

MMR AND SCIENTIFIC FRAUD **Harvey Marcovitch**

Is research safe in their hands?

To keep our science clean the lessons of the Wakefield saga must be embedded in research culture

In 2006, after suspicions were raised about a paper published in the *Lancet*, an investigation by the Norwegian Radium Hospital in Oslo found evidence of systematic fraud in the publications of Jon Sudbø, a cancer researcher at the hospital. The inquiry published its findings within months of the whistle being blown.

Scott Reuben, previously head of anaesthesiology and pain medicine at Baystate Medical Center, Springfield, Massachusetts, has just completed a six month jail sentence for healthcare fraud. Ten of his papers have been retracted from *Anesthesia & Analgesia*, and he is believed to have fabricated results in at least 21 and probably many more papers dating back to 1996. Dr Reuben was a key advocate of several mainstays of current anaesthetic practice, including the use of non-steroidal anti-inflammatories such as celecoxib and neuropathic agents such as pregabalin instead of opiates—practice that is now in question. Baystate Medical Centre, alerted by an internal reviewer, completed its inquiry in about a year.

In October 2010 *Anesthesia & Analgesia* again retracted a paper after readers complained that the quoted variability of certain results was too low to be believable. From publication to retraction (and dismissal of the lead author, Joachim Boldt, from his clinical post) took less than one year. Currently the local medical board is investigating 200 papers published by Professor Boldt.

Why, then, did it take more than a decade for Andrew Wakefield's paper to be retracted, six years for the General Medical Council to complete its task, and an investigative journalist's detailed investigation to uncover scientific fraud? One clue might come from an editorial in the very journal that championed Wakefield. The 2006 editorial in the *Lancet* by Nylenna and Simonsen decried the "bad apple" scenario,

whereby research leaders might deny personal responsibility and refuse to believe that misconduct is diffused throughout the scientific community, a concept supported by a subsequent systematic review revealing that about 2% of scientists admitted to scientific fraud while 14% believed that colleagues had falsified data.

Recommended solutions included the research community taking collective responsibility, regularly discussing and studying misconduct; senior researchers demonstrating sound ethical behaviour when training their subordinates; and the development of effective, independent national mechanisms to investigate misconduct.

What the original peer reviewers made of Wakefield's paper is not known. What is clear is that the peer review process emphasises methods and statistical analysis. Editors should demand similar stringency in ethical review—for example, confirming that study protocols and patient information literature reflect proper practice.

Experience of cases reported to the Committee on Publication Ethics, a body founded by medical journal editors, leads to a conclusion that universities and other funding bodies differ in their response to reports from suspicious editors, reviewers, or readers. Some investigate, some retreat into a Trappist silence, and others are adept at carpet sweeping. Brian Deer's report in the *BMJ* this week implies no shortage of shagpile in the Royal Free Hospital Medical School and the *Lancet* office.

Hopes of a national solution have been frustrated. The UK Research Integrity Office was set up in 2006 under the umbrella of Universities UK (UUK), with a galaxy of biomedical institutions as stakeholders and with support from the government. Many of us were disappointed by its lack of mandatory powers and

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• Brian Deer explains why it's been so long from the original publication of Wakefield's work in the *Lancet* to the revelations just published in the *BMJ*

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• Feature: How the case against the MMR vaccine was fixed (*BMJ* 2011;342:c5347)

• Editorial: Wakefield's article linking MMR vaccine and autism was fraudulent (*BMJ* 2011;342:c7452)

• Feature: How the vaccine crisis was meant to make money (*BMJ* 2011;342:c5258)

• Rapid responses: see the responses to Brian Deer's investigation at http://www.bmj.com/content/342/bmj.c7452/reply#bmj_el_247664

predicted its downfall if institutions bought into it more by word than deed. Such has proved to be the case: its funding ran out in October 2010, and it has now severed its links with UUK and reconstituted itself as a limited company providing independent advice and support to those who seek its assistance. On the way it produced an excellent blueprint for investigating research misconduct, founded a whistleblowers' helpline, provided independent assessors when requested, and responded to numerous queries from both funders and researchers.

That is the good news. The bad news is that the major funders are determined to set off on their own paths. In October a UUK and Research Councils UK working group proposed setting up an organisation that sounds like the Research Integrity Office in disguise, apparently to be termed the Research Service. Meanwhile, at the government's request the Academy of Medical Sciences is consulting on a proposal for placing responsibility for different aspects of medical research regulation within a single regulator.

