

## A view from the GMC

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The GMC was set up in 1858, and although its functions have been tinkered with, it may not be best placed to take a lead on how to deliver an entirely new organisation.

The GMC believes that the case has been made for an overarching body to deal independently with the investigation of research fraud and misconduct. The GMC has an important role, but it is partial.

The GMC was represented at the Edinburgh consensus conference and signed up to the joint statement. It has followed with interest the leaders and discussions in the pages of the *BMJ*, the *Lancet* and *Gut*.

There are plenty of international examples to draw on from Denmark, the US, and Australia, which we could use to find a model quite quickly. And we know that cases continue to emerge: the problem simply hasn't gone away.

There have been several meetings on the subject, and it is hard to escape the feeling of *déjà vu*.

We need to remind ourselves of continuing to talk rather than taking action. George Orwell put it eloquently when he described left wing academics in the 30s thus:

"Their words fall upon the facts like soft snow, blurring the outlines and covering up all the details."

### Where does research fraud fit in?

Sir Donald Irvine set up an independent working group in 1998 to look at how we might construct a more uniform system for the UK to investigate research fraud. Many discussions were held, and a report was written, but there was no consensus on the best way forward.

But from the ashes, the GMC produced its own guidance on the standards of good practice expected of doctors, which was published in January 2002. But this does not focus on misconduct.

The GMC's charitable purpose is the protection, promotion and maintenance of the health and safety of the community. The scope is enormous, and clearly has to be restricted.

The Medicines Act of 1983 sets out the GMC's functions. These include giving advice on standards of professional conduct and medical ethics and the right to take action against doctors who may not be fit to practise.

It would therefore not be appropriate for the GMC to say that wider issues of research misconduct were outside its remit. We can't take the view that we are simply responsible for registered doctors.

### Collaboration and partnership

The regulation of research is as complex as other aspects of health care, and one of the challenges we face is finding ways to weave together different burgeoning strands of activity. But we need to make sure that we support and help to provide an overall framework to promote good standards and ensure that research misconduct and fraud do not go undetected.

Our challenge is to work with others to ensure standards improve, complaints are dealt with promptly, and that we fulfil our unique function to deal with doctors whose conduct, health, or performance puts their registration at risk.

The GMC deals with referrals from a wide variety of sources, including employers, universities, and whistle blowers. It has been criticised for the slowness of its process and the narrowness of its approach.

These issues have been addressed over the past few years. The backlog of cases has now been eliminated, so long delays will no longer be the norm. The fitness to practice procedures are being reviewed in a bid to streamline and expedite the process. These reforms are due to be implemented by spring 2004.

The cases which come before the Professional Conduct Committee are, by their nature, the most serious kind. Since 2000, 16 cases of research misconduct have been heard. It is not always easy to define what falls into this category. These covered:

- Misappropriating research funds
- Failing to follow protocols
- Forging signatures of patients and co authors
- Falsifying data
- Failing to obtain patient consent for entry into clinical trials

The GMC is in a state of transition, with a new council of 35 since July of this year. The council would want to make sure that more regulation would lead to better regulation, that it would add value, and would want to know how it would be delivered.

We know that we can follow the models that have been introduced in other countries and we should get on with it. We should not delay until there is a catastrophe.

It's fairly obvious that there is now a familiar pattern in which a BSE, or a Shipman, or a Bristol has to occur before we do something. This does not seem a sensible or logical way of conducting our national affairs.

## What can the GMC do?

Our functions are defined by law and our relationships are primarily with doctors. Our powers are to take action where a doctor may not be fit to be registered. That clearly does not encompass all areas of misconduct.

The integrity of research is nevertheless key to our purpose of protecting and promoting the health of the community, and the new council is moving towards a more expansive view of how the GMC fulfils this.

The GMC welcomes the opportunity to engage with those at this seminar to work towards progressing this initiative.

## Proposal from Michael Farthing

I propose a joint working group to put together a proposal for consideration by the government.

Currently the investigation of allegations of research misconduct lies with employers, who in biomedicine are predominantly universities and the NHS. Both these parties need to be represented on the working group. But there are clearly other interested parties, such as the GMC and the Academy of Medical Sciences.

