The Stoke CNEP Saga

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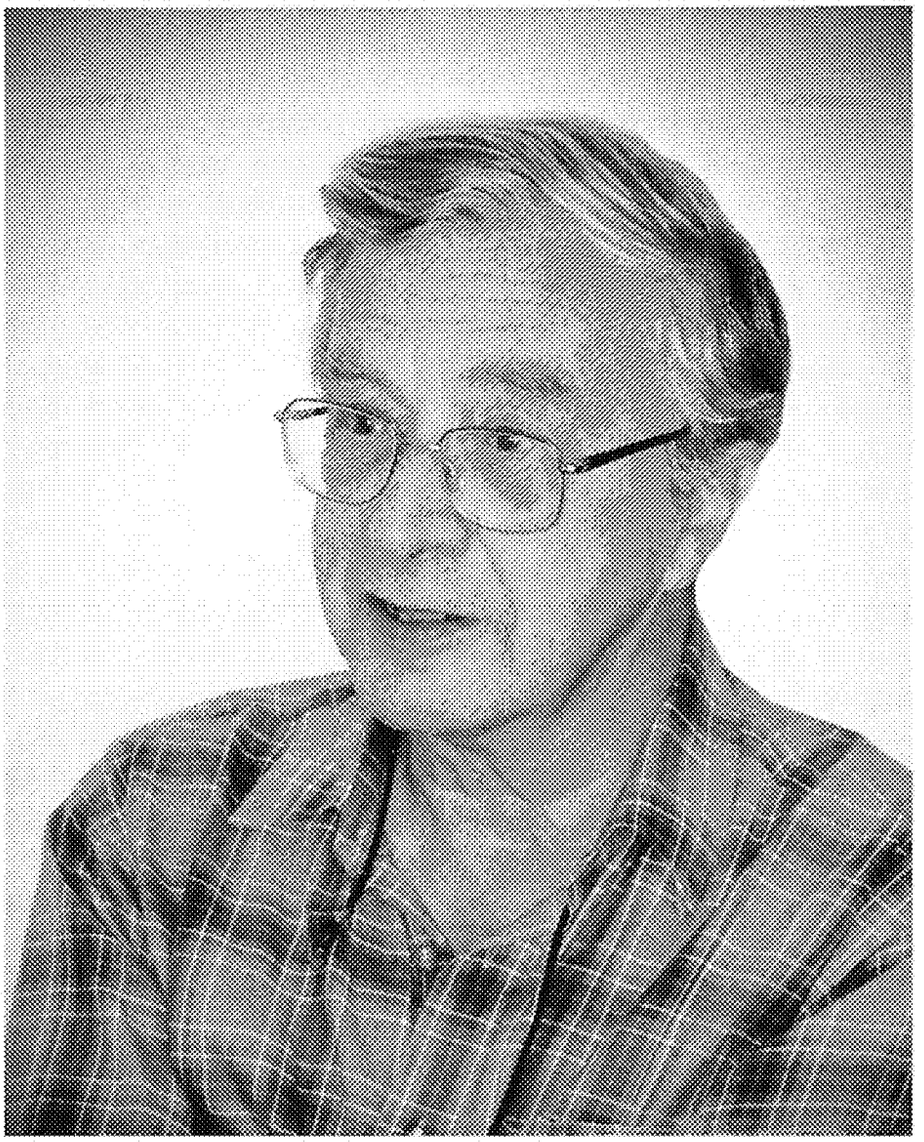

1934-2009

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The CNEP trial: how a good trial was turned rotten

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One man's pioneering research is another man's research misconduct. But back in October 1989, at the start of a randomized comparison of continuous negative extrathoracic pressure (CNEP) with intra-tracheal positive pressure ventilation in premature neonates, medical researchers were unquestionably shining knights. In the intervening two decades, many medical researchers have been attacked for their evil intentions. Sometimes fairly, when researchers have allowed competing interests, usually financial or career gain, to muddy their work and damage their integrity. Other researchers, however, have become victims of a shambolic and fragmented regulatory system, and a criminally amateurish system for investigating alleged research misconduct.

The researchers involved in the CNEP trial fall into the latter category argue Ed Hey and Iain Chalmers (*JRSM* 2010;103:132–7). The trial could be considered to have been ahead of its time. The protocol was alpha rated by the MRC. It was ethically approved – twice. It was publicly registered at inception. An information leaflet was provided for parents, and post-trial questionnaires were used to gather parental views. A sequential design was used to monitor accumulating results in the days before data monitoring committees became commonplace. And the trial report was co-authored by doctors, nurses and a statistician.

However, a combustible mix of circumstances turned the CNEP trial into the best example of how to *mis*-investigate alleged research misconduct. The accusations of distraught and vulnerable parents were understandable, the trial participants were newborn and at risk of early death. But those complaints were seized upon by campaigners seeking to interrogate the child protection work of two of the professionals associated with the trial – Martin Samuels and David Southall. The media amplified the noise, receptive to horror stories about doctors in the era of the Bristol Inquiry into paediatric cardiac surgery, the organ retention scandal at Alder Hey, and the murders of Harold Shipman. Doctors were vilified by the media, portrayed as a rogues' gallery of butchers and gropers.

The result for the investigators in the CNEP trial and the staff at North Staffordshire Hospital, where the trial was conducted, was a living hell of allegations, media attacks, intrusive scrutiny, and local and national investigations. After 11 years of accusations, investigations, and inquiries – and £6 million in costs – the GMC decided that there was no case for the researchers to answer in respect of the CNEP trial.

This month, the *JRSM* begins a six-part series examining the outcry that resulted from allegations made about the CNEP trial and its impact on regulation of medical research. Hey and Chalmers set out the background to the controversy and call for the first response to allegations of research misconduct to be that the facts be established by suitably qualified professional investigators. They also argue for a more robust response from professionals to unfair allegations. Why shouldn't professionals use our much maligned libel laws more often to protect their reputations? In subsequent issues, Jonathan Gornall will dissect the role of the media in creating a national scandal out of pioneering medical research. Rod Griffiths will give a blow-by-blow account of the much-criticized government inquiry he headed. He later described his brief as 'drinking from a poisoned chalice'. Theresa Wright will provide a personal insight into the experience of nursing staff at North Staffordshire Hospital during the height of the controversy. Graeme Catto will explain the GMC's role in investigating the complaints it received while he was president. And Frank Wells will explore some of the history of investigating research misconduct in the UK.

The story is complex yet compelling. But how can we prevent a repeat of this damaging episode?

We do now have enhanced systems of research governance, but are they enough? And what evidence suggests that the media will treat the next medical research scandal more responsibly? Our systems of regulation and investigation of researchers and research misconduct have been woefully inadequate, and remain so despite some new initiatives. One answer might be to professionalize research and accredit professional researchers under the auspices of a central regulatory authority, as Dixon-Woods argues in an editorial that accompanies the series (*JRSM* 2010;**103**:124–5). A proper, professional system of investigation, one strand of her proposals, should be a minimum requirement.

The tragedy of the CNEP trial controversy is that it could have been prevented, and the damage to people and medical research minimized. Well-intentioned individuals and organizations were asked to pass judgements on matters that they were ill-equipped to investigate. The media was too willing to extract every morsel of sensationalism out of the misery of families. Government was unable and unwilling to accept that its vilification of professionals might have been unfair and wrong, its investigations ill-directed.

Ultimately, though, the CNEP trial harmed medical research because the medical profession remains a quarrelling realm of fiefdoms and glory-hunters, readily manipulated by power brokers and public outcry. Medical research is a sideshow in an unending power struggle inside and outside medicine. Unlike the Bristol Inquiry and cardiothoracic surgery performance data, for example, it is hard to see what meaningful steps have been taken to prevent another damaging research scandal of the magnitude of the CNEP trial.

EDITORIAL

Regulating research, regulating professionals

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This issue sees the publication of the first[1] in a series of six articles about alleged research misconduct. Rarely does one feel so moved and disturbed by a collection of articles in an academic journal. All take as their focus the trial of continuous negative extrathoracic pressure (CNEP) for treatment of preterm infants with respiratory failure at North Staffordshire hospital in the UK, which ran 1989–1993.[2] That there is still controversy over a study that began 20 years ago is perhaps the first hint that this is an epic tale, complete with multiple twists and turns in the plot, and a cliff-hanger that is not quite an ending. In this short commentary, I offer some reflections on what might be learned from what, for many of the people involved, and as the articles demonstrate, was nothing short of a disaster.

Some insight is first needed into why the allegations about the CNEP trial gained the prominence they did, and why they were handled in the way they were. Much of the explanation can be traced to the historical period in which the allegations emerged, which was rife with scandals involving doctors. The murders committed by Harold Shipman were coming to light, while several doctors at around the same time were arrested and convicted of sexual assault on their patients or other forms of gross misconduct. Two 1990s crises – the paediatric cardiac surgery programme at Bristol, and the organ retention controversies – specifically involved children, and were the cause of intense anguish. The official Inquiries that were to follow these events were highly critical of the medical profession, and urged greater recognition of the need to listen to patients and take their concerns seriously.

Given what seemed to be an inexorable pattern to stories about abuse, exploitation and disrespect of patients, it is perhaps unsurprising that parents' complaints about CNEP (first made in 1997) were seen at first as plausible evidence of what the *BMJ* termed 'yet another NHS scandal'.[3] Despite this, it might have been possible to bring the matter to a much swifter and more satisfactory conclusion had regulatory and organizational systems been up to it. They were not.

Rod Griffiths' article, later in the series, will describe the challenges of trying to run an investigation at the same time as making up the rules about how the investigation was to be run. Graeme Catto's article will describe how the GMC's investigations into the doctors involved in the CNEP case were frustrated by having to operate under outdated and inadequate rules that had already passed into history but still applied because of the timing of the complaints. Institutional deficiencies further compounded the situation. The regulatory regimes for both doctors and for research have, since the 1990s, undergone substantial reform. But are they fit to prevent problems like those that beset the CNEP trial occurring in the future?

The emphasis of the current system of regulating research might be said to be geared towards prevention. The first problem with this is a familiar one, and concerns the proportionality and efficiency of the system of approvals. The regulatory environment for research remains complex, populated by multiple regulatory agencies and offices who have a say in what researchers can and cannot do, and there are multiple sources of guidance and requirements. Recent innovations such as the research passport and the Comprehensive Research Network portfolio may simplify the process for some types of studies, but make it more complex for others.

The second problem concerns the effectiveness of the system. No matter how many checks are

made before projects begin, it is virtually impossible to ensure that nothing will ever go wrong, or that no researcher will ever engage in misconduct, or that nobody will ever complain. But systems for the detection and investigation of problems are generally ill-specified and poorly coordinated, in practice relying on complaints from participants or others, or on the oversight exercised by academic journals (even though journals are not formally part of any regulatory system). Where misconduct is suspected, critical weaknesses remain. A procedure for investigating alleged misconduct in research[4] has been launched by the UK Research Integrity Office (a body that itself lacks a statutory basis), but it remains voluntary, and it is not clear how widely used it is. The situation is further confused, and responsibility is diffused, by the number of different parties who have a stake, including professional regulators, employers, funders, sponsors, academic journals and NHS trusts. Different types of investigation and sanctions may follow depending on who committed the misdemeanour, but many of the parties involved may have little experience or expertise in conducting investigations into research misconduct, and some indeed may have an interest in not exposing misconduct.

This leaves both research participants and members of the research community without the assurance that allegations will be investigated promptly, effectively, and fairly. Nor is there a good way of ensuring that if a researcher (particularly non-clinical) commits a misdemeanour relevant to their work, this information will be shared with future employers or trusts hosting his or her research. One way of helping to resolve the problems both with approving research and dealing with allegations is to recognize health research as a professional activity that should have a central regulatory agency.

Under such a proposal, this regulator would require that anyone who wants to conduct research in the NHS be a registered researcher. The regulator would make explicit the standards expected of researchers, including a code of conduct. It would carry out checks to ensure that researchers have the right qualifications and other bona fides before being registered. The regulator would act as the central agency for dealing with complaints or allegations about research; would have an agreed standard operating procedure for responding to complaints and conducting investigations; would be able to mobilize a specialist, trained team where needed to conduct investigations; and would have powers to deregister or place restrictions on researchers' activities. Where researchers are found to have committed misconduct, employers and professional regulators such as the GMC would be notified of such actions, and would be entitled to take appropriate disciplinary action, but not to repeat investigations – thus avoiding the multiple jeopardy problem Hey and Chalmers describe in their article.

Some may argue that having such a regulator simply introduces a further layer of bureaucracy into an area already stiff with it. But the current system amounts to licensing every project and every researcher, every time, and is wasteful and inefficient. Researchers and those who fund research are already paying dearly for this form of licensing; this proposal would move the costs to a more efficient and effective system. Registration would replace the research passport/honorary contract system, and NHS trusts could accept registered researchers to conduct research without further checks. Many of the details would require careful working out. But professionalising research would bring many benefits, in one place making clear and explicit the expectations of all researchers in health, providing a central repository for advice and guidance, and, by having a proper, professional system of investigation, helping to avert the kind of trauma that followed the CNEP trial.

