and physicians about the different needs of subsets of obese individuals is important. The tendency to treat obese individuals with a one-size-fits-all approach will be counterproductive with metabolically healthy but obese people. And in clinical research, data from cohorts mixing at-risk individuals with those with metabolically benign obesity might be difficult to interpret.

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I declare that I have no conflict of interest.

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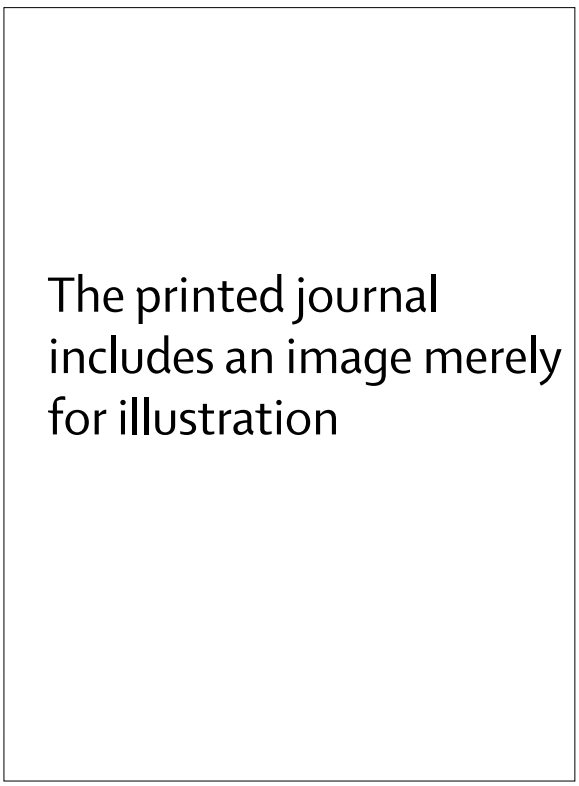
Collapse of GMC hearing into research misconduct

On July 4, the UK's General Medical Council (GMC) announced that their Professional Conduct Committee had halted a disciplinary hearing into a research study done in Stoke on Trent, Staffordshire, UK, between 1990 and 1993.[1] The study, the CNEP trial, was designed to compare two strategies for supporting the breathing of preterm babies.[2,3] A complaint about this study had been lodged with the GMC in April, 1997, but a public hearing finally opened only in May, 2008. The main allegations were of failure to obtain informed consent, misleading the research ethics committee, faulty trial design and analysis, and misleading presentation of results.

The GMC put the testimony of three experts before the Panel on behalf of the complainants. Two could find little to fault in the conduct of the study, and the Panel had considerable reservations about whether the third qualified as an expert because he had "little or no formal training in medical ethics" and was no longer on the medical register.[1] The Panel went on: "Furthermore, he has until recently published articles in his Bulletin of Medical Ethics and been quoted in the media such as to demonstrate a deep animosity towards Dr David Southall".[1] The ruling continued: "The Panel does not think that any reasonable Panel could safely rely on his opinion evidence." Hey[4] has already written, in 2006, that the allegations of consent forms being fabricated were highly implausible. The Panel observed that "given the lapse of time, it could not be proved to the required standard that consent was not taken properly".[1] They dismissed the case against the three doctors after listening to four barristers and 27 witnesses over a period of 8 weeks without even asking to hear what the defence had to say.

The GMC's first task is to protect the public, but the public will not think much of the protection on offer if review sometimes takes 11 years. It has been a costly as well as a lengthy business. The Department of Health will not reveal the cost of the inquiry they commissioned, or admit to its flaws.[5] Had they done so, the issues before the GMC would certainly have been settled much sooner. The local hospital Trust spent the best part of £1 million dealing with the complaint.[6] The medical defence societies have spent a similar sum in the past 10 years, and the GMC must have spent a substantial sum preparing its case, appearing in the High Court and the Court of Appeal, and holding its own hearings.



Rui Vieira/PA Archive/PA Photos

North Staffordshire Hospital, Stoke on Trent, UK

However, there have been a range of even more important intangible costs: to the doctors and nurses under scrutiny and their families, to the faith that the local community has in the care of children going into hospital in Stoke, to neonatal research across the whole of the UK for at least 6 years, and to the faith that doctors, and paediatricians in particular, now have in the competence and fairness of the GMC's handling of allegations of misconduct. The findings of the Department of Health's flawed inquiry were used to support the creation of an additional layer of bureaucracy for clinical research in the UK.

Clinicians are wondering if the GMC is now questioning the validity of consent forms on the basis of what parents can remember 15 years later, even though the forms were signed by a parent and countersigned and dated by a doctor at the time. How is a current researcher supposed to document consent now if this is not thought adequate? In the recent randomised CoolCap[7] and TOBY[8] hypothermia trials for term infants with hypoxic-ischaemic encephalopathy, treatment had to be started within 6 h of birth. This timing required recently delivered mothers to read and comprehend the concepts of secondary brain injury, uncertainty of therapeutic benefit, and random treatment allocation. These things are not always remembered.[9] Are the investigators of these trials to be subjected to a 2-month legal hearing in 2020?

And who regulates the regulators? To end up having the same basic complaint looked at seven times in 11 years seems to be a gross abuse of process to many of the clinicians involved (and more than ten were under scrutiny at one stage). To have the case collapse in this way certainly suggests a serious and sustained systems failure somewhere within the GMC. Paediatricians elsewhere in the world feel that the drawn-out repeated inquiries suggest a desire to target David Southall, one of the three clinicians in the dock.[10] Lessons certainly need to be learnt.

8 years ago, the editors of *The Lancet* and the *BMJ* said that the UK lacked a robust forum for looking into allegations of research misconduct.[11] Such a forum is still lacking, and the GMC has shown that it is not the body to take on this task.

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AW would have been an expert witness for the defence if the GMC case had not ended early. I thank Edmund Hey for detailed discussions on earlier drafts of this Comment. Edmund Hey has provided free advice to David Southall's lawyers and given personal support to all three defendents.

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