. As the judge observed in paragraph 70 of his judgment, the differing
ormulations of the test advanced (before him) by Mr Ian Wise and (before us) by Mr Philip Havers QC amount
o no more than an exercise in semantics.

5. However, I consider that, having identified the correct test, the PPC failed properly to apply it to the
material before it.

6. Under the heading 'Professor Southall', the decision letter dated 12 March 2004 records the following (in
he passage quoted by the judge in paragraph 43 of his judgment):

> "The Committee was of the view that, in the light of the Hull report, the Hey and Chalmers article, and the fact that the subsequent paper was published in Paediatrics and therefore subject to peer review, *the trial had been properly conducted*. ... The Committee ... considered that *the information leaflet and consent procedures were adequate* when judged by the standards in place at the time. In addition, the Committee considered that *the participating staff had been satisfactorily trained* and that *Professor Southall could not be held responsible for the erroneous inclusion of Sofie in the trial*." (My italics)

97. In my judgment, in making those findings the PPC went beyond the limits of its function as laid down in Rule 11(2). It is one thing to evaluate the available evidential material in order to determine whether in its opinion such material appears to raise a question whether the practitioner has committed serious professional misconduct, but (as it seems to me) quite another to purport to resolve disputed factual issues. I consider that in making the findings recorded in the passage from the decision letter which I have just quoted - and in particular the finding that the trial was properly conducted - the PPC went further than was necessary for the purpose of deciding whether the material before it raised the Rule 11(2) question. In so doing, it trespassed on an area which was properly the province of the PCC, should the case be referred to it.

98. Accordingly, I conclude that in the instant case the PPC exceeded its proper function as explained by Lightman J in Toth.

Non-disclosure of Professor Southall's response

99. Rule 16, as I read it, was only engaged once the PPC had decided not to refer the case to the PCC. By contrast, what we are concerned with in the instant case is the situation which obtains when, in the course the PPC's investigative process and before it has taken any decision on referral, the practitioner tenders evidential material to the PPC on terms that all or part of it is not disclosed to the complainant, or that disclosure to the claimant is subject to conditions (e.g. a cross-undertaking by the complainant not to disclose the material to third parties) which the complainant is unwilling to accept. In such a situation the PPC has, in

ıy judgment, an inherent discretion whether or not to take such material into account in reaching its ecision. Given that save in rare cases a complainant is entitled to an adequate opportunity to put his ase (see per Bingham LJ in *Cotton*, in the passage quoted by the judge in paragraph 47 of his judgment, nd that the PPC has a duty to act fairly, it seems to me that the PPC ought not to take such material into onsideration in reaching its decision unless it is satisfied that there is good reason why it should do so otwithstanding that the complainant has not seen it and accordingly is not in a position to respond to it.

00. As I see it, therefore, it is not a question of ignoring the terms imposed by the practitioner in relation to isclosure of the material submitted: rather, the question is whether in all the circumstances, and given such erms, it is appropriate for the PPC to take such material into account in reaching its decision.

01. In the instant case the complainant was willing to give an undertaking not to make use of Professor outhall's responses in any other context, but Professor Southall did not consider that such an undertaking ould afford him sufficient protection. Accordingly, he maintained his absolute prohibition on disclosure. That as a matter for him. However, the question then for the PPC was whether in all the circumstances, and given rofessor Southall's absolute prohibition on disclosure, it was appropriate for the PPC to take his responses nto account in reaching its decision. There is nothing to indicate that the PPC addressed that question. The udge (in paragraph 60 of his decision) concluded that the PPC had "proper grounds on which to refuse lisclosure in Professor Southall's case"; but, as I have indicated, that seems to me to be a different question. n the circumstances I consider that there is a real risk that, in reaching its decision not to refer, the PPC took nto account material (i.e. Professor Southall's responses) which, had it addressed the right question, it would ıave left out of account.

The Hey and Chalmers Article

.02. I agree with Sedley LJ, for the reasons he gives, that the PPC exceeded its proper function in placing ubstantial reliance on the Hey and Chalmers Article, and the criticisms of the Griffiths Report which it ontained. Like Sedley LJ, I cannot accept that, as Auld LJ puts it in paragraph 74 above, the Griffiths Report vas effectively before the PPC. It was only before the PPC in its guise as the target for the serious criticisms nade of it by Hey and Chalmers.

· i.e. before its extensive amendment by the Medical Act 1983 (Amendment) Order 2002, SI 2002/3135.

CS

C1/2004/2706

Neutral Citation Number: [2006] EWCA Civ 364
IN THE SUPREME COURT OF JUDICATURE
IN THE COURT OF APPEAL (CIVIL DIVISION)
ON APPEAL FROM THE QUEEN'S BENCH DIVISION
ADMINISTRATIVE COURT
MR JUSTICE PITCHFORD

Royal Courts of Justice
Strand
London, WC2

Tuesday, 31st January 2006

BEFORE:
LORD JUSTICE AULD
LORD JUSTICE SEDLEY
LORD JUSTICE JONATHAN PARKER

- - - - - - -

THE QUEEN ON THE APPLICATION OF
DEBORAH HENSHALL CLAIMANT/APPELLANT
- v -
THE GENERAL MEDICAL COUNCIL DEFENDANT/RESPONDENT
and
(1) PROFESSOR DAVID SOUTHALL
(2) DR ANDREW SPENCER
(3) DR MARTIN SAMUELS INTERESTED PARTIES

(DAR Transcript of
Smith Bernal Wordwave Limited
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Official Shorthand Writers to the Court)

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MR P HAVERS QC & MR I WISE (instructed by Messrs Irwin Mitchell, St Peters House, Hartshead, Sheffield S1 2EL) appeared on behalf of the Appellant
MR M SHAW QC (instructed by Messrs Field Fisher Waterhouse, London EC3N 2AA) appeared on behalf of the Respondent
MR A KENNEDY (instructed by Messrs Hempsons) appeared on behalf of the First Interested Party
MISS M O'ROURKE (instructed by Messrs Radcliffes LeBrasseur, London, SW1P 3SJ) appeared on behalf of the Second & Third Interested Parties

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JUDGMENT
(As Approved by the Court)

- - - - - - -

1. LORD JUSTICE AULD: The court in its order of 28 June allowed this appeal of Deborah Henshall and, by a majority, ordered that her complaint against the three doctors, the interested parties in this case, Professor David Southall, Dr Andrew Spencer and Dr Martin Samuels be remitted to a freshly constituted Preliminary Proceedings Committee ("PPC") for reconsideration. At the request of Miss O'Rourke, on behalf of Drs Spencer and Samuels, the court has reconvened to reconsider, in the case of those two interested parties, whether it has, and if so, whether it should exercise, a discretion to remit. The argument of Miss O'Rourke, for which we are grateful, is that in respect of two matters, where the court has found the PPC's conduct of the matter lacking, only one of them touches Dr Spencer and Dr Samuels – Dr Spencer hardly at all, and Dr Samuels a little more. That is the PPC's reliance on the British Medical Journal article, the Hey and Chalmers article, which this court, by a majority, as I have said, found to be in error.

2. Having considered her submissions and those of Mr Havers for Miss Henshall as to the significance of the reliance of the PPC on the British Medical Journal article in relation to Dr Spencer and Dr Samuels, we consider, and do so unanimously, that the proper approach of the court would be to adhere to the order originally expressed. In our view, the article loomed large in the considerations of the PPC, generally as between the three doctors, and not in an insignificant way in respect of Dr Spencer and Dr Samuels. Accordingly, we consider that the order should stand as drawn, save only subject to this amendment, that instead of the appellant's complaint in relation to each one of these three doctors, considered individually, being remitted to a freshly constituted PPC, it should be remitted to the General Medical Council's Investigations Committee, established under a new procedure but applying the former statutory scheme, namely that under the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee Procedure Rules 1988. The matter should be remitted with the utmost expedition.

3. It is common ground that the appellant's costs of the appeal in the court below should be borne by the defendant, the General Medical Council, and that there be detailed assessment of the appellant's costs in accordance with the Community Legal Service Cost Regulations of 2000, and, in addition, that the costs of the interested parties, the doctors, should lie where they fall.

Order: Application allowed.

fund exchanges without a research content, and the differences that still exist in the systems for specialist training in France and Britain may cause problems in deciding which posts in the two countries are comparable. The Ministère des Affaires Étrangères in France has recently been prepared to fund visits from fairly senior clinicians: at present there are two British doctors in Paris and one in Lyon working with full responsibility and paid at senior registrar level. Opportunities of this kind are not yet being fully used. For the time being, however, the advice for a British doctor wishing to work in a clinical rather than a research setting at SHO or registrar level in France is to make personal contact with a hospital specialist there who would be willing to sponsor his candidature.

Overview

In both contexts—clinical work and research—the impression on both sides of the Channel seems to be that interchange is far easier than most doctors believe. Anyone who would like the experience of working in France (or, in the other direction, Britain) should be able to arrange an exchange for any period between a few days and a year. Information about possible research exchanges is available from the MRC, INSERM, and CNRS; and possible sources of travel funds and grants for longer stays include the British Council, the Royal Society, the Ciba Foundation, and the Wellcome Trust, and in France the Ministère des Affaires Étrangères or the British Council (Paris).

Guidelines to aid ethical committees considering research involving children

Working Party on Ethics of Research in Children

The British Paediatric Association set up in 1978 a Working Party on Ethics of Research in Children (members Professor F Cockburn, Professor J A Dudgeon, Dr D M T Gairdner, Dr A D M Jackson). The following "Guidelines to aid ethical committees considering research involving children"* proposed by the working party have been accepted by the council of the BPA and have been published in the January issue of *Archives of Disease in Childhood* (1980;55:75-7).

These guidelines presume that four premises are accepted.

That research involving children is important for the benefit of all children and should be supported and encouraged and conducted in an ethical manner.

That research should never be done on children if the same investigation could be done on adults.

That research which involves a child and is of no benefit to that child (non-therapeutic research) is not necessarily either unethical or illegal.[1]

That the degree of benefit resulting from a research should be assessed in relation to the risk, of disturbance, discomfort, or pain—the risk: benefit ratio.

Defining "risk"

Risk, in this context, means the risk of causing physical disturbance, discomfort or pain, or psychological disturbance to the child or his parents, rather than the risk of serious harm, which no ethical committee would countenance in any case.

Negligible risk—Risk less than that run in everyday life.

Minimal risk—Risk questionably greater than negligible risk.

More than minimal risk.

*A *child* in this context is taken to include the infant from the time of birth (but not the fetus). Thereafter, an individual remains a minor until 18. The Family Law Reform Act (1969) provides that a minor who has attained the age of 16 has *capacity to consent to surgical, medical, or dental treatment (which* 'includes any procedure undertaken for the purpose of diagnosis . . . and applies to any procedure . . . which is ancillary to any treatment as it applies to that treatment'). This statute does not deal with consent for other procedures, e.g. nontherapeutic research, and therefore the general law applies to all minors until 18. Such law does not recognise any 'age of consent', for capacity to consent depends on the child's intellectual capability and the complexity of the procedure; age is simply one factor to be taken into account.[2]

Defining "benefit"

Non-therapeutic research

(*a*) The procedure is of no benefit to the subject but may benefit the health and welfare of other children or adults. A special case, but an important one, is if the subject suffers from a disorder and the research aims to benefit others suffering from a similar disorder.

(*b*) The procedure is of no benefit to the subject but may add to basic biological knowledge—for example, normal values; aging.

Therapeutic research

The procedure is of potential benefit to the subject.

Applying the risk:benefit principle in non-therapeutic research

Procedures requiring ethical judgments are usually those which are without benefit to the subject—non-therapeutic research. Most such procedures will fall into one of the following three categories.

(1) The procedure is either (*a*) part of the ordinary care of the infant or child (weighing, measuring, feeding), or (*b*) involves the non-invasive collection of samples—for example, urine, faeces, saliva, hair, or nail clippings, or, at birth, cord blood or placental tissue.

Risk is here likely to be negligible—for example, test weighing a breast-fed baby as part of a study aimed to promote breast feeding.

(2) The procedure involves invasive collection of samples—for example, blood, cerebrospinal fluid, or biopsy tissue—taken from a child who is undergoing treatment. The sample used for research may be (*a*) an additional amount to that required on clinical grounds; or (*b*) not an ordinary part of the child's treatment—for example, collection of biopsy material during a surgical operation.

Risk in (*a*) might be either negligible or minimal; (*b*) might be negligible, minimal, or more than minimal.

Examples—In cystic fibrosis, a research might be considered reasonable which involved an affected child having a sweat test that needed twice as much sweat as required for purely

diagnostic purposes. The added discomfort to the child might be assessed as negligible. If in addition a venepuncture was required, this might be judged to put the risk of discomfort and pain into the minimal risk category. But the potential benefit to other child sufferers from this common and serious disease might be deemed such as to make the risk:benefit ratio acceptable.

During the course of an operation for hernia, a fragment of skin from the incision might be required for a research involving tissue culture. The risk could be judged negligible, so that even if the research was not expected to have any direct clinical benefit but only to add to basic biological knowledge, it might be acceptable.

During the course of an abdominal operation, a renal biopsy might be taken for research purposes. The risk here would be judged more than minimal and the benefit would have to be very large to justify it. But suppose the research aimed to resolve the problem of rejection of transplanted kidneys, with resulting lifesaving consequences both for children and adults with renal failure; this might be considered a benefit of sufficient magnitude to justify the risk.

(3) The procedure is quite apart from the necessary care or treatment of the child. For example, blood sampling; passage of oesophageal tube for pressure recording; application of face mask for respiration studies; placement of infant in plethysmograph chamber for thermal or respiratory studies; needle biopsy of skin or fat; or *x*-ray or isotope studies (see below).

The risk might be negligible, minimal, or more than minimal. The benefit, as defined above in relation to non-therapeutic research, may fall within either the definition (*a*) or (*b*). If it comes under definition (*a*), the risk should, to be acceptable, probably be either negligible or minimal. If the benefit comes under definition (*b*), the risk should be negligible.

Examples—In thalassaemia, a common and lethal disease, progress might depend on taking blood specimens from both affected and unaffected children. The benefit could be assessed as great, so justifying the risk of causing more than minimal discomfort or pain to the children.

Many diabetic children will develop blindness or other severe eye complications in adult life. A research aimed at eventually learning how to prevent this might require several glucose tolerance tests to be done on a diabetic child, not for his own benefit but for the benefit of other diabetic children. The risk of discomfort or pain to that child would be assessed as more than minimal, but might nevertheless be justified by the potential benefit.

The physiology of the initiation of breathing by the baby at birth is poorly understood, and is of clinical importance because some babies fail to breathe. A study of normal newborn babies' first breath, using a face mask, may be judged to cause minimal risk with a justifiable risk:benefit ratio.

Applying the risk:benefit principle in therapeutic research

Therapeutic research offers potential benefit to the subject. It includes not only trials of new drugs or procedures but also trials of therapies which, though perhaps widely applied, are yet of unproved value. The risk:benefit principle may still be applicable, the potential benefit as well as the risk relating to the individual subject.

In general, ethical principles in therapeutic research involving children do not usually differ from those applying to adults, except that the age of the subject will often mean that parental understanding and agreement will be required.

In the common type of experiment where two therapies are compared in a controlled trial, two ethical questions are likely to arise.

(1) Is the research necessary? For instance, conventional treatment of a febrile convulsion in a child includes drastic cooling. A research project might question this form of management and entail a controlled trial. An ethical committee might consider it probable that data already existed enabling the question to be answered. The committee might therefore require the researcher first to provide evidence that the world literature had been effectively searched.

(2) Is the design of the trial such that a statistically significant result will emerge with the use of a minimal number of subjects and in a minimum period? Since one set of children will receive what may eventually turn out to be an inferior therapy, it is ethically imperative that this question be answered in the affirmative.

Examples—Current research in treating leukaemia in children often means comparing two different drug regimens. Since both sets of children receive therapies currently considered acceptable, ethical considerations are mainly confined to ensuring that the design of the trial is statistically sound.

A controlled trial of hyposensitising injections of allergens in asthmatic children differs from the foregoing example in that some children (the controls) receive injections of inactive material. This might at first sight seem ethically questionable. However, the following consideration may lead to such a trial being judged acceptable. Until the result of the trial is known the children in either the treatment or the control group have a chance of gaining an advantage. The active therapy may prove superior and those in the treatment group gain an advantage. If, however, there are unpleasant or harmful side effects from the active therapy, the control group will have gained some advantage by not being exposed to those side effects.

X rays and isotopes

An authoritative pronouncement on the ethical propriety of irradiating children—that is, the use of *x* rays or isotopes—for research purposes has recently been given by the International Commission on Radiological Protection.[3] It states that "the irradiation, for the purposes of such studies (that is, of no direct benefit to the subject) of children and other persons regarded as being incapable of giving their true consent should only be undertaken if the expected radiation is low (for example, of the order of one-10th of the dose-equivalent limits applicable to individual members of the public) and if valid approval has been given by those legally responsible for such persons."

This means, in common parlance, that exposure to *x* rays could be justifiable where the dosage was comparable to the normal variation in natural irradiation received by, say, individuals living in two different parts of the British Isles. In fact, using modern equipment, a single radiograph might fall well within such dosage limits, and thus be classifiable as a negligible risk.

Parental permission and co-operation. Agreement by the child

Parental (or guardian's) permission should normally be obtained—with rare exceptions such as the comparison of two treatments for some emergency condition—after explaining as fully as possible the nature of the procedure. Whether or not this should be a signed, witnessed declaration remains debatable. It is an advantage if the parents can be present during the procedure. Although the law in Britain does not recognise an age of consent, children much younger than 16 often have enough understanding to collaborate altruistically in a project.

