

FEATURE

Commentary: Skilled forensic capacity needed to investigate allegations of research misconduct

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An editorial introduction to the series of *BMJ* articles about research fraud and the MMR scare ends by noting that the affair “raises important questions about . . . what can be done to prevent something like this happening again.”¹ At least one of the answers to this question was identified a decade ago. Two years after a consensus conference on misconduct in biomedical research held in Edinburgh,² a proposed blueprint for the prevention and investigation of research misconduct was published by authors representing several medical royal colleges and the Faculty of Pharmaceutical Medicine.^{3 4}

One of its pivotal recommendations was the need to establish a rapid response process through which institutions could call on independent teams of trained external assessors, to investigate allegations of research misconduct.⁴ With the exception of one small private organisation, MedicoLegal Investigations,⁴ no other capacity yet exists within the UK.⁵ Meanwhile there continue to be scandalous and costly delays in investigating allegations and suspicions of research misconduct, and in identifying innocent as well as guilty researchers.

In 2004 the *Sunday Times* published an article by the journalist Brian Deer alleging misconduct by researchers at the Royal Free Hospital medical school in London.⁶ Six years earlier Andrew Wakefield and colleagues had reported an association between MMR vaccine and childhood autism in a paper published in the *Lancet*.⁷ John Reid, the then health secretary, called for an inquiry by the General Medical Council (GMC) as a matter of urgency.⁶ However, it was not until six years later, after extensive further research by Mr Deer, that the GMC’s fitness to practice committee upheld the majority of Mr Deer’s allegations. The committee found Dr Wakefield and his senior coauthor, John Walker-Smith, guilty of serious professional misconduct, including, in Dr Wakefield’s case, dishonesty. Charges were proved against a third coauthor, Simon Murch, but he apologised to the GMC; he was deemed to have shown insight and was therefore discharged. The role of the remaining 10 coauthors, who were not arraigned by the GMC, has not been investigated. Nor have the failings at Dr Wakefield’s institution, the Royal Free Hospital medical school, in its wholly inadequate response to serious allegations of misconduct in 2004.

In the late 1990s, another journalist, Brian Morgan, together with a pressure group and the then editor of the *Bulletin of Medical Ethics* Richard Nicholson, alleged that researchers associated with a controlled trial involving preterm infants in Stoke on Trent⁸ were guilty of research misconduct, including forgery of consent forms.⁹ A media frenzy followed.¹⁰ This led to numerous unpublished inquiries and one requested by the health secretary, none of which found any evidence of misconduct, let alone forged consent forms.⁹ However, the clinicians who had been targeted by the campaign had to wait 11 years before the GMC eventually judged that they had no case to answer.⁹ This delay in justice had devastating effects on the doctors and nurses and their families who had been publicly vilified¹¹ as well as on clinical research in the UK.^{9 12}

Apart from the failure to identify efficiently those guilty and those innocent of research misconduct, current inefficiency wastes millions of pounds. Taken together, the investigations of alleged research misconduct at the Royal Free Hospital and in Stoke on Trent have been estimated to have cost at least £12m (£13m; \$19m).^{9 13} In addition, many other costs may be incurred, as well as harm to patients, both because of failure to expose flawed research or because of unwarranted promulgation of doubts about reliable research.

These two examples show the consequences of the UK’s failure to make efficient and effective arrangements for establishing the facts in response to allegations of research misconduct. The UK Research Integrity Office (UKRIO) may be able to resolve uncertainties about whether misconduct has occurred in some cases,¹⁴ and it has issued useful guidance on how to undertake investigations. But UKRIO does not currently have the professional forensic expertise, the mandate, or the capacity needed to investigate allegations independently.^{9 15}

Although institutions that employ researchers do sometimes mount and report credible investigations into allegations of research fraud, the default assumption should probably be that they are not sufficiently independent. They have an obvious conflict of interest because of the inevitable pressures on them to protect their reputations. These pressures may trump a duty to protect the integrity of science.¹⁶

In addition to the need for independence, however, some investigations require forensic expertise so that the facts can be established before attempts are made to reach safe judgments. Although it will sometimes be possible to establish relatively easily that research misconduct has occurred (in confirming plagiarism, for example), skilled forensic experience is needed to establish the facts in other, less easily investigated allegations, such as the two we have cited. As a member of staff at the GMC remarked during discussion of the allegations made about researchers in Stoke on Trent, most institutions “would not have any idea how to set up and carry forward an inquiry into a difficult and high profile case.”⁹ As noted by the Organisation for Economic Cooperation and Development’s 2007 global science forum, “All those responsible for procedures to investigate research misconduct . . . should have received training in the application of the procedures and/or be experienced in their use.”¹⁷

Proper procedures for investigating allegations of research misconduct, including skilled forensic capability, are needed without further delay. Furthermore, publication of the outcome of each investigation should be required for all research, whether publicly or commercially funded. Because organisations that fund research have a strong interest in its integrity, they could support these measures by small pro rata payments. The costs would amount to a tiny proportion of total UK research expenditure.

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