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Mis-investigating alleged research misconduct can cause widespread, unpredictable damage

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Introduction

Twelve years ago, Deborah and Carl Henshall, whose prematurely born daughter Sofie had received respiratory support using continuous negative extrathoracic pressure (CNEP), alleged research misconduct by the clinicians responsible for the randomized comparison of CNEP with intra-tracheal positive pressure ventilation being undertaken in Stoke on Trent.[1] These allegations were very widely publicized, and separate overlapping investigations were mounted by the local NHS Trust, the NHS Executive, and the General Medical Council (GMC), causing hospital staff and their families stress severe enough to end a few careers. More generally, the allegations led to the introduction of a national Research Governance Framework, and much of the UK's current hyper-regulation of clinical research. It took 11 years for the GMC to conclude that there was no case for the defendants to answer, and that one of the study's principal critics (and the main expert called in to support the Henshalls' case) was neither an expert nor independent.[2,3]

Our involvement with this affair began when we were asked by a medical defence society to assess a Government report that had raised serious questions about the conduct of the CNEP study. We agreed to do this, and do it unpaid, on the understanding that: (1) our work would be confined to the report's critique of the CNEP trial; (2) we could have access to all the relevant documents to which the defence society had access; and (3) we would be free to publish our findings – whatever they were. Four months after the government report was released, the *BMJ* published our assessment. We concluded that 'The statements relating to the CNEP trial … contain so many errors of fact … that the whole report stands discredited'.[4]

Not only did we find no evidence of the alleged research misconduct, we noted that the trial had, in many ways, been ahead of its time. The protocol had been alpha-rated by the Medical Research Council; it had twice been ethically approved; it had, exceptionally, been registered publicly at inception; an information leaflet had been provided for parents; a sequential design had been used to monitor accumulating results during an era before data monitoring committees had become common; post-trial questionnaires were used to elicit parental views; the trial report was co-authored by doctors, nurses and a statistician; and it was published in a prestigious paediatric journal. Our *BMJ* article concluded that, since the whole edifice of administrative reform called for in the government report rested on the implied conclusion that the CNEP trial was conducted in a flawed and irresponsible way, the NHS Executive needed to retract its report and reassess the appropriateness of its recommendations.[4]

The Government, however, has never publicly admitted that its review was flawed. On 10 October 2000, Lord Walton of Detchant asked Lord Hunt of Kings Heath, the Parliamentary Under-Secretary of State at the Department of Health, 'whether they support the findings and conclusions of the Griffiths report … in the light of the criticisms published in the *British Medical Journal*'. This led to the following exchange:

> *Lord Turnberg:* My Lords, will the Minister agree that the Griffiths report appears to have given rise to a number of injustices, despite the Ministers' comments about the value of some elements of it, not least of those being the apparent denial of human rights to the doctors being criticised in that they were not allowed to see the report before it was produced

in order to be able to answer some of the criticisms.

Lord Hunt of King Heath: My Lord, I have no reason to believe the review was not conducted appropriately ...

Lord Campbell of Alloway: My Lords, I have listened to a plethora of words but I want to ask the Minister a simple question. Is he prepared to consider giving the apology sought by the noble Lord, Lord Walton of Detchant, or is he not? Can I have a straight answer to a straight question?

Lord Hunt of Kings Heath: My Lords, I always think that 'yes', 'no' answers are best avoided.

Seldom has the British public been told something that was so blatantly untrue, so consistently, and for so many years, as the story that first broke in 1997. At that time a quality newspaper came out with the headline:

Parents say 'guinea-pig' trial killed their babies

and claimed that 'Forty three premature babies, many only a few hours old, died or suffered permanent brain damage after being used as "guinea-pigs" in a radical hospital experiment'.[5] When no rebuttal seemed to appear even after the story had been repeated many times, people naturally began to believe that it must be true. And when, after three years, a Government enquiry offered tacit support for the story, this strengthened the public's belief that the press reports must be true.

It has now been established that the story was unfounded, but does the public know this? Do most doctors know this? Do most realize that the allegations were adopted immediately and used by a small pressure group to attack the work of two paediatrician co-investigators of the CNEP trial who had also been working in the fraught field of child abuse? The answer has to be 'no'. How could it be otherwise when the true story has never been told in the British lay press, and the medical press has remained almost as silent?

Since our article appeared 10 years ago we have reiterated, on several occasions, the vital need for 'due process' when investigating allegations of research misconduct.[6–9] This is the first of six articles to be published in this journal which will look at what happened, how it might have been different, and what is needed to prevent a recurrence.

What happened?

Box 1 summarizes the main events in this 20-year 'saga'. In the next article in the series, the investigative journalist Jonathan Gornall will look at the way the press ran with the story. Even respected national broadsheets implied that the CNEP study had 'killed premature babies';[10] and, when the paper's editor was later challenged about this by a Parliamentary Select Committee, he said he did not recall the details of the story.

The third article in the series has been contributed by Professor Rod Griffiths, who chaired the review that the government initiated in response to this media pressure. Professor Terry Stacey (a paediatrician, and regional director of research for the South Thames Region) and Mrs Joyce Struthers (the chair of the Association of Community Health Councils in England and Wales) were the other members of the panel whose report appeared 17 months later. Griffiths later characterized the brief he had been given as 'drinking from a poisoned chalice'.[11] The article he has now written gives a more detailed account of the way the enquiry was generated, and reflects on whether the Research Governance Framework that was then set up has, on balance, improved the quality and the amount of clinical research now being done.[12]

The fourth article provides a moving account of what it was like for all the staff at the North Staffordshire Hospital as they faced a seemingly unending series of enquiries. Although the CNEP trial had been about trying to find a better way of nursing babies, the voice of the nursing staff has so far gone almost unheard. The article has been written by Teresa Wright, the trial's senior research nurse. To be repeatedly pilloried in the media, to have nobody mounting an effective rebuttal, and to be barred from responding personally, was deeply demoralizing.

How might it have been different?

Employers and the medical defence societies routinely bar those they employ and represent from saying anything while under investigation, and professional respect for patient confidentiality has made the publication of rebuttals even more difficult. By contrast, there is nothing to stop the press from continuing to make unsubstantiated allegations of misconduct while full hearings are pending. Unsurprisingly, the public cannot understand

Box 1
Key events in the 20-year CNEP trial 'saga'

October 1989 A randomized study comparing continuous negative extrathoracic pressure (CNEP) with intra-tracheal positive pressure ventilation in premature neonates starts, first in Queen Charlotte's Hospital, London, and then in North Staffordshire Hospital, Stoke on Trent
November 1993 Recruitment closes when the trial statistician reports that one of the pre-agreed stopping points has been reached
July 1994 After they find that their 19-month old daughter Sofie (who had been treated with CNEP in the trial) has a disabling double hemiplegia, Deborah and Carl Henshall start a civil claim for damages alleging negligent neonatal care
October 1996 The Henshalls drop their action. Experts believe that their daughter's problem probably originated during pregnancy
December 1996 The American journal *Pediatrics* publishes the report of the CNEP trial, co-authored by eight doctors, two nurses and a statistician
March 1997 The Henshalls are contacted by a freelance journalist, Brian Morgan, who has been leading a media campaign against two of CNEP trial's authors (Professor David Southall and Dr Martin Samuels) criticizing the use of video surveillance by Southall and Samuels to identify why some young children only suffer sudden collapse when alone with their parents
March 1997 The Henshalls ask *Radio Stoke* and the editor of the local paper, *The Sentinel*, to help them make contact with other families with babies who had been in the CNEP trial
April 1997 The Henshalls lodge a complaint with the GMC alleging research misconduct and forgery of trial consent forms. The GMC's Preliminary Proceedings Committee finally decides in *January 2002* that no public hearing is warranted*
May 1997 Morgan writes an article published in the *Independent on Sunday* under the headline 'Parents to sue over clinical trial they knew nothing about' and persuades the *BBC Watchdog* programme to carry the same story a few days later
December 1998 After the parents of other children cared for using CNEP in the trial also allege research misconduct, Government ministers ask Professor Rod Griffiths (regional medical officer, West Midlands Region), 'to look into the general framework for both the approval and monitoring clinical research projects in North Staffordshire'
March 1999 An internal enquiry at the North Staffordshire Hospital concludes that all the trial consent documents are in order (but this finding is not reported to Professor Griffiths)
October 1999 The Hospital's chief executive asks Professor Sandy McNeish and Dr Geoff Durbin to review a sample of the research being done by Professor Southall. Southall and Samuels are suspended four weeks later
November 1999 The parents of several children treated with CNEP ask the police to investigate allegations that consent forms were forged. This investigation closed in *October 2002*
January 2000 After Samuels and Southall challenge their suspension, Sir David Hull undertakes a further review of the research for the hospital and reports in *December 2000* that it was of a high standard. Samuels and Southall are reinstated nine and 15 months later, respectively
May 2000 The Griffiths report is published. It raises questions about the conduct of the CNEP trial and the use of covert video surveillance, and recommends the creation of a new national framework for approving and monitoring all clinical research. Four months later the methods and factual accuracy of the review is criticized in the *BMJ*
March 2001 Hospital managers initiate an internal enquiry into whether eight CNEP consent forms had been forged, and concludes in *October 2001* that there is no evidence of this
January 2002 The Henshalls complain to the chief executive of the GMC that its committee had not looked at all the 1600 pages of evidence that they had submitted, so the case is sent back to a new committee in *September 2002*
March 2004 The GMC's new committee confirms the earlier committee's decision in January 2002 – ruling that the Henshalls' complaint does not merit a full disciplinary hearing
June 2004 The Henshalls appeal against this decision to the High Court, which rules in *October 2004* that the GMC's handling of the complaint had not been unreasonable
June 2005 The Henshalls appear against this ruling to the Court of Appeal, which rules in *December 2005* that the GMC's procedures had been flawed†
January 2006 The GMC re-opens the case, and starts a public disciplinary hearing in *May 2008*
July 2008 The case is thrown out, even before the case for the defence is heard, because the panel decide that there is no case to answer
August 2008 The Henshalls ask the Council for Healthcare Regulatory Excellence to overturn the GMC's decision. The request is declined

* The GMC's Preliminary Proceedings Committee, as is usual, only met to consider the Henshalls' allegations in October 2001, after all the confidential documents from the Trust's various disciplinary enquiries had reached them
† The Court of Appeal referred the case back principally because the GMC had relied on Hey's and Chalmers' criticisms of the Griffiths report, and the Department of Health had refused to respond to these. The Court of Appeal considered this a failure of due process because the Department's refusal meant that the reliability of the Griffiths report had never been properly tested. The GMC, therefore, decided to ignore the outcome of all the previous investigations and mount a disciplinary hearing based simply on the evidence presented by the Henshalls and Dr Richard Nicholson

why, if at least some of the allegations were false, no-one ever initiated a libel action. But libel is an expensive business and the doctors knew that if they took any such action themselves, they risked losing the support of their defence societies.

The hospital Trust's first investigation in response to the allegations, in 1999, looked at other research underway at the time, but not the conduct of the CNEP trial. Their investigation, which led to the two consultants being suspended, was conducted in a politically charged atmosphere and somewhat hastily (Box 1). So much seems apparent from the result of the Trust's second, equally secret investigation which ultimately found that there had been no case for disciplinary action, let alone for a two-year suspension.

The GMC's own investigation may have been less swayed by political pressure, but it took a scandalously long time. Even here, however, the GMC's Director of Public Affairs, Isabel Nisbet, was alerting colleagues to the dangers confronting the Council. In an e-mail (obtained under the Freedom of Information Act) sent to colleagues as early as 24 September 2000, she wrote that the GMC might well end up:

> *'on the wrong side of both phases of the debate' ... and be criticized 'first for not being vigorous enough in stepping in to protect patients ... and then – after we pull our socks up and start moving much more quickly, as we are now – for succumbing too readily to political/tabloid pressure to undertake "witch-hunts". If we do proceed against Prof Southall it is just possible that his case could emerge as a test, with a lot of (respectable) professional sympathy for Prof Southall, and us cast as witch-hunters.'*

She goes on, presciently, to make a more general point about the competence with which many allegations of misconduct are initially investigated, telling her colleagues that they may need to become:

> *'sensitive to the changing tone of the debate. There may be scope for an emerging role for us to define standards of fairness and rigour in Trust and other local NHS inquiries if we are to use them in FTP [fitness to practise] procedures.' The 'point was made to me last week ... that most of them [Trusts] would not have any idea how to set up and carry forward an enquiry into a difficult and high-profile case, that for many middle-sized and small Trusts it would only happen once (at most), and they would have no chance to learn from the experience.' ... 'I realise that it could be argued that it is the Dept's job to set standards for local inquiries (and that we have enough to do anyway), but we do, I think, have a locus when it comes to what we can and cannot use as evidence and when we should step in using our S35A powers. It is going to be very time-consuming for us to prosecute weak cases based on poor-quality NHS evidence.'*

The views expressed in that e-mail have clearly still not won general acceptance. It was the poor quality of the initial investigations that did much of the damage described in this and the subsequent articles in this series. And, unfortunately, when the Trust did get external assessors to undertake a more rigorous investigation, their findings were never made public, thus doing little to silence the media campaign.