This working group will need as much advice and experience as possible and it should be able to co-opt others as it sees fit.

It should have an independent chair, and it might consider whether its remit should extend beyond biomedicine.

The proposal might refer to the consensus statement and consider that the Council for Research Integrity might:

- Advise on all aspects of the investigation of alleged cases of research misconduct and on how to prevent these from occurring
- Promote models of good practice and ensure that guidelines and procedures are consistently applied throughout the UK
- Assist, not drive, allegations of misconduct, providing external advisors to join local investigating committees. The Council might also be the place to which whistle blowers could take their concerns.
- Collect, collate, and publish information on cases: at the moment we know only about cases reaching the public domain, and it's very important that as a nation, we can begin to describe the scale of the problem

## Comments

### *Learning from history*

**Iain Chalmers:** reminded delegates of the importance of learning from history and the dangers of not getting the process right.

He referred to the botched investigation into alleged

research misconduct in North Staffordshire, including 16 enquiries, all of which had failed to find substantive evidence. The GMC was still investigating allegations of forged consent forms there, he said.

He contrasted the events in North Staffordshire with the case of the Kent gynaecologist Rodney Ledward, for whom a great deal of effort was made to collect evidence.

**Michael Farthing:** "That's an extremely important cautionary tale, and those of us who have acted as external enquirers, will know how processes across the universities differ enormously, and how they often lack robustness.

The quality of the investigations is often poor, as is the assessment of whether there is a prima facie case to answer. That is why we need a robust and consistent approach across the sector at that preliminary stage."

### *Should public funds be sought?*

There was some discussion as to whether this proposed body be publicly funded. Shouldn't there first be proof of the impact of research fraud on the public? Otherwise it would have to be led and funded by a professional body.

Michael Farthing agreed. "But I would attest that there is, and that the point has been made time and time again. What we have failed to do is to convince the government and the key stakeholders."

He felt a real glimmer of hope, however. "The universities are for the first time engaging in discussions on this issue, and the NHS is tackling its own research governance. The question is the huge interface between the universities and the NHS. Many of these incidents cross the sectors. A university employee with an honorary NHS contract could be doing fraudulent research on patients."

### *Should we lobby politicians?*

**Richard Smith** wanted to know if there were grounds for involving politicians, in view of the profession's singular failure to get anywhere with self regulation.

"The US Office of Research Integrity happened because of the efforts of John Dingell, a politician. As we have heard today, when a politician wakes up with an idea it happens, whereas as doctors spend 20 years talking about something and nothing happens."

**Stephen Lock** commented that solicitors had just lost their right to police themselves. But he warned: "We risk sophisticating this to an extraordinary extent. What about a national office managed by two experienced people that anyone can ring up for advice?"

He added: "I am extremely disappointed that the Academy is not prepared to take this on. This is one unifying part of the whole of medical sciences, and surely it should be their job."

### *Has the case been made?*

**Mary Manning** said that the Academy quickly realised it would be swamped and would be unable to do

anything else. “We recognised that we did not have many of the skills needed: the legal complexities of this task must not be underestimated.

The Academy believes that data need to be collected to indicate the scale of the problem to make the case.

We are not unsympathetic to the issue, but fundamentally, we believe that the employers have to make it happen.”

**John Pattison:** “The case is made, but only for those people who believe the case is made, and most people you want to influence do not believe the case is made. You have to make the case from all its perspectives. The international dimension and how far behind the UK is in the league is an important case to make.

Secondly, you have to corral all the influential people in organisations to say the same thing. That tends to capture people’s interest. If there is a problem to be addressed, ministers will address it when it is clear the case has been made and a lot of people are concerned about it and want something done.

Thirdly, the last thing universities want is more obligations. Of course, they already have the responsibility [for research misconduct] whether they like it or not. It’s like health and safety and animal research, for each of which a national body monitors, helps, and polices what the local employer and employees are doing. You need to bring that in as well.

You have a lot of work to do before you get to the virtuous tipping-point where someone is prepared to do something about it.”

