

MMR **Evan Harris**

After Wakefield: the real questions

Have medical journals and hospital ethics committees yet got their act together?

In February 2004 I got a call on my mobile from a journalist at the *Sunday Times* saying he wanted to talk to me about the MMR (measles, mumps, rubella) vaccine and autism. I said firmly that I didn't have any concerns about MMR, I didn't want to assist a scare story, and if I did want to talk about public health it wouldn't be to the *Sunday Times*, given the paper's record on HIV and AIDS coverage. "Too bad," said the man. "I have an exclusive exposé about Andrew Wakefield's undeclared conflicts of interest surrounding his original 1998 *Lancet* paper." "Hang on a sec," I said. "I'll get Dr Harris on the line."

That was when I first encountered investigative journalist Brian Deer. Within a week we were in the *Lancet* offices explaining to a stunned editorial team what lay behind that fateful 1998 paper.¹

Brian Deer had discovered that Wakefield was being paid by the legal aid board to provide an expert opinion for plaintiff lawyers in a legal suit against the manufacturers of MMR, and that at least some of the children who were claimed to be "consecutive patients referred to the paediatric GI clinic at the Royal Free" were part of the class action.² Deer also had a freedom of information response from the research ethics committee of the Royal Free Hospital showing the applications and related correspondence (<http://briandeer.com/mmr/royal-table.htm>) for ethical approval of the *Lancet* study. My experience on a local research ethics committee, and on the BMA's medical ethics committee, helped me recognise that of more concern than financial non-declaration and double payment (www.gmc-uk.org/Wakefield_SPM_and_SANCTION.pdf_32595267.pdf) was the grossly unethical nature of the research and the inadequacies of the ethical oversight, and these issues were what I discussed first in my subsequent meetings with the General Medical Council. When the GMC published its findings of fact³ against the researchers, which amounted to serious professional misconduct,⁴ the most frequent and most serious related to the

ethical propriety of what was done to the children.

This week the GMC struck Dr Wakefield off the medical register, but this result cannot bring an end to the matter. A number of key questions are raised by the scandal, and there is no certainty that this case was isolated or unrepeatable.

(1) Why did the ethics committee at the Royal Free, which is charged with the responsibility of protecting patients (and it's hard to think of a more vulnerable group than children with autism) allow researchers to perform lumbar punctures and colonoscopies on children in a research project, when even the research standards of the day made it clear that any test more invasive than a blood test needed to be in the child's best interests?

(2) Why did the Royal Free, after the *Sunday Times* revelations, tell the *Lancet* that it saw no ethical wrongdoing, a view entirely demolished by the GMC?⁵ Was there a chronic failure in ethical oversight at that hospital and, if so, what other patients were put at risk?

(3) Indeed, although the *Lancet* paper dealt with 12 children, an abstract published by the same group in *Gut*⁶ mentioned 30 children undergoing these invasive tests, while a later paper⁷ in the *American Journal of Gastroenterology* suggested that 60 children were investigated at least to the extent of ileoscopy and biopsy. Should those papers not be expunged from the publication record as the *Lancet* paper has now been?

(4) The *Lancet* cleared the researchers of any ethical misdemeanours after its rapid "investigation" that merely involved asking the authors for an explanation⁸ and then settled for partial retraction by part of the authorship.⁹ By contrast, the GMC found proof beyond reasonable doubt that the study was unethical. Only after the GMC published its findings did the *Lancet* retract the entire article,¹⁰ accepting that the assurances for the hospital were unreliable. Will the Committee On



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Publication Ethics (COPE) now take a view on how this case was handled and how future ones ought to be handled? (5) Should we not now raise ethical peer review to the same level as statistical peer review? If at the time of accepting the 1998 paper the *Lancet* editor or the paper's peer reviewers had required not merely the assertion that the study had ethical approval, but a copy of the protocol and the patient information sheet that had been approved, that paper would never have been published. Such an approach would not only expose ethically questionable research—surely at least as important an issue as ensuring statistical integrity—but also raise the ethical standards of researchers and ethics committees. In 2008 COPE issued guidance¹¹ on what to do if a manuscript claims that ethical approval is not needed, but not about providing even a minimal check on whether ethics approval was complied with.

I raised these concerns, and others, on the record in March 2004 in the House of Commons when, having set out the bad practice that seemed to have taken place, I urged the government to investigate the issue.¹² The minister, in reply to the debate, made it clear that the government was hoping that the GMC would deal with it and rejected the idea of any inquiry. But the GMC was only ever going to look at the professional conduct of the treating or investigating doctors, not at any of the issues raised above.

Now that the GMC proceedings are over and findings of fact are on the record for all to see, there is an urgent need to see what really happened beyond the professional conduct of the doctors involved. It is time to forget about Andrew Wakefield and time to start asking whether medical journals and hospital ethics committees have, over the past six years, got their act together.

Evan Harris is former Liberal Democrat science spokesman
drevanharris@gmail.com

References and competing interests are online
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See also **NEWS**, p 1157