The one merit of the GMC hearing was that it was held in public. Those involved might have welcomed this had it used the factual information that earlier investigations had assembled, and had it been held seven years earlier. Yet two months before this public hearing finally opened, and 29 months after the Court of Appeal had told the GMC to consider the whole case afresh, it became clear that there were still no agreed 'heads of charge'; that the GMC had still not obtained the views of a single expert witness to support the case they were bringing on the basis of the Henshalls' complaints; and that no use was being made of any of the factual material gathered by the Trust before it had concluded, seven years earlier, that there was no case for the doctors to answer. Unsurprisingly, when the lack of substance supporting the allegations was finally made public, the GMC panel dismissed them in July 2008 without even requiring the defence to set out its case.

What is needed to prevent a recurrence?

In the fifth article in the series, Professor Sir Graeme Catto, President of the GMC until March 2009, admits that there were many mistakes in the ways in which the case was handled, but he sees no need for any additional investigative capacity to deal with allegations of research misconduct.

Furthermore, Sir Graeme suggests that there could not be any recurrence of this affair because disciplinary hearings will, in future, be in the hands of a body separate from the GMC (which remains responsible for setting standards).

The CNEP affair shows the extent of the 'collateral' damage that can occur when the initial investigation of an allegation is mismanaged. Employers and regulatory bodies often lack the experience needed to be able to establish the true facts speedily and well. In addition, when the whole investigative process is conducted 'in house', it often lacks the independence necessary to win the trust and respect of those involved, or the confidence of the wider public. In the final article in the series, Frank Wells, an editor of the leading book on research misconduct,[17] describes the origins and work of a consultancy established to offer forensic expertise to investigate suspicions or allegations of research misconduct.

What do we conclude and recommend?

The cost of dealing with the CNEP allegations to the NHS, to the defence societies, and to the GMC and its nursing counterpart probably exceeded £6 million. And there were other important, if less tangible, costs borne by those accused and their families, and by the clinical research community. Separate overlapping investigations were undertaken by the Hospital Trust, Keele University, the Nursing and Midwifery Council, the GMC and the government, and the GMC's investigation was then reviewed by the Court of Appeal. What is the point of delegating the review of most disciplinary issues to local employers, as the GMC did in this case, if, once the employers say they can find no fault, the Council *still* goes ahead with a further protracted review? Several doctors faced 'quadruple jeopardy' of a sort that would not be tolerated in the Crown Court system.

The National Clinical Assessment Service (NCAS) was set up at much the same time as many other clinical governance structures some eight years ago. It was tasked with advising Health Authorities on how to go about managing staff when 'concerns over performance' arose, and it appears to have dealt effectively with cases of concern in a constructive, non-confrontational way. What it has found is that an allegation sometimes reveals more about the person lodging the complaint than the person being complained about.

The problem is that there is no clear dividing line between 'concern over performance', which is supposed to be a matter for the NCAS, and concern over 'fitness to practise', which is the statutory remit of the GMC. There is a 'memorandum of understanding' between the two but this cannot conceal the huge unaddressed overlap of responsibility. We know of at least two cases where the NCAS came to a clear view about the rights and wrongs of an allegation only for the same complaint to be taken up by the GMC and trawled over again. It is just another example of the overregulation that is now strangling the health service and health research.

We do not accept that it can be assumed that there can be no recurrence of the expensive injustice represented by the CNEP affair, and we suggest there is a pressing need to develop a more just, timely and effective way of responding to allegations of research misconduct.

Increase forensic capacity to establish the facts

We believe that the GMC's director of public policy was right in what she wrote in September 2000 about the need for all disciplinary investigations to meet minimum standards. However, it is not enough to set 'minimum standards' – the facts needed to inform any subsequent disciplinary decisions also need to be established by people with enough experience of this sort of work to do it well. What seems to have been missing is ready access to the expertise needed to mount a timely and effective investigation of the *facts* that need to form the basis for any fair and effective ruling as to whether there has been research misconduct. This experience does not reside in the UK's Panel of Research Integrity, nor is that body wholly independent.[18] Currently, MedicoLegal Investigations appears to be the only UK organization experienced in the forensic investigation of possible research misconduct, whatever the professional discipline of the researcher, and which is transparently free of vested interest. It needs to be used more widely.

Increase selective use of the libel laws

The many investigations that the CNEP clinicians endured might have been avoided had they initiated an action for libel against those who first ran with some of the more florid and inaccurate versions of the story. The tactic of saying nothing can sometimes be counterproductive, and suing for libel can sometimes deliver justice to those who have been defamed.

After an NHS report had criticized one orthopaedic surgeon's role in managing a brain-injured patient who died after being flown 200 miles to another hospital because no neurosurgical intensive-care bed could be found for the patient in the southeast, the *Daily Mirror* dubbed him 'Doctor Dolittle'. The subsequent trial resulted in one of the largest libel awards in British legal history – £625,000.[19] Employers and defence societies should consider whether their current reluctance to sue for libel fulfils their duty of care to researchers.

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The role of the media in the Stoke CNEP Saga

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As the boxed summary in the first article of this series shows,[1] the way the Stoke neonatal CNEP trial was conducted between 1989 and 1993 was investigated 12 times between 1997 and 2008. Much of the public and political concern that led to this activity was generated by a decade of often sensationalist, irresponsible, frequently misleading and inadequately rebutted journalism.

Early media reports

On 24 March 1997, three months after the research paper about this trial was published in *Pediatrics*,[2] Carl and Deborah Henshall contacted the *Sentinel*, their local newspaper in Stoke on Trent. They did so because, as Deborah Henshall was to recall before the GMC more than a decade later, 'Having found out that my children had been in a research trial that I had no knowledge of, I wanted to know whether I was the only parent that did not know their child had been used in a research project'.[3] Two weeks later, the *Sentinel* reported the Henshalls' claim that their daughter Sofie had suffered brain damage 'caused by slow suffocation' while CNEP was administered in the course of the trial, a trial which, on their account, had been conducted covertly and without their knowledge. The newspaper report noted that the couple's barrister had 'advised [them] that if they establish liability against the health authority they would be seeking substantial damages'.[4] About a month later, the Henshalls lodged their first complaint with the GMC.[3]

Two of the Henshalls' children, born 10 months apart in 1992, had been entered into the trial, along with 242 other babies with life-threatening respiratory failure. Both were randomized into the CNEP treatment group. The first, Stacey, was born by Caesarean section at approximately 27 weeks and died two days later; Sofie was born 10 months later, also by Caesarean, at just over 32 weeks. The couple have six other children, all but the first of whom were born prematurely.[3]

'We were never told the procedure was part of a trial,' Mrs Henshall was quoted by the *Sentinel* as saying. The newspaper's headline – 'Brain tragedy of baby Sofie. Parents to sue over clinical trial they knew nothing about' – uncritically stated as fact the parents' version of events.[4]

When a national newspaper took up the story some weeks later, it contained new elements.[5] According to a report in the *Independent on Sunday* on 11 May 1997, sensationally headlined 'Parents say "guinea-pig" trial killed their babies', 'Forty-three premature babies, many only a few hours old, died or suffered brain damage after being used as "guinea-pigs" in a radical hospital experiment'. 'Parents of the babies,' reported the newspaper, 'claim they were not informed of the risks of allowing their children to take part in the trial' and that 'they found out about the experimental nature of the study only after the researchers wrote up their findings in a medical journal'.

'None of the risks,' the article continued, 'was spelt out to the parents', who said they had 'signed consent forms and were shown an information sheet but this claimed that CNEP was safe'. The report recorded that, '[a]mong the parents are Deborah and Carl Henshall from Stoke'. The Henshalls were quoted specifically, Mr Henshall as stating, 'We were not made aware that Sofie's treatment was part of a trial,' while Mrs Henshall was reported as saying, 'I honestly did not know Sofie was going into a research trial ... I was told this was a new, proven ventilator from America which would soon become the normal treatment for premature babies in this country. Now I know this wasn't true.'

Mrs Henshall, said the article, 'gave her consent when Sofie was between two and four hours old

when "I was still under the effects of morphine in the recovery room following a Caesarean".[5] The day the article was published, the Henshalls wrote a letter to the newspaper insisting that, contrary to the newspaper's suggestion, they had not signed a consent form.

Two days later, on 13 May 1997, the *Telegraph* carried a story stating that the 'parents of a number of babies who allegedly died or suffered brain damage during hospital trials of an experimental ventilator are planning a multi-million pound legal action'. The Henshalls' solicitor was quoted as saying that there were difficult legal hurdles to be crossed. It would be necessary to prove, he said, that the families who consented to the trial had not been properly informed, while 'The major problem is going to be showing the causative link that demonstrates that this machine alone was responsible for what had happened'.[6]

The Henshalls took their case to their MP, Llin Golding, whose intervention with health ministers led in 1999 to the setting-up of an NHS inquiry into research practices at Stoke, headed by Professor Rod Griffiths, then the regional director of public health.

Further new elements are added to the story

To coincide with the publication of the Griffiths report, in May 2000 the *Independent* reported a previously unpublished account of how the Henshalls said they had learnt that their two children had been in a trial. The article described how '[a] chance remark by a doctor at another hospital alerted Carl and Debbie Henshall to the fact that two of their daughters had been involved as guinea pigs in a research trial'.

The couple, reported the newspaper, had 'consulted a solicitor and started legal action against the hospital in 1994. In 1996 the solicitor sent them to a medical expert at St James's Hospital Leeds. He said to us "What do you expect from an experimental treatment?" We said "What do you mean experimental?" Until then we had believed that our daughter had been given the best treatment available."[7] Despite occupying a central position in the story, the newspaper apparently did not see fit to approach the doctor in question to see if his recollection of his encounter with the Henshalls accorded with theirs. Certainly he was not quoted in the article. As it happens, he denies that any conversation in the terms reported by the *Independent* ever took place (personal communication, 26 May 2009).

The *Independent* also failed to address or explain the fact that its article did not chime with the earlier version of the relevant events recorded in its own sister newspaper, the *Independent on Sunday*. Three years before the report of the doctor's 'chance remark' that had allegedly alerted the Henshalls to the fact that their child had been in a research trial, the *Independent on Sunday* reported that the experimental nature of the trial had been discovered by the Henshalls among other parents from a paper published in an American medical journal.[5]

The disciplinary authorities bow to media pressure

There is evidence that from the outset the GMC was more interested in the Henshalls' complaints because of the media coverage they had attracted rather than their intrinsic merits. In an internal email sent to GMC medical and lay screeners in February 1998, a caseworker wrote that while the allegations 'are serious – they include that consent was not properly obtained, that the potential benefits of CNEP were not adequately established before the trial began, and that the test results have been massaged', the case was 'long on speculation, particularly on the part of the Henshalls, but short on evidence, especially of an order which might result in charges against individual doctors'.

Nevertheless, added the GMC caseworker, the couple were 'aggressively mobilising the media, including Channel 4 News, and MPs, including Mrs Llin Golding, on their behalf'. The writer was 'not optimistic about the prospects of proving anything concrete against individual doctors. However ... in view of the serious nature of the allegations, we should respond to the campaign being orchestrated by the Henshalls by asking FFW [GMC solicitors, Field Fisher Waterhouse] to undertake an investigation ...'.[8]

The following year, North Staffordshire Hospital Trust responded in a similar manner to the wider campaign being waged against Dr Southall in relation to his child-protection work, noting that all complaints they received were being copied to the media as well as to a host

of people in Whitehall, including the Secretary of State for Health, the Home Secretary, the Social Services Inspectorate, the Lord Chancellor and Ann Widdecombe MP. As a Trust Board minute on 9 March 1999 noted, the normal response would have been to 'write back and ask for evidence before initiating an investigation. However because the allegations have received widespread distribution ... they warrant further investigation.'[9]

How the central media myth emerged

The central myth at the heart of the media coverage of CNEP, that it had 'killed babies', originated in one of the first articles published about the trial, written by Brian Morgan, a freelance journalist who had already developed a particular interest in Dr Southall and various aspects of his work.[5]

In 1995, before CNEP became headline news, it was Mr Morgan who had first written about the covert video surveillance being conducted by Dr Southall and colleagues to investigate suspicions of induced illness among children who had been referred for apparent life-threatening events. Covert video surveillance conducted in two centres between June 1986 and December 1994 had revealed abuse in 33 of 39 suspected cases. This was work later reported in *Pediatrics* as a 'descriptive, retrospective, partially controlled case study',[10] but characterized by Mr Morgan, writing for the *Times Higher Education Supplement* in 1995, as 'unapproved research'.[11]

Two years later, Mr Morgan turned his attention to CNEP, which he described in his May 1997 article for the *Independent on Sunday*, headlined 'Parents say "guinea-pig" trial killed their babies', as 'a radical hospital experiment'.[5] The article began: 'Forty-three premature babies, many only a few hours old, died or suffered permanent brain damage after being used as "guinea-pigs" in a radical hospital experiment'. Nowhere in the article was it made clear that 32 babies who had been entered into the control side of the trial suffered similarly.[5]

The inference – that CNEP had caused these outcomes – was clear, but there has never been any evidence of this;[12] indeed, a long-term study recommended in the report of the Griffiths inquiry later found the CNEP-treated survivors to be making progress similar to, and possibly better than that of the conventionally managed children.[13] But the myth had been born, and it stuck. In 1999, following the news that an inquiry had been ordered into the CNEP affair, the *Independent* reported unequivocally that CNEP had 'resulted in the death or injury of 43' premature babies.[14]

The *Independent* was far from alone in the nature of its coverage of the CNEP story and there are many examples of even worse treatment – one of the worst being the 'exclusive' story that appeared in the *Sunday Mirror* in July 2000, beginning with the words: 'Twenty-eight babies died after suffering appalling injuries in controversial experiments carried out by one of Britain's top consultants, the *Sunday Mirror* can reveal today'.[15]

MPs highlight the inaccuracy of press reports

In March 2003, Simon Kelner, editor of the *Independent*, was giving evidence during the fifth session of the House of Commons Culture, Media and Sport Committee, which was examining the work of the Press Complaints Commission. At one point, he was asked by Adrian Flook, the MP for Taunton, whether he thought the headlines in his newspaper 'should reflect the words underneath'. Yes, he said, 'I would be distraught if it did not always happen'.