With the annual number of retractions for scientific fraud in papers listed on PubMed rising from single figures in 2001 to more than 50 in 2009, it might be the case that editors are more vigilant (or authors more dishonest). But the increasing fragmentation of oversight in the UK means that we cannot bank on keeping our science clean.

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Competing interests: HM is a past chairman of the Committee on Publication Ethics and was previously a member of the board of the UK Research Integrity Office; he also chairs GMC fitness to practise panels. The views expressed are personal and don't represent the views of those bodies.

A longer version of this article with references is on bmj.com
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LIFE AND DEATH Iona Heath

How far is it from no society to Big Society?

It is clear that the prime minister is deliberately distancing the NHS from his vision of a “Big Society”

In 1987 Margaret Thatcher made her infamous claim that there is no such thing as society; the best part of a quarter of a century later the current prime minister is actively promoting the “Big Society” as part of his declared commitment to compassionate conservatism. The initial impression is that Conservative social policy has undergone a sea change, but closer examination suggests that the distance travelled has in fact been infinitesimal.

Mrs Thatcher’s statement was made in an interview for *Woman’s Own* magazine, published on 31 October 1987. She said, “I think we have gone through a period when too many children and people have been given to understand ‘I have a problem, it is the Government’s job to cope with it!’ or ‘I have a problem, I will go and get a grant to cope with it!’ ‘I am homeless, the Government must house me!’ and so they are casting their problems on society and who is society? There is no such thing!”

In a speech in Liverpool on 19 July 2010 David Cameron said, “The Big Society is . . . where people . . . don’t always turn to officials, local authorities, or central government for answers to the problems they face.” And suddenly, it sounds familiar and similarly perplexing for those of us working away in the NHS. When Mrs Thatcher made her claim we thought, “No—there is such a thing as society, and the NHS we work for is a big part of it.” When Mr Cameron describes the Big Society, we think, “Yes, that’s us—the NHS is the absolute centre of any Big Society the UK can muster.” In 1996 the sociologist David Towell put it like this: “The nature of our society is strongly reflected in the values embodied in national health care arrangements; transactions involved in health care delivery are the main way these values are experienced; given the significance of health in everyday life, these transactions are therefore an important part of the way our sense of society is constituted” (*Policy and Politics* 1996;24:287-97).

Yet it is clear that Mr Cameron is

deliberately distancing the NHS from his vision of a Big Society. He describes public sector workers as “disillusioned, weary puppets of government targets,” which does little for our motivation. He rightly says that “we’ve got to give professionals much more freedom,” but he goes on to describe an imperative to “open up public services to new providers like charities, social enterprises, and private companies so we get more innovation, diversity, and responsiveness to public need.” It seems to me that he makes a very serious mistake in putting for-profit companies into the same basket as charities and social enterprises. The NHS embodies the values of our society because it exemplifies shared and mutual responsibility for every citizen who becomes sick. The social contract is that we will all pay tax so that the sick can be treated on the basis of need without consideration of the ability to pay. This contract remains intact, but it is placed under increasing strain by the growing presence of global healthcare and management consultancy corporations at every level of the NHS.

The Centre for Civil Society at the London School of Economics, which perhaps significantly was closed in September 2010, defined civil society as being made up of third sector organisations such as “voluntary associations, charities, nonprofits, foundations and non-governmental organisations that do not fit the state-market dichotomy.” These third sector organisations provide a very important “arena of uncoerced collective action around shared interests, purposes and values,” which should be the stuff of any Big Society but which the current government actively undermines by deliberately blurring the distinction between the third sector and the market. The scandals surrounding the drug industry show how easily values are corrupted by the imperative of profit.

David Cameron says he wants a Big Society that is about freedom,



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empowerment, and responsibility, but it will work only if it is also inclusive and fair. Michael Marmot has drawn particular attention to fairness as an essential determinant of health to the extent of entitling his strategic review of health inequalities in England *Fair Society, Healthy Lives* (BMJ 2010;340:c818). How can the much vaunted Big Society flourish within a policy context that promotes regressive rather than progressive taxation and that continues to allow the gap between rich and poor to widen?

