

Debate at the Royal College of Physicians, London, 5 November 2001

Research fraud in Britain

“This house believes that Britain should be ashamed of its response to research fraud and take action at once”

Richard Smith, Editor of the *BMJ*, organiser and chair of the debate

I would like to dedicate this debate to Stephen Lock, who has been talking and writing about this for ages, but considered by many to be mad for having done so. But he has, of course, now been vindicated.

In the introduction of the third edition of his book on fraud and misconduct in biomedical research, co-authored with Michael Farthing and Frank Wells, he writes that it has been 30 years since the paradigm shift in the unthinkable idea that research misconduct might happen. Ancien Regimes, such as Britain and France, have been less resolute, with no formal system in place despite the continuing evidence that the problem is no different from that in other countries where the issue has now been taken seriously.

The exception might be the Royal College of Physicians, who in 1990 set up a commission to look in to the matter, which produced a report the following year.

But there was no press conference to mark its publication. Postgraduate deans did not even know about it.

Stephen Lock writes: “Would that a fourth edition will not need to include again a plea for creating a system in the UK and a few other countries, but can instead be devoted to sharing worldwide experiences of success. However we remain sceptical.”

Professor Michael Farthing, Chair of COPE and Executive Dean and Professor of Medicine, Faculty of Medicine, University of Glasgow

It was once said that the British were fast to talk, but slow to act. And in this case it is not because they have not written or thought about it. There just is not an adequate process for dealing with the full spectrum of research misconduct in 2001.

Among the many high profile cases, there are well respected medical figures who say that publication misconduct is not a big problem, serious cases are rare; the issue is overblown. There is no need to use a sledgehammer to crack a nut, they say.

But many of the people who pontificate about research misconduct, don't see this problem at the grass roots. Editors have been vociferous about it because we see it. And much of it remains unresolved because we have limited powers.

Banerjee's case took over a decade to be resolved. There was an internal inquiry and no action was taken. This case should make us ashamed. It took an external whistleblower to make it happen.

At the centre of it all is integrity or honesty. And there's a spectrum of misconduct, from minor offences which encompass errors of judgment or poor design, to misdemeanours which leave out inconvenient data, right through to fraud and fabrication.

As far as publications are concerned, there are author disputes, dual submissions, and salami publishing, through to reviewers and editors with conflict of interest, who breach confidentiality. But how frequent are the serious offences? Do misdemeanours at the “safe” end of the spectrum lead to serious fraud? We don't know the answers. We have no database, no repository of information.

Stephen Lock first asked the question as to whether it existed in 1988 in the *BMJ*. The Office of Research Integrity in the US published its report for 1993–97 detailing more than 150 cases of fraud. In addition, there were more than 1000 allegations where no action was taken because of inadequate primary evidence or a mischievous whistleblower.

The Royal College of Physicians' report in 1991 states that there is no reason to believe the problem is rife, but there are no data on its prevalence. That was 10 years ago. I believe it is now time for Britain to follow the example of the ORI.

It is true there have been some efforts to tackle the problem. The Wellcome Trust will not fund grant applicants unless they sign up to their guidelines. But last year Sir Richard Peto said that he felt a national body would do more harm than good.

Peter Wilmshurst catalogued some cases of misconduct from 1988 to 1997 in *The Code of Silence in The Lancet*. It was not a reassuring picture. And COPE is the only repository of information on cases of research misconduct other than the GMC.

There was a potential turning point at the Edinburgh

Consensus Conference in 1999, which concluded that action was needed to establish a national panel, and a blueprint has been produced by the Royal College of Physicians of Edinburgh. But the Americans established their panel in 1989, renamed in 1992. The Fins, the Danes, the Norwegian, Swedes, the Germans, and most recently, the French, have all established national panels.

A sample of Dundee students reported in the *BMJ* earlier this year showed that almost a third of them had written up in the case notes that the CNS was normal when they had not undertaken this investigation. We have to send a powerful signal to the medical profession that dishonesty is totally unacceptable.

The struggle that Pappworth had to set up ethics research committees in the UK is similar to what we are going through now. The response from some senior doctors at that time would now be considered deplorable.