Kelner had walked into a small trap. Earlier that day, the MPs had heard from another witness, Ivor Rowlands, a retired engineer, who had brought to their attention the front-page CNEP article that had been published in the *Independent* in 1999, under the headline: 'Investigation ordered after 28 babies die in hospital experiment'.[14] That headline, suggested Flook, 'was not completely accurate'. Neither, he added, was the one that followed in the *Independent* a year later: 'Parents were misled over hospital trials which killed premature babies'.[16]

In the first story, said Flook, the *Independent* had buried 'right at the end' the fact that, despite its headline, the 'rates of death and disability among the 122 babies who received the experimental treatment were no different from those who received conventional treatment'. In fact, he said, 'it was not "28 babies die in hospital experiment", it was 50 in total. Yet they were all premature and there is a mortality of 20–25%, so you would expect something along those lines.'

The headlines, said Flook, were 'very emotive ... bear no resemblance to the story [and] have done a lot of damage to the hospital and doctor concerned'.

Kelner told the committee he did not remember the details of the story.[17]

But the inaccuracies keep on coming

Even the finding that CNEP was no more harmful than the standard treatment, which was reported in March 2006,[13,18] failed to halt the tide. The following year the *Sunday Express* repeated yet again allegations that '[c]hild specialist Dr David Southall ran research on babies which was likely to lead to brain damage or death', while also labelling its reports 'exclusive'.[19,20] The article that appeared in March 2007, under the headline 'Baby doctor experiment left our girl paralysed', added another twist to the tale, imputing an extraordinary allegation to the Henshalls that 'Women have had unnecessary caesareans to provide premature babies for controversial research'.[20]

The role of an expert

In the 10-year period 1997–2007 during which the CNEP-related claims repeatedly resurfaced in the media, several newspapers and television programmes made use of a 'medical expert' who always seemed ready to make himself available to speak out against Dr Southall on a wide range of topics, namely, Dr Richard Nicholson, the editor of the *Bulletin of Medical Ethics*. It was, therefore, a matter of some surprise to interested observers that Dr Nicholson was called to give expert evidence at the GMC fitness to practise hearing convened in 2008 to evaluate the charges against three doctors, including Dr Southall, arising out of their conduct of the CNEP trial. This decision to call Dr Nicholson led to some of the more startling findings to be made by the GMC panel in deciding to dismiss all the charges: that Dr Nicholson not only lacked independence and objectivity but over the years had, in the words of the panel, also 'conducted himself as a supporter' of the Henshalls and had shown 'a deep animosity towards Dr Southall' in interviews he had given to the media.[21,22]

Why the witch-hunt?

The explanation for the CNEP media witch-hunt must lie in part in the potent nature of the more general campaign against Dr Southall, which had been attacking his child-protection work for several years. For some in the media, CNEP was merely a convenient way of extending that campaign to discredit him, but as a result all involved in the CNEP study, and paediatric research in general, suffered severe collateral damage (Modi and Macintosh, submitted for publication). If anyone doubts the potency of such a sustained media campaign, they need look no further than the decision taken by Keele University in 2005 not to offer Dr Southall the customary title of 'professor emeritus' when he retired, largely because the university feared a backlash of 'adverse publicity'.[23]

Irresponsible journalism: lessons

The unnecessary and unjustified nature of the whole media-driven CNEP Saga was emphasized in revelatory postscripts written by two of the key players. The report published by Professor Griffiths in 2000 was severely criticized[24] and in 2006 he wrote that he had come to look on the task he had been given as 'a poisoned chalice'. In an article for the *BMJ* he also revealed the extent to which media pressure had led to the inquiry. There had, he recalled, been 'repeated headlines' about CNEP, alleging 'that excessive deaths had occurred'. As regional director of public health, he had 'already commented to the media that premature babies of that age had a significant mortality and that the children in the trial had fared no worse that expected'. Nevertheless, 'the story did not go away and local MPs took it up' – and the inquiry went ahead.[26]

In 2007, the Henshalls' former MP, now Baroness Golding, publicly expressed her regret at the chain of events she had helped to set in motion. In an open letter to the *Sentinel*, she wrote that she wished to apologise to Dr Southall 'and say how sorry I am if my initial concern has given fuel to what can only be described as a witch-hunt, aided and abetted by some professional people who surely should know better'.[27]

One of the key lessons to emerge from the CNEP Saga is that, left unchallenged, adverse media coverage can have a catastrophic outcome

for medical professionals, institutions, research and, ultimately, patient care.[1] The MP who triggered the initial inquiry and the man who then led it have both acknowledged that it was unchallenged media pressure that set the ball rolling. Internal minutes, memoranda and emails show that it also drove the actions of the hospital in Stoke, Keele University and the GMC.

If those in authority take only one lesson from the costly CNEP Saga, perhaps it should be this: that what interests the public should not be confused with what is in the public interest.

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The Stoke CNEP Saga – the Government enquiry in retrospect*

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***Disclaimer**
The events to which this article relates occurred a long time ago. The organization for which I worked at the time has since been reorganized several times, and I left it five years ago. I have no access to a comprehensive set of papers. This article is based on my memory of events and is written with the intention of assisting learning.

Why was there a review of research governance in North Staffordshire?

Sustained media coverage of allegations about the CNEP trial created pressure on the Department of Health. The responsible minister quite rightly stuck to the line that appropriate mechanisms already existed to investigate matters of individual care (the NHS complaints process) or individual professional misconduct (the GMC and other professional regulators) but this was not enough to make the problem go away. Eventually the minister came to the conclusion that one aspect that was not being investigated was the framework through which research was supervised in the North Staffordshire NHS Trust. The review thus covered research governance, though many have mistakenly assumed that it was about misconduct. Had it been about research misconduct I might well have refused to lead it.

Why was it called a review?

The minister believed that the issue did not justify the cost and complexity of a legally-based enquiry, under any of the available protocols. This lack of a legal framework had the side-effect that witnesses could not be subpoenaed, and there was no sanction if they make false statements.

The terms of reference

Following the minister's announcement there was a widely communicated general invitation to submit written evidence. A research consultancy was commissioned to interview all those who appeared to have something relevant to say, and a group of witnesses were selected for oral hearings. This wide process led to the submission of massive amounts of material related to child abuse, and this led to that topic being included in the review. In many ways coupling these two issues together makes little sense, but it was a pragmatic solution to the problem and less complex than having two reviews. The review thus examined a number of research studies in North Staffordshire, as well as issues related to child abuse. This paper discusses only aspects related to the CNEP trial, but all the recommendations made by the government review are included in Box 1.

Criticisms of the review

Some months after publication, Hey and Chalmers[1] made a number of criticisms, some of which are dealt with below. They wrote, 'Almost everything that the review said about the CNEP trial was wrong'. This was hardly surprising because every witness gave a different version of events. The job of the panel was not to make judgements as to what was right and wrong, it was to examine the governance issues. Furthermore, the lack of legal or forensic resources meant that the panel could not determine in a secure way whether some of the witnesses were mistaken, or did not understand events, or may have been malevolent. From a governance point of view it does not matter who is correct, each can be viewed as a test of the governance system and process.

We concluded that careful thought given to the governance process might strengthen both supervision of research and learning, to the benefit of everyone. That is why we recommended that a better system of research governance be developed.

I have avoided using names of individuals in order to try to depersonalize the content, and to focus instead on understanding the issues

Why was the review not in public?

Several potential witnesses indicated that they were only prepared to speak or write in confidence. These included the NHS Trust and several parents of children who had been involved with either CNEP or child protection issues. A small number of people refused to appear in person, some because they were abroad and others because they had considerable fears. All the latter were parents who had in some way interacted with the child protection system. They feared that giving evidence in person would lead to their children being taken away from them. Whether these fears had any basis in fact we were not able to determine, because they remained anonymous, but it does give some idea of the emotional intensity that surrounded parts of the review. I find it distressing that some of those interviewed found the process intimidating. The panel did everything it could to avoid that – we allowed any witness who wished it, to be accompanied by friends or trade union representatives, and every witness was interviewed before the oral hearing by the research consultants and was allowed to edit the record of their first interview. No-one could have been in any doubt as to the process. An obvious lesson to learn is that any process is probably intimidating to someone who has not encountered it before. A public, legal hearing would probably be the most intimidating of all.

It was quite clear that if we did not agree to confidentiality then we would have a biased and incomplete review. If we had been able to subpoena witnesses and take evidence under oath then we would not have been in this position.

A further issue was that ministers wanted 'to avoid a circus'. If we had taken evidence in public then there is no doubt that it would have been a much more complex and expensive process. Many of those who did submit material to us also sent it to the media at the same time. Several gave press conferences. If we had worked in public then there would have been significant costs in security and in providing facilities for the media, and the process would have taken much longer.

I have written elsewhere[3] that the ideal might be a public process. I support the notion that things need 'to be seen to be done', and I think that there would have been less controversy afterwards if everyone had heard what the review panel had heard. There are disadvantages, of course: witnesses can feel intimidated and there is a risk that innocent researchers might be smeared.

Box 1
Review main recommendations

(1) That formal guidance on research governance within the NHS be developed and issued to the NHS and to partners whose research it hosts.
(2) That the Department of Health, professional and regulatory bodies cooperate to consult on and produce agreed guidance clarifying issues of consent for participation in clinical trials.
(3) That Department of Health considers the establishment of a surveillance system for unexpected outcomes from non-drug treatments.
(4) That a substantial audit of the use of CNEP in North Staffordshire Hospital NHS Trust be carried out to see if claims of significant benefits or damage can be substantiated; and that North Staffordshire Hospital NHS Trust considers carefully the use of CNEP, and defines the scope of its use by a strict protocol until the evidence base is stronger.

Why was the report not shown to those it affected?

We were criticized because those who had given evidence were not shown the final report before it was published. I asked for permission to do this, but it was denied. To some extent that was unfair, but in the months before the report was published, and indeed before it was even drafted, some of the witnesses claimed to have seen the report and made press statements announcing what they said it contained. None of these had any basis in fact, but it is easy to see why officials at every level were reluctant to feed this 'rumour mill'.

Attempts to raise the stakes

The process was inherently more transparent than the processes used by the GMC and the Trust, both of which, for most of their course, were out of sight of the public and media. As soon as the minister's office announced the review, however, there was media interest. Unfortunately, interest from a number of quarters made the review appear more important than was intended. Various lobby

groups saw the review as a means of claiming that what they had to say was important. The more important that the review appeared to be, the greater their status and credibility appeared to be. A mirror image of that was seen in the attitude of the press department within the region, which seemed to regard the review as a means of enhancing their reputation. I doubt if this phenomenon is unique to our review. I imagine that all processes with a public profile may suffer in this way.

One question leads to another

The original research question addressed in the CNEP trial was perfectly sensible and, seen in the context of supporting newborns in intensive care, it is easy to see why outcome measurements ceased when the children were eight months old. That limited follow-up carried a risk, however: from the viewpoint of the parents, life usually goes on after eight months. If survival is associated with handicaps, particularly neurological handicaps, these may not become obvious until later. Neurological handicaps are not uncommon among children born prematurely, and such children will often attend specialized facilities. It was inevitable, therefore, that there would be a cohort of children who had been in the CNEP trial who would meet regularly, along with their parents as they progressed through nursery and infant school. There is no escape from chronic handicap; parents are reminded of it every day. It is not difficult to imagine the conversations that may have gone on alongside the daily routine of taking children to nursery. If one parent wondered if the research trial had affected their child, then it would not be long before they all did.

These questions could only be resolved by extending the follow-up of survivors of children who had participated in the CNEP trial. One of the advantages of trial methodology is that it is theoretically possible to re-contact trial participants. Accordingly, one of our recommendations was that a follow-up of trial participants should be undertaken. Obviously there would be a risk that participants could not be found or that those who could be found might be a biased sample of the original cohorts, but that could be tested in a follow-up study. Interestingly the cost of the follow-up study was three times that of our review. The Department of Health in Whitehall refused to provide funds for this, but I eventually persuaded West Midland Regional Office to support the follow-up. The report by Kate Telford and her colleagues[4] did not detect any statistically significant advantage or disadvantage of CNEP compared with intra-tracheal positive pressure ventilation.