New drugs: new immunisation procedures

In general these should be first tested on animals, then on adult volunteers, then on older children able to take part voluntarily in the research, and only then on younger children.

However, there are instances where this sequence might be inappropriate; for instance in the development of a vaccine against respiratory syncytial virus, where few uninfected subjects may be available above the age of infancy.

British Paediatric Association: Standing Ethics Advisory Committee

(1) The British Paediatric Association has set up a Standing Ethics Advisory Committee. The function of this Committee will be to offer advice on the ethics of research projects involving children.

(2) The Committee will respond to requests for advice from individuals planning research projects, from local ethical Committees, or from editors of journals, but its opinions will not be binding. Approval of research projects must remain the responsibility of statutory local ethical committees.

(3) The Committee will base its opinions on guidelines drawn up by the British Paediatric Association, and if it is consulted often enough it will in time establish some uniformity of policy for research in children throughout the country.

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Letter from . . . Western Australia

Flying to the rescue

BOB MILSTED

When Paddy Hannan discovered gold east of Perth in 1893 he started the gold rush which gave birth to the town of Kalgoorlie. It's a mining town, first and last, and has relied for its existence ever since on the world demand for gold or, more recently, nickel, and on a slender pipeline which brings water pumped from Perth 350 miles away. Kalgoorlie boasts the near perfect proportions of 20 000 people to one set of traffic lights, and sits like a small island in a huge sea of arid bush. Having arrived in Perth jobless and penniless after four months' driving overland through Asia, the opportunity to work for the Eastern Goldfields section of the Royal Flying Doctor Service was definitely not to be missed. The service employs two doctors, three nurses, and four pilots and covers an area around Kalgoorlie slightly larger than the United Kingdom —surely the largest general practice in the world. The hub is the radio base, which serves as the sole link between the outside world and the isolated sheep stations and Aborigine camps of the Central Desert. The base deals with telegrams and provides a school of the air for children on stations, as well as dealing with medical calls. Each morning at 11 am there is a regular schedule for non-urgent medical inquiries. Each station has a medical chest with a variety of numbered drugs, which they take according to advice received.

"I suggest you take two 93s and a 15," sounds a little strange coming over the air, but the system works very well. Emergency calls after hours trigger a radio telephone in the home of the doctor on call. Diagnosis over the radio takes a little practice, but the decision whether to send out a plane is helped by the knowledge that an emergency call from a station is unlikely to be trivial—perhaps a child with an arm lacerated by farm machinery, or an adult bitten by a snake. The pastoralists, who live up to a 100 miles from their nearest neighbours, survive the rigours of running a station and raising a family in an unforgiving environment with unfailing good humour. In the process, they seem to become as tough as their lifestyle. The most bizarre call was from a dogger (who baits traps for dingos), who called in to ask whether there was an antidote to strychnine as he had just inhaled some. He survived, despite having a supposedly lethal level of strychnine in his blood.

Kalgoorlie, Western Australia
BOB MILSTED, MD, MRCP, medical officer

Snags and kangaroos

Many people are under the illusion that flying doctors actually pilot the planes. Fortunately, this is no longer the case. Any such romantic notions disappear rapidly when landing on a bush strip at night by the light of car headlights and a few fruit cans filled with kerosene. On one night-landing we touched down only to find ourselves bearing down on a kangaroo. Unperturbed, the pilot lifted the plane over the bemused animal's head and touched down again behind him. The planes are twin-engined Navajos, capable of taking two stretchers, but definitely not the ideal place to carry out emergency procedures. Transporting patients in unpressurised aircraft creates unique problems. An undrained pneumothorax will expand as the atmospheric pressure decreases, as will distended bowel. Patients with respiratory problems may deteriorate, and labouring women seem to progress rather more rapidly than is good for the doctor's nerves. Simple things become difficult; drips stop running and the cuff of an endotracheal tube expands at altitude. The rule is to do whatever is necessary for the patient's safety before taking off. Whenever possible, pregnant mothers are brought to Kalgoorlie two weeks before term to await delivery in the hospital there and avoid mid-air drama. One priority after delivery is, of course, to radio the good news to the husband. The "Bloody beaut!" response of one proud father was an uninhibited expression of delight which, transmitted as it was over the whole network, brightened the day of everyone within a radius of several hundred miles.

The twice-weekly visits to the small towns of Leonora and

D1D

Date of Hearing: 14 and 16 September 2001

Name of respondent doctor: ROGERS John — depart a fait

Registered qualifications: MB BS 1979 Lond SR:

Registered address: [redacted]

Panel:
Chairman: Professor McKay
Dr Akinkunmi
Mr Doven
Dr Montgomery
Dr Rennie
Dr Sayeed
Dr Winstanley

LegalAssessor: Miss Eleanor Platt QC

Committee Secretary: Remi Gberbo, Scott Geddes

Type of Case: Preliminary hearing to consider abuse of process

Representation

GMC: Mr Ian Stern, instructed by Field Fisher Waterhouse, Solicitors to the Council, represented the Council.

Doctor: Mr Rogers was present and represented by Mr Robert Seabrook QC, Counsel, *instructed by Theodore Goddard Solicitors.*

Determination

The Committee have given careful consideration to the submissions made on behalf of the doctor and of the GMC in this application by the doctor to stay proceedings.

In accordance with the advice from the legal assessor, the Committee first considered *the date when reasonable time began to run in relation to Article 6 (1) of the Human* Rights Convention and the Human Rights Act. The date the Committee have decided upon is 16 April 1999, based upon the letter of that date from the GMC to Mr Rogers informing him that a decision had been taken to refer his case to the Preliminary Proceedings Committee. Having considered all the facts, the Committee did not conclude that the earlier date of March 1999 or the later date of October 1999 were appropriate.

The Committee then considered the reasonableness of the time that had elapsed since that date. Whilst accepting that a considerable volume of documentation had to be obtained and scrutinised, the Committee considered the case was not technically complex or difficult.

The Committee also noted the effect on the doctor in relation to his suspension by his employers and that this suspension has been continued pending the outcome of the issues before the GMC. The Committee accepts that the withdrawal of admitting privileges to private hospitals has been a direct consequence of the delay in the proceedings.

The chronology (document C3) submitted on behalf of the GMC was considered carefully, in particular from 17 November 1999 when the file on the case was opened by their solicitors. There was little evidence in support of this chronology which contained time gaps that concerned the Committee.

The Committee therefore considered that the two years and 10 months that will have elapsed between 16 April 1999 and the date of the anticipated PCC hearing date of February 2002 would be unreasonable.

In considering the unreasonableness of the timescale the Committee also considered the alternative start date of October 1999 which had been suggested. Even taking that date as the start date, the Committee considered the timescale to be unreasonable. Accordingly, the Committee have concluded that there has been a breach of Article 6(1).

The Committee then moved to consider and balance their duty to protect patients, the interests of the public and the interests of the doctor. In doing so, they considered all the circumstances of the case, the submissions of counsel, the allegations contained in the charges, and the findings of the Tribunal. On balance the Committee considered it would be disproportionate to continue with the proceedings.

Confirmed

October 2001

Chairman

In medicine we need regular assessment of our skills by respected and senior colleagues. Such a system has been started for public health doctors in the West Midlands. The quality of the work we do and the effectiveness and efficiency of the management in our departments are reviewed annually. I for one would rather be told that my professional skills were not suitably in line with modern standards, should this ever be the case, before the population of Shropshire began to die unnecessarily as a result.

I agree with the BMA that self regulation is important[2] and that our professional skills should be assessed by other doctors in our specialty. If doctors were unable to listen and heed advice during such processes, however, then management would have to act. I cannot believe that an airline would allow pilots to continue flying its passengers if, after assessment by their senior professional colleagues, they were considered unfit to fly.

Rosemary J Geller *Director of public health*
Shropshire Health Authority, Shrewsbury, Shropshire SY3 8XL

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Supraregional neonatal cardiac surgery works in Western Australia

EDITOR—Having read Treasure's editorial about the lessons to be drawn from the Bristol case,[1] we wish to put the case for supraregional neonatal cardiac surgery despite extreme distances. Western Australia has a population of 1.8 million with an incidence of congenital heart disease of 7.65/1000 live births. A mean of nine infants a year require cardiac surgical intervention with cardiopulmonary bypass in the neonatal period. These infants are transported in commercial aircraft by the Western Australian Neonatal Transport Service from Perth to the Royal Children's Hospital, Melbourne.

The distance between the hospitals is nearly 3000 km, and the trip lasts six hours. The infant travels in a transport incubator with inbuilt ventilator and infusion pumps attached. Monitoring is by electrocardiography and pulse oximetry, with blood pressure and blood gas tensions being measured. The medical escort is a paediatric registrar or consultant or a neonatal intensive care nurse, or both. The infant's parent(s) usually travel on the same flight.

We have recently conducted an audit of 10 years of interstate transports to assess mortality and morbidity.[2] The largest subgroup in this audit comprised 46 patients with transposition of the great arteries. The first arterial switch operation was performed in Melbourne in 1983. The unit currently performs an average of 30 switch operations each year, in a catchment population of 10 million. Between January 1986 and December 1995, all 46 patients with transposition of the great arteries had the arterial switch operation. Of these patients, seven were ventilated and 17 had prostaglandin E, infusions. The one year survival was 100%, and the current cohort survival is 98% (45/46). This compares favourably with quoted rates in Treasure's editorial.[1] The youngest patient in this group is now 2½ years old and the oldest 12. Initial developmental follow up data on 43 of the patients shows a 7% incidence of important problems, three patients having borderline intellectual function or hemiplegia, or both. Again, such figures compare well with those in other published reports[3] and show that Western Australians are served well by current management with supraregional transfer.

The financial costs of interstate travel and accommodation for the parents are paid by the state health department. Although the parents of infants who are transported over ultralong distances suffer additional emotional costs, they benefit as a group from the excellent survival rates of their infants.

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Patrick J Pemberton *Head, department of neonatology*
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Techniques for measuring quality of care need to be assessed

EDITOR—I agree that we should be concerned about providing the best quality care possible, and we should do what we can to improve health care. But hard questions should be asked about the planned solutions to the Bristol cases. It is easy to jump on the Bristol bandwagon[1]; what happened there was wrong, but will the suggested solutions improve health care? And would they have prevented what happened?

It is disturbing that a failed suggestion from the United States—publishing hospital mortality league tables—is the prime consideration.[2] The concept of a Commission for Health Improvement is likewise noble, but inspecting hospitals every three or four years indicates a role similar to that of the Office for Standards in Education in Britain, which has been criticised for expensive and contradictory outcomes. Attempts in the United States to measure quality of care have foundered, usually because of inability to take account of severity of illness.[2,3] When attempts to stratify for disease severity are used, major limitations become apparent—for example, the data collected are amenable to manipulation, are unreliable, or ignore important outcome variables.[4]

I applaud and support any research into how quality should be measured. But it is research and should be subjected to the same rigour as a new medicine is. Is there evidence that quality is measured? Is outcome improved? And, as for any new product, what is the cost? At present, such expensive and time consuming techniques are not developed enough for general use; as for any medical advance, we should wait for the evidence base that these procedures do improve quality of care and are cost effective.

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Students must be taught more about ethics

EDITOR—Taken with his letter in a previous issue,[1] Johnson's editorial on self regulation is another nail in its coffin.[2] His concern in "making self regulation credible" is to make it credible to doctors, not the public. In his letter he complained that the *BMJ*'s use of a photograph of a bereaved Bristol parent sensationalised the issue.[1] Maybe he saw only the model coffin in the picture. But doctors need to be reminded of the depth of sorrow and anger in that mother's eyes—the natural response when your child died unnecessarily.

It is the sorrow and anger caused by doctors to real, live people that self regulation must address. Patients with all their emotions have to be at the centre of self regulation—not some mechanically performed peer review. Johnson's editorial may read well in the corridors of medical politics, but it gives no comfort to patients trying to deal with the General Medical Council.

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

Nor does the editorial give hope that the General Medical Council will better fulfil its statutory responsibility for medical education so that doctors will be trained not to abuse and misuse their patients. One possible approach is to teach students more of the humanities and, in particular, about ethics. Recognising this, the council instructed medical schools to teach medical ethics over a decade ago. Yet it has not withdrawn approval from those schools that still have no regular medical ethics teaching, one of which (the Middlesex/University College London) is right on its own doorstep.

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

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1 Johnson JN. Cover picture meant that BMJ had descended to level of tabloid newspapers. *BMJ* 1998;316:1851. (13 June.)
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Bristol case highlights potential weaknesses of Calman system

EDITOR—The Bristol case has implications for clinical governance, audit, management, and the provision of services,[1 2] but what are the implications for specialist training? Having a rigorous training before acquiring *independent contractor status is the ideal* way to ensure high standards, as is acquiring self directed skills of learning and self criticism. Although this represents the traditional method of training in the United Kingdom and has generally led to a fairly high standard, some changes are now inevitable.

How does the Calman programme of specialist training fit these new demands?[3] In many specialties the time available for training has been reduced. Additionally, on call rotas are being made less onerous as a result of European Union directives. Although training schemes are becoming better structured, these measures may lead to young specialists being well trained but less experienced than young specialists were previously. As a result, training posts have been set up for doctors who have gained a certificate of completion of specialist training. Another challenge will be for consultants to demonstrate their track record to patients and purchasers of care. How will a newly appointed specialist be able to do this without a sustained period under the proctorship of a more senior established colleague? Does this mean that "junior" consultants are inevitable?

The Bristol case highlights a further potential weakness of the Calman system in that some of the poor results were attributed to one surgeon having received most of his training under a senior colleague who himself later came under scrutiny. Previously, specialists spent time in two or three centres; in the Calman system a specialist's training might well be centred in one region. Therefore rotations are vital, and exchanges with other centres in different regions and travelling fellowships overseas will become important.

Close audit of both the trainees' and the trainers' case mix and outcomes is essential. This might best be supervised by the appropriate specialist society under the aegis of the royal colleges and postgraduate deans. *This will particularly apply to complex and* subspecialist work, for which the first direct exposure might previously have been as a newly appointed consultant. Supervised training has implications for time, resources, and throughput of patients. How will established consultants acquire new skills and techniques safely? Proctorships and sabbatical leave to other centres followed by close audit may be the only acceptable solution *and yet have many consequences for* the provision of services.

The training of specialists presents the medical profession with major challenges. Failure to meet these will jeopardise the whole ethos of self regulated postgraduate medical education.

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1 Klein R. Competence, professional self regulation, and the public interest. *BMJ* 1998;316:1740-2. (6 June.)
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Private practice has similar problems

EDITOR—I applaud the sentiments in Smith's editorial, but the focus seems to be on NHS medicine.[1] An equal focus should be applied to private practice, where the motivation for inappropriate and excessive treatment is financial.

It was reported in *BMA News Review* that private practice could come under scrutiny by the Commons health select committee during the next parliamentary session, and David Hinchliffe MP was quoted as saying, "There is serious concern that certain operations, primarily in the private sector, are not performed by those sufficiently qualified to do so." I would suggest that unnecessary operations are a greater problem, some being performed by doctors who have had only basic training in the techniques while they were passing though a specialty.

The Bristol case has given every chairman of every medical advisory committee of every private hospital a great responsibility—that of "policing" his or her colleagues' activity in the private sector. Moral support and advice are readily available from the General Medical Council, as I have recently found, and the medical director of the local NHS trust would also be an appropriate person to speak to.

What does one do if a colleague who is not an orthopaedic surgeon or hand surgeon operates on Dupytren's contractures, or a colleague who is not a plastic surgeon performs breast reductions, or a colleague who is not a gynaecologist inappropriately operates on genital prolapse? What do you do if a colleague always finds something to operate on no matter what the patient is referred with? And what do you say to the anaesthetist who always puts in a regional block as well as giving a general anaesthetic in order to bump up the fee? It astounds me that the medical insurance companies themselves have not policed these sorts of activities in order to reduce their own financial outgoings. All of *these examples are observed every week by* all of us who have our eyes open. Worse, they are obvious to our nursing and paramedical colleagues, who wonder why we are doing nothing to correct these anomalies.

Smith concluded his editorial with the spectre of micromanagement of doctors. It is therefore urgent that we put our own house in order and do not lose the impetus for change that the Bristol case has produced.

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1 Smith R. All changed, changed utterly. *BMJ* 1998;316: 1917-8. (27 June.)
2 GP crisis wins Commons scrutiny. *BMA News Review* 1998 *Jun 15:13.*

Formal mentoring might have helped

EDITOR—One additional point that I think needs to be made after the Bristol case[1] is how we are adequately to support doctors, particularly consultants. Senior doctors and particularly consultants (in all specialties) carry enormous loads; these are not only of basic clinical care and decision making but also managerial and educational roles; counselling roles for both patients, their families, and junior doctors; terminal and palliative care; and many other endless demands. In many other professions sensible arrangements have been made about mentorship and supervision of work in order to support people doing these difficult jobs—for example, in social work and psychology.

We need to help doctors by providing a much more structured form of mentorship or supervision to support them in the work they do. Otherwise we will continue to use our informal mentors of family and friends to share this load. If some formal mentoring or supervisory system had been in place for Mr Wisheart and colleagues, these doctors might have been able to express their anxieties and concerns about their surgical work; formal steps might then have been taken to address these issues. The current system clearly fails and does not allow such expression.

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1 Treasure T. Lessons from the Bristol case. *BMJ* 1998;316: 1685-6. (6 June.)