The call for a Big Society is accompanied by proposals for yet another hugely disruptive reorganisation of healthcare in England. Supposedly, clinicians are to be given much more power to redesign services in the interests of their patients’ needs; but once again this laudable ambition is undermined by the over-riding top-down directive that all services are to be open to competition from any willing provider. Monitor, currently the independent regulator of foundation trusts, is to take on new roles from April 2012 (News, BMJ 2011;342:d325). Two of these roles are potentially contradictory: promoting competition and supporting the continuity of services. Clearly, even the government recognises that competition risks rapid fragmentation of services, with different providers competing to deliver different aspects of the care required by a single patient. However, it is far from clear how Monitor, an economic regulator, is to support continuity of services. There is a looming gap here, between fragmentation and continuity, through which many of the most vulnerable patients can fall. No wonder so many clinicians are worried. Without a cohesive and coherent NHS, we risk a rapid regression from Big Society to no society. Iona Heath is president, Royal College of General Practitioners, but writes in the *BMJ* in her personal capacity iona.heath22@yahoo.co.uk

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LOBBY WATCH Jane Cassidy

Civitas

Who are they?

Civitas: The Institute for the Study of Civil Society is a right leaning think tank on social policy with a major focus on health. It was described by the BBC Radio 4 *Today* presenter Justin Webb as “a champion of free market solutions.”

It believes that allowing a greater role for market forces and commercial competition in the NHS would improve a service currently hidebound by central planning. Many who oppose private sector encroachment in the health service fear that this is a key aim of the latest government reforms.

However, the director of the think tank's health unit, James Gubb, is a critic of health secretary Andrew Lansley's plans (*BMJ* 2010;341:c6087). Gubb says that he supports a greater role for general practitioners in commissioning but finds the timetable for rolling out the plan by 2013 “quite tight.” Furthermore, the commissioning structure is being thrown up in the air at a time when the NHS has major financial problems, he says.

Gubb also says that he disagrees with the idea of every general practice becoming involved in commissioning. The health service has a long history of similar unsuccessful top down organisational changes and attempts to take examples of existing good practice and apply them nationally, he says.

He argues for a more permissive and flexible framework that allows GPs to take over commissioning in areas where they are ready but for commissioning to stay with existing primary care trusts in areas where these may be doing a good job. “Not all PCTs are rubbish,” he asserts.

Civitas press releases with stark headlines such as “Mismanaged NHS reform could flatline patient services” and “PCT meltdown threatens a return to rationing” underscore Gubb's reservations about wholesale reorganisation.

What agenda do they have?

The lofty mission of Civitas, which was founded in 2000 by its current director, David G Green, and Robert Whelan, is to deepen public

understanding of the legal, institutional, and moral framework that makes for a free and democratic society.

Its main activity is the advancement of education, directly within schooling and more broadly by informing the public on important issues. In terms of health this means promoting debate. Young Civitas for Medics aims to engage medical students about the future of healthcare.

It also carries out research, some of which has compared the NHS unfavourably with health systems in other European countries. Models

used in Switzerland and the Netherlands are seen as the way forward, with services funded through universal insurance schemes rather than taxation. These create what they see as more competitive, responsive, and patient led systems.

A Civitas report last month called for a more radical approach to shaking up the health service (*BMJ* 2010;341:c7359). Higher productivity will be achieved only through “disruptive,” innovative, and fundamentally different service models from new providers with fresh ideas,

applying pressure on existing ones to “up their game.” Entrepreneurs could take over failing services or step in where commissioners wanted to use them, the report suggests.

Civitas has adopted its own radical approach to providing extra English and maths lessons for failing primary school children, setting up a network of out of hours schools that use traditional teaching methods.

What does the government think of them?

The think tank is probably not flavour of the month, given its opposition to the health reform programme.

Where do they get their money from?

Civitas is a charity funded through grant making trusts and individual and corporate donations. Its income for 2009 was £765 594 (€910 200; \$1.2m).

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Gubb: critical of Lansley's plans



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Health reforms: keep up to date on our website

The coalition government is introducing fundamental changes to the NHS in England that will affect all doctors and healthcare professionals as well as the general public after a decade of increasing satisfaction with the service. The *BMJ* is following the debate very closely and has already published many news stories, comment articles, podcasts, blogs, and debates on the doc2doc clinical community.

Our new microsite provides a complete hyperlinked list of everything that we have published so far on the reforms, and is updated every day.

Articles posted so far include:

- Editorial on the Health and Social Care Bill
- Briefing on the bill
- An open letter to the health secretary: how to really save money on the NHS
- Why the plans to reform the NHS may never be implemented
- Commissioners doing it for themselves
- New kids on the block
- What does the white paper mean for hospital consultants?
- Do GPs want to commission?
- Do GPs have the stomach for the battle ahead?
- More brickbats than bouquets?
- The coalition government's plans for the NHS in England
- What will the white paper mean for GPs?

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