GMC WAKEFIELD VERDICT **Trisha Greenhalgh**

Why did the *Lancet* take so long?

The retraction of the infamous MMR paper may be overdue, but it is a good thing for science

On 28 February 1998 the *Lancet* published a study with the inauspicious title “Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children” (*Lancet* 1998;351:637-41). The paper has been much criticised, and the *Lancet* finally retracted it this week. But why did it all take so long?

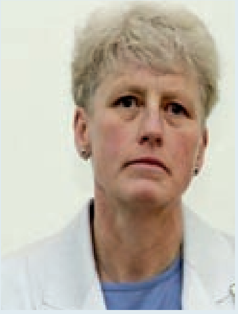
The story is well known. Wakefield’s paper implied an association, later shown to be spurious, between gastrointestinal illness, the combined measles, mumps, and rubella (MMR) vaccine, and an autism-like disorder in a sample of 12 children. At a controversial press conference Wakefield appeared to conflate association with causation, and in the eyes of the tabloid press his tiny, skewed sample represented children in general. The immunisation record of then prime minister Tony Blair’s infant son became the most politically sensitive item of data held in the NHS. Private clinics enjoyed a brief boost to business by offering the three vaccines as separate, spaced injections as recommended by Wakefield. Measles returned—and did considerable damage.

On 18 February 2004 the investigative journalist Brian Deer complained to the *Lancet* that far from being “consecutive” referrals to the gastroenterology clinic, as claimed in the paper, several children in the sample had been referred to Wakefield by a medical negligence lawyer who sought grounds for pursuing a legal action on behalf of parents of allegedly vaccine damaged children. Deer claimed that Wakefield had not obtained ethics committee approval for invasive tests conducted on the children (including lumbar puncture and colonoscopy) and that the paper had been submitted under cover of ethics approval for a different study.

On 6 March 2004 the *Lancet* rejected Deer’s allegations relating to ethics approval and stated that “children reported in the 1998 *Lancet* paper were consecutively referred to the Royal Free [Hospital] and were not deliberately sought by the authors for inclusion in their study based on parents’ beliefs about an association between their child’s illness and the MMR vaccine” (*Lancet* 2004;363:747-9). However, it agreed that funding from the Legal Aid Board for what it considered to be “parallel and related work” should have been declared as a conflict of interest (defined as: “Is there anything . . . that would embarrass you if it were to emerge after publication and you had not declared it?”).

In the same issue 10 of the paper’s 13 authors published a “retraction of an interpretation” (*Lancet* 2004;363:750). Despite this, two of those 10—Simon Murch and John Walker-Smith—joined Wakefield on the ropes in 2007 for what has already become the longest hearing by a fitness to practise panel in the history of the General Medical Council. In a judgment published last week the GMC declared that invasive investigations on children in the “*Lancet* 12” group were undertaken without proper ethics committee approval and without due regard to their clinical needs (www.gmc-uk.org/static/documents/content/Wakefield__Smith_Murch.pdf). Wakefield’s presentation of the referrals as consecutive and routine was deemed “dishonest” and “irresponsible” and was found to have “resulted in a misleading description of the patient population in the *Lancet* paper” (paragraph 32b, page 44).

An academic journal is not a collection of blank pages on to which authors inscribe important scientific facts as they discover them. Rather, science is made and shaped as authors consider the declared areas of interest, impact factors, and instructions for authors of candidate journals for their work and as the papers they submit clear the successive hurdles of eligibility screening, selection of peer reviewers, responding to reviewers’ comments, statistical approval, technical editing, and distribution of press releases. My own collection of rejection slips from journals with a high impact factor represents research that could have become important scientific facts but that turned out to be findings of marginal significance in publications to which neither politicians nor journalists subscribe.



> **Once the article appeared with the *Lancet* kitemark—cautious accompanying editorial notwithstanding—the arguments were considered by many to be proved, and the ghastly social drama of the demon vaccine took on a life of its own**

A graph showing first a precipitous fall in immunisation rates in the United Kingdom and then a corresponding rise in the incidence of measles was later reproduced in the broadsheets (and in at least one GCSE biology syllabus) as an iconic symbol of bad science.

Leaving aside for a moment the questions of research ethics and fraudulent sampling claims raised by the GMC, there is an alternative interpretation of the same graph: that the acceptance for publication of some very preliminary laboratory findings by one of the world’s leading medical journals was, at the time that editorial decision was made, more a symptom than a cause of declining professional and public confidence in the MMR vaccine. But once the article appeared with the *Lancet* kitemark—cautious accompanying editorial notwithstanding (*Lancet* 1998;351:611-2)—the arguments were considered by many to be proved, and the ghastly social drama of the demon vaccine took on a life of its own.

In an ironic admission to the GMC panel (paragraph 30a, page 43) Andrew Wakefield disputed that the piece he submitted to the *Lancet* should be referred to as a “scientific” paper. And this week the *Lancet* stated that it had “become clear that several elements of the 1998 paper . . . are incorrect, contrary to the findings of an earlier investigation [*Lancet* 2004;363:824],” adding, “We fully retract this paper from the published record.” Although the retraction seems overdue, it can only be a good thing for science.