Roles of GMC, royal colleges, and Department of Health remain unclear

EDITOR—As Treasure and Klein point out, one the main questions arising from the Bristol inquiry is why so many warning signals went unheeded.[1 2] In particular, although audit data from the United Kingdom cardiac surgery register seemed to raise questions about the performance of the Bristol unit, they were not acted on. In some ways this is not surprising. When audit was first introduced there was great reluctance to associate it with policies for professional accountability. One of the consequences was that royal colleges had no mechanisms in place to act on the findings of the national and regional audits they commissioned. Research on the audit programme of the Royal College of Physicians, undertaken in the early 1990s, found that audit had the characteristics of a research activity—owned by the individuals

D10

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IN THE HIGH COURT OF JUSTICE

No CO/3296/2001

QUEEN'S BENCH DIVISION

THE ADMINISTRATIVE COURT

Royal Courts of Justice

The Strand

London WC2 A2U

Thursday, 15th November 2001

Before:

MR JUSTICE KEITH

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THE QUEEN ON THE APPLICATION OF HENSHALL

V

GENERAL MEDICAL COUNCIL

- - - - - - - - - - - - -

(Computer-Aided Transcript of the stenograph notes of

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MR D SQUIRES (instructed by Irwin Mitchell) appeared on behalf of the Claimant.

MISS J COLLIER (instructed by Field Fisher Waterhouse) appeared on behalf of the Defendant.

JUDGMENT

As Approved by the Court

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1. MR JUSTICE KEITH: The claimant's daughter was the subject of clinical research at a hospital in Staffordshire into a particular method of treating premature babies born with breathing difficulties. The claimant subsequently questioned the quality of that research and whether she had given her consent for that research in relation to one of her daughters. She was in contact with the media over her claims. A representative of the media confronted the Chief Executive of the hospital, Dr Keith Prowse, over her claim that her signature on a consent form authorising the research purportedly signed by her might have been forged.

2. In order to demonstrate that the claimant's signature was genuine, Dr. Prowse authorised the release to the media of consent forms admittedly signed by the claimant presumably to show (a) the fact that her consent had been obtained on other occasions and (b) the similarity of her signature when her signature on the questioned consent form was compared with her signatures on the unquestioned consent forms. Dr. Prowse did so without having obtained the claimant's consent to the release of those consent forms.

3. The claimant and her husband complained to the General Medical Council ("the GMC") about Dr. Prowse's authorisation of the release of those consent forms without her consent. In due course the GMC's professional conduct committee found that the facts alleged were not sufficient to support a finding of serious professional misconduct. In particular, the committee found that the release of the consent forms had not been prohibited by the professional rules governing confidentiality. The claimant now renews her application for permission to apply for judicial review of those findings, her application having been refused by Moses J. on the papers.

4. The committee found as a fact that the allegation of forgery was false. I am sure that what the committee meant by that was that the claimant had indeed signed the questioned consent form. It was not a finding adverse to her honesty or credibility, in view of the fact that she may have signed the form while she was experiencing the after-effects of anaesthetics and therefore she may well have forgotten what she had signed.

5. It is unnecessary for me to consider whether it is arguable that this finding of fact was not supported by the evidence, or indeed whether it was within the power of the committee to consider whether the claimant had signed the questioned consent form. That is because it is not disputed that the issue as to whether the claimant signed the form was not relevant to the inquiry which the committee had to conduct. The critical question was the issue of confidentiality, and in my opinion there is nothing which suggests that the committee's conclusion on that issue was coloured by the finding which it had made that the claimant had indeed signed the questioned consent form. It is, I think, not seriously arguable that the reference to the falsity of the allegation of forgery was no more than an aside, an important aside maybe, but nevertheless an aside which was simply designed to relieve the anxiety of those against whom the allegation of possible forgery had been made. The reference, therefore, to the falsity of the allegation of forgery was not taken into account at all.

6. On the critical question which the committee had to decide, the exercise which the committee had to conduct was to balance the competing public interests which militated for or against the public disclosure of the consent forms admittedly signed by the complainant. Accordingly, permission to apply for judicial review should only be granted if it is arguable that the committee's approach to the issue of confidentiality was flawed.

7. The basis on which it is said that it was flawed is that the committee concentrated on the important public interest in maintaining public trust and confidence in the paediatric ward of the hospital, and in doing so the committee failed to take account of two countervailing public interests. The first was the importance of protecting patient confidentiality, i.e. the importance of patients knowing that details of their medical condition and treatment will not be revealed without their consent. The second was the importance of ensuring that patients would not be deterred from approaching the media when they believe that a hospital has been guilty of serious malpractice by the fear that the hospital might reveal any part of their confidential medical history.

8. I do not think that it is seriously arguable that the committee ignored the first of these countervailing public interests. Patient confidentiality was at the heart of the issue which the committee had to decide. It is, I think, inconceivable that the committee was not aware of that. Indeed, the fact that the committee realised that it had to balance that interest against the desirability of maintaining public trust and confidence in the hospital is borne out by the following sentence in its reasons:

> "The committee wish to make clear that the circumstances in which you were placed were truly exceptional and nothing which the committee have decided should in any way be understood to diminish the obligation upon doctors, whether or not they are acting as managers, to preserve the confidence of patients."

9. It is, I think, arguable that the committee did not take into account the second of the two countervailing public interests. But I do not believe that had the committee done so, it could have affected the outcome of this particular complaint. The fact is that the claimant and her husband did approach the media and were not deterred by any fear of what the hospital might do. Since the committee regarded the circumstances of the case as truly exceptional, the committee must be taken to have regarded that as a sufficient message to the medical profession that patient confidentiality would only rarely be overridden by the need for disclosure. So it can safely be said that the committee would inevitably have regarded the possibility of complainants being deterred by the committee's conclusion in this case from complaining of malpractice as far too remote to affect the outcome of this case.

10. For these reasons, the renewed application for permission to apply for judicial review as currently formulated must be refused. However, it is now said that at the very least the claimant is entitled to have removed from the committee's reasons the finding of fact that she had indeed signed the questioned consent form. I accept that the claimant has passed the test for severability, but I am nevertheless not persuaded to give the claimant leave to amend her grounds to seek relief. No useful purpose would be served. The finding was not relevant to the inquiry. It was not a finding which bore on the claimant's honesty or credibility. It has no bearing on the claim which the claimant is proposing to bring against the hospital about the quality of its research and its impact on her daughter's condition. And even if it had some relevance to that claim, it could not form the basis of any issue estoppel since the claim against the hospital is the claim of the claimant's daughter. In the absence of an amendment, no question of permission to apply for judicial review on any alternative basis can arise.

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D14

Negative extrathoracic pressure in treatment of respiratory failure in infants and young children

M P Samuels, D P Southall

Abstract

***Objective*—To assess the efficacy of a newly developed system for applying continuous or intermittent negative (subatmospheric) extrathoracic pressure in respiratory failure.**

***Design*—Uncontrolled clinical trials in infants deteriorating or failing to improve despite standard medical treatment.**

***Setting*—Paediatric and neonatal intensive care units and paediatric wards.**

***Patients*—88 infants and young children aged 1 day to 2 years with respiratory failure due to bronchopulmonary dysplasia, the neonatal respiratory distress syndrome, bronchiolitis, myopathy, the congenital hypoventilation syndrome, pneumonitis, and postoperative phrenic nerve palsy. At the start of treatment 59 were receiving ≥50% inspired oxygen and 40 positive airway pressure ventilation.**

***Intervention*—Treatment was provided within purpose built Perspex chambers of appropriate size. The chamber incorporated safe and effective latex neck seals; facilities for access, monitoring, and observation; and a heater to control the ambient air temperature.**

***Main outcome measures*—Inspired oxygen concentration and carbon dioxide pressure before application of negative extrathoracic pressure and two and 48 hours afterwards; duration of treatment; and final outcome (discharge home or death).**

***Results*—While arterial oxygen saturation was maintained at constant values 75 infants showed reductions in inspired oxygen concentrations (range 4-50%, median 15%) two hours after starting treatment and 74 showed reductions at 48 hours (2-79%, median 20%). Of 59 infants who had carbon dioxide pressure measured before and after starting negative extrathoracic pressure, 21 showed a reduction (range 0·6-8·9 kPa, median 2·0), 30 no change (±0·5 kPa), and eight a rise (range 0·6-5·1 kPa, median 2·1). In 28 patients extubation was facilitated, 54 patients were discharged home, where six continued treatment, and 34 died. Treatments lasted for between two and 236 days (median 13 days).**

***Conclusion*—Negative pressure respiratory support is a non-invasive yet effective treatment for respiratory failure. It may avoid the need for intubation, reduce the pathophysiological consequences of positive airway pressure ventilation, and aid extubation.**

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Br Med J 1989;299:1253-7

Introduction

The management of respiratory failure in infancy and childhood traditionally includes the administration of additional inspired oxygen and the use of positive airway pressure either continuously or intermittently. The use of intermittent positive airway pressure usually follows endotracheal intubation and produces an increased risk of lower respiratory tract infection. In addition, positive airway pressure ventilation produces barotrauma, has adverse haemodynamic effects, and may contribute to the development of chronic lung disease, particularly in preterm infants. It is mostly practised in intensive care units and requires the use of complicated equipment by highly trained nursing and medical staff.

Subatmospheric (negative) extrathoracic pressure as a means of respiratory support has a long history.[1,2] It was used to treat children with respiratory failure due to poliomyelitis and in the 1960s and 'seventies was found to be effective in the management of the neonatal respiratory distress syndrome.[3-10] More recently it has been used in persistent pulmonary hypertension of the newborn[11] and pulmonary interstitial emphysema.[12] Its value, however, has been hindered by technical problems,[9] which have included upper airway obstruction and soreness from the neck seal and difficulties in achieving access to the patient and maintaining a neutral thermal environment for newborn infants. These problems have been overcome by the development of a new system for applying negative pressure respiratory support. We present the results of the system's use in uncontrolled trials during which it was developed.

Patients, materials, and methods

Table I shows the clinical details of 83 patients treated with continuous negative extrathoracic pressure and of five who received intermittent negative pressure ventilation. In all of them their clinical condition had deteriorated despite standard treatment.

TABLE I—*Causes of respiratory failure and ages of patients treated with negative extrathoracic pressure*

Diagnosis	No of patients	Age range
Bronchopulmonary dysplasia	47	4-38 weeks
Neonatal respiratory distress syndrome	13	1-12 days
Phrenic nerve palsy (postoperative)	10	12 days-2 years
Bronchiolitis or asthma	7	2-12 months
Myopathy	5	5-17 months
Complications of cardiac surgery	2	6 and 12 weeks
Pneumonitis	2	17 days and 5 months
Congenital alveolar hypoventilation syndrome	2	Both 3 weeks
Total	88	1 day-2 years

Before starting treatment 40 patients were receiving positive airway pressure ventilation and 59 required ≥50% inspired oxygen to maintain adequate arterial oxygen saturation (defined below), 35 of them requiring 95-100% inspired oxygen. Continuous negative extrathoracic pressure was used to avoid intubation in acute respiratory failure, to reduce additional inspired oxygen concentrations and positive airway pressure in infants already intubated, and to help in weaning infants from positive airway pressure ventilation. Two infants with bilateral phrenic nerve palsies (after cardiac surgery), one with myopathy, and two with the congenital alveolar hypoventilation syndrome were treated with long term intermittent negative extrathoracic pressure ventilation to continue respiratory support after extubation. Treatment was started in this hospital (38 patients) or in the hospital of referral (50 patients).

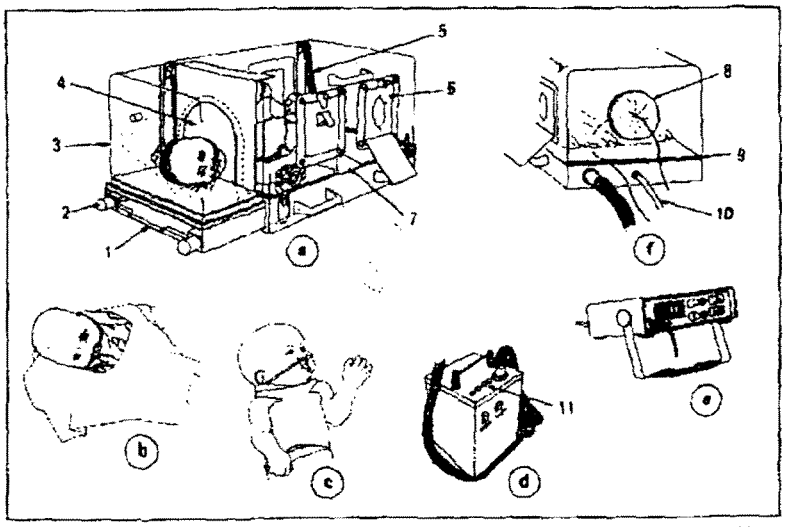

FIG 1—*System for applying negative extrathoracic pressure. (a) Negative pressure chamber with head box, latex neck seal being placed over infant's head, (c) stockinette neck protector, (d) electrical fan unit with facility for continuous or intermittent suction, (e) pressure monitor, (f) foot end of chamber showing access for monitoring leads, infusion lines, and suction hose. Details of the chamber include release for head section (1), rods on which it slides out away from chamber base (2), head box (3), latex neck seal taped up over arch in lid (4), gas strut hinges (5), foam gasket in porthole (6), footplate to support infant when chamber is tilted up (7), porthole for infusions, etc (8), rubber strip below which monitoring leads, etc, can enter chamber (9), tubing to pressure monitor (10), and controls for inspiratory and expiratory pressures and time intervals (11)*

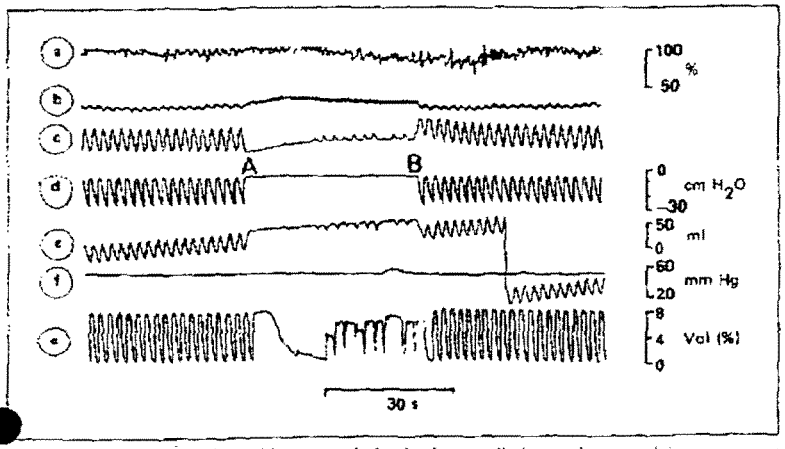

FIG 2—*Recording from infant with congenital alveolar hypoventilation syndrome receiving intermittent negative extrathoracic pressure during sleep. (a) Arterial oxygen saturation in beat to beat mode; (b) plethysmographic waveform from which arterial oxygen saturation is derived; (c) inductance plethysmography (inspiration is upward deflection); (d) negative extrathoracic pressure; (e) tidal volume from pneumotachograph; (f) transcutaneous carbon dioxide pressure; and (g) expired carbon dioxide concentration. Between A and B intermittent negative extrathoracic pressure was discontinued: the infant's own breathing efforts were ineffectual*

APPARATUS

The system we used to apply negative extrathoracic pressure was developed over two years (fig 1). The chamber has three different sizes: neonatal (<4 kg), infant (3-8 kg), and toddler (5-20 kg) (Horner and Wells, Chelmsford). It has a Perspex lid hinged to one side of an aluminium base with a rubber seal around its edge. The lid has two portholes on each side, which provide access to the patient. While the carer's arms are inside the chamber subatmospheric pressure is maintained by the use of packed cell foam gaskets. Most care procedures can be performed with the infant under subatmospheric pressure, including nursing observations, reapplication of monitoring sensors, physiotherapy, and nappy changes.

The lid of the chamber has a rubber strip along its lower edge that allows monitoring leads and infusion lines to enter the chamber between the base and lid without being constricted and yet still maintain subatmospheric pressure. A recent addition includes a fifth porthole in the end of the chamber lid that allows attachments to be applied and removed without opening the chamber (fig 1 (*f*)). Intra-arterial lines may run into the chamber without any damping of signal content.

The patient's neck lies under an arch in the head end of the chamber lid. An almost complete seal is obtained with a rectangular sheet of latex (thickness 350 μm) (Pentonville Rubber Products, London) in which a hole has been cut with an area about two thirds that of the neck; because of its elasticity it can be stretched over the head of the infant. The side and uppermost edges of the latex are taped (Micropore, 3M) to the lid of the chamber while the lower edge is dropped between the base and head section. The head section, which travels in and out on sliding rods, can then be locked into a position that grips the lower edge of the latex. Suction created by the subatmospheric pressure within the chamber causes the latex to adhere and seal both around the arch and over the base of the patient's neck. The elasticity of the latex allows a skin tight seal without circumferential pressure, which might obstruct the upper airway. In addition, an effective neck seal, the patient's comfort, and the avoidance of neck soreness are achieved by the use of double thickness elasticated tubular stockinette (Esiban, E Sallis, Nottingham). This is cut for the purpose of forming a polo neck vest with a long collar (5 cm) that lies between the latex and the skin.

Urgent access to the patient can easily be gained by removing the tapes holding the latex on to the lid and releasing two quick release latches that hold the lid down. The lid swings open gradually on gas strut hinges and leaves the patient lying on the base and head section, so that access to the head, trunk, and arms and legs is possible. In addition, intubation or ventilation with a facemask, or both, are facilitated by the removal of one of a pair of head pillows. This allows the patient's neck to be fully extended. Patients breathing spontaneously have additional oxygen supplied within a specially designed head box that fits over the head section or through nasal cannulas (DeVilbiss, Feltham).

