



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

Edmund Hey¹ • Iain Chalmers²

¹ Retired Paediatrician, Newcastle upon Tyne

² James Lind Initiative, Summertown Pavilion, Middle Way, Oxford, OX2 7LG, UK

Correspondence to: Iain Chalmers. E-mail: IChalmers@jameslindlibrary.org

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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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