

## Plans for a UK national panel

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Is there a problem? I think we wouldn't be here if there weren't. So the question is, what is the extent of it? There have been small numbers of highly publicised cases and increasing numbers of cases coming through the Association of British Pharmaceutical Industries (ABPI) who have been particularly active in this area. And there is a suspicion that it is a common problem, with pressure to publish, and so forth.

But we really do not know how common it is and I think that is one of the difficulties we face. My feeling is that minor misconduct, rather than fraud, is probably very common, and often unintentional because of poor training.

### Definition of fraud

So how do we actually define it? The answer is, with difficulty. But there have been several attempts. In 1991 the Royal College of Physicians defined it as piracy, plagiarism and fraud; alternatively, theft, fabrication and destruction. These are nice punchy definitions but with very little actual meaning when you examine them more closely.

The Medical Research Council (MRC) definition of not so very long ago, which was developed at the GMC under my chairmanship, was fabrication, falsification, plagiarism or deception in proposing, carrying out, or reporting results of research, and deliberate, dangerous or negligent deviations from accepted practices in carrying out research.

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It then goes on to say failure to follow established protocols and facilitating of misconduct in research by collusion in, or collusion of, such actions by others. It also includes intentional, unauthorised removal of, or damage to, research related property of another person. It includes apparatus, materials, writings, data and so forth, or any other substances or devices used in, or produced by, the conduct of research.

If we explore our experience, many of us can come up with a series of examples of probably most of these. The definition does not, however, include honest error, or honest differences in the design, execution, interpretation or judgment in evaluating research methods or results, or misconduct unrelated to the research process. The difference between misconduct and research misconduct is very important and needs to be clear. The other very important issue is plain old crummy research, which is also not included.

An aspect of publication misconduct, which doesn't come to COPE's attention so much, is failure to publish. And that may be driven by industry. It is often driven by sloth. Just how far back can you go? But undeclared conflicts of interest, inappropriate authorship, deliberate delays of competing manuscripts, false criticism, bogus data etc, are some of the many aspects of publication misconduct.

What are the causes of all of this? Professor Farthing says that it is human nature. Ambition plays a part in it. Competitiveness plays a part when it comes to minor fraud and actually major fraud too. And laziness: it is a lot easier to add a few extra numbers when you can't be bothered to do the experiments. Ignorance comes into it as well, as does failure of good supervision. And that is partly induced by the current health system where clinical academics are so busy that they no longer sit down and go through raw data with their research students.

### What is being done to combat it?

What has been done recently? A lot of people have been urging vociferously for action to be taken, but really quite a lot has been going on. The MRC issued a series of guidelines, as did COPE which has been very, very proactive in this regard. Our own report is due out shortly and the GMC has produced good practice in research guidance.

NAPAG (National Association of Professional and Academic Groups: British Academy, Royal Society, the Academy of Medical Sciences, Academy of Medical Royal Colleges and Engineers) have come to a full stop after their coordinating group decided about three years ago to tackle fraud, covering not just biomedical research. Then we have the recent joint consensus conference, the paper that has just appeared from the two Scottish colleges and the faculty of pharmaceutical medicine. The *BMJ* and *The Lancet* have also had leaders on the subject. So there is a lot of will for something to be done now; we just need to get on and do it.

What are the actions we could all be doing to minimise the problem? There is prevention, which is terribly important, and monitoring of research, with each institution having a dedicated policy. When The Royal College of Physicians surveyed the medical schools, less than half had any sort of plan. And these ranged from a 24 page document to one paragraph in the university statutes somewhere, although the situation has improved over the past three years. You need good local and national investigative procedures and we contend that you also need a national panel to coordinate all of this.

On the prevention side I think we need much, much better training, and this really hasn't happened. The supervisors or mentors need training in research supervision. It is just assumed that when you get to the point of being a lecturer or you have a new research student that you know how to do it. The new researcher needs formal training and proper supervision.

I am not sure you can ever get properly informed consent in clinical research. You can certainly tell patients or subjects what is going on, but whether they understand it is quite a different matter.

## The role of institutions

What about the institutional side? I think we need to have proper systems in place, with written guidelines, spot checks, and a senior named officer. I am not just talking here about teaching hospitals or medical schools and universities; I am talking about the entire community in which research takes place. A lot of the problems in the past, for example, in primary care research, have arisen because no one is really in charge, no one is really trying to help people do good research.

You need clear institution guidelines and this is where a central panel can help achieve some uniformity of approach. We have suggested in our own college report that there should be nominated screeners at each level. For example, a department of child health would have its nominated screener who would be the first port of call if there were a hint of a problem. They would then refer to a more senior institutional panel if they thought there was a case to answer. And they in turn would then call in external advice if it was found to be serious and could not be dealt with locally.

It is a stepwise approach, but every institution needs this sort of thing in place, and very, very few have at this time. It begins with a nominated individual, who invites a detailed written statement from the complainant. They decide whether it is justified, or if uncertain, they refer to the panel. The person about whom the complaint is being made is informed and then either the senior officers of the institution are informed and call for external advice, or the matter is reported to the GMC, or local action is taken. This is

what was outlined in the 1991 RCP report and I don't think that it necessarily has changed very much. It is just a pity that nothing has happened in the past 10 years.

## Format of a national panel

There is a lack of consistency in approach; there is no major coordinating source of advice; and there is a lack of coordination, overall, so I think there is a very strong case for a national panel.

What should its role be? The following are the sorts of things that we have suggested in our own report and which are not dissimilar to the very good Edinburgh statement:

- producing and revising guidelines;
- advising institutions on prevention and detection;
- coordinating advice from the many other bodies who are involved.

It is very important to provide a list of people who could go on rapid response teams. That will require training; it is real work, but without that a national panel becomes yet another talking shop. This panel could also keep a simple record of what is going on and produce annual reports, etc.

What I have called the Scottish model comes out of the Edinburgh report. This emphasises the education of researchers and supervisors, the development and maintenance of standards and audit, with a coordinating function for allegations or suspicion of misconduct.

What about membership? We suggested representatives from the major bodies, people from the legal profession and pharmaceutical industry who are very important players here; the Human Genetics Commission because a lot of things revolve and will increasingly revolve around the genetics arena; government/NHS and patient associations.

After consultation the government should nominate an individual to lead the panel, who must nevertheless be independent of government. The issue affects not just the NHS, but universities as well. We have got enough "hit teams" emanating from the Department of Health so I think independence will be very, very important.

Accountability is a difficult issue. One suggestion has been that NHS Research and Development should be the accountable body, but research misconduct is an issue that goes beyond the NHS. Parliament, an independent quango, and the GMC have all been suggested, but again we are not just talking about medically qualified people on the register. The GMC may be a partner, but should not be the final accountable channel.

So my feeling is that it should be an independent quango, and that is the view of one or two people in government with whom I have discussed the matter. I believe we have an absolute need for a national panel to get our national act together to make sure that institutions behave sensibly, that whistleblowers are looked

after, be they mischievous or otherwise, and to train impartial experts, protect subjects and researchers.

To summarise by quoting from two of our organisers today, Richard Smith and Michael Farthing “While

our leaders are fiddling, the research enterprise may be starting to burn. Please, men and women in gowns, do something.” I think we should rise to that challenge now.