One lesson now easily seen is that if funding had been available from the outset to support to school age the whole sad tale might have been avoided. The cost of such follow-up would have been substantial, but far less than all the costs incurred by the various enquiries. It is a difficult dilemma for any researcher when faced with limited funds. Is a limited study better than no study at all? In this particular case, the initially limited follow-up resulted in costs in the long run.

The need to protect researchers, patients and the public interest

Research is about the unknown, and going into the unknown involves risks. Neither the clinicians prescribing the treatments compared, the researchers studying them, the patients receiving them, nor the public who pays for them, knows for sure what will happen when a new treatment is compared with an existing treatment. Each of them has something different at stake, and each must be protected, as far as is possible, from misunderstandings or even mistakes that might occur. A governance system should provide that protection and it should have a means to mount an investigation when something appears to have gone wrong.

We examined the various statements about research governance that were current at the time. It was clear that some professional bodies had produced recommendations that were in advance of Department of Health policy. We tried to identify Trusts similar to North Staffordshire which would be prepared to allow us to compare the system we had been asked to review with their own. To our surprise, all the Trusts we asked refused. That seemed to be a further indication that change was needed. We briefed the Research and Development Directorate of the Department of Health in depth as we developed our thinking, and everything that we said about research governance in the report was approved by them.

A political failure in research governance

I was disappointed with the way that research governance developed subsequently. I thought it

was too bureaucratic and seemed to have 'lost the plot'.[5] I think this was partly because, although the Research and Development Directorate developed the policies, people with little experience of research often implemented them. At a local level it sometimes appears that the simplest way to avoid trouble is to make it as difficult as possible to carry out research. In such circumstances it is hardly surprising that horror stories began to appear. Lengthy documentation was required, even for very simple studies, and this in turn incurred delays and costs that made research more difficult.

If so many people now say that the current system is inadequate why was it not possible to do it better? Ultimately the failure was political. At the time the NHS was undergoing repeated reorganizations at every level, and research governance, and the training and education that should have underpinned it, were simply not a high enough priority. As a result there was inadequate leadership and resources, at every level, for ensuring that the governance process was fit for purpose.

What can we learn?

Research governance should have included three things: a framework for the conduct of research, a system for learning and training, and a mechanism for investigating suspected or alleged misconduct. Some of this is now in place, but I believe that the learning and investigation elements are still weak.

The establishment of the UK Research Integrity Office (UKRIO)[6] followed publication of the second edition of the Department of Health's Research Governance Framework. UKRIO should at least provide a repository of expertise. It recommends that a named local individual should investigate allegations of research misconduct. Unfortunately, this means that investigations will usually be carried out by someone who has never conducted such an investigation before, and who therefore lacks legal and forensic expertise. A better solution might be for UKRIO to make available a panel of independent experts who know what they are doing.

What were the outcomes of the review?

The main recommendations from the review are set out in the Box 1. They contain no criticisms of individuals, nor do they criticize the CNEP trial. Research governance was introduced. Guidance on consent was issued.[7] The idea of a system to report an adverse event from non-drug treatments was later endorsed by the government document entitled *An Organisation with a Memory*.[8] This was published in the year following our report, and responsibility for implementing it now resides within the National Patient Safety Agency. At a system level I believe that our recommendations were sensible and the UK health system is better for the actions taken. I am particularly pleased that we found the resources that made possible the extended follow-up of the children who had participated in the CNEP trial.[4]

Unfortunately there is more to say. Despite our insistence, reiterated at several press conferences and in interviews, that we were looking at system issues, much of the report was interpreted as criticism of individuals. Sometimes people see what they want to see and read what they expect to see. Because our report was the first to appear (long before those conducted by the Trust or the GMC), it became the vehicle for a number of groups to continue to air their particular views. *An Organisation with a Memory* would later say how important it is to try to avoid blame and learn lessons, but when we reported we were probably the first to try that line. It needs repeating many times.

What did I learn about report writing?

Writing a report as a civil servant responding to a request from a minister is not the same as writing a report as an independent investigator. Our report was a team effort, and was in two parts. The first contained a set of recommendations, which were accompanied by an explanatory text, following, in spirit, the legal model of judgement and *obiter dicta* ('said by the way', words introduced by way of illustration, or analogy or argument). The second part was the evidence submitted to the minister, which was not published.

The draft report was circulated for comment to the relevant divisions in the Department of Health. The recommendations remained unchanged, but publication of the report was delayed because there was disagreement between the public relations people, who thought it read better in a certain order, and the legal team, who had a different view. The published report eventually followed the advice of the legal team, which coincided with the original draft.

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It is interesting that many subsequent criticisms of the report related to the explanatory material, which was derived from the conflicting views that had been presented to us. I sometimes wish we could have simply published our recommendations, with a short statement noting that everyone had told us something different. But that is not the way these things are done.

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SERIES

The Stoke CNEP Saga – how it damaged all involved

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After one family made allegations about the way the study of an innovative strategy for providing nursing care was conducted, staff in the neonatal unit at North Staffordshire Hospital endured 11 years of disciplinary enquiry. And, because staff are barred from talking while under investigation, it has only recently become possible to describe in detail much of what then went on.

CNEP was a study of nursing care

Watching a tiny, preterm baby supported by invasive technology cling tentatively to life, or struggle to breathe for itself, is something most people have never seen. Providing these fragile infants with continuous negative extrathoracic pressure (CNEP) presented quite a nursing challenge, and the trial in which we participated was a test of what was basically a nursing procedure.[1] There was, as a result, substantial nursing input right from the start, much of which went unreported at the time. Had some of those who criticized the trial[2] been aware of this, their views about parental involvement, and the way consent was sought, might have been more balanced.[3]

Nurses realize just how bewildering the first few hours can be for the parents of any recently born sick or premature baby, and are trained to handle this sensitively and supportively. Their decision to try and advance neonatal care, and avoid some of the long-term consequences of conventional ventilation with a tube through the larynx, was taken with some care. It was a decision also balanced by a clear recognition that the need to get parental consent as soon as eligibility was confirmed (just four hours after birth) also presented a major challenge. This was highlighted by a small nurse-instigated survey, performed midway through the study, which showed that two-thirds of the mothers had not been able to visit the unit and see the various pieces of equipment, before agreeing to support the trial. To meet this need, the assistant research nurse[4] produced a 14-page booklet with photographs of the unit and the equipment, to supplement the trial's information leaflet.

This small survey also showed that, although 90% of the parents understood that their baby was in a clinical trial, one-third did not fully understand what the trial was about. This highlighted the need for staff to make sure that families were kept fully informed, and given ample opportunity to ask questions over the subsequent days and weeks. A serious nursing concern from the outset was that families would have less access to their babies due to the complexity of the equipment, or concern that the CNEP equipment caused discomfort. A questionnaire about these and other issues was distributed to all parents in Stoke, and 79% (n=137) of these anonymized questionnaires were returned. The replies were very reassuring, suggesting that parents did not think that CNEP impeded access or cause more discomfort. Nor did it seem to reduce the chance of the baby being breastfed. Almost all the parents in both trial groups felt that neonatal staff had done a lot to help them relate to, and interact with, their baby.

As the lead research nurse, together with my assistant researcher Kate Lucking, I was responsible for collecting all the clinical data and, because I was also responsible for training the medical and nursing staff in the new equipment, I was on-call 24 hours a day, seven days a week, for much of the trial, to answer questions about eligibility, randomization and getting CNEP started. Luckily I found myself working with a team of highly-motivated nurses, and had the unstinted support of all the medical team. I also had excellent technical support from a senior member of the biomedical engineering team, Dave Evans, who played a vital role in the development and maintenance of equipment.

My special thanks to Edmund Hey for his guidance, support, encouragement and commitment to us as individuals. Without his determination for the truth, I would never have been able to tell our story

The first complaint surfaces

Mr and Mrs Henshall lodged a first complaint about their child's care with the Trust in August 1994. Initially this was dealt with by discussion using the hospital's complaints procedure, but allegations started to proliferate in May 1997 after a campaign was launched in the local press. Much of the publicity claimed that parents had not realized, or been told, that their baby was in a clinical trial. Eventually the claim was made that consent forms, including the Henshalls', had been forged. This aspect of the whole affair particularly puzzled and saddened the nursing staff, because they had always tried to work with families openly, honestly and closely, with an emphasis on continuity of care.

It is well-known that, when questioned after an interlude, recall of events can be fragile,[5] but this only makes contemporaneous records an even more valuable way of showing that staff were diligent in the way that they took consent, and kept families briefed on progress after trial entry.[6] Thirty-five junior doctors were involved in taking consent, and all had to try and establish their careers while knowing that allegations of dishonesty could come back to haunt them at any time. The Trust had 10 allegations of consent form fraud under review at one stage.[7] Most of these allegations were later dropped, but for one family doctor this issue still remains unresolved because the GMC, for legal reasons, declined to rule on this issue when it finally got round to hearing the Henshalls' complaint in May 2008.

When the press onslaught went unrebutted, staff morale soon started to suffer. Indeed, as the second article in this series has documented,[8] the press were soon linking our CNEP work with the child-abuse work being done elsewhere in the Trust. Banner headlines proclaiming that 'Parents say guinea-pig trial killed their babies',[9] were soon followed by 'Spy cameras capture torture of innocents'.[10] Reports claimed that 43 babies died or 'suffered permanent brain damage' but failed to say that, because all had to be seriously ill to be eligible for the study, this was also true of 32 'control' babies. In fact the true figures were 35 and 27, because double-counting failed to allow for the fact that many of the babies with a severe cerebral ultrasound abnormality died.

I had recently had a new baby and, within weeks, the nightmare began. Like other members of the nursing team, I found myself giving 'statements' to the Trust solicitor. The early months of family life were blighted by bewilderment, anxiety and the fact that it was all so public.

The Henshalls report the Trust's Medical Director to the GMC

By mid-1997, the press were repeatedly publicizing the most shocking of all the Henshalls' allegations – that their signature on Sofie's consent form had been forged – and totally ignoring all the Trust's vigorous denials. Finally, on hearing that the allegation was to be repeated yet again on Channel 4 News, Dr Keith Prowse, the Trust's Medical Director, decided to show the completed form to the press because of 'fears for the morale, status and future of the paediatric department'. However, even this action was turned on its head, because the Henshalls promptly complained to the GMC that Dr Prowse had failed to obtain their consent before showing anyone this form. He remembers the 'awful sinking feeling' when he read that he was under investigation for serious professional misconduct, and might, if found guilty, be struck off.

Worse still was the fact that the preliminary hearing took nearly three years, while the full public hearing only took place almost four years after the initial complaint had been lodged.[11] While Dr Prowse had to endure this lengthy investigation, he did, however, have 'immense support' from within the Trust. More than 50 of his patients also took the trouble to write to him personally offering their support. When it was pointed out that certain families were 'serial' complainers, the GMC merely said that 'it was their duty to investigate all complaints' – a response that led most people in the Trust to conclude, like Dr Prowse, that the GMC seemed more concerned with its own survival and with public criticism, than with the facts of the case. It also seemed very clear that the continued press frenzy over anything remotely related to David Southall was having a widespread effect.

Facing the first Government-sponsored enquiry

Early in 1999 I was asked to attend the first of two interviews in connection with the Griffiths enquiry.[2]

I was not told what the interview would be about, but I was told that it would be informal and I would not need to prepare for it. What actually happened left me deeply shocked. The questioning felt hostile and, because I was not allowed access to any research material, I found it very difficult to respond adequately.

My experience was not unique, however. Several of the medical team also reported a lack of information prior to interview, and 'aggressive' questioning.[12] Most staff appeared with no representation and no supporting documentation. No-one saw a draft of the report so they could make comments prior to publication, even though the Trust had a copy. My nurse colleague and I felt so misrepresented in the final report that we felt we had to respond in the *BMJ* and say 'We strongly refute the suggestion that there was an inadequate protocol or means of documenting all of the material relating to each of the patients in the trial ...'.[13] It seemed as if the complainants' testimony was simply accepted at face value and never checked against medical notes. Nor were the doctors who witnessed the signing of consent forms ever asked to testify.

Facing yet further investigation

Soon after this interview was over I was told that the Henshalls had lodged a formal complaint with the United Kingdom Central Council (UKCC) – the regulatory body with the power to strike nurses off the register. The worst allegation was that I had 'supplied inaccurate information and corrupt data, giving the trial a false conclusion'. I was told that I would have to wait for the Henshalls to provide evidence to support their allegations, but 16 months later I was informed that no supporting evidence had materialized. In parallel with this the Trust then launched their own internal enquiry, and I faced two more long, hostile interviews and was told not to speak to my medical colleagues. Indeed all the nurses who had helped to care for the Henshall babies were questioned, which was distressing because they could not understand what was supposed to have gone wrong.