**Michael Farthing:** “The case has not been made at that level, partly because major stakeholders have been pulling in different directions and have conflicting interests. Why would a vice chancellor want to admit that he has corrupt research staff and bring that out into the public domain?”

**John Pattison:** “Making the case is a substantial piece of work. But once done all the colleges, regulatory bodies, educational institutions and key individuals need to support the initiative. It won’t work if one institution leads it.

The universities are in a difficult position, and it’s clear that they don’t want to take on another obligation [as in clinical trials directive]. But there’s no way of avoiding that, as there is no way of avoiding this. A scandal will seriously damage somebody, and nobody wants to be in that position.

I am not sure it is as onerous as people imagine. People look at something new and configure the worst case scenario in terms of the responsibilities, risk, and liability involved. Yet it rarely works out like that. But it’s a considerable task is to convince them of that.”

**Peter Wilmschurst:** “The people with the greatest vested interest in concealing misconduct are the people who are being asked to set up this institution. The great and the guilty in medicine are those who have most reason to conceal it.”

**Gordon Murray, Royal College of Physicians of Edinburgh:** echoed the college’s frustration that so

little had been done, and endorsed the proposals.

He added: “A major theme of the consensus statement that is often forgotten is that research misconduct is much broader than research fraud. If our concern is about the contamination of the medical record, far more harm is done through incompetence than malicious fraud. There is a huge body of research undertaken by people who are not suitably trained or qualified to do it, and that should be part of the agenda for promoting good practice.”

### *The “dialogue of the deaf”*

**Ian Kennedy, shadow chair of the new Commission for Health Audit and Inspection:**

“The NHS is setting up certain processes, which are important but only part of the game.

There is a ‘dialogue of the deaf’ going on, and it’s been going on for some 20 years. The pragmatist must therefore seek a way through this, with concrete proposals. What COPE is now proposing is not a million miles away from what the Academy suggested last year.

We need sufficient time, commitment, and funding to ensure that this work can be carried out. Unless we bring the two groups together, we will still be here in 10 years’ time.”

He suggested persuading a variety of groups, including the government, to put up some money in a time limited manner to investigate, collect, and publish information, and work on models of good practice, looking at international comparisons and circumstances.

**Stephen Evans:** “One of the late Roger Robinson’s approaches was to examine a paper and decide on its ‘sledge hammer to nut ratio.’ Recent responses had been excessive, he argued. Simplicity would be best.

“But we must look to do things that have very wide benefit across the whole scientific community, which will then have collateral effects in the area of scientific misconduct.”

### *Mandatory archiving of data*

**Doug Altman, Cancer Research UK Medical Statistics Group:** “Misconduct is the tip of a large problem. We shouldn’t forget that we should see this as part of a general effort to improve the quality and relevance of research, and arguably reduce the body of it.”

But he said one of the factors hampering investigations was the lack of raw data and relevant documentation, the archiving of which should be mandatory for researchers. Employers should take on this responsibility, he said. There were also valid research reasons for the preservation of data.

“It seems to me unbelievable and completely unacceptable that people can do research using public money and yet throw away the data. We could consider a failure to keep the data as research misconduct.”

**Iain Chalmers** pointed out that the MRC had decided that the researchers they support should

archive their data. There was a working party convened by Peter Dukes looking into the practicalities, which were not inconsiderable, he said,

**David Katz, editor, *International Journal of Experimental Pathology*:** “In this kind of journal there are plenty of non-medical researchers, who may be as serious and fraudulent as clinicians. It’s whether we should start small with medicine or whether we should be going bigger that is one of the difficulties.

The GMC seems to be far more concerned with consent issues than with the actual research misconduct and collection of data, and I don’t see that they have taken on board in their regulations of the medical profession quite the same degree of emphasis as they place on the other.”

### *Taking responsibility*

**Marc Taylor:** “There’s a clear view in the NHS arrangements that a different job is required in different areas of collaboration between the NHS and its partners. People need to take responsibility for their own business rather than being threatened that someone else will take charge. We need to set clear standards and be quite public about what those are, as well as creating better mechanisms of feedback to see where in the system problems arise.