The chamber can be tilted with the head uppermost by between 10° and 20°, and the patient can be nursed prone, supine, or on his or her side and be moved between these positions. The toddler and infant chambers are used on bed or cot bases and the neonatal chambers either on a platform incubator or on a modified incubator base (Horner and Wells, Chelmsford, and Vickers Medical, Basingstoke) which provides the circulation of warmed air, servo controlled to the ambient air temperature within the chamber. This development is particularly important for preterm infants with the respiratory distress syndrome, allowing them to be nursed naked within the chamber.

Subatmospheric pressure was produced by a specially designed unit (DHB Tools, Leamington Spa) incorporating an electrical fan, a safety valve set at −40 cm H_2O, and a control to adjust the airflow. The first developed suction units provided only a continuous airflow, but the addition of a twin valve system allowed the provision of intermittent larger negative pressures (settings most used were −18 cm H_2O to −30 cm H_2O) superimposed on to a constant background pressure (usually −6 cm H_2O to −10 cm H_2O). These can be provided between one and 60 times a minute, with a variable ratio between the inspiratory and expiratory times. Commonly used settings are 20 breaths/min with a ratio of inspiratory to expiratory times of 1:2.

The suction unit is connected to the chamber base by a short length of hosing. The pressure developed within the chamber is monitored by means of a purpose built electronic monitor (March Designs, Dunstable) with appropriately set alarm limits. Figure 2 shows the analogue output of the pressure monitor and the

pressure changes generated within the chamber. In infants receiving intermittent negative pressure ventilation the presence of a constant background negative pressure prevents any large to and fro body motion with each breath.

PROTOCOL FOR USING NEGATIVE EXTRATHORACIC PRESSURE IN RESPIRATORY FAILURE

All patients were continuously monitored with a validated pulse oximeter[11] (Nellcor, California) and SaO_2 maintained between 92% and 95% before term and 95-98% after term. The inspired oxygen concentrations required to achieve these values were measured while the infant was asleep or quiet with a calibrated oxygen analyser placed by the infant's nose in a head box; if the infant was intubated the oxygen concentration delivered by the ventilator was measured. In addition, depending on the condition of the patient, the following variables were continuously monitored: electrocardiogram, systemic arterial blood pressure, transcutaneous carbon dioxide concentration (Hewlett Packard with Draeger electrode, Uxbridge), and core or peripheral temperature, or both. Arterial or central venous blood samples for measuring pH and validating transcutaneous carbon dioxide concentration were taken before starting treatment and, depending on the severity of respiratory failure, at variable intervals after starting treatment.

Continuous extrathoracic pressures of between -6 cm H_2O and -10 cm H_2O were instituted over several seconds. In the patients already receiving positive airway pressure ventilation the positive peak inspiratory and end expiratory pressures were reduced by the magnitude of negative pressure used. For example, an infant receiving peak inspiratory/end expiratory airway pressures of +30/4 cm H_2O would change to +22/0 cm H_2O immediately before a constant negative pressure of -8 cm H_2O was applied. In some patients receiving high rate positive airway pressure ventilation it was not always possible to obtain end expiratory pressures of 0 cm H_2O, values of +2 cm H_2O to +3 cm H_2O being accepted. On starting intermittent negative extrathoracic pressure ventilation in patients who were intubated the positive airway pressure would first be discontinued including any end expiratory pressure, leaving only a constant flow of humidified gases down the endotracheal tube.

In the sickest patients full nursing care and physiotherapy could be performed while negative pressure was maintained. In the less acute cases of respiratory failure the chamber was opened every 4-12 hours for feeding and parental contact. While patients were receiving negative pressure feeds were given through a nasogastric or nasojejunal tube.

To remove the patient from the chamber, when feasible, the negative pressure was tailed off slowly over 5-15 minutes to avoid a sudden fall in lung volume. In infants previously receiving positive pressure ventilation airway pressures were increased appropriately—for example, a patient receiving 15/0 cm H_2O would change to 23/5 cm H_2O on discontinuing negative extrathoracic pressure of -8 cm H_2O.

On extubation an infant would usually be kept on either continuous or intermittent negative extrathoracic pressure for a minimum of 24 hours. As the patient's condition improved, increasingly longer times were spent out of the chamber and the pressure was gradually reduced to between -4 cm H_2O and -6 cm H_2O. The treatment was discontinued when no change was noted in inspired oxygen concentration with or without negative pressure.

When the patient's condition allowed, parents were encouraged to learn to take part in nursing their child both in and out of the chamber. The parents of patients who were to continue treatment at home had training in the use of the negative pressure respiratory support system and a transcutaneous oxygen monitor (Kontron 821S, Watford).

Results

Table II shows the concentrations of inspired oxygen required to achieve the previously defined arterial oxygen saturation before and after applying negative extrathoracic pressure. Table III shows the outcomes in the patients. Seventy five infants required reductions in inspired oxygen concentration two hours after starting treatment (range in reductions 4-50%, median 15%) and 74 required reductions after 48 hours (range 2-79%, median 20%). The greatest reductions in

TABLE II—*Inspired oxygen concentrations (percentages) according to diagnosis in 88 infants before and after start of negative extrathoracic pressure*

Diagnosis	No of patients	Inspired oxygen concentration		
		Before	After 2 h	After 48 h
Bronchopulmonary dysplasia	47		Samuels and Southall[9]	
Neonatal respiratory distress syndrome	13	40, 60, 100, 100, 100, 100, 60, 100, 100, 100, 100, 100, 100	30, 55, 55, 85, 85, 80, 40, 70, 90, 80, 90, 87, 55	21, 30, 21, 100, *, 85, 30, 100, 65, 97, 95, 50, 35
Phrenic nerve palsy	10	50, 40, 40, 60, 60, 40, 30, 60, 60, 40	30, 30, 30, 60, 50, 30, 30, 60, 60, 50	30, 21, 21, 60, 25, 30, 21, 60, 60, 40
Bronchiolitis or asthma	7	30, 30, 40, 30, 100, 40, 100	21, 21, 21, 30, 85, 30, 80	21, 21, 21, 21, 95, 21, 28
Myopathy	5	30, 40, 21, 40, 60	25, 30, 21, 35, 40	21, 21, 21, 21, 30
Complications of cardiac surgery	2	50, 25	50, 21	50, 21
Pneumonitis	2	100, 100	75, 80	30, 55
Congenital alveolar hypoventilation syndrome	2	30, 40	30, 30	30, 25

*Died.

TABLE III—*Outcome of treatment with negative extrathoracic pressure in 88 infants*

Diagnosis	No of patients	No with reduction in inspired oxygen concentration after:		Proportion of patients receiving PAPV who were extubated	No of deaths	No discharged home (continuing treatment)	Duration of treatment (days)
		2 h	48 h				
Bronchopulmonary dysplasia	47	45	44	8/13	20	27 (3)	2-147
Neonatal respiratory distress syndrome	13	13	9	6/11	6	7	2-126
Phrenic nerve palsy (postoperative)	10	5	6	7/8	3	7 (1)	3-120
Bronchiolitis or asthma	7	6	7	0/1	1	6	2-69
Myopathy	5	4	4	2/2	2	2 (1)	13-122
Complications of cardiac surgery	2	1	1	2/2	1	1	3 and 8
Pneumonitis	2	2	2	1/1	0	2	7 and 14
Congenital alveolar hypoventilation syndrome	2	1	1	2/2	0	2 (1)	28 and 236
Total	88	75	74	28/40	34	54 (6)	2-236

PAPV = Positive airway pressure ventilation.

inspired oxygen were found in infants with the neonatal respiratory distress syndrome and pneumonitis (range 5-45% (median 20%) at two hours and 3-79%, (35%) at 48 hours). Results for the infants with bronchopulmonary dysplasia are given elsewhere.[14]

Of the 14 infants who required no reduction in inspired oxygen concentrations after 48 hours, one underwent plication of the diaphragm (unilateral postoperative phrenic nerve palsy), two were extubated and were given long term intermittent negative pressure ventilation, and 11 died.

Five patients were given intermittent negative extrathoracic pressure: two with bilateral phrenic nerve palsies, one with a metabolic myopathy and two with the congenital alveolar hypoventilation syndrome. In all five cases arterial carbon dioxide pressures were maintained within the normal range for between 12 days and nine months.

In a total of 59 infants carbon dioxide pressures were measured just before and shortly after starting continuous or intermittent negative extrathoracic pressure: 21 showed a reduction in values (range 0·6-8·9 kPa (median 2·0 kPa)), 30 showed no change (±0·5 kPa), and eight showed a rise (range 0·6-5·1 kPa, (median 2·1 kPa)).

Of 40 patients intubated at the start of treatment, extubation was facilitated in 28 and 24 survived. Longer term respiratory support with negative extrathoracic pressure was provided at home in three patients with bronchopulmonary dysplasia, one patient with bilateral phrenic nerve palsies, one with congenital myopathy, and one with the congenital alveolar hypoventilation syndrome.

A total of 34 infants died: 29 from respiratory failure, three from congenital heart disease, one from a cerebral periventricular haemorrhage, and one from necrotising enterocolitis. Four patients who were intubated were able to be extubated before dying of their respiratory disease. In two patients with myopathy treatment with continuous negative pressure was electively discontinued; both subsequently died.

Observation of physiological variables showed that there was a consistent fall in heart and respiratory rates on starting negative extrathoracic pressure.[14] Systemic blood pressure usually remained unaffected, although there was an increase in some infants receiving positive airway pressure when the peak and end expiratory positive pressures were simultaneously reduced. In the more acutely ill patients the beneficial effects were evident each time negative extrathoracic pressure was given. As respiratory failure resolved the improvements resulting from the treatment remained even when negative pressure was not used, and this dictated the time at which weaning could be pursued.

Chest x ray films showed improvements in the lung fields at varying times after negative extrathoracic pressure was started. Most evident was the resolution of diffuse, soft shadowing. In bronchopulmonary dysplasia hyperlucent and cystic areas did not enlarge. No pneumothorax or other evidence of air leak was seen after starting treatment. Pulmonary vascular markings showed no clearcut changes, although cardiomegaly from right sided heart failure often resolved. Patients seemed to be more settled and showed less respiratory distress after starting respiratory support with negative pressure. Over long periods (up to six months) treatment was often given only overnight and was well tolerated by patients. Parents rapidly learnt to place and care for their children within the chamber.

Potential complications such as fluid retention, intrathoracic air leak, and gastro-oesophageal reflux with aspiration were not experienced. In addition, a pre-existing pneumothorax did not preclude treatment being effective. Upper airway obstruction became evident in only one infant who had bronchopulmonary dysplasia and required tracheostomy for subglottis stenosis after extubation; the tracheostomy still allowed an effective neck seal to be obtained. Neck soreness was not encountered once the most appropriate material to lie between the latex and the neck was found and adopted (see apparatus). Both the neck seal and the modified incubator base overcame problems with cooling in the smallest infants (<1000 g).

Discussion

Irrespective of the pathophysiology resulting in respiratory failure (excluding upper airway obstruction) we have shown that the application of negative extrathoracic pressure is a practicable, non-invasive, and effective form of treatment. Negative pressure respiratory support dates back to 1838,[12] but it fell into disuse because of technical reasons: airway obstruction and soreness from the neck seal, heat loss, and difficulties in access. Access was difficult in earlier versions of the chamber because the patient's head had to be inserted through an iris diaphragm within a rigid aperture. Our system has overcome these problems.

The absence of airway invasion, ease of use by nursing staff and parents, and the recent availability of continuous non-invasive monitoring equipment has made this technique for respiratory support particularly suitable outside intensive care and in non-industrialised countries. In addition, there are physiological reasons why negative extrathoracic pressure lung inflation may be preferable to positive airway pressure: these have been documented in both animal experiments and clinical practice.[10 15-19]

Continuous negative extrathoracic pressure and continuous positive airway pressure both increase transpleural pressure, thereby helping to splint open small airways and alveoli and re-expand atelectatic regions. Systemic oxygenation depends, however, not only on alveolar expansion and diffusing capacity but also on adequate pulmonary capillary perfusion with matching of perfusion to ventilation. Positive airway pressure reduces cardiac output,[19 20] probably by impairing venous return to the right atrium and by increasing pulmonary vascular resistance. Thus at a certain unpredictable point[21] increases in positive airway pressure may cause a fall in effective pulmonary blood flow with a resulting increase in ventilation-perfusion mismatch[22] and worsening of hypoxaemia.

Negative extrathoracic pressure, however, increases thoracic volume with less compression of vascular structures and consistently reduces pulmonary vascular resistance,[15 16] particularly at the pressures used in our patients. In addition, it may dilate pulmonary capillaries and improve ventilation-perfusion matching. This may explain its recently reported value in persistent pulmonary hypertension of the newborn.[23]

Bancalari *et al* reported the physiological effects of negative extrathoracic pressure in infants with the neonatal respiratory distress syndrome.[24] They showed a rise in arterial oxygen pressure, a fall in minute ventilation, and no change in arterial carbon dioxide pressure. Our results confirm the effects on gas exchange, and work in progress supports the idea that negative extrathoracic pressure has predominant effects on ventilation-perfusion matching. The changes in carbon dioxide concentrations, however, suggest that an increase in alveolar ventilation does occur in some patients. In addition, our observations that some patients maintain good respiratory function during the day when treated with negative pressure at night suggests that other mechanisms may also be operating. An increase in the patient's functional residual capacity, an increase in lung compliance, support of a compliant chest wall, or a reduction in diaphragmatic fatigue may

all occur as a result of inflation of the lung under negative pressure.

In hyaline membrane disease constant negative extrathoracic pressure has been compared with nasal positive airway pressure.[5] Both were effective, although negative pressure produced a more rapid improvement in oxygenation. This may have arisen partly because negative pressure produced a more definitive change in transpleural pressure than a technique relying on the transmission of positive pressure through the nose. In addition, ventilation to perfusion matching may have been enhanced by negative pressure support as discussed above.

The presence of an endotracheal tube is associated with increased bronchial secretions, impairment of ciliary clearance, mucus plugging, and upper airway trauma. It also increases the risk of airway and parenchymal infections. All of these factors may contribute to a continuing need for respiratory support after the acute condition has resolved. Both our experience and that of Mokrin and Bancalari has supported the idea that early initiation of treatment for respiratory failure will reduce the need for intubation.[8]

Non-invasive means of respiratory support will reduce the incidence of factors that contribute to chronic lung disease, particularly in preterm infants.[24] Fanaroff *et al* reported that infants with the respiratory distress syndrome treated with negative extrathoracic pressure had less need for positive airway pressure ventilation and a shorter need for supplemental oxygen than infants treated with oxygen alone.[4] Monin *et al* compared intermittent negative and positive airway pressure ventilation in 115 infants with the respiratory distress syndrome.[10] There was equal oxygen exposure and no difference in the incidence of patent ductus arteriosus, intracranial haemorrhage, or mortality but a significant reduction in the incidence of pneumothorax and bronchopulmonary dysplasia in those treated with negative pressure.

We cannot state that our system of ventilation is better than other forms of respiratory support. We measured blood gas concentrations and survival, but as we had no control groups interpretation of the results is limited. Our system was developed over two years and appopriate historical controls for the treatment of patients in over 20 centres is not appropriate. We have shown, however, that our system is an effective and safe respiratory support that can be managed by nursing staff and parents in intensive care units, general wards, and at home. Randomised controlled trials in neonatal respiratory failure and in infants still dependent on oxygen or positive airway pressure ventilation, or both, at 28 days of age are now in progress. Their conclusions may have important implications for the future management of respiratory failure in infancy.

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Original articles

Pulse oximeter and transcutaneous arterial oxygen measurements in neonatal and paediatric intensive care

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SUMMARY Pulse oximeter (SaO_2P) measurements were compared with direct arterial line oxygen saturation (SaO_2) from co-oximeters in 92 instances in 43 patients, and with arterial line oxygen measurements (PaO_2) in 169 instances in 81 patients. The mean (SD) absolute difference between SaO_2P and SaO_2 was 2·6% (2·4) after attempt to correct for the co-oximeter falsely measuring a proportion of fetal haemoglobin as carboxy haemoglobin. For 19 infants and children ≥5 months old, who have very little fetal haemoglobin, the mean (SD) absolute difference of 27 comparisons was 1·8% (2·1). Comparison of SaO_2P and PaO_2 measurements in 46 instances when PaO_2 was ≤6·67 kPa showed SaO_2 to be <90% on 40 occasions. In 24 instances when PaO_2 was ≥13·3 kPa the SaO_2P was ≥98% on 22 occasions. In 23 infants undergoing neonatal intensive care, transcutaneous oxygen monitors were compared with arterial PO_2 measurements in 60 instances. The mean (SD) absolute difference between PaO_2 and transcutaneous oxygen measurements was 1·60 kPa (1·73). Ten of the 60 comparisons had differences >2·67 kPa and three >5·33 kPa (maximum 8·40 kPa).

Pulse oximetry is a clinically useful technique for managing oxygenation but further studies are needed to confirm its safety in premature infants at risk of retinopathy of prematurity.

Information concerning the adequate uptake, transport, and unloading of oxygen is vital in the management of infants and children undergoing intensive care. While indwelling arterial lines can be used to obtain these data, insertion of catheters may be difficult and cause discomfort and serious side effects: thrombosis and blood loss may occur. Samples taken by stab give unreliable data and the procedure is painful. Correction of the anaemia caused by repeated blood sampling is usually achieved by transfusion of adult haemoglobin. By changing the position of the oxygen dissociation curve, these transfusions may compromise uptake of oxygen in the lungs if there is a low alveolar PO_2. To overcome the problems inherent in repeated blood sampling heated transcutaneous PO_2 monitors ($TcPO_2$) have been widely adopted. Although overall correlations between $TcPO_2$ and arterial PO_2 (PaO_2) are high,[1–4] a considerable proportion of the comparisons reported have shown differences between transcutaneous and arterial line measurements. This is particularly important when these monitors have been used for clinical rather than research purposes.[2 5 6] Lack of agreement between $TcPO_2$ and PaO_2 measurements is particularly likely in infants older than 8 weeks[7] and when skin perfusion is poor.[8 9] To compensate for these errors it is the policy in some intensive care units, including ours, to validate $TcPO_2$ measurements using samples from arterial line.