Nine months later, I eventually took extended sick leave and never returned to work – a source of much regret. The press onslaught seemed relentless but it was my only source of information, because I heard nothing from the Trust. Just as the UKCC finally closed their investigation of the Henshalls' allegation of serious professional misconduct, I was told that yet another complaint about my involvement in the trial had been filed with the UKCC by another person. I had never had any contact with the complainant but was told that she was representing 'other parents' who had children involved in the CNEP trial. Yet again the UKCC only dropped this further investigation after seven months, when I was informed once again that no supporting evidence had been supplied.

This became a recognizable pattern as the press campaign gained momentum. At least 18 doctors were so targeted by one pressure group, allowing them to tell the press that those doctors 'were under investigation by the GMC'.[14] And when no further supporting evidence was submitted for more than a year those named, if they pressed the GMC, were merely told that the investigation was no longer 'current'. Modified rules allowing 'vexatious complaints' to be dealt with more quickly were eventually agreed by the GMC seven years later, but their effectiveness has yet to be assessed.

One senior nursing colleague within the research team with an extremely promising career before her was in the unfortunate position of applying for posts in other Trusts when targeted in this way. A steady flow of complaints about her were reaching the regulatory body. This greatly complicated the whole appointments process as each complaint generated fresh correspondence with the Nursing and Midwifery Council. My close colleague throughout the trial, Kate Lucking, also eventually decided to leave the profession and says that her experience of the way the 'CNEP Saga' was managed certainly contributed to that decision.

Further problems for the whole Trust

One major problem was the amount of time the Trust had to spend responding to the press and to requests for information from the District and Regional Health Authorities, and the GMC. The media posed a particular problem because, each time a fresh allegation appeared, the Trust was asked for an immediate response and, for a while, fresh allegations were appearing almost daily. Management felt under 'siege' and were given no support by the District and Regional Health Authorities. External advisers were brought in to

deal with the press, and this cost the Trust even more money. The reported cost at the time was around £1 million, but it is now thought that it was closer to £3 million. Dr Prowse, as Medical Director, tried very hard to rebut press lies, and felt great frustration that all the Trust's statements fell on deaf ears.

The Trust did, however, resist the pressure for suspension of Professor Southall until early November 1999 when there was an abrupt change of approach shortly after a meeting with the Director of the West Midlands NHS Executive.[15] Two independent experts were then asked to examine the Paediatric Department's other research work. After holding just a single formal meeting, they quickly issued a verbal recommendation that Professor Southall should be suspended, and be referred to the GMC.[16] The Trust also suspended Dr Samuels at the same time because of still unresolved child protection issues.

Two of my medical colleagues are suspended

As a result of this very quick investigation both the consultants were promptly interviewed by the Acting Medical Director and the Director of Human Resources, told that they were being suspended, and that they had to leave the hospital within an hour. They were expressly forbidden to talk to any hospital employee or return to the hospital site without permission. I was never formally told about this, and when I did hear through 'the grapevine' it only further increased my fear and confusion.

At no stage prior to suspension was Dr Samuels told that his conduct was under review, and the Trust were not, at first, able to give any reason for either of the suspensions. Once the inadequacy of the initial investigation became apparent seven weeks later after the two doctors did finally get to see copies of the preliminary reports, two more comprehensive investigations were started, but it was a full 12 months before the case-notes of one of the consultants were sent for expert review. The further externally-staffed inquiries eventually exonerated both doctors, recommending reinstatement because there was no valid case against them, but Dr Samuels only returned to work after 20 months, and Professor Southall only returned after 27 months. When the National Audit Office undertook a country-wide review of the way NHS staff suspensions were managed, they highlighted the way these two doctors had been treated as particularly gross examples of inappropriate Trust practice,[17] but Trust management say that it was lawyers at the Regional Health Authority who made them handle the suspensions this way.

Dr Samuels has, not surprisingly, said that he felt 'criminalized' when told not to make contact with colleagues or enter any hospital building. Both the doctors received many letters of support from colleagues after their suspension and several also wrote to the Trust. Letters also came in from the parents of patients, and letters of support also appeared in the local paper,[18,19] but support from the Trust was conspicuous by its absence even though the press statement that they had put out stressed that the 'suspensions are not a disciplinary action'.

The oft unrecognized family repercussions

One thing that is often forgotten is the impact that this has on the families of those involved. There is no 'normal' family life when one member is not working and is distracted by the need to defend themselves. Constant media reports only make things worse. 'The press "informs" the community, within which they work, live, attend school and play.'[a] 'Being the wife or child of a doctor who kills, harms and experiments on babies, and who forges consent forms ... does not make for a comfortable existence.' It can be very difficult to interact with others in the local community when you know that this, though untrue, is what others are reading in the local paper week after week. The doctors themselves 'have their own community and network of support' but their family have none. The fact that the investigations took so long further exacerbated the feelings of frustration, anger and (in my own case) depression.

I know that this distress was ultimately responsible for the breakdown of at least one and possibly two marriages. The effect on the children also went largely unrecognized. Some were bullied and

[a] All the quotations in this paragraph come from a letter written by the spouse of one of the clinicians involved

abused at school as children of 'baby killers' and, for one child, this had a serious and long-lasting psychological effect. What compounded this distress was the failure of the authorities to counter the exaggerated press claims, while simultaneously barring all staff from talking to the media. The families feel that the Trust failed 'in its moral duty' to the staff in its employ, and saddled them with a 'life-long sentence'.[a]

Knock-on consequences for others in the Trust

Inaccurate and sensationalist media reports also contributed to a lack of trust and suspicion in the local community. One mother whose baby was admitted with cyanotic episodes, became concerned that she had been 'secretly filmed' when the local press reported the child protection work that had been going on. In the absence of any balanced and informed reporting, she must have been one of many who imagined that every parent had been filmed, if their child had been under the care of the two consultants concerned.

And, long after an externally conducted review had shown that that the CNEP trial had been well-conducted, Whitehall was still refusing to accept this.[15] In 2002, for example, the Paediatric Intensive Care Unit was initially denied a Charter Mark Award for Excellence simply because it was in the same hospital as the Neonatal Unit and was treated, in the eyes of the civil servants in the Department of Health, as being part of a unit that they still classified as being 'of concern'. Although the Trust eventually managed, on appeal, to get this ruling withdrawn, the initial intervention had, by then, made many staff in the Paediatric Unit both cynical and angry.

The wider damage to research

Professors Neena Modi and Neil McIntosh, present and former Royal College of Paediatrics & Child Health Vice Presidents for Science & Research, comment that 'the CNEP trial was well designed, and could have been used as a template for sensible and effective research governance. Instead it was attacked by a lobby group and received a flawed evaluation, thus compromising the protection that babies and all patients deserve to receive from research to assess the effects of treatments'. It also remains a loss to the neonatal and paediatric community that the expertise gained in non-invasive ventilation was then squandered. Calls for further research and development continue to be made,[20] but clinicians in Stoke are still barred from using CNEP even in older children despite the interest in this type of treatment that persists elsewhere. As recently as 2008 an Italian team published a small trial using a hood-and-neck seal instead of 'nasal prongs' to deliver continuous positive airway pressure.[21] This showed that pharyngeal pressure was more stable when a hood-and-neck seal device was used. The only difference between the approach that we had started to use in 1989 and the approach now being studied in Italy is that we used negative pressure round the chest and they are now using positive pressure round the head.

Paediatric research came to an almost complete halt, and the careers of several medical and nursing staff were abruptly ended or curtailed. Professor Southall was eventually forced to resign. Dr Samuels was made to 're-train' before coming back to work, not because he had been found to have done anything wrong, but simply because he had been suspended from all work for 20 months. Dr Spencer, who had been deeply involved in a range of innovative research, has vowed to do no more. All three were only finally acquitted of any wrongdoing by the GMC in July 2008. The unit has been urged to join several important, nationally funded, multicentre trials in the last 10 years but turned all requests down. The scars still run deep.

Conclusion

Behind this very public story, the private cost to the individuals concerned has been painful and far-reaching. The 'fall out' did not only affect the doctors whose names appeared in the press, and their families, it also involved the nursing staff, and Unit and Trust managers as well as 'shop floor' clinicians. The way complaints were handled seemed grossly unfair and unjust – and this feeling was only reinforced when it eventually became clear that almost all had been misguided, if not overtly malicious. When clinical staff mismanage the care of patients they can, rightly, expect to be held to

[a] All the quotations in this paragraph come from a letter written by the spouse of one of the clinicians involved

account, but when allegations are mishandled in the way that these allegations were, those responsible for that mismanagement never seem to be held to account.

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SERIES

The Stoke CNEP Saga – a view from the General Medical Council

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The General Medical Council's (GMC) purpose is to protect, promote and maintain the health and safety of the public by ensuring proper standards in the practice of medicine. To support that purpose, the GMC has four main regulatory functions: registration (which, in future, will include revalidation); education and training; standards and ethics; and the fitness-to-practise procedures (sometimes misleadingly labelled disciplinary procedures).

The fitness-to-practise procedures seem guaranteed to polarize opinions; over the years, there have been criticisms from both sides of the yawning divide that separates those who believe the GMC is too lenient and those who believe it is too harsh. Neither caricature is accurate, as evidenced by the outcomes of appeals and other referrals to the High Court. As with all activities based on human judgements, errors are made but the numbers are very small and they do not reflect systemic bias. The GMC is committed to having processes and procedures that are fair, objective, transparent and free from discrimination.

Nevertheless, some criticisms of the fitness-to-practise procedures have been justified. The procedures that operated in the 1990s and in the early part of the 2000s were no longer fit for purpose. That is why the GMC launched a programme of fundamental review in 2000 and introduced reformed procedures in November 2004. It is also why, at the Shipman Inquiry in November 2003, the GMC frankly recognized past deficiencies in three areas – operational effectiveness; consistency and quality of decision-making; and the architecture of the procedures.

Other criticisms are not justified. Some reflect a historical rather than a current perspective; some are based on misunderstanding; and some are partisan. They include that the GMC bears down unfairly on particular groups of doctors, for example paediatricians; or that the GMC is ill-equipped to investigate allegations of research misconduct. Both are contradicted by the facts; and neither is substantiated by the CNEP case.

This is not to say that the GMC did not make serious errors in relation to the CNEP allegations. The GMC has acknowledged that there were mistakes and has apologised for them. But those mistakes do not justify the claims sometimes made.

The GMC first received allegations about the CNEP trial in 1997. The allegations included: that consent had not been properly obtained; that some of the babies had not been suitable for inclusion in the trial; and that the trial had not been conducted properly and safely. Although the CNEP case ran beyond the introduction of the reformed procedures, in November 2004, it continued, for legal reasons and all practical purposes, to be subject to the legislation in force when the allegations were received in 1997. To understand why this is significant, it is necessary to look at the architecture.

The fitness-to-practise procedures are governed by the Medical Act 1983 (as amended from time to time) and by statutory Rules. Before November 2004, the procedures had three stages – screening; preliminary proceedings; and an inquiry conducted by the Professional Conduct Committee (PCC). The Rules determined the nature of the test to be applied at each stage. The GMC's interpretation and application of the law are subject to the oversight of the courts, whether by way of judicial review or appeal.

The Rules also provided that the complainant was a party to the proceedings and was, therefore, entitled to pursue the complaint against the doctor. This included a right, which was exercised by the complainants in the CNEP case, to instruct the

legal team and to control the conduct of the case, including their choice of expert witnesses. There are no corresponding provisions for complainant cases in the reformed procedures.

Within the first stage, the allegations were considered by a medical screener who, at the time, by law had to be a medical member of the Council of the GMC. The screener decided whether the case should proceed to the Preliminary Proceedings Committee (PPC). A decision not to refer the allegations to the PPC had to be agreed by a lay screener, who was also a Council member.

The presumption in the Rules was that the allegations should be referred by the screener to the PPC unless 'it appears to the screener that the matter need not proceed further'. It was a test that screened out, not a test that screened in. Mr Justice Lightman (*R v GMC* ex parte Toth [2000] 1 WLR 2209) had said:

> *'The role of the screener is a narrow one. It is to filter out from the formally correct complaints ... 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.'*

Within the second stage, the allegations were considered by the PPC. The role of the PPC was to decide if the allegations should be subject to an inquiry conducted by the PCC. The test in the Rules was whether the matter 'ought to be referred for inquiry by the PCC ...'.

The PPC's discretion was also limited. Again in the words of Mr Justice Lightman, 'The PPC may examine whether the complaint has any real prospect of being established; ... and may refuse to refer if satisfied that the real prospect is not present, but it must do so with the utmost caution ... It is not its role to resolve conflicts of evidence ... In the case of the PPC (as in the case of the screener) any doubt should be resolved in favour of the investigation proceeding.' The limited role of the PPC in resolving issues of evidence proved to be significant in the CNEP case.

Within the third stage, the allegations were considered by the PCC, which conducted an inquiry. The PCC decided whether the allegations had been proved; whether those found proved constituted serious professional misconduct; and, when serious professional misconduct was found, the nature of any sanction to be imposed on the doctor's registration.

Having received the CNEP related allegations in 1997, the GMC was slow to take effective action. In January 1999, the NHS Executive commissioned a report from Professor Rod Griffiths. The GMC concluded that it should await publication of that report before making any decisions on the allegations. The report was published in May 2000; and it contained criticisms of the CNEP trial. Separately, the Trust had commissioned a report from Professor Sir David Hull, whose report was delivered to the Trust in December 2000.