Professor Sir George Alberti, President of the Royal College of Physicians

Is this a real problem or a witch-hunt? Let's step back a pace and ask: who is responsible? Why is there a problem?

It is human nature to be dishonest. People are honest unless put under pressure. And editors are the prime culprits. They love dramatic stories. They want press releases and to up their citation index. So authors produce them.

Solid, boring, negative result studies won't get published, they know. So they tweak them. Professor Farthing complains about salami publishing, but what about all those letters from editors saying that the manuscript is too long?

And then there's the Research Assessment Exercise which requires many publications, and in high impact factor journals. And there's the pharmaceutical industry offering easy money, grants and trips.

And what about egos, ambition, and prizes? Look at exclusive institutions like the Royal Society. And people get destroyed by not winning the Nobel Prize. Let's tackle these first. Let's get rid of this exclusivity.

The assumption is that nothing has been done, yet Michael gave a good account of what has been done. There's a big emphasis on training and an immense amount has been done at the educational level. The NHS R&D programme has published a massive document on research governance. Scottish colleagues have proposed a council, so something is happening. This motion would have been a lot more credible five years ago.

Over the past few years this country has had a knee-jerk reaction. One case in the media and a new gestapo is set up to deal with it. Yet another surveillance body will put people off, and most people are doing research in their spare time so we shouldn't be discouraging them.

Peter Wilmshurst, Consultant Cardiologist, Royal Shrewsbury Hospital

I agree with Professor Alberti's quote in *Hospital Doctor* in which he said that current standards for dealing with research misconduct were "shambolic" and there was a lack of clear guidance on what to do.

I have blown the whistle. I was the person who reported Banerjee and Peters to the GMC because I was dismayed that they had not already been reported.

In that case we know that three colleagues refused to be coauthors on their work because they had no recollection of it having taken place. Seven colleagues complained to Peters that Banerjee was fabricating data. When confronted with the evidence, Banerjee was forced to admit some fabrication in 1990.

An internal inquiry in 1991 concluded that much of Banerjee's research data were at best unreliable "and in many cases spurious." But the documentary evidence was shredded and the whistleblowers threatened. The funding bodies were neither informed nor refunded their grant monies.

A thesis on the same research was submitted to the University of London, but despite being alerted by a whistleblower to the fabricated research, Banerjee was still awarded a Master of Surgery degree.

He was also awarded a Hunterian Scholarship to present his falsified research at the Royal College of Surgeons, although senior fellows of the College knew of the doubts about its honesty.

When Banerjee resigned from King's he took with him a good reference. He received further research grants and published more papers. He became a consultant surgeon.

He was suspended seven months before his GMC hearing for unrelated serious allegations which included charges of dishonesty. Yet even while under investigation, he was nominated for Fellowship of two of the three UK Royal Colleges of Physicians.

Sir George was right. The current standards for dealing with research misconduct are shambolic. The institutions to which we look for guidance failed in this case, as in many others.

In 1986 I went to *The Guardian* about a pharmaceutical company doing unethical research. It had tried to bribe and pressurise investigators into altering data and had prematurely terminated trials with unfavourable trends. The GMC, the CSM, the ABPI, and various others all failed to take action. *The Guardian* published, and the company did not sue.

The MDU was consulted and they informed a senior physician at my hospital who pressurised me to drop the matter.

I subsequently reported concerns about other trials involving senior British cardiologists and cardiac surgeons, in which patient mortality data had been falsified.

Eventually my position became untenable. I was told

that if I didn't leave the hospital it would manufacture a reason for my dismissal.

However, the most serious threat to me came from the GMC, who investigated me for eight months for disparagement of an author who had published research. I was convinced that his research contained fraudulent data, and managed to persuade the editor of this. We reported the matter to the GMC, who received a counter charge from the author.

The GMC did not start to investigate this case until it had exonerated me, and it is still investigating my allegations some four years later. Is disparagement of one doctor by another more serious than research misconduct? It seems that way. The GMC was used to intimidate a whistleblower.

I truly believe that Britain should be ashamed of its response to research fraud and take action at once.