In other units, however, $TcPO_2$ values are regarded as reliable enough to direct changes in inspired oxygen concentrations and mechanical ventilator management without such validation.

In this study we report our experience with pulse oximetry (S_tO_2P) and $TcPO_2$ measurements in the monitoring of oxygenation in neonatal and paediatric intensive care.

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Patients and methods

A total of 85 infants and children were studied. Twenty four were undergoing treatment in the neonatal intensive care unit at St Mary's Hospital. Their ages ranged from 1 to 47 days, gestational age at birth from 24 to 40 weeks, and birth weights from 690 to 3970 g. Most of them (99%) were receiving additional inspired oxygen, 70% were being ventilated, and 12% were receiving continuous positive airways pressure (CPAP).

The remaining 61 infants and children were undergoing treatment at the Brompton Hospital: 53 were receiving paediatric intensive care and eight undergoing cardiac catheterisation. Their ages ranged from 1 day to 13 years: 53 had congenital heart disease and eight had major respiratory disorders.

A pulse oximeter sensor (Nellcor) was used to obtain non-invasive measurements of arterial oxygen saturation. In this technique[10 11] light of two wavelengths is transmitted through a tissue bed from the surface of the skin. On the opposite side of the tissue bed there is a photodetector which senses the transmitted light. Within the oximeter a light plethysmograph is constructed for each arterial pulse waveform in the tissue bed and calculations made of the light absorption with each pulse. Thus background colour change is ignored (except in terms of the intensity of the light source), and only pulsatile (arterial) light absorption measured. The technique is independent of skin colour, thickness, or texture. The response time is affected if the application site is cold, even if pulsations are present, and the instrument cannot work in the presence of very low arterial blood pressures. Audible alarms can be set for low saturation readings and for high or low heart rates. The amplitude of the light plethysmograph used to calculate each saturation value is displayed on the front of the machine as a linear array of diodes emitting light. The calculation of saturation by the oximeter was expressed as an average over a particular time period: an average of two to three seconds of data was taken in this study, during which time the arterial waveforms had to be of adequate quality—that is, resemble blood pressure waveforms and be of adequate amplitude compared with baseline noise. For most of our comparisons the analog output of each arterial waveform was examined on an oscilloscope.

The pulse oximeter sensor was attached to the child's finger, toe, or lateral side of the hand or foot in a position which matched the arterial line, thus avoiding possible errors caused by intracardiac or ductal shunts. The sensor was covered with a dark blue mitten or sock to reduce the effect of ambient light, particularly during phototherapy.

PaO_2 measurements from the arterial line samples were made on autocalibrating blood gas analysers (Corning 178 and Radiometer ABL) within two minutes of sampling. Calibrations were checked daily by chemical pathology technicians against standard reference solutions at three levels. Samples of blood from arterial lines were analysed for oxygenated and reduced haemoglobin, carboxyhaemoglobin and methaemoglobin on co-oximeters (Corning 2500 or IL282), also within two minutes of sampling. These instruments were calibrated against control solutions once daily.

Pulse oximeter measurements were compared with arterial line PO_2 concentrations on 169 instances in 81 patients, and with arterial line saturation measurements corrected for methaemoglobin and carboxyhaemoglobin on 92 instances in 43 patients.

Measurements of $TcPO_2$ (Hewlett Packard 78850A, Radiometer TCM20, Kontron 820, and Novametrix 850) were made at skin temperatures of 44°C, and the sites for comparisons were chosen to avoid inconsistencies that could result from a right to left shunt. All $TcPO_2$ sensors were applied by trained nurses, and were recalibrated before each application (at four hourly intervals) for each patient. No infant was allowed to lie on the sensor. $TcPO_2$ monitors were used only in the neonatal intensive care unit.

Measurements of $TcPO_2$ were compared with arterial line PO_2 measurements in 60 instances on 23 infants (mean age 10·5 days, maximum 47 days).

When comparing alternative methods of measurement, correlation coefficients may be of interest but in many cases are misleading, so they were not included. The absolute differences were analysed on the assumption that measurements from arterial line samples are more accurate than any other method.

The pulse oximeter measures oxyhaemoglobin as a proportion of the total functional haemoglobin present—that is, only oxygenated + reduced haemoglobin. Co-oximeters also measure methaemoglobin and carboxyhaemoglobin, and these must be taken into account when comparing pulse oximeter and arterial line sample measurements. With samples from infants younger than 5 months, a variable is the unknown amount of oxygenated fetal haemoglobin present. Although this is a functional haemoglobin and is treated as such by the pulse oximeter, part of the fetal haemoglobin is falsely estimated as carboxyhaemoglobin by both co-oximeters. The proportions of fetal and adult haemoglobin, together with as yet undetermined factors, have been shown to affect the relation

between this measured carboxyhaemoglobin and true carboxyhaemoglobin.[12,13] To overcome this problem comparisons of SaO_2 in this study have been shown separately for infants above and below 5 months of age. After 5 months, fetal haemoglobin concentrations will be low.[14]

For all measurements a correction formula described by Brown[15] and recommended by the manufacturers of the co-oximeters was used to provide values for functional SaO_2. This formula is: functional SaO_2 (%) = Fractional $SaO_2 \times 100/100 -$ (carboxyhaemoglobin + methaemoglobin); fractional SaO_2 = oxygenated haemoglobin/(oxygenated haemoglobin + reduced haemoglobin + carboxyhaemoglobin + methaemoglobin).

Results

Comparisons of SaO_2 P and arterial SaO_2 were made on 65 occasions in 24 infants less than 5 months old, and on 27 occasions in 19 infants and children over 5 months of age. Fig 1 shows the results of all comparisons, and fig 2 those for infants and children over 5 months of age. The variability between the two values, measured as the mean (SD) absolute difference for all patients, was 2·6% (2·4). Twelve of 92 comparisons (13%) showed differences ≥5% (maximum 10%). For 19 infants over 5 months old the mean (SD) absolute differences of 27 comparisons was 1·8% (2·1), and only four (15%) showed absolute differences ≥5% (maximum 7%).

The mean actual (signed) difference for infants under 5 months old was +2·05%, and for those over 5 months +0·74% (in both instances the mean for the co-oximeter exceeded the mean for the pulse oximeter).

Fig 3 shows the pulse oximeter values plotted against arterial line PaO_2 measurements made on 169 instances in 81 patients. Some of the variability shown in this figure may be due to a range of dissociation curves showing differing displacements to the left, typical in preterm babies with high concentrations of fetal haemoglobin. Comparisons of SaO_2 P and PaO_2 in 46 instances when PaO_2 was <6·67 kPa showed SaO_2 P <90% on 40 occasions.

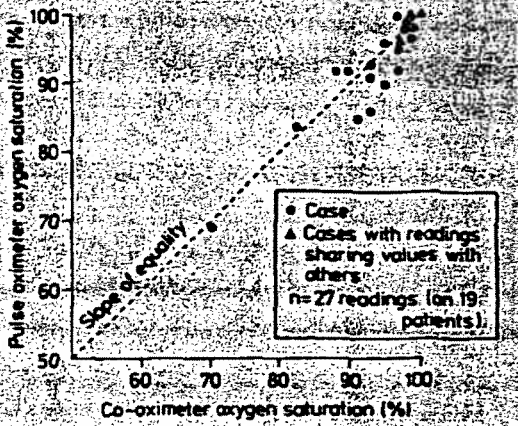

Fig 2 *Comparison of SaO_2 from pulse oximeter with functional SaO_2 from arterial line blood samples measured by co-oximeter in subjects over 5 months.*

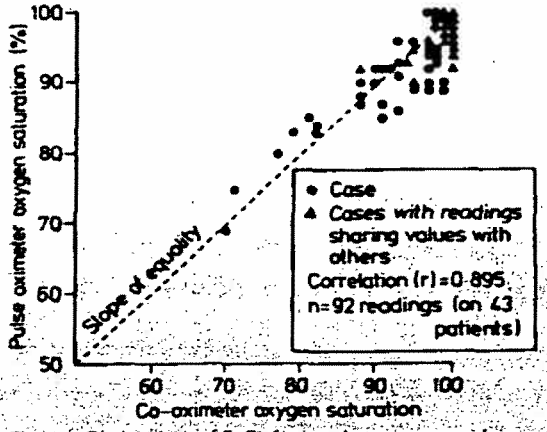

Fig 1 *Comparison of SaO_2 from pulse oximeter with functional SaO_2 from arterial line blood samples measured by co-oximeter in all subjects.*

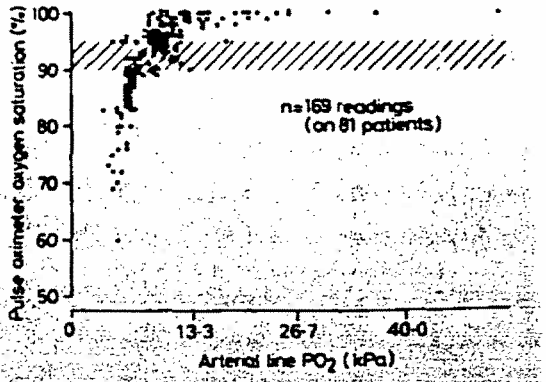

Fig 3 *Comparison of SaO_2 from pulse oximeter with PO_2 from arterial line blood samples.*

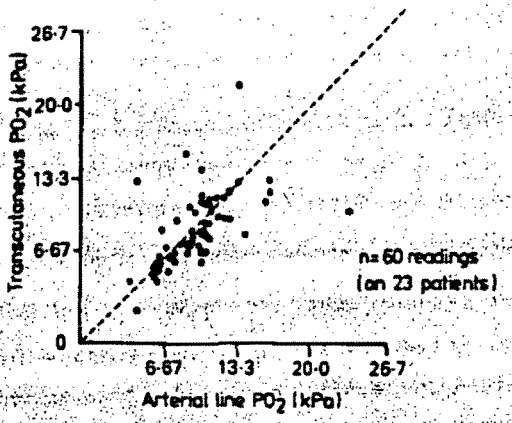

Fig. 4 *Comparison of transcutaneous PO_2 with PO_2 from arterial line blood samples.*

while in 24 instances when PaO_2 was ≥13·3 kPa the SaO_2P was ≥98% on 22 occasions.

$TcPO_2$ and arterial line PaO_2 were compared on 60 instances in 23 infants (fig 4). The mean (SD) of the absolute differences between $TcPO_2$ and PaO_2 was 1·67 kPa (1·73). Ten of the 60 comparisons (on six different infants and four different machines) showed differences of >2·67 kPa. Three comparisons on three different infants showed differences >5·33 kPa (maximum 8·40 kPa).

Discussion

When care is taken to use only high quality arterial waveforms, pulse oximetry is a useful, non-invasive technique and represents a considerable advance in monitoring oxygenation in infants and children undergoing intensive care. Our experience is similar to that of others,[2 16–20] but this study has highlighted the problem of measuring fetal oxygenated haemoglobin saturation in infants under 5 months old when validation of SaO_2P is seriously limited by the inaccuracy of the co-oximeters. After an empirical correction for the false measurement of a proportion of oxygenated fetal haemoglobin as carboxyheamoglobin, the mean absolute difference between SaO_2P and SaO_2 was 2·6%. When comparisons were limited to an age at which fetal haemoglobin concentrations were low, the mean absolute difference was 1·8% and exceeded 4% in four of 27 comparisons.

Recently corrections according to the proportions of fetal haemoglobin have been published by Cornelissen *et al*[13] and Ryan *et al*.[12] Nevertheless, we suggest that in future studies the base line measurement would be better obtained by using a non-spectrophotometric method of measuring arterial blood sample oxygen saturation—for example, from direct measurement of oxygen content.

Over the steep part of the dissociation curve, the most important part of the reading in ill patients with problems associated with tissue oxygenation or the uptake of oxygen from the lungs, the quantity of oxygen transported in the blood, and the availability of oxygen are more usefully reflected by oxygen saturation than by PaO_2. In the presence of fetal haemoglobin where the curve is shifted to the left, SaO_2 may be adequate at relatively low values of PaO_2, and increasing the PO_2 may not increase the unloading of oxygen to the tissues. With fetal haemoglobin present oxygen saturation may be 95% at a PaO_2 of 6·67 kPa. When the curve is shifted to the right, as in acidosis, with increasing temperature, or following transfusion of adult blood, optimal availability of oxygen to tissues may require relatively higher PaO_2 values. Under these circumstances a PaO_2 of 12·7 kPa may be required to provide 95% saturation, the saturation being only 70% at a PaO_2 of 6·67 kPa.

As far as clinically important hypoxaemia is concerned, analysis of our data shows that in 46 instances with a PaO_2 <6·67 kPa, oxygen saturation was <90% on 40 occasions. Figure 3 shows that the steep part of the curve begins at about 90%. We suggest that values less than this should be avoided.

The problem of avoiding hyperoxaemia when using SaO_2 rather than PaO_2 measurements is of major concern in neonatal intensive care because of the risk of retinopathy of prematurity[1–3]: a large and possibly harmful change in PO_2 can occur in the presence of small or, in the case of 100%, zero change in saturation values. In this respect, $TcPO_2$ could provide a more reliable indicator of hyperoxaemia. In practice, however, the reliability of $TcPO_2$ measurement decreases as PaO_2 increases.[4–5,6] It was reassuring to note that using pulse oximetry in the 24 instances when PaO_2 was ≥100 mmHg, the SaO_2P was ≥98% on 22 occasions. Nevertheless, in the presence of additional inspired oxygen or CPAP, our data suggest that to avoid PaO_2 values of >13·2 kPa in newborn preterm infants true arterial oxygen saturation values of >95% should be avoided. In our data from patients over 5 months of age the co-oximeter exceeded the pulse oximeter by 2% or less in 85% of instances with a maximum of 7%. This relatively small quantity of information from older infants does suggest that pulse oximeter values of 90% should avoid hyperoxia. Nevertheless, more investigations into the calibration and validation of pulse oximeters for use in neonates are required. Without additional inspired oxygen,

SaO_2P values in healthy normal infants are often >98%, and this safety level of 91% is only relevant when additional oxygen is being given.

In practice it is vital that the operator appreciates the number of arterial pulse waveforms (or the time) over which the pulse oximeter is averaging saturation. Measurements of saturation averaged from over a long time period should theoretically decrease errors and dampen any short term oscillations in saturation. Long term average measurements will, however, provide accurate readings only if all of the waveforms are of adequate quality. Measurements made more often over short average times should avoid this possible source of error, and are probably a safer way of using this instrument. It is essential that the quality of all waveforms used to derive a particular saturation value are adequate. Fig 5 shows the kind of artefact that may result from inadequate waveforms. The monitor used in this present study provided a bouncing light display to indicate the quality of each waveform: we consider that this may be insufficient. A monitoring oscilloscope showing the quality of the waveforms on which the calculations were based would be useful. Alternatively, the analog output of the arterial waveform signals could be displayed on ECG monitor at the bedside.

Previous investigators[1-4] have examined correlations between $TcPO_2$ and arterial line PO_2 measurements, and the lack of reliable comparisons by clinicians as distinct from research workers has been well documented.[2 5 6] Fanconi *et al*[2] reported a mean absolute difference of 0·93 kPa (range −1·87 to +6·53), with 10 of 108 values differing by >2·67 kPa, and Kraus *et al* reported that about 20% of values differed by more than 2·67 kPa.[6] Similarly our data (fig 4) shows that 10 of 60 comparisons differed by more than 2·67 kPa, and three of 60 by >5·33 kPa, (maximum 8·40 kPa). Inexplicable and clinically relevant differences between $TcPO_2$ and PaO_2 measurements have been identified,[3] and our study confirms that $TcPO_2$ measurements must be validated frequently, and that changes in inspired oxygen must not be based on $TcPO_2$ alone but always checked by blood gas analysis.

$TcPO_2$ measurements are known to become less reliable as patients get older,[7] and they are unsuitable for older preterm infants with chronic lung disease who are receiving additional inspired oxygen. Pulse oximetry may be particularly valuable in this group.

Potential advantages of the pulse oximeter include the rapidity of achieving a measurement after the probe has been applied, the internal calibration, the lack of skin heating, and the fact that the characteristics of the arterial waveforms indicate whether the probe has been correctly applied. This last advantage is particularly important: $TcPO_2$ electrodes do not have this capacity.