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GMC WAKEFIELD VERDICT **Brian Deer**

Reflections on investigating Wakefield

What will become of the man at the centre of the GMC's longest running fitness to practise case?

It was the longest General Medical Council fitness to practise hearing ever: three gastroenterologists hit with a Chinese menu of charges.

The highlights, I suppose, were the panel's conclusions last week and the *Lancet*'s retraction five days later of the controversial paper. Andrew Wakefield, the "MMR research doctor," stood exposed, in disgrace, and the paper that caused the mischief is no more.

"The allegations against me and my colleagues are both unfounded and unjust," he declared to the cameras on 28 January. "I repeat: unfounded and unjust."

As the journalist whose investigations led to the charges and the retraction, I sometimes wondered whether we would ever see a result from the GMC. This was the Jarndyce versus Jarndyce of medical proceedings. The five member panel sat for 197 days.

For me the story started with a lunch. So many do. "I need something big," said a *Sunday Times* section editor. "About what?" I replied. Him: "MMR?"

But I didn't fancy that one at all.

This was September 2003, and litigation was pending in the High Court over alleged damage to children from the MMR vaccine. Better to hang on and cover that, I suggested. But the next week that trial was cancelled. Expert reports had been swapped, and the claimants' lawyers said they couldn't make the case.

So I took an empty notebook and made my own inquiries. It was the largest *Sunday Times* medical investigation since thalidomide. No media have yet itemised the verdicts produced last week, and I've space only for those found proved against Wakefield: dishonesty (four counts); research on developmentally disordered children without ethical approval (11 counts); contrary to their clinical interests (nine counts); causing a child to undergo lumbar puncture without clinical reason (three counts); ordering medical tests without appropriate qualifications and in breach of a non-clinical employment contract (three counts).

Then we get the birthday party. Wakefield paid children £5 each for blood samples. Also, the now retracted 1998 *Lancet* paper: the original focus of my interest. This, the GMC panel confirmed, included a false claim of ethical approval and a "dishonest" description of inclusion criteria.

You don't need to ask Confucius to know what will happen at the hearing's next stage, to run between April and June: the panel will undoubtedly decide that serious professional misconduct occurred and that Wakefield should be struck off.

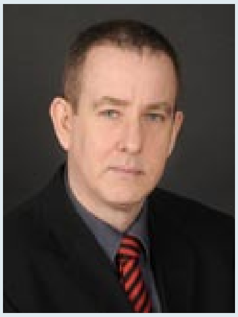
"It's a case about breaches of some of the most fundamental rules in medicine," Sally Smith QC, for the GMC, told the panel: a GP, a psychiatrist, a geriatrician, and two lay members.

But let's not forget the two doctors left in the shadows: John Walker-Smith, 73, and Simon Murch, 53. They were also last week walloped with a raft of proved charges, although neither was found to be dishonest.

What they were found to have done was to collaborate with Wakefield in his bid to make a case against the vaccine. Together, in the late 1990s, they brought a dozen brain disordered children, aged 2 to 9, to the Royal Free Hospital, north London.

There, in stays of six days, those kids endured batteries of tests that in many cases, the panel found, weren't indicated. Ileocolonoscopy: 12. Lumbar puncture: 9. Barium meal: 10. Magnetic resonance imaging: 10. Electroencephalography: 9. Upper endoscopy: 2. Blood tests: 12. Some of the kids, moreover, had general anaesthetics, while others were bowel prepped through nasogastric tubes.

The point of this exercise: to hunt for measles virus in guts and spines. Wakefield's theory was that the virus—live in the MMR vaccine—caused Crohn's disease and autism. He failed to prove it.



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At the time a lawyer was paying Wakefield £150 (€170; $240) an hour as the claimants' expert for the MMR lawsuit I had planned to report on. So, the longer the show stayed on the road, the more money he made. I say: nice work if you can get it.

In the end he grossed £435 643, plus expenses: eight times his reported annual salary. But the real sting was his call for the triple vaccine to be suspended in favour of single shots. Remember that?

As the chief expert in a lawsuit, he *had* to say that the triple vaccine was unfit for marketing, or the case would have collapsed, the vaccine scare wouldn't have happened, and the shedloads of money would have stopped.

This underbelly wasn't known until I brought it to light. I ought to feel proud. And I do. So many people have told me that to nail a baseless health scare is, in itself, justification for a life.

But I also think about the chief clinician: Professor Walker-Smith. A tragedy. He'd been warned time and again about Wakefield. "Prof" surely hadn't qualified, 50 years ago last month, to act against the interests of children.

I've seen a photo of Walker-Smith as a student in 1958, at the King George V Memorial Hospital, Sydney. He's washing a baby that he'd just delivered, and his face betrays the tension you sometimes see in young doctors. He was trying to look professional while amazed.