Sir Donald Irvine, President of the GMC

In four or five years a lot has been done to reverse these trends. And I must pay tribute to Richards Smith and Horton for their joint editorials four years ago which led the GMC to take action.

We feel that honesty and integrity apply to all things that doctors do. Bad research damages the integrity of the profession. And it damages patients. The GMC has clearly set out sanctions. Since 1995 there have been 11 cases of serious professional misconduct; two have been suspended; eight erased from the register. The message is: you do it; you lose your licence to practise.

There is various guidance and many clinical guidelines in place, but clear explicit guidance is needed from the GMC. And after wide consultation, on Wednesday that will be in the public domain. It will leave people in no doubt about the link between conduct and registration.

But what do you do locally? And how do you deal with non-medical scientists. There is no really consistent approach.

In research the lessons and solutions are remarkably similar to clinical work. We back a national body. We want it to happen. But let's not confuse ourselves by saying that nothing has been happening. Standards will be out there on Wednesday. This motion is misplaced.

Comments from the floor

Stephen Evans, Medicines Control Agency:

Peter Wilmshurst does make us ashamed. Are we going to take action?

Dr Sinclair, self professed "elderly physician":

I was chair of a research ethics committee in a teaching hospital for several years. It's the local committee that looks at research very carefully. They should be on the ground in each institution. Local people all know.

Mrs Jean Robinson, Occupational and Environmental Diseases Association, Enfield:

Allow patients/research subjects to get involved. They want to see original research protocols and they are always refused, because they are told it's confidential.

The ethics committees are told what the researchers are going to do, not what took place.

Richard Smith commented that editors support calls to publish research protocols. It was pointed out that the GMC paper does give patients the right to get involved.

Mrs Robinson continued: How do we get a central body? We do need one. We should hold the institutions to account and ensure that they have proper provisions. It can't be the GMC because that excludes non-medical researchers. Could it be the government, the Wellcome Trust or the Academy of Medical Sciences? Someone needs to volunteer.

Frank Wells, MedicoLegal Investigations, Ltd, Knebworth:

The government must be involved. It is not right that pharmaceutical companies have to rely on commercial bodies such as us.

The University of Oklahoma had a research unit shut down by the OHRP. This is what we can, and should do, here. I urge the Physicians and all other royal colleges to meet with the government to take this forward.

Dr Marks, London:

The real failure is not to investigate the cases of people who have been "pressurised" to do harm.

Roger Goss, Patient Concern, London:

In the end it doesn't matter how trust is breached. The end result is always a nibbling away at public trust in medical mores. We should support [the motion]. Anything less is an insult to anyone suffering as a result of any kind of fraud.

Professor Roy Pounder, Royal Free Hospital:

The MRC and the Wellcome Trust don't appear to audit anything they commission. And they should do.

Dr Richard Tiner, ABPI, London:

We do audit clinical research. Those who don't as rigorously as pharmaceutical companies may have to address that.

Summing up:

Professor Alberti said that there was a need for training, but patient involvement was already happening in some places. There was a need to re-emphasise that things have been happening, even if this was only recent.

He had received an endorsement from Sir John

Pattison, head of NHS Research & Development, who also said that he would be happy to facilitate a discussion.

There needed to be local mechanisms for training, he said. "I feel enormously strongly about having mechanisms in place, but not setting up a major investigative organisation because that will put people off."

Professor Farthing agreed that things had changed but "too little too late." He reiterated that education was at the heart of all this. But he was utterly dissatisfied with the lack of protection for whistleblowers. Editors were targets for them, he said, because it was unsafe for a whistleblower to report his or her own institution. Internal reports were buried, he said.

Many local enquiries were carried out by people too inexperienced—because they did not see enough cases—to be carried out competently, he added.

"Things have been moving towards a universal agreement about the need for a national body, but they have been hampered by institutional rivalry." The royal colleges had provided different responses, and the Academy of Medical Sciences was only interested in education, he said.

Leadership should come from within higher education and NHS institutions, the major employers. An independent leader was needed.

A show of hands indicated that the motion was carried and that some doubters had been won over.