The major disadvantage of the pulse oximeter is its susceptibility to artefacts caused by movement. This is probably inherent in the 'transmission' method and may be difficult to overcome. While the babies were crying, squirming, or having seizures, when SaO_2 may well fall, the monitor was unable to identify satisfactory arterial waveforms for the measurement of saturation. Fig 6 illustrates short lived episodes of true arterial hypoxaemia during short apnoeic pauses and periodic breathing in normal preterm and fullterm infants, which may

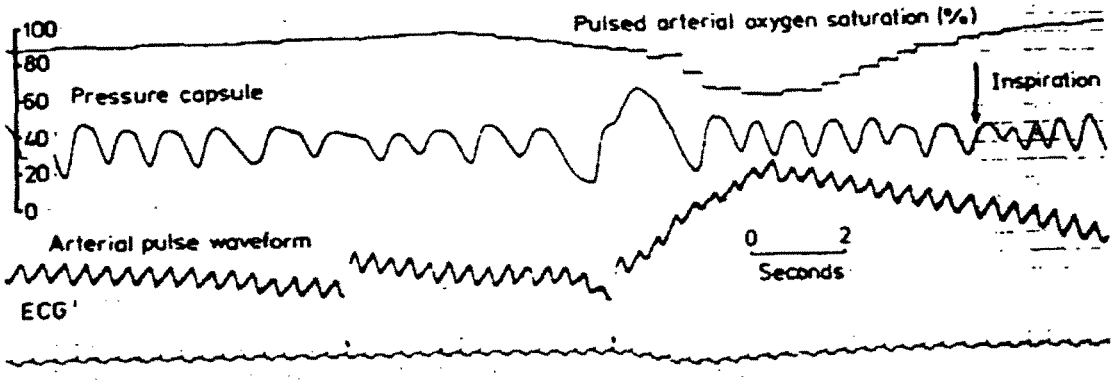

Fig. 5 *Recording of healthy fullterm infant aged 3 months in mode 2 of pulse oximeter: dip in oxygen saturation to almost 60% without an apnoeic pause is due to artefact.*

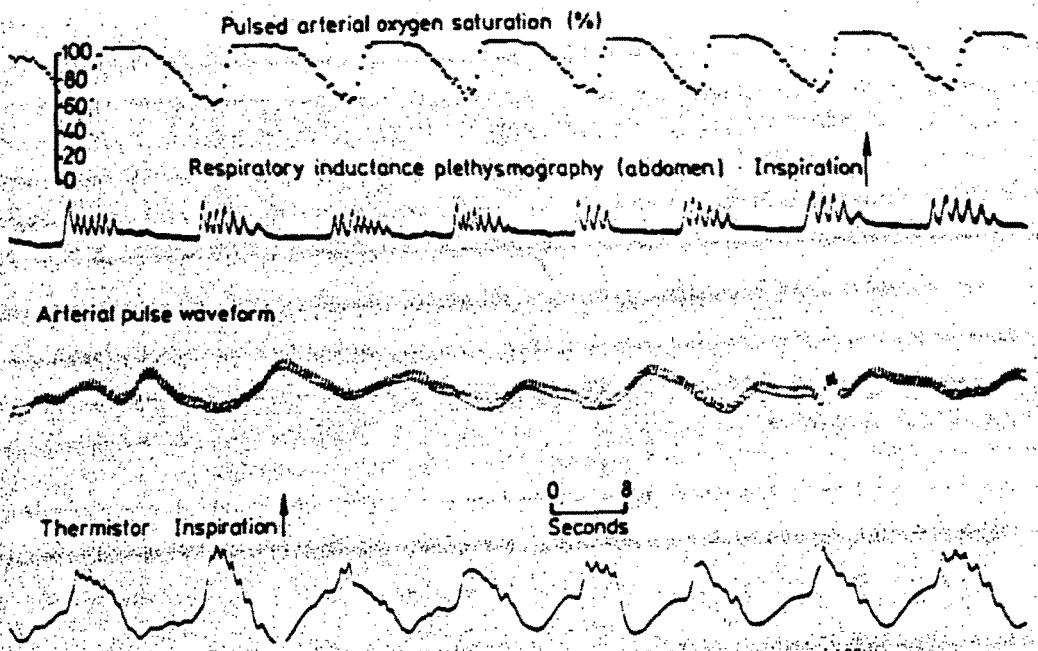

Fig. 6 *Periodic breathing in apparently healthy preterm infant with dips in SaO_2 signal to around 60% after each apnoeic pause.*

produce many low saturation alarms. To overcome this problem it would be necessary to be able to measure the duration of the hypoxaemia, or track a breathing movement signal, so that episodes of hypoxaemia associated with short apnoeic pauses and periodic breathing could be differentiated from persistent baseline hypoxaemia, or from hypoxaemia associated with prolonged apnoea. Other problems include the difficulty of being sure that the arterial waveforms are adequate and the relatively high cost of the probe: this may tempt nursing staff to use them on more than one patient, so increasing the risk of cross infection.

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(See pages 879–81 and 957–8.)

Editorial

Trialists should tell participants results, but how?

Calls for clinical trialists to be more accountable to study participants have given fresh momentum to the long-standing bioethical argument that those who consent to enrolment in research have a right to know the results. A study presented at last week's 5th European Breast Cancer Conference added to growing evidence that research participants covet this right: 98% of 1431 individuals enrolled in the Taxotere as Adjuvant Chemotherapy (TACT) study requested the trial's results. But although this practice has been promoted as a key part of ethical research, implementation remains patchy. Why? Because the issue is not as simple as bioethicists make out.

Individuals' responses to trial results can be varied and sometimes very negative, depending largely on how they interpret the results in terms of their own health. Choosing an appropriate method of conveying the message can ameliorate some of the problems, but little research has been done on what approach works best. The TACT study attempted to clarify this uncertainty by asking participants about their preferred communication method: post, telephone, or face-to-face consultation. However, the researchers did not tackle the most difficult aspect of the communication strategy—helping trial participants understand what the results mean to them.

Trial summaries do not, and cannot, provide personalised information. But qualitative research has revealed that individuals' desires to know trial results may conceal anxieties about how their trial-arm allocation affected their health. Individualised results—ie, unblinding—and communication of summary findings may be separate issues to researchers, but trialists must understand that participants are unlikely to make this distinction.

The potential for extreme and negative responses to trial results means that communication constitutes an intervention in its own right. It therefore requires appropriate evaluation. However, the debate will suffer if abstract concepts of participant autonomy and rights to knowledge are pitted in direct opposition to the perceived paternalism of trialists. This delicate issue is one that needs subtle, not sweeping, solutions. ■ *The Lancet*

For the TACT communication study see http://80.247.210.88/ciw-06ebcc/index.cfm?fuseaction=CIS2002&hootonav=Abstracts&content=abs.details&what=FREE%20TEXT&search text=TACT&topicselected=*&selection=ABSTRACT&qryStartRowDetail=1

Southall's CNEP trial more than stands up to scrutiny

David Southall

In the late 1990s, the UK Department of Health asked Rod Griffiths to investigate whether David Southall, Martin Samuels, and their colleagues had done a clinical trial in newborn infants with respiratory distress syndrome according to best practice. Some parents had alleged that the trial was poorly supervised and that they had not given informed consent for their children to be enrolled in the study, which compared continuous negative extrathoracic-pressure ventilation (CNEP) with standard treatment.

One of the recommendations of the highly controversial Griffiths inquiry, published in May, 2000, was that the children should be followed up to determine whether CNEP is more harmful than conventional therapy. Katherine Telford and colleagues, who had no role in the original trial, were commissioned to assess the long-term data from the children, who are now aged 9–15 years. The results of their study are presented in this week's *Lancet*. They conclude that there is no evidence of poorer long-term outcome after CNEP than standard treatment.

Telford and colleagues' study, together with Edmund Hey's and Iain Chalmers' earlier assessment of the CNEP trial in the *BMJ* in 2000, prove that the trial methodology was sound; indeed, in many ways it was ahead of its time. As Rod Griffiths notes in a Comment, David Southall and the other investigators should be congratulated on their trial, which has stood up to the closest of scrutiny. It is a sad indictment of the UK's research oversight process that it has taken so long to vindicate Southall and colleagues.

Some parents still maintain that they never gave informed consent for their children to be enrolled, although the GMC, the local hospital, and the police have all investigated the claims. Importantly, however, the Department of Health has never attempted to answer the criticisms of the Griffiths' report. This drawn-out process has been hugely damaging to the researchers, whose careers have been put on hold for considerable lengths of time, and to the parents of the children enrolled, anxious to know whether their children received the best possible care. But perhaps most importantly of all for children, the long-term health of paediatric research in the UK has been seriously damaged because the Government failed to bring this case to a close in a timely manner. ■ *The Lancet*

See Comment pages 1032, 1033, 1035, and 1037; and Articles page 1080

For Hey's and Chalmers' assessment of the CNEP trial see *BMJ* 2000; 321: 752–55

Opportunity cost refers to the value of the opportunities lost by allocating disposable resources in a particular way.[9] Is paying for cholinesterase inhibitors, even if deemed worthwhile for severe Alzheimer's disease, the best use of scarce resources? Without knowing more of the opportunities forgone, we cannot decide. This issue is outside the scope of the trial as reported, but faces policymakers, administrators, clinicians, and families daily.

More meaningful outcomes are needed in dementia trials. Before a trial starts, we should define what will be a clinically important outcome for an individual patient and explore the use of outcome measures such as goal-attainment scaling.[10] If not, we are doomed to never-ending debates about the meaning of the tea leaves at the bottom of the cup.

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I have participated as a principal investigator in studies sponsored by Janssen-Ortho, Neurochem, Novartis, and Pfizer, and I have received speakers' fees from Merck, Novartis, and Pfizer within the past 3 years.

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Are any of the criticisms of the CNEP trial true?

See Editorial page 1030; Comment pages 1033, 1035, and 1037, and Articles page 1080

"Parents were misled over hospital trials that killed premature babies"

Those who saw this banner headline on the front page of *The Independent* on Monday, May 8, 2000,[1] could be forgiven for thinking that something had gone seriously wrong with clinical research in the UK, and with the oversight of neonatal research in particular. The story was triggered by a Government inquiry into clinical research done in Stoke-on-Trent.[2] Richard Smith, Editor of the *BMJ*, was in no doubt at the time that "yet another NHS [UK National Health Service] scandal" had been uncovered.[3] "At best", he wrote, "the episode will lead to an overdue improvement in research practice throughout the NHS. At worst, it will further undermine public confidence in the NHS and doctors, and lead to a proliferation of bureaucracy that will increase the difficulties of doing research."

Even though doubts about the reliability of the Government inquiry[4] subsequently prompted Smith to call for an "inquiry into inquiries",[5] many people, including influential experts in research ethics and governance,[6,7] continue to believe that a scandal was uncovered in Stoke. So had hospital trials killed premature babies? No. The two-centre trial[8] compared two ways of nursing babies with lungs so immature that most would have died without respiratory support at birth, yet four-fifths survived. Has *The Independent* ever acknowledged its error? No. The paper's Editor, Simon Kelner, was still refusing to apologise for its misleading headline when questioned by a Parliamentary Select Committee 3 years later.[9]

The article in today's *Lancet* by Katherine Telford and colleagues[10] shows that, compared with babies assigned standard treatment with a tube through the larynx, marginally more of the babies whose lungs were kept open by continuous negative extrathoracic pressure (CNEP) died, and marginally fewer of the survivors were disabled. Both differences are so small as to be well within what might be expected by chance. Unfortunately this finding does not bring the affair to a close, because some parents have been saying for 9 years now that they never gave consent for inclusion of their children in the study. Whether their allegations are true remains unclear,[11] but, like *The Independent*, some people made up their minds long ago. The Editor of the *Bulletin of Medical Ethics*, for example, has stated that: "The core of

the misdeeds in Stoke-on-Trent, that have led to research governance and the governance arrangements for research ethics committees, was that CNEP was used in research without parental consent."[11]

The allegations that parents were misled and consent forms forged have been investigated by the local hospital three times; by the General Medical Council (GMC) twice; and have even been referred to the police. None of these investigations has publicly reported finding evidence to support the claims. The fact that the Department of Health has never responded to criticism of its inquiry has not helped to reduce public doubts. Perhaps last December's Court of Appeal judgment will force the Department to do so. Allegations of serious professional misconduct levelled against several doctors involved in the CNEP trial have been under investigation by the GMC for 9 years. The Appeal Court has now ruled that the GMC should not have dismissed these allegations without trying to ascertain whether the Government had answers to the criticisms directed at its report,[13] and the GMC is having to review the allegations for a third time.

As feared by the Editor of the *BMJ*, these allegations have badly damaged public confidence in the NHS and clinical research, and the proliferating research governance arrangements that he predicted would follow have done little to put this right. Unsurprisingly, the allegations of research misconduct in Stoke have also made many clinicians reluctant to take part in research. 6 years ago, the editors of *The Lancet* and the *BMJ* said that the UK urgently needed a body capable of investigating such allegations fairly, efficiently, and fast.[14] Yet these allegations still hang over the heads of the 34 doctors who sought parental consent in Stoke more than 12 years ago. It is high time that the public received an authoritative statement about whether the allegations are true or false.

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We declare that we have no conflict of interest.

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CNEP needs to return

We welcome the findings of the study by Katherine Telford and colleagues[1] in today's *Lancet* about the absence of evidence of harm to the long-term neurodevelopmental outcome of preterm infants treated with continuous negative extrathoracic pressure (CNEP) in our randomised trial. Support for babies and young children with respiratory failure is usually achieved by intubation and positive pressure ventilation. However, this approach can damage the immature lung, increases the risk for secondary infection, and needs analgesia or sedation. In an attempt

See Editorial page 1030; Comment pages 1032, 1035, and 1037; and Articles page 1080

Premature baby undergoing ventilation

to avoid these hazards, in the 1980s we developed new equipment for providing respiratory support with CNEP.[2]

Although our pilot work gave encouraging results in infants and older children, we remained uncertain whether CNEP would prove beneficial in preterm babies, and in particular, prevent chronic lung disease. Therefore we set up a randomised trial in 1989 to assess the merits of CNEP and standard care in preterm infants in two hospitals. The short-term results were published 10 years ago.[3] Although infants treated with CNEP had less chronic lung disease than those treated in the standard limb of the trial, there were no other statistically significant differences in outcome. The follow-up published today suggests that there is no substantial long-term advantage or disadvantage to CNEP in the very preterm baby.

It has become recognised that it is probably better, and certainly simpler, to sustain lung aeration in preterm babies by offering continuous positive airway pressure (CPAP) through the nose, rather than by providing CNEP around the chest. However, in more mature infants with conditions such as bronchiolitis, congenital diaphragmatic hernia, and phrenic nerve palsy, we believe that CNEP can be a valuable means for nurses and even parents to provide non-invasive respiratory support. Accordingly, we continued to use CNEP in our clinical practice during most of the 1990s[4–6] in spontaneously breathing infants with viral bronchiolitis, in which there is often nasal blockage, which impedes the value of nasal CPAP.

As with our treatment of preterm babies, we planned to assess in a controlled trial our strong impressions of the value of CNEP for these older babies with bronchiolitis. However, the treatment was associated with such a clear and immediate reduction in the child's distress, that, 15 months after our trial began, our nursing colleagues refused to continue recruiting children as they felt it was unethical to withhold CNEP; so the study had to close.[7] A retrospective study of infants with apnoea-related bronchiolitis treated in our paediatric intensive care unit has shown that they were less likely to be intubated and treated with positive pressure ventilation than infants in another unit that did not use CNEP (26% vs 86%).[8]

Our development and use of this promising treatment was halted abruptly in 1999. A woman campaigning on behalf of parents accused of child abuse went to our employers at the University Hospital of North Staffordshire and made serious allegations about our child protection work, including the claim that we were procuring children through the child protection system to experiment on them. Although our hospital received and found no evidence to support any of these allegations, they suspended us for nearly 2 years while the allegations were investigated.

The Government inquiry chaired by Rod Griffiths into CNEP began a few months before these hospital investigations into our research and child abuse work, and used the same organisation—the Midlands Health Care Network (MHCN)—to investigate the research issues. Instead of examining the veracity of the campaigner's allegations, however, MHCN spent less than a week reviewing some of the paper records on our CNEP research and concluded: "It is the unanimous view of the panel that there is a prima facie case for Professor Southall to answer in respect of his competence as a researcher at the most senior level. It was also the view that the contents of this report should be drawn to the attention of the General Medical Council, for their

investigation of a public interest matter." 2 years passed before the conclusions reached by MHCN and its paediatric advisers were overturned by a more carefully constituted investigation by our hospital.[8]

CNEP was discontinued in our hospital in November, 1999, just before we were suspended. As a result we fear that over the past 6 years many infants with bronchiolitis presenting to our children's unit have received unnecessarily intensive care.[9] Furthermore, an editorial agreed that the development of CNEP had been held back. It stated that our "call for a prospective randomised controlled trial of respiratory support strategies in the treatment of bronchiolitis related apnoea is reasonable... However, given the well publicised curtailment of activities of one of the principal research active groups in this field, it may be some time before such a trial sees the light of day".[10]

The Griffiths inquiry had other harmful effects. It seriously damaged the morale of the children's unit. The senior nurse who had meticulously overseen the data collection and treatment of babies in the CNEP trial became so stressed as a result of the allegations that she retired early and no longer practices as a nurse. We also consider that the failure to develop CNEP equipment has meant that infants in developing countries, where intubation and therefore intensive care is unavailable, might also have suffered.

It is now clear that Professor Griffiths was under political pressure to find someone to blame, irrespective of the lack of evidence that there had ever been any misconduct.[11,12] The damaging results of this political pressure and the lack of due process cannot easily be overcome. At the very least, we hope that our hospital will now allow our paediatric department to use CNEP for those patients likely to benefit, and that we will be permitted to research and develop this very promising technique further.

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The opinions expressed in this Comment are our own and do not necessarily reflect the views of the University Hospital of North Staffordshire. We declare that we have no conflict of interest apart from a wish to see CNEP being reintroduced.

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Southall and colleagues vindicated once more

See Editorial page 1030; Comment pages 1032, 1033, and 1037; and Articles page 1080

The pioneering research of David Southall and colleagues[1–4] has been subjected to unprecedented scrutiny. Southall's work has often been at the cutting edge of knowledge and he has ventured into areas that are inherently controversial. He has made many important contributions to the published literature and many lives have undoubtedly been saved by his research.