The medical screener decided that the CNEP allegations should be referred to the PPC. This was inevitable given the screening test to be applied. On 16 January 2002, the PPC decided that the threshold required for reference to the PCC had not been reached. The complainants protested and, on review in September 2002, it emerged that the screener had not been presented with all the relevant material when making the screening decision. Consequently, the PPC had not been presented with a complete picture. The decisions were set aside; and the medical screener, having considered all the material, again referred the allegations to the PPC.

By this stage, the GMC had made three mistakes. First, it had taken too long before making the first screening decision. Second, the first screening decision and the PPC decision were defective because relevant material had not been taken into account. Third, it took too long to make the second screening decision, based on all the available material. Over six years had passed from receipt of the original complaint. The GMC has apologized for the mistakes made and for the delays.

In February 2004, the PPC again decided not to refer the allegations to the PCC, and the complainants were notified of this decision on 12 March 2004. The complainants sought judicial review of the PPC's decision. Following Mr Justice Pitchford's refusal of that claim, in December 2004, the complainants were granted permission to appeal. The appeal was heard in June 2005.

In December 2005, the Court of Appeal, by a two to one majority, quashed the PPC's decision[1] and remitted the case for consideration by a differently constituted PPC. One of the grounds was that the PPC had exceeded its proper function in placing substantial reliance on the *BMJ* article by Hey

and Chalmers, which had criticized the Griffiths Report. Lord Justice Jonathan Parker said:

> *'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 … 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.'*

As a result of the judicial review and the appeal, almost two further years had passed since the screener's decision in January 2004 to refer the allegations to the PPC.

It took further time to comply with the Court of Appeal's directions. A differently constituted PPC decided in November 2006 to refer the allegations for inquiry by the PCC. Given the reasons for the Court of Appeal's quashing of the earlier PPC decision, this is not, perhaps, surprising.

The PCC inquiry was held between May and July 2008. Having heard the evidence of the complainants and their witnesses, the panel accepted the argument advanced by Counsel for the doctors that insufficient evidence had been adduced to support a finding of serious professional misconduct. The doctors were, consequently found not guilty of serious professional misconduct.

It has been argued that the eventual outcome, in July 2008, demonstrates that the PPC was wrong, in November 2006, to refer the allegations for inquiry by the PCC. That is based on a misunderstanding. Unfortunate though it was for the doctors concerned, the limited function of the PPC, under the pre 2004 Rules which continued to apply, did not entitle it to trespass on the role of the PCC. The implication of the Court of Appeal's decision is not that the GMC should have closed the case earlier but rather the reverse.

It has also been argued that the CNEP case demonstrates the GMC's inability, when there is alleged research misconduct, to fulfil the required investigative function in a transparently fair and independent way. Again, that is based on a misunderstanding. The GMC certainly made mistakes. However, those mistakes were tardiness and a failure to heed the limited discretion available to screeners and the PPC under the statutory Rules. They were not the result of ineffective investigation. There may be an argument for a UK organization equipped to investigate any allegation of research misconduct but it is not made by the GMC's handling of the CNEP case.

Nevertheless, doctors and others are entitled to ask whether the GMC would or could make the same mistakes again. The confident answer is no.

The reformed fitness-to-practise procedures, introduced in November 2004 after extensive consultation, have two stages – the Investigation Stage and the Adjudication Stage.

Within the Investigation Stage, allegations are considered by medical and lay case examiners who have been recruited by open competition and trained for the role. In deciding whether to refer allegations to the Adjudication Stage, they apply a 'realistic prospect' test. The question is whether, if established, the facts would demonstrate that the doctor's fitness to practise is impaired to a degree justifying action on registration. 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 for inquiry when they are bound to fail. On the other hand, cases that raise a genuine issue of fitness to practise are for an adjudication panel to decide.

There is detailed guidance for case examiners, including the criteria they must apply, and this guidance is published on the GMC's website.[2] Case examiners have access to all the material available at the point of decision, and the full decision is disclosed to all parties, including the reasons for the decision.

Within the Adjudication Stage, inquiries are conducted by fitness-to-practise panels whose members are recruited by open competition and trained for the role. Panels decide whether the allegations have been proved, whether the doctor's fitness to practise is impaired, and when fitness to practise is impaired, the sanction to be imposed on the doctor's registration. Panels take into account the GMC's Indicative Sanctions Guidance, which is published on the GMC's website.[3]

Much has changed since the CNEP allegations were lodged with the GMC in 1997, and the causes of the GMC's mistakes have been addressed in all three areas identified for the Shipman Inquiry –

operational effectiveness, consistency and quality of decision-making, and architecture. A decade ago, the PCC typically considered 40–60 new cases each year. Fitness-to-practise panels now consider 200–300 new cases each year. Despite this huge expansion, or perhaps in response to it, the GMC's operational performance and the consistency and quality of decision-making stand comparison with any regulator.

The GMC's mistakes in relation to the CNEP allegations were not related to the quality of the investigation. Nevertheless, an obvious question is whether it would help, when there is alleged research misconduct, if there was a body, separate from the GMC, with the expertise needed to mount a timely and effective investigation of the facts?

On the face of it, the existence of such a body may do no harm and it may do some good. However, the claimed advantages, or some of them, could prove illusory.

A fitness-to-practise panel has three tasks: determine the facts; determine whether fitness to practise is impaired; and, if fitness to practise is impaired, determine the sanction on registration. Determining the facts is what takes the time – and rightly so, given what is at stake. Panels often have to choose between two or more conflicting accounts, sometimes based on hazy recollection and imperfect records.

In very specific circumstances, the GMC is not required to put allegations to strict proof – broadly speaking, criminal convictions and determinations by other regulators, which, if properly certified, are accepted as fact.

In theory, it would be possible to add a third category that could be accepted without strict proof – facts found by a (new) competent authority charged with investigating allegations of research misconduct. However, even if that was acceptable in principle, it could simply shift the problem. The (new) competent authority's processes and procedures would need to provide all the safeguards, and rights of representation, that are present in criminal and regulatory proceedings. A professional's right to pursue their profession is a civil right and any process that threatens this civil right has to comply with the European Convention on Human Rights.

No doubt it could be argued that, even if the (new) competent authority's findings of fact could be challenged in front of a fitness-to-practise panel, they would, nevertheless, assist the case examiners, within the Investigation Stage, to decide whether there was a realistic prospect of finding fitness to practise impaired. Thus, fewer doctors would be required to appear unnecessarily before a fitness-to-practise panel.

This is an argument for effective investigation before the case examiners' decision: it is not an argument for a new body. The shift to effective investigation was reflected in the reformed procedures introduced in November 2004. Most cases considered by the case examiners are not referred for adjudication. The majority are concluded without further action, or with a formal warning that is placed on the doctor's registration record, or through consensual disposal when the doctor is willing to give and comply with undertakings as part of a programme of retraining or remediation.

Regulation is dynamic and must continue to develop in order to command the confidence and support of key interests. An effective regulator must learn from experience and be willing to try to foresee, and to meet, the legitimate expectations of those whose interests it is there to protect. The procedures in place today are substantially more effective, and fairer, than those they replaced. There is, however, no room for complacency and the GMC continues to encourage and to welcome constructive debate about what more might be done. That is why the GMC is consulting this year on further changes to the fitness-to-practise procedures, to ensure that they remain fit for purpose.[4,5]

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SERIES

The Stoke CNEP Saga – did it need to take so long?

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In 1999, the Royal College of Physicians of Edinburgh, the Royal College of Physicians and Surgeons of Glasgow, the Royal College of Physicians of London, and the Faculty of Pharmaceutical Medicine convened a consensus conference on Misconduct in Biomedical Research. The conference concluded that a national panel should be established – with public representation – to provide advice and assistance (on issues of research misconduct) on request.[1] It was suggested that the panel might develop and promote models of good practice for local implementation; provide assistance with the investigation of alleged research misconduct; and collect, collate and publish information on incidents of research misconduct. It was hoped that the report of the Conference would be given the fullest possible dissemination by the sponsoring bodies, and that they would convene at the earliest opportunity a meeting with the General Medical Council and appropriate partners to establish and consider the remit of the national panel.[2]

A national proposal, 2001

For over a year, nothing seemed to happen. As a result, a striking editorial in the *BMJ* stated that 'the largely submerged problem of research misconduct is surfacing like a decomposing corpse'.[3] Behind the scenes, however, there was some appropriate activity. In 2001, a proposed blueprint for the prevention and investigation of misconduct in biomedical research was published, under the title *A National Panel for Research Integrity*.[4] The authors of this blueprint represented the Royal College of Physicians of Edinburgh, the Royal College of Physicians and Surgeons of Glasgow, and the Faculty of Pharmaceutical Medicine, with subdued support from the Royal College of Physicians of London. We concluded (for I was one of the authors) that the outcome of the 1999 Edinburgh conference had been a landmark in highlighting an agreed need – though with hindsight the word 'agreed' was far too optimistic – namely, that all stakeholders (in biomedical research) should collaborate in establishing a national body to promote education, standard-setting and audit of biomedical research within the UK. We had discussed with many other parties the practical developments needed, and, by publishing our 'blueprint', we thought we had done enough to help establish a National Panel on Research Integrity during 2002. In retrospect, we were unrealistically optimistic.

One of the pivotal recommendations within the 'blueprint' was the need to establish an agreed and recognized 'rapid response process' through which institutions could call on independent teams, with members drawn from national lists of trained external assessors, to investigate confidentially allegations of research misconduct. One such team already existed – MedicoLegal Investigations Ltd (MLI). I had helped to set it up in 1996 with a colleague, Peter Jay, who had previously been in the Metropolitan Police and had latterly been a forensic investigator of alleged cases of research misconduct referred to the solicitors employed by the General Medical Council (GMC). He and I had worked in sequence for several years before we established MLI. In my capacity as medical director of the Association of the British Pharmaceutical Industry (ABPI), I had received suspect cases from pharmaceutical company medical directors who were concerned that data had been fabricated or falsified and, above all, that patients had been exploited. I had worked up the cases as far as I could from within the ABPI,

enough to warrant referral to the GMC; Peter then completed the forensic investigation. On my retirement from the ABPI, it made sense for us to work together. We were always aware that the gate was wide open for other investigatory teams to enter this field, and we would have welcomed that.

It was emphasized in the 'blueprint' that the external investigations should be conducted according to due process,[5] using standard operating procedures (SOPs), as agreed by the National Panel. Additionally, it was emphasized that the principles of such confidential external investigations should include a rapid response to requests; investigation by a team of trained, impartial experts; protection of patients and volunteers in research studies; protection of whistleblowers;[6] and protection of clinical and scientific researchers from unjustified allegations of research misconduct.[5] Cases seldom took more than about six months to complete. MLI remains the only independent operator in this field, has appropriate SOPs, and subscribes to all the requirements just mentioned.

So what has happened since 2001? Did all the stakeholders get together in order to establish a National Panel in 2002? No. Things have moved on, though not to establish what the authors of the 'blueprint' recommended. The UK Research Integrity Office (UKRIO) was launched in 2006, hosted by Universities UK. It purports to offer support, both to research organizations and to individual researchers, and to promote integrity in research and good practice in addressing misconduct in research.[7] Although its advice and guidance is available to all, by the end of 2008 it had a profile so low that seemingly very few workers in the field knew of its existence.[8] The *Lancet* was dismissive. It called the UKRIO an 'ineffective enterprise' which 'is at best bound and gagged by its ties – at worst … a smokescreen set up by universities themselves'.[9] It was critical of the fact that its procedure for the investigation of misconduct in research, published in 2008,[10] failed to encourage organizations faced with cases of alleged research misconduct (be they universities, research councils, pharmaceutical companies or other bodies) to involve an independent, trained, rapid response team to advise at an early stage on how the investigation should be handled. This omission is a fundamental flaw.

My own more recent experience

The way in which the CNEP case was handled (see previous articles in this series) demonstrates very clearly what went wrong, and what will continue to go wrong if current UKRIO advice is followed. The overwhelming evidence is that the GMC, the Royal Colleges, the universities and NHS Trusts are unable to fulfil this investigative function and to do this in a transparently fair and independent way. My experience, before and after the inception of MLI, confirms that this function requires an experienced, but above all, independent, approach. It also requires great sensitivity, particularly when a case, on investigation, proves not to have been dishonest, which happens not infrequently. Then, indeed as always, any whistleblower also has to be handled and advised appropriately, so that no criticism follows when the whistleblower has acted in good faith.

