

## The Research Integrity Initiative: progress report

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The initiative is based on a NAPAG (National Academies Policy Analysis Group) inquiry. NAPAG is made up of four learned academies in this country: the Royal Society; the British Academy; the Royal Academy of Engineering; and the Academy of Medical Sciences.

The remit of NAPAG was to discuss:

- Fundamentals of good practice and definitions of research misconduct and fraud
- The scale of the problem
- Whether there are factors in the current organisation and funding of research that promote research misconduct
- Procedures for dealing with fraud and misconduct in the UK and elsewhere
- Proposals for improvements, if appropriate, in such areas as good practice and audit
- Perceptions and concerns among policy makers and the public
- Education and training
- Prevention
- Legal aspects and a code of practice

A full report was not published, but the proceedings can be obtained from the Academy.

### Definitions

There are no generally agreed definitions. The headings of fraud, deceit, and theft (Drenth, 1999) are probably a good place to start. The intent to deceive is probably essential for a definition of major misconduct.

But NAPAG felt that financial fraud is a separate issue. If invented patients are included in trials to obtain money, that's a clear case of commercial fraud and a matter for the criminal courts. No sophisticated education is needed to tell people not to do that.

We also felt that publication misdemeanours, such as gift authorship or publishing the same data in two papers, are best dealt with by the journals with whom contributors have contracts. Major theft of ideas is, of course, a different matter.

### Extent of the problem

We were not convinced that there were any reliable data on this point, and the reported incidence figures lack denominators. Effectively, we are dealing with anecdote.

In the Nordic countries, the feeling is that there are one or two cases per million of the population,

including all science and the humanities, of which 20 per cent are considered to be serious (Riis, 1999). Most of their investigations conclude that there was no basis to the allegations.

If these figures are applied to the UK, that would suggest a total of 60 to 100 cases every year (Riis, 1999), of which 12 to 20 would fall into the serious category.

It's worth comparing this with the data from the NHS Counter Fraud Directorate, which investigates financial malfeasance in the health sector. In 2001 they investigated 22 hospital doctors, 126 GPs, 35 dentists and 122 pharmacists (Hangartner, 2001). There is still more financial fraud than any other category, and British insurers suggest a considerable degree of minor misreporting.

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### Why is research fraud important?

Research fraud undermines the scientific enterprise and corrodes trust both among scientists and between scientists and the public. That is enormously important because science relies on credibility.

But it is quite unrealistic to believe that this trust culture can be replaced in any way at all by an accountability or audit culture. The scientific enterprise simply wouldn't work if people felt the need to check up on everything, and it would simply become corroded by suspicion and mistrust.

Second, it damages careers. Even allegations of fraud tend to ruin people's careers, and the damage can go on for decades whether the allegations are proved or not. They damage the careers of those against whom the allegations are made and they can also seriously damage the careers of the people making them. Malice may be behind some allegations.

Third, it's extremely costly—not just to investigate, but to go over all the science again and unbutton all the consequences of any fraud.

## What needs to be done?

We must promote high research standards by example and by teaching. There is no good evidence base on how this should be done, but it's not clear to me how giving graduate students courses in good research conduct is going to be much more helpful than having them work for supervisors whose own standards are high.

It's essential to establish the extent of the problem, as well as robust and fair procedures for dealing with allegations of misconduct. And the interests of whistleblowers and of those against whom allegations are made must be protected.

The Academy of Medical Sciences proposes to maintain a database of allegations and their outcomes and it will collect experiences with procedures, to provide robust guidelines for dealing with fraud and misconduct.

Guidelines written round a committee table, when subjected to the messiness of real life, often turn out to be inadequate and sometimes to do harm. This problem will not be solved by more experienced people devising even more guidelines, but by sharing experiences and explaining what did and didn't work. This will allow us to produce a template for proper procedures.

Finally, the Academy will provide employers with independent expert help in the early phase of an investigation, when impartial views from outside the institution are critical.