It’s important to decriminalise ‘near misses’ so as to encourage people to get out information about what might go wrong and not always have the mindset of whistle blowing. This makes it easier to own up to systems failures.

But at the same time we need to be much more vigorous about prosecuting cases that are clearly fraudulent. But that’s against a background, not of assuming that everyone is a criminal, but that you have systems, which remove temptation.”

### *Reaching the “tipping point”*

**John Pattison:** “We think the system is good, and we haven’t had the catastrophes like Bristol or Alder Hey. We haven’t got that tipping point. But eventually you reach a point where people you think have had vested interests in hiding things, actually realise that’s not appropriate. Otherwise why would we have CHAI and the NPSA? It’s not in the NHS’s vested interests to have either of these organisations.”

**Michael Farthing:** “Some of us here think there have already been enough high profile cases to suggest that we should have responded some years ago. Editors think there are many more that have not been ‘outed.’

There is unequivocal evidence that speed cameras work, despite the fact that we all hate them. And unless we have the equivalent in other areas, including research, we won’t have a major preventive intervention.”

**Ian Kennedy** felt this argument was flawed. “While we have no doubt that cars kill people and the evidence is there in A&E departments, what we hear countless times is that people don’t accept there’s a problem in research. We have to confront this belief and lack of concern, and persuade people. Your proposal is a way

forward, and all I would add is a time limit.”

**Richard Tiner, medical director of the Association of the British Pharmaceutical Industry** said that the number of incidents of serious research misconduct from member companies had definitely diminished over the past few months.

“It’s unlikely that member companies are picking these up with their standard operating procedures which most have introduced. The reason is that the research governance framework has had a very positive effect, because there are other people in the trust who are monitoring researchers’ activities. Of the cases referred to the GMC, 24 out of 26 were found guilty and there was no doubt that they were intent on serious misconduct.

Next year’s statutory requirement for clinical trial site inspections will inevitably throw up dubious practice. We are in discussions with the MHRA about how these can be investigated. And that’s one area where we really do need a national council, as cases not currently being picked up may be unearthed.

A body with investigatory powers will require huge amounts of resources. But there are various ways and means of fitting in with NHS systems and processes. This might be a more pragmatic and economical approach.”

### *Scope and costs*

**Jane O’Brien** wanted to know what level of fraud and misconduct might be expected for the UK’s number of doctors and population? Were there comparable data, and if not, should that be part of evidence collected?

**Michael Farthing** said there were good data from Europe, but little from the UK, because universities don’t report these. But he suggested that compared with Scandinavia, the numbers would be higher.

**Mary Manning:** “My instincts are to support a lot of the proposals. There are two possible sticking points: is this only about medicine or all scholarship? This is an issue for universities. When I raised the medical issues with them, their response was to ask what the Royal Society’s position was. This means that there are some very significant and powerful voices that have not yet been heard.”

The universities would not welcome attempts by the Department of Health to regulate them. Some of the NHS hasn’t taken on board sufficiently its role as a research employer.

The proposals from COPE are sensible and we would be prepared to join in with them, but on the understanding that we are joining in with a consensus that other people would support.

A police force does not operate without the people’s consent and it’s no good acting like an invading army of military police.”

### *Starting small and simple*

**Stephen Lock:** “I was both impressed and depressed by John Pattison’s statement about how far back we are. When I first went to the then president of the Royal

College of Physicians (Bill Hoffenburg) with my concerns, we concluded that data were needed. I undertook to write to every professor of surgery and medicine in the country. I received replies from all of them, indicating a large number of probable or definite cases of fraud, almost all of which have not been addressed.

If we are going to achieve anything, we have to keep it simple. The first thing COPE could do is to acquire some data. Let's draw on the expertise we have here to devise a good questionnaire and administer it."

**Michael Farthing** concluded the morning's proceedings. "There is a sound basis on which to move forward. We will see in a year's time how much we have achieved and whether we have gone any way to coming up with a firm proposal that a number of interested parties can sign up to.

I believe the evidence is there, but it is not always assembled in an easily digestible way. Stephen Lock's book provides plenty of evidence, and we should trawl through the European committees and their reports. And we may be able to get time trends from the GMC as well."