That he should be brought down by a man who I say is a charlatan is part of the legacy of the MMR scandal. The epidemics of fear, guilt, and disease are now passing. But I hope that the lessons for medicine endure.

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See also EDITORIAL, p 271, NEWS, p 281

LIFE AND DEATH **Iona Heath**

The double face of discrimination

There are both scientific and moral arguments against the complete abolition of age discrimination

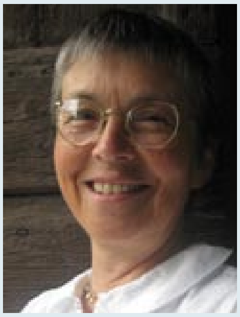
The government is currently consulting on preparing the NHS and social care services in England for the age requirements in the Equality Bill. The commendable intention of the bill is "to ban age discrimination against adults in the provision of services and exercise of public functions."

The use of the word discrimination is tantalising because of its two almost contradictory meanings. The first is deplorable—"the making of distinctions prejudicial to people of a different race or colour from oneself"—and is extended within the Equality Bill to seven characteristics other than race. However, the alternative meaning is admirable—"the faculty of discriminating; the power of observing differences accurately, or of making exact distinctions; discernment"—and the effective practice of medicine is entirely dependent on the skilled exercise of this form of discrimination. These conflicting meanings underline Anatole France's warning—"Every vice you destroy has a corresponding virtue, which perishes along with it"—and should perhaps give our ever enthusiastic legislators a little pause for thought.

Age as an attribute of the human body is intensely relevant to the practice of medicine, and there are both scientific and moral arguments against the complete abolition of age discrimination. Physiology, immunology, and all other body systems are slowly undermined by ageing, and to seek to treat a patient of 90 in the same way as a patient of 20 or even 50 would be unscientific and ill advised. Indeed the high rate of hospital admissions of older people with adverse drug reactions or interactions is testament to the caution needed. In the Quality and Outcomes Framework for general practice in England, which makes no allowance for age in the setting of targets, we are seeing increasingly aggressive treatments for blood pressure and blood glucose concentrations that are likely to be detrimental to the very old.

The moral case relates to the late Alan Williams's courageous presentation of the "fair innings" (*BMJ* 1997;314:820). He wrote: "This attempt to wring the last drop of medical benefit out of the system, no matter what the human and material costs, is not the hallmark of a humane society. In each of our lives there has to come a time when we accept the inevitability of death, and when we also accept that a reasonable limit has to be set on the demands we can properly make on our fellow citizens in order to keep us going a bit longer." Most clinicians have learnt from experience that many older people take the same pragmatic and altruistic approach and, if offered the choice, always prioritise the needs of those younger than themselves—and especially the very young—in the allocation of healthcare resources. There comes a point too when an individual has simply sustained too many losses—of friends, spouse, children, health, energy, hope—to want to struggle on much longer. These are general truths that slide towards prejudice when these sorts of feelings are assumed without a proper conversation between patient and doctor. Prejudice begins when we judge without asking, listening, imagining, and thinking.

In his 1992 book *Inequality Reexamined* Amartya Sen was at pains to indicate the challenging reality of tackling inequality and pointed out that "demanding equality in one space—no matter how hallowed by tradition—can lead one to be anti-egalitarian in some other space." It is another timely warning. Age is only one facet of a unique individual; other characteristics will fall into other spaces, and the individual's priority for equality may well lie elsewhere—in relation to race or sex or sexual orientation, for example.



> **"The fear must be that the well intentioned desire to create and then police a totally just system that has no place for age discrimination will incur substantial costs"**

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Iona Heath's review of Amartya Sen's latest book, *The Idea of Justice*, is on bmj.com (*BMJ* 2010;340:c659), and will appear in next week's print journal.

Sen's most recent book, the magisterial *The Idea of Justice*, can be seen as an extended refutation of the thinking behind the government's Equality Bill and could usefully be considered as a response to the current consultation. Sen's contention is that recent thinking about justice has been overly concerned with the challenge of establishing totally just institutions at the expense of dealing with actual injustices that are immediately obvious and clearly remediable. The Equality Bill and the consequent ambition to eradicate age discrimination within the health and social care services fall plainly within this tradition of attempting to define and create a totally just society. Sen writes: "What moves us, reasonably enough, is not the realization that the world falls short of being completely just—which few of us expect—but that there are clearly remediable injustices around us which we want to eliminate."

Remediable injustices in relation to older people within our society are not hard to find. They include, among much else, the systematic, historical failure to involve older people in medical research studies; the recasting of dementia as a social problem rather than a disease so that those with it can be charged for their own care; the insensitive and inappropriate use of PEG tubes for artificial feeding at the end of life; and the failure to acknowledge that, in extreme old age, gentle, sensitive, hands-on care becomes more important and high tech interventions less so. The fear must be that the well intentioned desire to create and then police a totally just system that has no place for age discrimination will incur substantial costs and absorb much of the energy and money necessary to tackle these immediate and obvious injustices.

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