

Setting the scene

Stephen Lock

Editor of the *BMJ* 1975–91

What is the scene? It's a wasteland. After 20 years Britain has got nowhere.

The clear signs are that we are not yet going to get the national body which other countries have had for years, and which our medical grandees have continually promised us.

One of the reports that Michael Farthing did not mention is the one produced by the Royal College of Physicians in 1991, which is perhaps one of the most buried reports the College has ever produced.¹ No one has ever heard of it, and those with the responsibility for implementing its recommendations were not told about it.

We've had undertakings from the Royal College of Physicians of Edinburgh. And we've had similar words from the Academy of Medical Sciences. But nothing has been done.

Yet the mission statements of these various bodies reveal a dedication to upholding standards of good practice.

The Royal College of Physicians says that for over 450 years it has played a pivotal role in maintaining standards of medical practice in hospitals throughout England, Wales, and Northern Ireland.

The Edinburgh College speaks of promoting the highest standards of internal medicine throughout the world. The Academy of Medical Sciences states that it campaigns for better structures and support for the medical sciences. It promotes excellence in research, provides scientific advice, and encourages better communication of science.

Surely all these mission statements mean that none of the bodies involved can escape responsibility for the management of reported cases and the prevention of research misconduct?

We've tried argument, and it's failed. Why are we so far behind the rest of the civilised world? Only recently the French voted to set up a central committee. Italy has one. We stand alone.

Inaction has its roots in history

What can history tell us? We've got a tradition in this country of following the practice of *dolce fa niente*. As a nation we are the masters of preferring talk to action.

Many of the advances in every day life have taken scores, if not hundreds, of years to come about. When the Royal Society was formed in 1660 it owned slaves. Twenty years later in Philadelphia, an anti slavery movement began. But it took us another 110 years. And it wasn't until 1834 that slavery was finally abolished in this country.

The smoking chimneys of London had been an

issue since King James. But only the Great Smog in 1952 prompted the Clear Air Act.

We had four major cholera outbreaks in England in the 1800s. The Thames was known to be an open sewer, but it took the Great Stink in 1858, which stopped parliament sitting, to provide us with the sewerage we needed.

This trend continues today. Where is the Freedom of Information Act that we've been promised? What about the reform of the House of Lords? Cross Rail, the underground line that was going to link Paddington with Liverpool St, was first talked about in 1912. The first mention of any medical academy was in 1942.

The arrogance of power

Why as a nation are we so slow to follow international, proven agreed reforms? The answer is a fundamental smugness and complacency as a nation, which dates back to our imperial past.

Today politicians often say: "After all I think it's generally acknowledged that we've got the best army/transport system/ health service/ teaching profession/financial regulation in the world." These assertions are not based on proper evidence or data.

Similarly, some people still believe that misconduct doesn't occur in Britain. Or if it does, it's the domain of single handed general practitioners or just a bit of noise in the system.

Much more serious is what Senator William Fulbright called "the arrogance of power." That's to say that people whom we elect as our leaders, whether in politics or in medicine, come to believe that they can act totally independently of general opinion or logical argument.

We've never seen this so cogently as in the recent debacle in Iraq and the Hutton Inquiry. And in medicine, 20 or 30 years ago, we saw it in the debate over the need for research ethics committees.

The good and the great from the Medical Research Council, the universities, the General Medical Council, continually pontificated that it was a God given right of the profession to police itself, despite the evidence of abuses.

We see the arrogance of power in the British medical grandees' approach to research misconduct. It's easy to understand why the glitterati are so reluctant to get their hands dirty. It involves a lot of work. It's a very negative activity. It may even involve friends.

In the past 10 years I have served on two major committees of inquiry. Both took an inordinately long time, not only to read all the documents and

background information, but also to hear the evidence.

Time is hard to find for already busy people. So we've got to have encouragement from our mandarins that taking part in these kinds of activity is an essential component of professional life.

Crucially, this activity needs to be based at a permanent central body. If a registrar sees his or her boss spiking tubes, who does s/he call? We need a central repository of experience and legal expertise that is truly independent.

If we fail to put one in place, we will be condemned to perpetuate this dishonest and unethical practice, let alone remain the laughing stock of the world.

What do we need to make progress?

Firstly, we need a major scandal in the public domain, probably some deaths, and a lot of money lost, as a direct result of research misconduct. Extensive media coverage would put great pressure on the grandees to do something about it.

Secondly, we need a charismatic leader to convince his or her colleagues to take action—the equivalent of a medical Nelson Mandela. But Mandelas are short on the ground politically and medically.

