

Experience in the USA

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I stopped being interested in research misconduct six years ago when I stepped down from a commission established by the US government to look into this. The fact is that in the United States the whole business of research misconduct is old, boring, and above all, routine.

I'm not here to tell you that you should adopt the US system. But what you should aim for is something that is routine. For example, if there is an allegation of theft, the administrators of the institution don't have to scurry around trying to invent a wheel that deals with theft. There is a whole system: police, magistrates, lawyers, courts, prisons and so on. There is a routine for dealing with theft and what you should aim for is a routine for dealing with allegations of misconduct.

In the States there has been almost no media coverage since this became routine. And I suspect you will hear exactly the same has happened in Scandinavia. It has become routine; people have moved on. That is one very good reason for doing something because the handling of misconduct in the UK is not routine. It is very clear that dealing with misconduct here is very unroutine and everybody has their own ideas about it.

Why should editors be involved?

I used to be the deputy editor of the *New England Journal of Medicine* and within a very short time I saw gross cases of scientific misconduct coming in, and allegations of completely plagiarised or false research. Like everybody else I couldn't believe it could happen. And then I watched all sorts of officials and senior academics falling over themselves, bumping into each other in the dark, and so on, as they fouled things up. And the media had a field day with every eruption that occurred. And that is more or less what is happening here now in the UK.

Editors see it because when work is submitted to a journal it is the first time that work is fully outside the institution, and the allegations start coming in when it is published.

The role of government

Politicians got involved early: there were 13 separate congressional hearings on this, the first of which was started by Al Gore when he was a congressman. He poured scorn on senior members of the scientific establishment who were adamant that it was very rare while case after case after case appeared in the newspapers. Eventually the American Association for the

Advancement of Science, an umbrella organisation for all scientists, got together with the American Bar Association, among others, and held a series of meetings.

And this was justified not in moral terms; it was justified by "following the money." Most of the money for research, certainly in biomedicine, comes from the government: the National Institutes of Health (NIH) and the National Science Foundation. The NIH dish out about US\$25 billion a year, the National Science Foundation about \$7-8 billion.

What the congressmen said was that the government had every right to come in to every institution that had signed a contract with it, and if anything other than good research was being done, it would want to know why. The Office for Scientific Integrity was set up in 1989. It came up with a definition for research misconduct, which is the single most important thing you should do first. Because you certainly can't accuse people of doing something wrong when you have not defined what is right and what is wrong.

So first of all there came a definition: fabrication, falsification and plagiarism and other conduct, which is spectacularly out of line and deliberate, and a process was decreed. And numerous cases were tried, and I mean tried, because very soon lawyers got involved. And the lawyers rapidly started showing scientists that we didn't know about things like standards of evidence. Were we talking about reasonable doubt as you see in a murder case or were we talking about a preponderance of the evidence? What was to be the standard of proof?

The definition and process were slightly modified and expanded to include more and more disciplines, and then this last November both were applied to encompass all science so that a mathematician, an astronomer, a clinical researcher—everybody—would be covered by the same rules. No exceptions at all. They had to abide by the definitions and they had to abide by the process. And the process was as follows: an initial enquiry; then a full investigation; then a report to the Office of Research Integrity, as it subsequently became, and so on, and built into that was an appeals process.

The government process became *de facto* what everybody abided by in their institution. Everybody is now governed by the same rules in the United States, if their institution gets any government money at all. And since there isn't a single institution in the United States that doesn't get some government money, it's the same for everybody.

The commission I sat on in 1994 and 1995, set up

by the public health service, held 15 meetings all over the country, and interviewed about 300 to 400 people in public. We made all sorts of suggestions, including ones for the protection of whistleblowers. Those were rejected almost entirely by the scientific community, which does not, I can assure you, want whistleblowers to be protected. They said there was sufficient protection already. But there aren't.

So the system, good and bad, in the United States, is built on a huge experience, with reports published every year. Everything is done at the institutional level, which reports to the government. Why is there that reporting? Because you can't trust professional bodies to self-regulate.

It is the same with all of us—All the advantages of a profession without the responsibilities is what we most like about being in a profession.

If there is an allegation of theft, the administrators of the institution don't have to scurry around trying to invent a wheel that deals with theft. There is a whole system: police, magistrates, lawyers, courts, prisons and so on. There is a routine for dealing with theft and what you should aim for is a routine for dealing with allegations of misconduct.

How should a national panel work?

What you have to ask about a proposed national panel for research integrity is: does it have a clear workable definition? The Edinburgh definition is a joke in that it includes conduct that is both intentional and unintentional. If you leave your thesis on a train by mistake, or some of the data fall into a canal and you leave them out, is that intentional? No. Is it a case of misconduct? Clearly not.

Next you need to ask, does it have a clear workable process? Who do you phone if you've got a problem? Who deals with the appeals all the way through? Who does the initial investigation? How do you keep

conflict of interest out of the panels that deal with this? Who are those panels? Do they include external people? Are they just experts in the field, or what?

To make the process stick, you have to involve all the stakeholders. Otherwise you'll find that three of your researchers are covered by your regulations and the fourth isn't, and you'll have a shambles on your hands. People really have to buy into this. And by that I mean everyone really has got to feel that this is worth while.

Then you have to ask yourselves: is it legal? The process must satisfy legal standards, and here we have to be extremely humble because we have a lot to learn about the law and we will find that most things that we suggest are illegal, improper, and unfair. The law has had a lot of practise at dealing with just this sort of thing, so it is worth listening to.

Forget the causes. No one has a clue about the causes of research misconduct. For example, the "pressure to publish" argument is a nonsense. The papers on this all show that the cause isn't the pressure to publish, although people keep talking about it. And indeed there are several examples, starting with John Long in 1978, who pleaded this, but once found guilty, said that he had said it only to get a lighter sentence.

Why do we have any regulations at all? Public trust in research: that's the single most important one. But there are others. There's preserving the research record, getting all the retractions; accounting for the money, to which I will return; and preventing these embarrassing explosions in the press.

Restoring morale is enormously important, as the few cases of misconduct that occur are very destructive to morale, especially to those whom they involve. A lot of (particularly young) people will get out of the business altogether when they see bad people getting away with murder. Doing the thing speedily is also very important: justice delayed is no justice at all. Trying to stop the destruction of two careers by protecting the whistleblower is also critical.

All of this may be pre-empted by the Wellcome Trust. About 20 per cent of research institutions are funded by the Wellcome Trust, which isn't nearly as much as the US government, but the "following the money" principle is the same. The Wellcome system is a pretty good system, with definitions and process all defined, requiring both institution and researcher to sign on before the money is allocated. My bet is that this will become the general standard in just the same way that the government money forced the general standard in the US. So it may be that the bold action of the Wellcome Trust may force the issue.