What it will not do is to police research conduct, or sit in judgement, or act as a national "fraud busting" committee. We have no doubt that the responsibility for investigating misconduct rests with the employer with whom the research worker has a contract. Unless there is a contract with the person under investigation there is very little that can be done except by a statutory body.

There is a further reason why a body such as the ORI wouldn't work in the UK: the patenting system. In America patents are issued on first discovery whereas in Europe they are issued on first filing, and as a consequence, the whole attitude to record keeping is entirely different.

In order to establish first discovery, a research notebook has to be signed off every evening. It must be in non-loose leaf format and information contained in it must not be altered. This is counter cultural to Europeans. No one does this except industries wishing to patent in the USA. Until we adopt this approach we won't have the kind of records on which the ORI depends.

## Proposals for the database

Information will be solicited from employers and other relevant bodies, such as the Royal Colleges, including those of nurses, midwives and vets, the GMC and journal editors. Information on the nature of the

allegation and the outcome will be essential.

The consent of parties involved will be sought, although exactly what will happen if it is refused is not clear. It will probably still be possible to obtain the data in anonymised form.

The database will have to be registered with the Information Registrar whose regulations will have to be followed. The database will be held on a secure computer that cannot be accessed from the web, with back-ups kept in a safe.

An anonymised annual report will be supplied to subscribers to the initiative.

## The template for good practice

We would like information from anyone who undertakes investigations. They can also choose to remain anonymous.

Experiences with existing guidelines will be distilled. Most of these are unenforceable because many of the actions they recommend are not written into employment contracts. Employers will therefore have to be advised on what they should include in contracts to enforce good practice.

Most universities have not yet written into their contracts of employment clauses that give them the right to oblige people to hand over their research records.

Preliminary assessments are particularly difficult. They require robust and fair procedures that adhere to rules of evidence, right to representation, and conflict of interest, although we do not envisage the need for lawyers.

The consent of the parties to be investigated will normally be required. We will have to see how often this is refused. If those involved can't agree whether the Academy should be involved in this, they may have to leave it to their employer.

The assessors are legally required to be competent, to act in good faith, and to have no conflict of interest. They may therefore need training and they might need a contractual relationship with the Academy to ensure this.

The Academy itself will need insurance or indemnity from employers against any possible legal actions, probably the former. And the output will be limited to a report to the employer, with the conclusions restricted to what can be drawn from the evidence available to the panel, and nothing more.

The details will need to be drawn up by a lawyer and we will have to persuade the Council of the Academy to go along with it.

It was suggested that we should provide a conduit for whistleblowers, but we have decided against this following discussions with Public Concern at Work, which has long and considerable experience of dealing with whistleblowers.

## How it will be run—probably

I say probably because there are several contingencies that have to be met. We will probably recruit a management board to run the initiative, including a lawyer and experts in relevant areas.

It is absolutely dependent on the NHS, universities, and others employing research workers subscribing to the initiative, because funds are required to run it. Whether the major research charities or journals wish to sign up, has not yet been explored.

We haven't yet worked out the budget sufficiently carefully to propose subscription costs, which will, of course, depend on how many people come on board. HEFCE, the NHS Research and Development Directorate, and the GMC have already contributed funds towards the costs of setting up the initiative.

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## “COPEing” with misconduct

Some journals are sometimes part of the problem rather than part of the solution.

- 1 Editorial triage is practised by journals that consider themselves to be very popular. This is not peer review in any sense of the word and actually subverts the process. It has undesirable effects on the research enterprise because it focuses effort on what the journals think will appeal to popular interest. How the triage is done is often not clear.
- 2 Editors don't always keep to COPE guidelines. One of these is that papers should be published only for their scientific merit, and not to attract media attention and raise impact factors. Several popular journals have published papers, which they know to be wrong.
- 3 COPE states that all significant contributors should agree to publication, nevertheless there was a notable case in the *Lancet*, which published a paper despite the editor having received a letter from a major contributor disassociating himself from the work.
- 4 Publication bias against negative findings certainly still exists. And there is an obsession with bibliometrics, which has done no favours to science at all. The whole business of citation indices and impact factors is corrupting. The fact that people judge work on where it is published rather than on what the paper says is highly damaging.

