Regulating research, regulating professionals

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This issue sees the publication of the first1 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 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.

References
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4 See http://www.ukrio.org/sites/ukrio2/the_programme_of_work/procedure.cfm