Southall's use of covert videotape surveillance to investigate babies who had repeated apnoeic attacks showed clearly, and extremely uncomfortably, that some parents deliberately try to suffocate their children.[1] Importantly, videotape surveillance was used only after social services and police had carefully considered every case identified and decided that use of cameras was the only way to confirm what was going on. Southall's other work on breathing control and on monitoring of babies' cardiac rhythms has led to improved understanding of sudden infant death.[2,3]

The CNEP (Continuous Negative Extrathoracic Pressure) study[4] received funding only after rigorous independent scientific review by the UK Medical Research Council (which gave it an alpha rating, but could not provide funding) and the charity Action Research. Furthermore, these bodies only considered the study after independent assessment

David Southall

of the science and ethics by a research ethics committee, on which the lay public are not usually sleeping members. Why, therefore, has Southall had to justify his actions to the General Medical Council and the mass media?

For the CNEP trial, Southall and colleagues took an emerging technology and applied it in a new way to ascertain whether some of the adverse effects of conventional ventilation could be mitigated. In the 1980s, as now, chronic lung disease was a common and costly consequence of positive pressure ventilation. There was a suggestion that CNEP might cause less damage than conventional ventilation and oxygen therapy to the developing lung.[4]

Published in 1996,[4] the report of the trial confirmed early pilot results and showed that babies randomly assigned CNEP needed to be given oxygen for fewer days and developed less chronic lung disease than those assigned conventional therapy. There was, however, a non-significant excess of death and intracranial haemorrhage in the CNEP group. Concerns were raised by parents whose children had died during the study period or been left brain-damaged, leading to a series of inquiries and investigations into the undertaking of the trial and Southall himself. None of the concerns has been substantiated. A Government-requested inquiry, led by the then Regional Director of Public Health, Prof Rod Griffiths, was done, though it seems with less rigour than the scientific study.[5] Nevertheless, the findings of the inquiry indicated that survivors of the trial should be followed-up.

The results of the follow-up are published in today's *Lancet* by Katherine Telford and colleagues,[6] who confirm the absence of detriment to those treated with CNEP; indeed, they suggest an advantage over conventional treatment. Despite these findings, CNEP should probably be reserved for older children with bronchiolitis because, since publication of the original trial by Southall and colleagues, other and improved techniques—surfactant, nitric oxide, high frequency oscillation, and better ventilators—have all reduced the need for long-term ventilation of premature babies.

The public must be protected from maverick researchers. The inquiries into this case have shown that the systems to control research that were in place in Stoke-on-Trent and the other hospitals involved in the CNEP study were at least as good as any at the time, and that Southall and colleagues were not mavericks but careful and dedicated researchers. The development of the bureaucracy that surrounds research was underway at the time of, and accelerated by, the highly critical Griffith's report.[5] Several multicentre neonatal trials in progress around that time were delayed or unable to recruit enough patients to confirm or refute well-designed research hypotheses.[7,8] Public condemnation of Southall probably contributed to the failure of these studies. We hope that the current review of research governance will not deter future generations from participating in vital research.

Southall and the members of his team have come under unprecedented scrutiny and, apart from the findings of the Griffiths inquiry,[5] have not been found wanting. Southall and his colleague Martin Samuels, were suspended from all practice for long periods, the former for more than 2 years. The pressure on them personally and on their families has been incalculable. We must protect patients, but we must also find better ways to protect professionals. If we do not, medical progress will cease, particularly in controversial and distressing areas.

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CNEP and research governance

See Editorial page 1030; Comment pages 1032, 1033, and 1035; and Articles page 1080

Repeated headlines about baby deaths associated with experimental treatment—continuous negative extrathoracic pressure (CNEP)—attracted the attention of Members of Parliament. Their pressure on Ministers led to the question, "Could there be a problem with the system?" and this led to the review[1] I chaired. Matters were further complicated when groups of parents insisted on child protection issues being considered, but they have no place here.

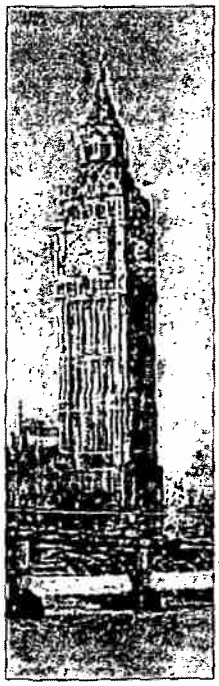
The Minister, Baroness Hayman, the Parliamentary Under Secretary of State for Health (Lords), wished to keep the review simple, it was not to be a legal inquiry, and evidence was not taken under oath. Learning from this, I now agree with Edmund Hey and Iain Chalmers[2] that a specialist function for investigating research issues would make sense, but in the frenzied media attention that we encountered there would have been controversy whatever the nature of the inquiry.

All the evidence that we received about the CNEP trial had something different to say; the ethics committee, the clinicians, the published work, the trust, and the patients all said things that differed substantially. It was clear that much of what we were told must be wrong and different witnesses had different axes to grind. I think we were bound to conclude that research governance should be improved to try to avoid such confusion in the future. We were pressed from all sides to attach individual blame, but did our best to avoid this (from reference 1, para 1·5), and tried to blame the system rather than individuals. An Organisation with a Memory[3] had still to be published and the notion of trying not to allocate blame was unusual at the time.

So far I believe that the implementation of research governance has been disappointing. The implementation seems to me to be overbureaucratic, clumsy, and restrictive. Some of those responsible seem to think that the only safe research is no research. That view does not serve the interests of clinicians or patients. I still believe that if a proper governance system had been in place, the trust could have avoided the suspensions and disciplinary hearings that took place; both parents and clinicians need a governance framework that provides a safe environment for research. Patients must be sure that they or their children will not be experimented on in unsafe ways and clinicians needed a safe structure within which they can research difficult and emotive issues, without risk of being pilloried in the mass media.

We also concluded that a longer-term follow-up was needed from the original trial to give a more definitive answer on the vexed questions of possible benefit and harm; the short follow-up period of the trial left too many loose ends, particularly as many signs of brain damage would not have been detectable at the chosen end of the trial. After discussion the study was commissioned that has now been reported. It could lend support to many conclusions.

First, I think that David Southall and his team have to be congratulated on having done a randomised trial when they did. After our report, material became available which suggested that the design of the trial was better than we had been led to believe, and had it been made available to us we would have written some paragraphs differently, making less of some of the criticisms and referring to the register of clinical trials (from reference 1, paras 7·1.2–7·1.7). The important thing, which we acknowledged in the report, was that the randomised design gave a good possibility of effective longer-term follow-up, which has proved to be the case.



Second, we now know that despite what seemed to be an increase in issues related to brain damage when the original trial reported, the longer-term study shows that CNEP might, if anything, be kinder on the brain. The paediatric community now has to decide whether CNEP has a place in the care of these babies or whether everything has moved on.

Third, we can now see the headlines about baby deaths in perspective. They were lurid and misleading and in making such headlines the mass media did not do anyone a good service; it created unnecessary anxiety and did nothing to further the research that might save lives in the future.

Finally, we should acknowledge the parents. Assistance from Mr and Mrs Henshall is acknowledged in Telford and colleagues' paper.[4] Many of the parents who gave evidence to the review met each other regularly because their children attended the same special-care nursery. It is not surprising that parents with that burden to bear would want answers even when there are none. I am pleased that one outcome of our review is that we now know that CNEP did no more damage than any other treatment that might have been used to try and help these infants. Hopefully, if we can get research governance right, we can look forward to constructive partnerships between clinicians and parents that could help us find other important answers.

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I declare that I have no conflict of interest.

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How specific are therapeutic monoclonal antibodies?

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See Lancet 2006; 367: 960

The tragic events at Northwick Park, Middlesex, UK, in which six participants in a phase I clinical trial of the monoclonal antibody TGN1412 became seriously ill on March 13–14, forcefully remind us of the potency of the compounds that modern biotechnology can provide. While the exact cause of the unexpected reactions continues to be investigated, it would be well to pause and consider a founding principle of the widespread use of monoclonal antibodies—that they are exquisitely specific. It is all too easy to accept the potentially dangerous concept that monoclonal antibodies are harmless proteins that are highly specific and safe therapeutic agents binding only one specific molecular target.[1–3]

Monoclonal antibodies are key elements of much of modern medicine. Indeed, many sophisticated diagnostic tests that are now taken for granted are based on these remarkable molecules. However, even in the in-vitro tests, cross-reactive binding to substances other than the test substance is often seen. Such unwanted binding occurs even though reactions take place under optimum conditions, in very simple controlled environments, with a relatively simple sample. Molecularly, monoclonal antibodies are compromises selected because they bind their target antigens extremely well, but they do not express the exact lock-and-key fit so beloved by textbooks. They can, and do, bind to molecules other than their intended target.

The situation becomes even more intricate when antibodies are used therapeutically in a more complicated environment, the human body. Here, we are concerned not only with unwanted, and possibly damaging, cross-reactivity with normal tissues, but also with localisation away from the target due to the body's efficient sequestration mechanisms and by persistence in the circulation. A further major complication is the distribution of the targeted antigen itself. Few, if any, therapeutic antibodies currently target molecules that are totally disease-specific.[4,5] For instance, overexpressed cellular receptors used as targets in cancer therapy are often present, albeit at lower concentrations, on normal cells.[3–5] When all these factors are taken into account, it is unsurprising that truly cancer-specific tumour antigens are thought to be virtually unattainable.[5] All these

Outcome after neonatal continuous negative-pressure ventilation: follow-up assessment

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See Comment page 1032
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Summary

Background A previous randomised trial of continuous negative extrathoracic pressure (CNEP) versus standard treatment for newborn infants with respiratory distress syndrome raised public concerns about mortality and neonatal morbidity. We studied the outcome in late childhood of children entered into the trial to establish whether there were long-term sequelae attributable to either mode of ventilation.

Methods Outpatient assessment of neurological outcome, cognitive function, and disability was done by a paediatrician and a psychologist using standardised tests. 133 of 205 survivors from the original trial were assessed at 9–15 years of age. Of the original pairs randomly assigned to each ventilation mode, the results from 65 complete pairs were available. The primary outcome was death or severe disability.

Findings Primary outcome was equally distributed between groups (odds ratio for the CNEP group 1·0; 95% CI 0·41–2·41). In unpaired analysis there was no significant difference between treatment modalities (1·05; 0·54–2·06). Full IQ did not differ significantly between the groups, but mean performance IQ was 6·8 points higher in the CNEP group than in the conventional-treatment group (95% CI 1·5–12·1). Results of neuropsychological testing were consistent with this finding, with scores on language production and visuospatial skills being significantly higher in the CNEP group.

Interpretation We saw no evidence of poorer long-term outcome after neonatal CNEP whether analysis was by original pairing or by unpaired comparisons, despite small differences in adverse neonatal outcomes. The experience of our study indicates that future studies of neonatal interventions with the potential to influence later morbidity should be designed with longer-term outcomes in mind.

Introduction

One of the most important factors in the improvement in survival for premature infants since the 1970s has been neonatal ventilation. Despite the obvious success of providing respiratory support, few trials have looked at long-term outcomes in terms of disability, and the more subtle outcomes seen in preterm survivors,[1] in terms of the different modalities of support that are available. Real concerns have been raised that the use of positive-pressure ventilation via an intratracheal tube might be one factor leading to the high prevalence of chronic lung disease in these children.

In the early 1990s, Samuels and colleagues[2] did a randomised controlled trial of continuous negative-extrathoracic-pressure ventilation (CNEP) as an additional modality for treatment of respiratory distress syndrome. The control group received standard ventilatory support, which consisted of either supplemental oxygen alone or positive-pressure ventilation. Sequential analysis was done of matched pairs of infants. One potential advantage of this design was the opportunity to stop the trial as soon as possible if there was either an obvious benefit of CNEP or serious harm, but the design has the disadvantage of extra complexity and in particular the need for information about both babies in a pair for analysis of the effects. The study showed benefit for CNEP over standard treatment in terms of an overall composite illness score (the primary outcome of the trial). Importantly, there were also advantages for the CNEP group in terms of 18 fewer days spent on oxygen treatment in the first 2 months and fewer infants with chronic lung disease. However, on secondary analysis, there was higher mortality and more children with abnormalities on cranial ultrasonography and pneumothoraces in the patients allocated CNEP, although this difference was not significant.

After publication, concerns were raised by parents whose children had been included in the trial that CNEP might lead to the death or the occurrence of disability in their children, on the basis of a small excess of deaths and infants with abnormal brain scans in the CNEP group. Concerns were also raised about the conduct of the trial. Such concerns resulted in an enquiry, and a public report.[3] One recommendation of this report was that the outcome of the study should be audited.

We were commissioned by the West Midlands Regional Health Authority to undertake a study to establish whether there were long-term consequences of the treatment given in the trial. We hypothesised that the use of CNEP and the associated neck seal might compromise cerebral circulation and therefore lead to an excess of disabilities in this group. None of the investigators had any involvement in the original trial.

Methods

The original randomised trial of CNEP for treatment of neonatal respiratory distress syndrome took place at the

North Staffordshire Maternity Hospital, Stoke-on-Trent, and the Queen Charlotte's and Chelsea Hospital, London, UK, between 1989 and 1993.[1] 259 infants were randomly assigned to receive either standard ventilatory support alone or additional CNEP. Of these infants, 244 were paired by the end of the study. Pairs were matched for gestational age, hospital of delivery, oxygen requirement, and intubation status at 4 h of age. Exclusion criteria and outcome at 56 days are detailed in the original paper.[1] The study design included sequential analysis of matched pairs of infants so that the trial might be concluded when prespecified criteria were met. These analyses showed that surviving infants who received CNEP were significantly less likely to have chronic lung disease than controls, but there was a non-significant increase in mortality and in the frequency of abnormalities on cranial ultrasonography in the CNEP group. We proposed to adhere to the original sequential matched-pairs design in our analysis whenever possible.

We attempted to trace all surviving children entered into the original study through hospital records from each unit. A senior doctor from each unit (not a member of the original trial group) wrote to each family inviting them to attend a formal outpatient assessment at either the North Staffordshire Maternity Hospital or the Hammersmith Hospital (the Queen Charlotte's and Chelsea Hospital had closed and been rebuilt on the Hammersmith Hospital site). If a family did not respond, their address was checked via their family doctor, and a second attempt at contact was made.

The assessment comprised a formal clinical and neurological assessment by a paediatric fellow (KT) and a formal cognitive assessment by a clinical psychologist (LW). Visual acuity was assessed with a Snellen chart, and a screening test for hearing impairment was done with a pure-tone audiometry sweep (1 kHz, 2 kHz, 4 kHz, and 500 Hz at 25 dB). Overall cognitive function was measured with the Wechsler Abbreviated Scale of Intelligence (WASI),[4] and neuropsychological function investigated with NEPSY[5] (covering the areas of attention and executive function, language, sensorimotor and visuospatial function, and memory). The WASI scores and each of the NEPSY subscales produced a standardised score, normalised to a mean of 100 and SD of 15. Behaviour was assessed by parents' and teachers' reports on the Strengths and Difficulties Questionnaire (SDQ),[6] from which we report overall behavioural scores, the number of children who scored for behavioural disorder, and the impact score, indicating whether behaviour interfered with daily life. Health-related quality of life was assessed with the Health Utilities Index (HUI-3), which produces a score from −0·36 (worst quality of life) to 1 (normal quality of life).[7] Scores for unimpaired healthy children are generally more than 0·95. From the clinical and psychological findings an assessment of disability with prespecified definitions of mild, moderate, or severe disability was done (webtable, adapted from criteria used in the UK Collaborative trial of

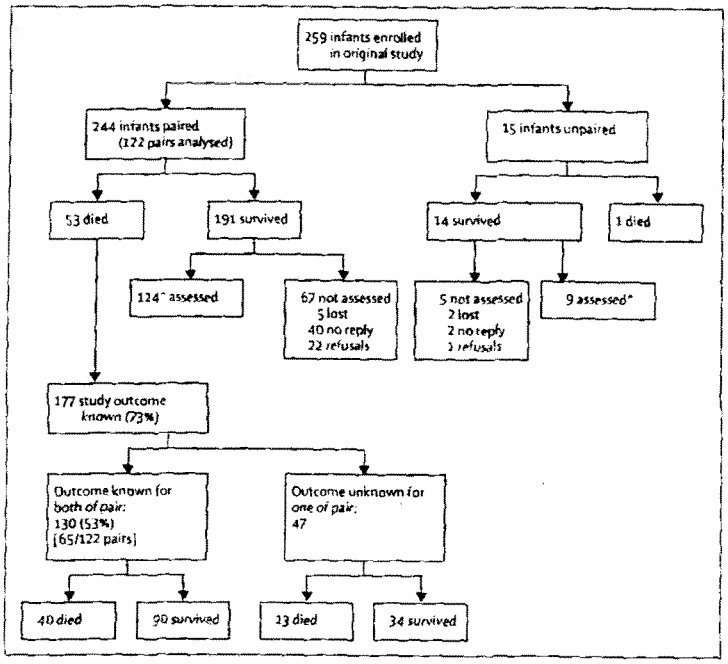

Figure: Derivation of study groups for outcome analyses
*Included in secondary analyses (n=133).

extracorporeal membrane oxygenation[8]). Both investigators were masked to the neonatal course. Demographic data were recorded from parental reports on a standard questionnaire.

Before undertaking the study, we had calculated that at 85% recruitment we had 80% power in the paired comparison of the primary outcome to detect a minimum relative risk of 1·70 and an unpaired difference of 7 points in the WASI IQ score (equivalent to 0·4 SD).

The primary composite outcome of death or severe disability was investigated by use of a logistic regression model, with the difference between treatments quantified by estimated odds ratios and 95% CIs. Where possible, statistical methods appropriate for prospective studies with matched-pair designs were used.[9] However, for the primary outcome the status of some children was unknown and adherence to a paired analysis meant that the corresponding matched, but known, observation was also deleted. An unmatched analysis of all available data was done to confirm the results,[10] with adjustment for the matching variables (intubation at 4 h, oxygen requirement at 4 h, gestational age at birth, treatment centre). Unmatched analyses were also done for the secondary outcomes, in which only survivors were investigated.