The media has a dangerous obsession with maverick science, illustrated by the following examples.

- Jacques Benevise's theory of extreme dilution and memory in water to explain homeopathy
- Peter Duesberg's studies on HIV not causing AIDS
- Alan Ebringer's assertion that bovine spongiform encephalopathy is an automimmune disease and therefore not contagious
- Arpad Pusztai's research that genetically modified potatoes poison rats
- Andrew Wakefield's study showing that MMR gives rise to autism and colitis.

## Discussion

How should editors bring out controversies was the first topic for discussion.

Sir Peter was clear that peer reviewed publication in the scientific press was not the way to do it. “If people wish to have meetings about controversies, that's fine, but to publish something in what is considered to be a reputable journal gives it to the public prematurely which is damaging.”

The publication of the Pusztai paper in the *Lancet* was followed by comments that if it was published in the *Lancet*, the editors must believe it to be true, he said.

But truly innovative science is almost always controversial, countered Richard Smith. “Are you saying that if it's controversial it should not be published?” he asked.

Sir Peter agreed with the COPE guidelines. If it is of scientific merit, it should be published whether it's controversial or not, he said. But this was different from publishing material that was known to be untrue and where there were obvious flaws in the science, the statistics were wrong, and there were no controls, etc.

One of the ways in which patients get information is from conference abstracts and proceedings which are not peer reviewed. Should we steer clear of this, suggested another delegate?

More and more publications will be put on the web without peer review. Some scientific groups communicated in networks on the web all the time, responded Sir Peter.

He added that he had once surveyed the content of FASEB abstracts, and found that a substantial proportion never reached the literature. “It's people publicising preliminary results which they hope turn out to be true and which establish priority, but which, if they don't work out, then disappear. Anyone can write exciting sounding abstracts, but the data don't always stand up.”

Sir Peter was asked if was right that publication conferred a standard or stamp of approval to a piece of work, in the scientific community and if not, then how should work be judged?

Publication was essential, he said. “It doesn’t matter where it’s published as long as it’s peer reviewed. Since citation indices came in, and to avoid having to read the work, people assume that a history of appearing in high impact journals means that the work must be good. Scientific papers are meant to be read, not to be counted.”

Richard Smith wanted to know if Sir Peter agreed that scientific papers were not truth, but provisional truth? Many of them turned out ultimately to be wrong in some sense.

Yes, said Sir Peter, but in interpretation only. The data should be relied on. “You certainly don’t have to rely on how people interpret them. And that’s how science progresses.”

There was some discussion on the difficulties of improving the peer review process for journals with a low impact factor. Sir Peter felt that the society journals, which often fell into this category, had a peer review process that was probably as rigorous as any. This was because they expected to have all the technical information and were not being asked if the study was of interest to a general body of readers. It was also mentioned that *Nature* and the *Lancet* were considered to be better journals before the introduction of citation indices.

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Sir Peter disagreed with the assertion that the whole peer reviewed process was biased towards the best journals. He suggested that a retrospective review of different journals would not reveal any difference in the quality of referee reports.

Richard Smith felt that there was plenty of research showing what a deeply flawed inadequate process peer review is. But Sir Peter said: “Peer review is to science what democracy is to politics. It’s not the most efficient mechanism, but it’s the least corruptible.”

Michael Farthing suggested that without the numbers, researchers would still know what the hierarchy of journals was. “The only way to get rid of this is to abolish the journals and put everything up on PubMed Central and go through the laborious process of peer reviewing everything we read ourselves.”

He then went on to say that he doubted financial fraud was more common, but that it was easier to detect because it was audited both internally and externally. “The problem with research is that we have no audit process. Shouldn’t we be aspiring towards

much better record keeping and some sort of internal and external audit? Why is scientific research any different from financial probity?”

