

Autism and MMR Vaccine Study an 'Elaborate Fraud,' Charges BMJ

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[Authors and Disclosures](#)

January 6, 2011 — *BMJ* is publishing a series of 3 articles and editorials charging that the study published in *The Lancet* in 1998 by Andrew Wakefield and colleagues linking the childhood measles-mumps-rubella (MMR) vaccine to a "new syndrome" of regressive autism and bowel disease was not just bad science but "an elaborate fraud."

According to the first article published in *BMJ* today by London-based investigative reporter Brian Deer, the study's investigators altered and falsified medical records and facts, misrepresented information to families, and treated the 12 children involved unethically.

In addition, Mr. Wakefield accepted consultancy fees from lawyers who were building a lawsuit against vaccine manufacturers, and many of the study participants were referred by an antivaccine organization.



Dr. Fiona Godlee

In an accompanying editorial, *BMJ* Editor-in-Chief Fiona Godlee, MD, Deputy *BMJ* Editor Jane Smith, and Associate *BMJ* Editor Harvey Marcovitch write that there is no doubt that Mr. Wakefield perpetrated fraud. "A great deal of thought and effort must have gone into drafting the paper to achieve the results he wanted: the discrepancies all led in 1 direction; misreporting was gross."

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Although *The Lancet* published a retraction of the study last year right after the UK General Medical Council (GMC) announced that the investigators acted "dishonestly" and irresponsibly," the *BMJ* editors note that the journal did not go far enough.

"*The Lancet* retraction was prompted by the results from the [General Medical Council] hearing and was very much based on the concerns about the ethics of the study," Dr. Godlee told *Medscape Medical News*.

"What we found was that it was definite fraud and that is a very important thing for the world to know. This article shows that the science was falsified and should be discounted," continued Dr. Godlee.

This evidence "should now close the door on this damaging vaccine scare," the editorial authors add.

Damage to Public Health

Although it included only 12 patients, faced almost immediate criticism, and never had its findings replicated, the study received wide media coverage and set off a panic among parents, with the result that MMR vaccinations decreased dramatically.

The 2003 to 2004 vaccination rate of 80% has now recovered slightly in the United Kingdom, but it is still well below the recommended 95% level recommended to ensure "herd immunity." A measles epidemic was also declared in England and Wales in 2008.

"Perhaps as important as the scare's effect on infectious disease is the energy, emotion, and money that have been diverted away from efforts to understand the real cause of autism and how to help children and families who live with it," the editorialists write.



Mr. Brian Deer

Mr. Deer did his first investigative stories on the Wakefield paper in 2004 for the *Sunday Times* in London and a UK television network. On the basis of his findings, the GMC's Fitness to Practice panel convened in 2007 and heard from 36 witnesses during a period of 2 and a half years.

At the end of January last year, as reported by [Medscape Medical News](#), the panel used strong language in condemning the study's methods and noted that Mr. Wakefield and 2 other colleagues had broken guidelines.

The Lancet [issued its retraction](#) 5 days later, citing the panel's findings that the participants were not consecutive patients seeking treatment and that the study had falsely reported being approved by an ethics committee.

Although the GMC later found that Mr. Wakefield and coauthor John Walker-Smith committed serious misconduct and struck them off the medical register, Mr. Wakefield has repeatedly denied doing anything wrong. In addition, he was not among the 10 of 13 coauthors who disavowed the study's findings in 2004.

"Instead, although now disgraced and stripped of his clinical and academic credentials, he continues to push his views. Meanwhile, the damage to public health continues," the editorialists write.

Multiple Discrepancies Found

Last spring, the *BMJ* went to Mr. Deer to ask if there was more to this story. In this newest article, he reports that "multiple discrepancies" were found, including the following:

- Only one of the studied 9 children actually had clear regressive autism and 3 did not have a diagnosis of any autism type;
- Five had preexisting development concerns — although all 12 were classified in the study as "previously normal"; and
- The exclusion of important allegations helped create "the appearance of a 14-day temporal link."

In addition, none of the 12 patients were "free of misreporting or alteration," he writes.

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"My number 1 takeaway is that it cost a tremendous amount of time and money to penetrate the veil of confidentiality that surrounded just these 12 children. So how on earth would anybody penetrate the veil over other larger medical research? When Wakefield did what he did, it was on the assumption that no one would ever be able to find out the truth," Mr. Deer told *Medscape Medical News*.

BMJ fact-checked Mr. Deer's article against the 6 million-word transcript of the GMC panel's hearing. Dr. Godlee said she is now calling for reexamination of all of Wakefield's past studies to determine whether others should be retracted. "Past experience tells us that research misconduct is rarely isolated behavior," she writes.

But how did a small case-control study like this set off such a panic in the first place? "I think a lot of people would like to know the answer to that," said Dr. Godlee.

"I think Andrew Wakefield is a terrifically good publicist. He managed to convince his institution to run a press conference for this very small piece of research. The media attention for this grew, and concerns were raised with his subsequent publications."

In addition, she said that many parents have questions about why their children have developed autism and are looking for reasons to explain the onset of its behavioral symptoms. "MMR is a very common intervention, it seemed to fit the picture, and it's very hard to prove that something is safe despite overwhelming evidence that there is no link.

"If you're looking for an explanation, this may seem plausible, although the science is nonsense. Overall, I think it's a combination of very desperate parents looking for answers and a very clever man who was willing to lie and cheat, who was willing to try to advance his own career and financial benefits," noted Dr. Godlee.

Editor's Dread

With questions raised almost from the start, how culpable is *The Lancet*? And how can other journals protect themselves from publishing falsified studies?

"That is the dread of any editor," said Dr. Godlee. "I think editors' main responsibility is to make sure that what is published is valid in terms of being good research. And I think *The Lancet's* decision to publish this in the first place was a very questionable decision, especially as it dealt with such a serious issue.

"Why publish research that is not going to advance science and is going to create a vaccine scare? I think there is culpability there. But as for fraud, that is very tricky because science is based on trust," she added.

"None of us go back and ask for the case records of patients involved. But we need to become aware that any article that comes in could be fraudulent. And we have to be absolutely vigilant and investigate properly when concerns are raised. It's a constant cycle of oversight that needs to be done."

Medscape Medical News contacted *The Lancet* for its reaction to the *BMJ* series of articles, but officials there had "no comment on this."

Dr. Godlee said that she would also hope that coauthors would serve as backup for honesty in reporting and that all of this study's investigators "failed in their duties as authors" — especially since there were only 12 patients involved.

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Diversion of Research Funds

The editors write that although a breach of trust this large is "almost certainly rare," it raises questions about what could have been done earlier, what further inquiry is needed, and what can be done to keep it from happening again.

Future *BMJ* articles in the series, to be published during the next 2 weeks, will deal with these questions and about *The Lancet's* actions from study publication through retraction.

"We wanted to also look at what motivated Andrew Wakefield, looking at the commercial schemes he established to exploit the MMR scare, and then we examine what happened when the issues of concern were first raised back in 2004 and why it was not taken more seriously at that time," explained Dr. Godlee.

"To people who might ask why we're interested in all of this now, the answer is that what Brian Deer has unearthed is much more substantial than what most of us knew or what came out in the GMC hearing. This study was not only bad research but fraudulent as well. And it's taken an enormous amount of time and effort and money away from legitimate lines of inquiry," she concluded.

Mr. Deer's original investigation was funded by the Sunday Times of London and the Channel 4 television network. The current articles were funded by the BMJ. He reported receiving no other funding except for legal costs from the Medical Protection Society on behalf of Mr. Wakefield. The editorial authors have disclosed no relevant financial relationships.

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