Our study was designed independently of the original trial and was approved by the local research ethics committees at Queen's Medical Centre, Nottingham, the North Staffordshire Hospital, and the Hammersmith

See Online for webtable

	Assessed (n=124)	Not assessed (n=67)	p*
Matching variables			
Median (IQR) gestational age, weeks	31 (29–33)	31 (28–33)	0·54
Median (IQR) FiO, at study entry, %	51 (45–65)	56 (44–70)	0·51
Intubated at 4 h (study entry)	85 (69%)	49 (73%)	0·51
Other neonatal variables			
Median (IQR) birthweight, kg	1·59 (1·19–2·03)	1·47 (1·11–1·89)	0·21
Median (IQR) duration of supplemental oxygen, days	6 (4–24)	6 (4–28)	0·56
Sex (male)	74 (60%)	39 (58%)	0·84
Antenatal steroids	21 (17%)	11 (16%)	0·93
Surfactant therapy	38 (31%)	14 (21%)	0·15
Postnatal dexamethasone	12 (10%)	5 (8%)	0·61
Abnormal cranial ultrasonography†	8 (7%)	4 (6%)	0·89

Data are number (%) of children unless otherwise stated. FiO =fraction of inspired oxygen. *χ² or Mann-Whitney U test. †Abnormality on scan at 56 days or last scan before death. Abnormalities include periventricular leucomalacia, parenchymal haemorrhage, cortical atrophy, porencephalic or subcortical cysts, and hydrocephalus with shunt inserted.

Table 1: The distribution or frequency of neonatal variables in children assessed compared with survivors not assessed

Hospital. Data were encoded for computer analysis with a Microsoft Access database. Data were double entered independently by KT and LW. SPSS for Windows (version 11.0) was used for all analyses.

Role of the funding source

The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Of 259 infants enrolled in the trial, 244 were paired by the end of recruitment (figure). Of these infants, 53 died. 124 (65%) of the 191 survivors were subsequently assessed as part of our study. We had no information for the 7 children we could not trace. All other children who were not assessed were alive at the time of the assessment. The outcome of death or severe disability was known for both members of 65 of the 122 original pairs and for a further 47 children where information for the other member of the original pair was missing (figure, left column). A further 15 children remained unpaired by the end of recruitment of the original study: nine of 14 survivors were assessed as part of our study (figure, right column). Thus, 133 of 205 survivors were included in the unpaired secondary analyses. Children were assessed at a median age of 11·3 years (range 9·6–14·9).

	Number of observations		CNEP	Standard	p*
	CNEP	Standard			
Matching variables					
Median (IQR) gestational age, weeks	96	89	30 (28–32)	29 (27–33)	0·33
Median (IQR) FiO, at study entry, %	96	89	57 (44–70)	55 (45–70)	0·91
Intubated at study entry	96	89	71 (74%)	70 (79%)	0·45
Born at QCCH	96	89	11 (11%)	11 (12%)	0·85
Other neonatal variables					
Male	96	89	58 (60%)	60 (67%)	0·32
Antenatal steroids	93	86	17 (18%)	15 (17%)	0·88
Surfactant therapy	93	86	34 (37%)	29 (34%)	0·69
Postnatal dexamethasone	94	86	4 (4%)	11 (13%)	0·04
Abnormal cranial ultrasonography	90	79	9 (10%)	8 (10%)	0·98
Median (IQR) birthweight, kg	95	86	1·45 (1·10–1·85)	1·15 (0·88–1·87)	0·03

Data are number (%) of children unless otherwise stated. QCCH=Queen Charlotte's And Chelsea Hospital. *χ² or Mann-Whitney U test.

Table 2: Comparison of the distribution or frequency of neonatal factors among 185 infants included in unpaired analyses

Because of the high dropout rate, the frequency of important neonatal variables was compared between survivors assessed and not assessed (table 1). A lower proportion of children cared for at Queen Charlotte's and Chelsea Hospital were assessed than at the North Staffordshire Maternity Hospital (11/27, 41% *vs* 113/164, 69%). There was an excess of surfactant-treated infants in the assessed group, but this excess was not significant. In other respects, the children not assessed did not differ systematically from those assessed.

To investigate whether the use of only 53% of the original pairs might have introduced bias, the outcomes for all 187 children (177 plus nine survivors and one child who died from 15 children remaining unpaired) with known outcomes were also compared. Death or severe disability was investigated with an unpaired multivariable logistic regression model including the factors used in the original matching. Oxygenation values used for matching were missing for two infants (both of whom had died) in the original records, so 185 (71%) children were included (96 allocated CNEP, 89 standard treatment). The odds ratio for death and severe disability in the CNEP group compared with the standard treatment group was 1·05 (95% CI 0·54–2·06). The potential effect of the two excluded deaths was investigated with a range of plausible values for the missing oxygenation values, but only small changes in the estimated odds ratio were recorded. Comparison of important neonatal variables between the two groups revealed a significant difference in birthweight (table 2). There was also a significant excess of infants treated with dexamethasone in the standard-treatment group.

To examine the influence of allocated treatment on survivors, we combined data from all 133 children seen for follow-up (69 allocated CNEP, 64 standard), including nine of the children who remained unpaired at the end of the original study. Although there were no significant differences in age at assessment or the frequency of demographic variables between the two groups (table 3), more families in the CNEP group than in the standard group were headed by a lone parent or were of manual socioeconomic status.[11]

The composite primary outcome was first investigated in the 65 pairs for which the outcome was known for

	Number of observations		CNEP	Standard	p*
	CNEP	Standard			
Median (IQR) age at assessment, years	69	64	11·5 (10·4–12·9)	11·3 (10·6–12·7)	0·97
Median (IQR) maternal age at time of study, years	67	61	39 (35–43)	38 (35–43)	0·86
Family headed by lone parent	69	61	19 (28%)	9 (15%)	0·08
Maternal education less than completed high school	67	61	46 (69%)	44 (72%)	0·67
Manual socioeconomic group	69	63	33 (48%)	22 (35%)	0·13

Data are number (%) unless otherwise stated. *χ² or Mann-Whitney U test.

Table 3: **Comparison of the age at assessment and selected demographic variables in the two treatment groups**

	Paired analysis			Unpaired analysis		
	CNEP n=65	Standard n=65	Adjusted odds ratio (95% CI)	CNEP n=96	Standard n=89	Adjusted odds ratio (95% CI)
Death or severe disability	26 (40%)	26 (40%)	1·00 (0·41–2·41)	33 (34%)	32 (36%)	1·05 (0·54–2·06)*
Died	21 (32%)	19 (29%)		27 (28%)	25 (28%)	
Severe disability	5 (8%)	7 (11%)		6 (6%)	7 (8%)	
Mild or moderate disability	15 (23%)	21 (32%)		25 (26%)	28 (31%)	
Normal or impairment only	24 (37%)	18 (28%)		38 (40%)	29 (33%)	

*Binary logistic regression adjusted for gestational age, intubation at randomisation, FiO_2 at 4 h, hospital of birth.

Table 4: **Frequency of death and disability in the study population**

both children (130 children). In the CNEP group, 21 children had died and five children had severe disability; in the standard-treatment group, 19 had died and seven had severe disability. The combined variable (death or severe disability) was thus present in 26 (40%) children assigned CNEP and in 26 (40%) assigned standard treatment; odds ratio 1·0 (95% CI 0·41–2·41). The frequencies of other outcomes are shown in table 4.

In the unpaired analysis of survivors, no significant differences were recorded in terms of matching variables: median gestational age at birth (CNEP 31 weeks [IQR 29–33] *vs* standard 31 weeks [28–33]; p=0·41), FiO_2 at study entry (54% [44–65] *vs* 50% [45–65]; p=0·70), intubation at study entry (46 [67%] *vs* 45 [70%]; p=0·65), or hospital of recruitment (Queen Charlotte's and Chelsea Hospital: seven [10%] *vs* eight [13%]; p=0·67). Nor were there significant differences in neonatal variables (not shown).

The distribution of disability by our prespecified classification is shown in table 5. Notably, 25% of children allocated CNEP had no impairment or disability at follow-up compared with only 11% of those allocated standard treatment (data not shown). Overall, 66 (50%) children had a disability in one or more domain. The most common domain of disability was cognitive followed by behavioural. 46 (35%) children were classified as having a cognitive disability, which was severe in ten of these children. 36 (27%) children were classified as having a behavioural disability and 25 (19%) a motor disability. The prevalence of visual or hearing disabilities was low.

Most of the total SDQ difficulties scores were normal (table 6). Overall, parents reported 30 (23%) children with abnormal scores, whereas teachers rated 18 (14%) abnormal. The impact score was used to assess the effect of the child's behaviour on home or school life. For nine (7%) children, parents reported behaviour affected greatly compared with 20 (18%) on the teacher report. The frequencies did not differ between the two treatment groups. Pervasive behavioural disorder was defined as an abnormal impact score on both parents' and teachers' rating, which was seen in 4% of the CNEP group and 14% of the standard-treatment group; however, this difference was not significant. No significant differences were seen in SDQ subscale scores.

Mean scores and differences in means for psychometric outcomes are also shown in table 6. Full IQ did not differ significantly between the two experimental groups. However, differences were seen in favour of the CNEP group in terms of performance IQ, language production, and visuospatial performance, all of marginal significance after allowance for multiple comparisons.

	Normal/impairment		Mild disability		Moderate disability		Severe disability	
	CNEP	Standard	CNEP	Standard	CNEP	Standard	CNEP	Standard
Worst overall grade*	38 (55%)	29 (45%)	18 (26%)	16 (25%)	7 (10%)	12 (19%)	6 (9%)	7 (11%)
Cognitive†	48 (70%)	38 (60%)	14 (20%)	12 (19%)	3 (4%)	7 (11%)	4 (6%)	6 (10%)
Motor	54 (78%)	54 (84%)	10 (15%)	9 (14%)	3 (4%)	1 (2%)	2 (3%)	0
Sensory‡	63 (93%)	58 (92%)	5 (7%)	5 (8%)	0	0	0	0
Behaviour§	50 (72%)	46 (73%)	13 (19%)	5 (8%)	4 (6%)	9 (14%)	2 (3%)	3 (5%)

Details of the definitions used for each category are given in the webtable. *"Worst" includes all disabilities shown and "other" disabilities not already included (eg, other medical conditions requiring frequent hospital admission). †One child missing from standard group, not assessed by psychologist. ‡One child missing from each group; could not be assessed because of severe cognitive or motor disabilities. §One child missing from standard group because of failure to complete questionnaires.

Table 5: Details of the functional outcome grades for children allocated CNEP (n=69) or standard treatment (n=64)

	Number of observations		CNEP	Standard	Adjusted comparison (95% CI) (CNEP vs standard treatment)	
	CNEP	Standard			Effect size	Odds ratio
Behaviour (SDQ)						
Parents' overall score	69	61	10·8 (7·1)	12·3 (8·3)	−1·5 (−4·3 to 1·2)	
Parent abnormal SDQ	69	63	14 (20%)	16 (25%)		0·73 (0·32 to 1·66)
Parent SDQ impact ≥6	69	63	5 (7%)	4 (6%)		1·11 (0·28 to 4·38)
Teacher's overall score	55	52	6·8 (6·9)	9·9 (8·3)	−3·4 (−6·4 to −0·4)	
Teacher abnormal SDQ	55	51	4 (7%)	14 (28%)		0·17 (0·04 to 0·61)
Teacher SDQ impact ≥3	59	53	9 (15%)	11 (21%)		0·64 (0·23 to 1·73)
Cognitive function (WASI)						
IQ	69	63	96·7 (15·0)	92·6 (14·6)	4·3 (−0·9 to 9·5)	
Performance quotient	69	63	98·4 (15·8)	91·8 (14·3)	6·8 (1·5 to 12·1)	
Verbal quotient	69	63	95·8 (14·4)	94·5 (15·0)	1·4 (−3·7 to 6·5)	
Neuropsychological function (NEPSY)						
Attention	69	64	99·4 (15·4)	97·7 (19·0)	1·7 (−4·3 to 7·7)	
Language	69	64	97·9 (15·0)	92·5 (14·6)	5·4 (0·2 to 10·5)	
Sensorimotor	69	64	94·2 (18·1)	92·8 (15·2)	1·1 (−4·8 to 6·9)	
Visuospatial	69	64	100·0 (18·7)	93·0 (17·4)	6·8 (0·6 to 13·1)	
Memory	69	64	96·4 (17·9)	95·1 (16·5)	1·4 (−4·5 to 7·3)	
Health-related quality of life (HUI-3)						
Parents' utility score ≤0·95	69	63	32 (46%)	35 (56%)		0·68 (0·34 to 1·39)

Analyses were done with linear regression or binary logistic regression with original matching criteria as covariates. Data are mean (SD) or number of children (%). SDQ=Strengths and Difficulties questionnaire.

Table 6: **Comparison of the measures used to assess behavioural, cognitive and neuropsychological function, and health related quality of life in the two assigned study groups**

We assessed health-related quality of life using the parental report on the HUI-3.[11] About half the children in each group had a multiattribute utility score of less than or equal to 0·95.[11]

Discussion

Our study provides no evidence of disadvantage in terms of disability or detailed psychometric and behavioural outcomes attributable to the use of CNEP to treat neonatal respiratory illness in preterm babies. Indeed, the trend was towards better outcomes for the CNEP group in terms of disability, behavioural problems, and psychomotor, language, and visuospatial performance, which allowed us to reject the study hypothesis. The observation of a small increase in mortality is balanced by less severe morbidity to produce identical frequencies of the composite primary outcome variable. These observations are robust in that they show similar results whether paired or unpaired analyses were used.

The frequency of disability might seem high in view of the mature gestational age of most of the babies, by contrast with contemporary cohorts of premature infants, which concentrate on babies born at marginal viability.[14] However, our system for classification of disability was deliberately inclusive. The frequency of moderate or severe motor disability was reassuringly low. Although moderate or severe motor disability was more frequent in the CNEP group (five children *vs* one child in standard-treatment group), the overall rate was low and these differences could have arisen by chance. The proportion of cognitive or behavioural disabilities was higher in the standard-treatment group than in the CNEP group, but not significantly so. The cognitive disability assessment was based on WASI and NEPSY scores. The mean scores attained on these tests are close to the population standardised means. Since both tests have been recently standardised, this finding is likely to represent outcomes in the normal range. There is much comorbidity between cognitive and behaviour disability as defined in our study.

We were concerned by the low proportion assessed; therefore we used paired statistics alongside unpaired statistics. We had predicted that the response would be greater in light of the public interest in the original study and the care taken to maximise recruitment. All but seven of the children enrolled in the study up to 14 years previously were located with NHS tracing procedures, and the address and status of the children were confirmed by contact with the family doctor's surgery. Senior doctors at the original hospitals wrote asking for consent, and up to two follow-up letters were allowed by the local research ethics committees. External advice was taken over the content of the letters to ensure the greatest participation, and a stamped addressed envelope was included. The research team was not allowed to contact parents directly until consent had been received. Despite these concerns, the children assessed as part of the study were representative of the whole population enrolled after birth over the matching variables, and other important neonatal

variables, and we believe our conclusions are thus valid. However, the low number of children included will have reduced the power of the conclusions leading to wide confidence intervals.

For the unpaired analysis, there was a significant difference in birthweight, with the CNEP group being heavier. The confounding influence of this difference on our outcome measure is likely to have been in favour of a better outcome in the CNEP group on all of our measures. Furthermore, a smaller proportion of infants in the CNEP group received postnatal dexamethasone therapy, probably secondary to the lower rate of chronic lung disease. We could not analyse timing, dose, and duration of therapy in our study, but these factors are likely to have moderated some effects on neurodevelopmental outcome.[15]

Assessment of the long-term outcome of neonatal trials in terms of benefits and safety is important. The original study was not designed to assess such outcomes and thus these results have wide confidence intervals. Furthermore, we could not investigate associations between short-term neurological morbidity such as intraventricular haemorrhage and later disability, although there might be poor correlation between the two.[16] In the HiFi trial,[17] which compared high-frequency oscillatory ventilation against conventional ventilation, an excess of intraventricular haemorrhages in the high-frequency group became apparent. At follow-up, these events translated into an excess of children with abnormal neurodevelopmental status.[5] Despite the enthusiasm for high-frequency oscillatory ventilation, the long-term effects of the modality, as applied in the trial protocol, were clearly not advantageous. One further trial of such ventilation has also reported an excess of haemorrhages.[18] Thus, especially in view of recommendations from the West Midlands report on the original CNEP trial,[1] our follow-up assessment was important to undertake, despite the small size of the study population. We do not know of any other large-scale controlled trials of CNEP as an acute treatment for neonatal respiratory disease.[19]

In the original study report, there were advantages to children who received CNEP in terms of neonatal respiratory measures: our long-term follow-up of the original trial participants also suggests no evidence of disadvantage, in terms of long-term disability or psychological outcomes, from the use of neonatal CNEP. This experience indicates that future studies of neonatal interventions with the potential to influence later morbidity should be designed with longer-term outcomes in mind.

Contributors

K Telford designed and did all the clinical assessments, clinical data entry, initial analyses, and produced the first draft of the manuscript. L Waters designed and did the psychological assessments and did the initial data entry. H Vyas was a co-applicant for the grant, designed the medical assessment, and contributed to the paper. B N Manktelow provided statistical input into the design of the application and protocol, and did the analyses with K Telford. E S Draper provided methodological expertise for the application, and contributed to the analysis and write-up. N Marlow was the principal applicant for the research grant, was responsible for coordinating the application protocol, supervised K Telford and L Waters, and contributed to the final manuscript.

Conflict of interest statement

We declare that we have no conflict of interest.

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