The first case in which I was involved was that of a consultant psychiatrist in Durham. He was suspected by the sponsoring pharmaceutical company to have fabricated biochemistry and haematology results for patients recruited into a pivotal study for a new tricyclic antidepressant.[11,12] The company did not wish to be involved in investigating the case itself and sought the advice of the ABPI. Although not fully independent, as medical director of ABPI I was sufficiently remote from the company itself to set up lines of investigation that were not readily open to the company, and thus to establish the facts of what had happened. The psychiatrist claimed that he had delegated the management of the trial to his registrar (whose name he had forgotten) and that it was her responsibility to ensure that the data were correct. His claim was incorrect: it had been accepted since 1986 that it was the principal investigator's responsibility to ensure the veracity of data submitted to a sponsoring company. After the regional medical officer of the Northern Regional Health Authority had provided the maligned registrar's name and new place of work, I invited her to comment on the accusations of her former consultant. She responded, indignantly, that she had had nothing whatsoever to do with his research projects. The company was pleased that the ABPI had been involved, as they did not feel confident enough to refer the case to the GMC by themselves, so the ABPI presented the case to the GMC on

behalf of the company, by means of a statutory declaration. The case was eventually considered by the GMC's Professional Conduct Committee; the doctor was found guilty of serious professional misconduct; and his name was erased from the medical register.

Several cases followed. Some were referred to the ABPI only after a series of company procedures, others were referred just as soon as suspicion of an irregularity had been aroused. By the time I retired from the ABPI in 1996, I had handled 12 confirmed cases of research misconduct, all of which were referred to the GMC by means of statutory declarations. Subsequently, many more cases were referred direct to MLI, because we had inspired confidence within the pharmaceutical industry and between us had a track record of cost-effective, rapid and expert forensic investigation, and at least another 17 ended up being referred to the GMC. Many other referrals turned out to be examples of sloppiness or misunderstanding, not of fraud or misconduct. The companies concerned soon learnt not to use these doctors again. Referral to the GMC only occurred where data seemed to have been generated with an intent to deceive. All of the cases were handled in the strictest confidence: those doctors under suspicion, but who were not guilty of any misconduct, never knew they were being investigated and were found innocent; all the more serious cases, where the suspicion was justified, only eventually found out that they had been found out when a letter arrived from the GMC setting out the case against them. All of the cases dealt with in that way were referred to the Professional Conduct Committee or its successor, the Fitness to Practise Committee. All but one were found guilty of serious professional misconduct and dealt with appropriately. The procedure we used worked well, and, indeed, still does, though few cases have been referred recently.

Two cases involving two different universities are worth describing in detail in the context of this series of articles. The first is that of a consultant physician at the Western General Hospital in Edinburgh, a distinguished doctor who had previously served as an office holder in one of the medical royal colleges.[13,14] A clinical trial monitor working for one of the major pharmaceutical companies had noticed that several patient signatures on the study consent forms differed from their signatures in the hospital notes. The company drew the attention of the ABPI and the hospital authorities to its concerns. Neither the hospital nor the medical faculty of the university took any action, possibly because the hospital was in a state of considerable geographical flux at the time. By contrast, the ABPI called on MLI to investigate and a number of witnesses were interviewed. It transpired that several of the recruited patients were not aware that they had been put into a clinical trial; their consent had not been sought, let alone obtained. Several other irregularities were revealed and the case was referred to the GMC, which found the doctor guilty of serious professional misconduct. It is not clear what the conclusion of this case might have been if the independent forensic team (MLI) had not been available. At best, it would have taken considerably longer to reach the same outcome.

The second case concerned a professor of psychology at a university in the United Kingdom. He had devised a frequently cited model for making rats either depressed or stressed.[15] The model was based on the drinking of a glucose solution by the rats: if they were stressed, they drank less. He asked a PhD student to be an investigator in an early trial of a new anxiolytic produced by a French pharmaceutical company, using the model to see if the stressed rats became less stressed after ingesting the anxiolytic. She duly began the trial, dividing the rats into subjects and controls, using the model devised by the professor, but could not make the model work, as the so-called stressed rats drank exactly the same amount of glucose solution as the control rats. The professor asked the student to repeat the study, telling her that the rats came from different breeding sources, and to switch the stressed and control groups round. There were still no differences. Undaunted, the professor instructed the student to proceed with any of the rats that had been subjected to stress, and to give them the new anxiolytic. They drank as much glucose as the control animals but, as the student had pointed out, they were never demonstrably stressed in the first place. Despite this, the professor submitted a report to the sponsoring company on the success of the new anxiolytic in eliminating stress in the rats.

The student expressed her concerns to her tutor, who shared them, and they duly challenged the professor, who took no notice. They then went to the relevant senior officer within the university,

who effectively told them to go away as the professor had an international reputation and who were they to challenge him! The student and her tutor then turned to MLI. At the same time the student decided to take her PhD studies to a different university, over 200 miles away.[14] I was closely involved in this case and suggested that the validity of the rat model be tested by the student for the benefit of her new professor, who confirmed that it did not work. I also visited the sponsoring pharmaceutical company in France, where there was incredulity that an eminent psychologist, whose model for stressing rats was widely cited, might be misleading them. The evidence from the second university nevertheless confirmed the likelihood that the results from the first university were flawed because the rats had never been effectively stressed before being given the anxiolytic. The company disregarded the results of the research from the first university and took their subsequent studies elsewhere.

The inconsistencies and anomalies revealed in this case could not be accounted for by chance, nor did there appear to be other innocent explanations. There appeared to be *prima facie* evidence of falsification of data with the intent to deceive, and thus serious professional misconduct. At that time there was no regulatory body (comparable to the GMC for doctors) for psychologists, so MLI submitted the case to the vice-chancellor of the university. The outcome of this case was far from satisfactory, but the professor eventually retired. Had there been a proper mechanism in place within the university for the consideration of such cases, much of the time and effort spent internally on trying to come to terms with an irregularity would have been saved and much useless research would have been avoided. The forensic team had nevertheless produced robust evidence, quite fast, that a report to a sponsoring pharmaceutical company had been false.

So, where do we go from here?

So I come to the CNEP case, in which MLI was involved transitorily, at an early stage. We were approached early in 1997 by one of the families alleging forgery of consent forms. We spent a day with the person who had contacted us and emphasized that these allegations were very serious and needed to be confirmed or refuted. We said that MLI could undertake the investigations needed, but that we were not able to do so philanthropically. As the family who had contacted us was not in a position to fund this exercise, and the regulatory authority investigating the allegation never asked for help, MLI's involvement ceased at that point.

Looking dispassionately at these three cases, what could have been done differently and how might outcomes have been altered if these differences had been made? The early successes of MLI were because we were recognized as a small dedicated team of experts in the handling of suspected or alleged research misconduct, in whom pharmaceutical companies could have confidence. We were always funded by the sponsor who had called us in; we were scrupulously confidential in our dealings with clients, witnesses and patients; and we were fast. The cases we submitted to the GMC were, beyond all peradventure, likely to lead to a finding of serious professional misconduct. As a result, we were told we had inspired confidence in the veracity and integrity of our submissions among members of the Professional Conduct Committees, who heard the cases we brought forward. Subsequently, however, the climate changed and the GMC increasingly insisted on its own solicitors being more involved in the work-up of cases, which added considerably to the delay that already occurred between submission and hearing.

The confidence that pharmaceutical companies had in our ability to do a complete and effective investigation on their behalf, including many cases where we concluded that there was no case to answer, was never reflected by other outside bodies, including the universities, although one NHS Family Practitioner Committee did use our services to investigate a series of false claims made by one of its GPs. The National Health Service, unlike the University Grants Committee, does at least have a Counter Fraud Service, but this feely admits that it does not deal with research fraud, only financial fraud. Many will, of course, find the distinction hard to grasp. Indeed in America it was precisely because federal money was underpinning at least some aspect of almost all research activity that central Government felt able to tell the Office of Research Integrity that they ought to investigate what was going on if no adequate investigation had been organized locally. The attitude in

the UK has always been that universities, NHS Trusts and the medical research charities all have their own internal procedures, which can be invoked in time of need. Paradoxically, because that need is, fortunately, rare, the procedures become rusty and there is no recently used expertise available to activate such procedures with any degree of confidence.

So is this where UKRIO should come in? Certainly it appears that recently it is raising its profile and is able to offer good advice on what to do if it is suspected that something in the research context has gone wrong.[7,10] But UKRIO has no intention of investigating any cases itself, having encouraged the various stakeholders involved in research to have standard operating procedures in place on how to conduct such an investigation. Other countries in Europe have also adopted the same approach at present. However, in the UK at least, the evidence suggests that this is not working as it should. I reiterate that one of the pivotal recommendations of the original 'blueprint' was the need for a recognized rapid response to any allegation, with confidential external investigation using teams from national lists of trained expert assessors who could be called in by institutions as required.[4] As already stated, only MLI currently fulfils this criterion of trained expert assessors, but it was never intended to be exclusive. However, it does exist, as a unit to be invoked whenever required. If UKRIO were to invoke such experts or, more usefully, to recommend that institutions should call in the experts themselves at the earliest opportunity, then the future for the management of research misconduct may become less bleak than it currently appears.

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Edmund Hey – a personal appreciation

Iain Chalmers

Editor, James Lind Library

Edmund Hey was my friend and colleague for over thirty years, and a fellow campaigner for human rights during the decade before he died. With others, we worked together to expose untruths propagated about paediatricians and paediatric nurses in Stoke on Trent, and to draw attention to the resulting injustices they suffered. The articles collected here provide a record of a cynically manufactured 'non-scandal', and the damage it has caused. The series begins and ends by emphasising that allegations of research misconduct should be judged only after the facts have been ascertained by suitably qualified forensic investigators.

This compilation of articles is dedicated to the memory of Edmund Hey, not just because his attention to detail and sheer hard work was the main driving force in bringing the series to completion, but also because, as one of his last projects, it reflects the moral and scientific principles that have characterised his whole career.

I came to know Ed in the autumn of 1978, soon after I had become director of the National Perinatal Epidemiology Unit (NPEU). Ed's first visit to the Unit resulted in friendship and longstanding collaborations with him and his colleagues in the Northern Region in a variety of epidemiological studies of perinatal mortality and morbidity. Under Ed's leadership the quality of this epidemiological research became second to none in the world, as did the Region's contributions to collaborative clinical trials.

During the 1980s, Ed was a member of the NPEU's advisory committee. He tended not to make many verbal contributions during meetings. Instead, promptly after meetings, he sent up to four pages of thoughtful, single spaced assessments of the matters – scientific and 'political' - to which he felt we needed to pay attention. When I left the NPEU in 1992, I wrote to him to say that his loyalty to the Unit had been second to none, and that I did not know how to thank him adequately for everything he had done to help us.

After leaving the perinatal field in the early 1990s, my contacts with Ed were sporadic; but other things were anyway happening in his life. After contacting him in May 1995 to find out what he was up to he wrote:

> *'When I eventually decided to take early retirement from my university post late last year I made a binding promise to Sue and the family that I would not take on <u>any</u> new work for at least a year, and that I would also clear my desk of all the backlog of old work before taking on anything new. A complete break with my workacoholic past was part of an important family pact, and one that I am not going to rat on at this stage after discovering, for the first time since I qualified, what it is to have a bit of what is [rather unctuously] called 'quality time', both for myself and for the family.'*

Over the subsequent couple of years Ed occasionally copied me messages sent to others. In response to one of these sent in August 1999, I replied "It's so good to know that you're alive and kicking. I miss you."

A few days later he wrote:

> *'I took early retirement three years ago in order to make up for my workaholic past and have some time with my wife but, sadly, she developed multiple sclerosis not long after that and it has run rampant in the recent past. She could walk three miles a year ago, but cannot move a single muscle now and needs round the clock home nursing care. It only makes me more relieved that I did decide to get out of paid employment when I did, so I could have some quality time with her and the children. You may think that your own hints to that end went unheeded but they did not. There will be enough time to bury my head in medical matters afresh once this is all over.'*

Sue died two months later, at home, in Ed's arms.

Unsurprisingly after this bereavement, in addition to continuing to spend time with his children and grandchildren, Ed began to crank up his work schedule again – compiling his *Neonatal Formulary*, chairing a Wellcome Witness Seminar on the story of prenatal corticosteroids, and contributing to various research advisory committees, becoming particularly deeply involved in plans for BOOST-2 UK, one of several ongoing trials to address longstanding unanswered questions about what level of oxygen to aim for in prematurely born infants. In addition, Ed continued to respond to people who looked to him for wise counsel, and particularly to provide advice and moral support to paediatricians and other professionals whom he believed had been unjustly accused of wrongdoing.

It was unjust accusations of health professionals which led us, a decade ago, to resume the collaboration we had enjoyed during the 1980s. Our article in the series collected here provides some idea of the features of our collaboration over the past decade. The work has not been straightforward, and, like the clinicians in Stoke-on-Trent and many others who are deemed to have encouraged belief that parents sometimes abuse their children, Ed and I have both been reported to the General Medical Council. Indeed, because he was 'under investigation' by the GMC, payment could not be made to him for one of his research advisory roles. However, I think he would have regarded this injustice to have been compensated by eventual publication of the series of articles on which he had worked so hard.

Two days before Ed died, I called him to discuss aspects of the draft articles about which the journal's lawyer was still not satisfied. He seemed fine. I suppose it must have been later that day or the next day that he may have tried to ignore a developing headache while working to finalise the forthcoming edition of his *Neonatal Formulary*, only to be struck down by meningitis - a potentially treatable condition. It was a tragedy.

As I wrote to Ed in a book I gave to him not long ago, "You have been and are an inspiration – one of the most hard-working and generous-spirited people on the planet. Thanks for everything."

Oxford, April 2010