Jim Petrie, president of the Edinburgh College of Physicians, was one such Mandela. As a professor of clinical pharmacology, he knew of several egregious cases of research misconduct both in academia and the industry, some of which were in the public domain.

Unfortunately, many people simply don't have any idea of what is going on. We need to gather some data, because one of the arguments opponents use is too much effort for too little return. But as a congressman pointed out in the US Congress, you don't ask how many bank raids there are in a small mid western town before you set up a police force.

If every member of COPE were to ask half a dozen colleagues, including the deans and heads of departments, of their experience, we might get somewhere. We know that half the members of the profession know of a suspected or definite case of research misconduct.

COPE might well have to change its articles of association; rather more difficult would be the need to devise a proper, rigorous structured questionnaire and the ways of administering it. But, again, COPE has a lot of expertise among its membership, including methodologists, epidemiologists, and statisticians.

We have the Commission for Health Improvement. We have the National Institute for Clinical Excellence. And we have a proposal for editors to police themselves. Why can't we police research?

I would suggest that if we want to go forward, we adopt the Danish model, confine it to medicine, have a central resource, and that we publicise it widely.

But I come back to my analysis of British national characteristics. We have to remember in this country that we are subjects, not citizens and that the veneer of democracy over Britain's political elite is very thin. Britain elects fewer people to office than any other

democratic country.

The very words franchise and ballot are borrowed from France and Italy: voters are still treated as the enemy, as an unreliable, potentially explosive force somewhere beyond the pale. You just need to substitute voters for members of COPE, trying to do something about research misconduct and pit them against the grandees and the mandarins.

1 Royal College of Physicians of London. *Fraud and Misconduct in Medical Research*. London: RCP, 1991.

Comments

Who should be included?

Richard Smith, editor *BMJ*: Physicists think that physics is an international business as far as research misconduct is concerned rather than focusing on individuals. Should COPE do this as well?

Stephen Lock: "In 50 years' time, perhaps. But it's better to start small, and with one discipline. And we ought to follow the example of the Danes, who despite never having had a case, were willing to consider the possibility and looked to the experience in the US, Canada, and Australia.

The following year they were prepared when an egregious case of misconduct occurred. Ten years later, they included disciplines other than biomedicine. Until there is something in place that can handle one discipline it is inadvisable to start with several."

There was some discussion about how to define biomedicine and therefore whom to include—laboratory technologists, for example, who are not disciplined by the GMC, but who have their own disciplinary bodies.

It was pointed out that the Medical Research Council covers both clinical and non-clinical scientists in their guidance for grants, and the National Institutes of Health includes medical and non-medically qualified researchers.

Who censors research?

Iain Chalmers, editor *James Lind Library*: "All trials given the go ahead should be registered at inception. It is quite possible that people have died because of the failure to publish disappointing results. That's an issue that is frequently overlooked."

Stephen Lock: "We used to wonder at the *BMJ* who was censoring the non-appearance of negative reports. Was it the authors? Or was it the editors? It seemed to be the authors, who felt that editors would not want these papers."

It was pointed out that pharmaceutical companies know the viability of a product relies on accurate and honest research.

Stephen Lock said this was taking far too much for granted. "We might have the best system in the world, but I don't think we have the data to prove it." He commended the industry for its good clinical practice guidelines. "In some way it has led the way. But there is still an awful lot left to do, which is why we are here today."

Peter Wilmshurst, consultant cardiologist, Royal Shrewsbury Hospital: “I have given up replicating studies in cardiology, [with less convincing results than the originals,] because when I submitted them to the original journals, they always refused to publish, even though the studies were larger than the original publication.”

Where will the leadership come from?

Michael Farthing reflected that perhaps it had been a mistake not to nominate a leader/body to take forward the recommendations at the end of the 1999 consensus meeting. The stakeholders agreed to meet, but no one was given ultimate responsibility to pull everything together, he said.

He felt the employers, should take the lead, because they inevitably ended up investigating most allegations of research misconduct.

Stephen Lock wanted to know where the impetus for all the NHS bodies, such as the National Institute of Clinical Excellence (NICE) and the Commission for Health Improvement (CHI) had come from.

John Pattison, Director, NHS R&D: “I think we have to ask ourselves: What is the body or coalition of bodies that could actually push it forward? This will not just happen by itself. The idea for CHI/CHAI had tremendous ministerial backing. That’s how most of the NHS bodies have come into being.”

He added that employers and universities are not sure if they should look to the Department for Education and Skills or the Department of Health.

It was suggested that perhaps research fraud might come under the aegis of the Department of Health’s prescription fraud sector or the business group for standards and quality headed up by the Chief Medical Officer.