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Sir Peter said this went back to the difference between a trust and an audit culture. The case of Enron undermined the assumption that audit picked up fraud. “I’m sure the amount of undetected financial fraud is also quite high; there’s no reason to think it isn’t.”

“The disadvantages of substituting hyper-accountability and audit for the trust culture is a very high price to pay. You should look at the consequences this will have on the way that science is done just as it has had consequences on the way the health service is run.”

Michael Farthing countered: “We used to trust doctors, now we audit their practice.”

Sir Ian Kennedy pointed out that the Nordic countries and the UK were not comparable, in terms of the number of pharmaceutical companies and universities. He also said that the case of Enron demonstrated that if you had a system there would always be criminals. That’s the reason to have criminal law rather than to abandon the idea, he said.

Sir Peter agreed that the UK and the Nordic countries were not entirely comparable. In which case, responded Sir Ian, the notion that fraud misconduct was not common was unsustainable.

That was precisely why there was a need for a database, said Sir Peter. “My own view is that we have no satisfactory data. I personally suspect that serious fraud is uncommon. It exists, but since there are no denominators there is no way of establishing one way or another. But there is no reason to believe that the accounting and finance agencies are any better regulated than science is without them.”

He said that the engineers believed there was quite a lot of commercial fraud but that this was dealt with internally and never actually reached the public domain. In the other sciences, such as the hard physical sciences, fraud was also a feature, but because the research was much easier to replicate, it was probably easier to get found out. There was fraud in the humanities, too, but the general public didn’t take this seriously whereas research fraud was a disaster, he said.

A delegate pointed to the importance of impact factors are incredibly important, and the attendant pressure from funding bodies and institutes to publish in the top impact factor journals. Editorial boards

round the world thought about how to attract high quality authors to raise the impact factors, he said.

“You’re right, but it’s a tragedy and a corruption of science. And one should fight against it,” commented Sir Peter.

Tim Albert thought the Academy’s proposals to have a committee of eminent people, who have written many papers, to sort out a register in retrospect was a “very British solution. The world I inhabit is full of young researchers who are confused about what ethical standards are and get all kinds of conflicting messages,” he said. Were there any plans to inculcate proper ethical standards among these people?

Sir Peter said that some guidance was possible, but he disagreed with the assertion that confusion was rife. “I don’t think anyone has any real doubts about the ethical standards of science, and they should learn them from their supervisors. If there is a problem, then it will have to be addressed. When people fabricate data or falsify controls, they know what they are doing.”

Richard Smith was not convinced. When the next high profile scandal of fraud in biomedicine occurred, would Sir Peter be able to confidently say, ‘you really don’t need to worry, because the Academy has got a very well considered response to this and we’re on top of the problem?’

Sir Peter responded that the essential function of dealing with misconduct belonged to employers. The

Academy was there to help them sort things out. But Richard Smith suggested that this has always been the case, and there were plenty of examples of universities burying these problems.

Sir Peter said this used to be the case 30 years ago, but that the situation had improved. It was a case of seeing how the procedures worked and being patient. The answer was not to have a national fraud-busting committee that chased fraudsters.

“I don’t think it will work and it is deeply counter cultural in this country. I think the US examples are horrifying, and the examples in Scandinavia suggest that they are putting a great deal of effort into relatively little,” he said.

But Richard Smith wanted to know why the Academy took a different line on a national body from all the other members of the consensus panel in 1999, including the colleges, the GMC, the MRC, the Wellcome Trust and members of the public? Sir Peter said he believed the Academy’s view to be widely shared.

Sir Peter said that the Academy was already carrying out one investigation, to inform future procedure. Meetings with Universities UK and the NHS R&D Directorate were planned, after which final approval would be sought from the Academy Council. But he warned that if no one signed up to the scheme, it would die through lack of funds.