

A view from the General Medical Council

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This is not *the* view of the GMC (General Medical Council), it is *a* view of the GMC, expressed by me in my role as chairman of the Committee on Standards of Professional Conduct and on Medical Ethics. The Council itself has not actually debated research misconduct, and the view of the GMC can only be expressed after the full Council has debated the issue and approved whatever documents or procedures it thinks appropriate.

What is clear, is that the GMC regards research misconduct as wrong, and in most instances that have been reported to it, the outcome has been that a charge of serious professional misconduct has been sustained and the individual has lost their registration with the Council either permanently or temporarily.

As part of the Council's overall review of its functions and its methods of working, and particularly in response to the widespread public concern marshalled by journal editors to whom I think we owe a great debt, Sir Donald Irving convened a meeting of representatives from the medical Royal Colleges, the BMA, the National Academy's Policy Group, COPE, the Association of Medical Research Charities, the Council heads of medical schools, the Committee of Vice Chancellors' Principles, the Joint Consultants Committee, and the NHS Executive Research and Development unit. A committee, chaired by George Alberti, President of the Royal College of Physicians, was subsequently set up to produce clear guidance on good research practice.

Role of the GMC

The GMC is concerned only with doctors (registered medical practitioners); it is not concerned with research carried out in medical schools, or in faculties, or institutes of biomedical science when the researchers are non-medically qualified scientists. But much of what goes on in our medical schools is carried out by such scientists, and I think that at some stage we will have to address that. Certainly, the difficulties I've had as the dean of a medical school have been as much concerned with those individuals as they have been with those who are registered medical practitioners.

Secondly, the 1858 Act which set up the GMC only gave mention in passing to the notion that the GMC might actually be concerned with the conduct of doctors on the register. Nowadays that is the activity which dominates the headlines on the work of the GMC. When the Conduct Committee meets, it does so under very strict judicial guidelines. An assessor who is a Queen's Council acts in an advisory role, much as a

judge would act to make sure that a fair process took place in a court of law. Rules of evidence apply and the truth is sought through an adversarial process. The standard of proof required is that the committee has to be sure that the facts of the case have been established beyond reasonable doubt. This emphasises the importance of an adequate audit trail when conducting an enquiry into misconduct.

The GMC has several committees, including the one I chair. It is this committee which is charged with the task of developing standards for practice, which if, and when, endorsed by the Council itself, will become the standards with which doctors are expected to comply. And if they fail to comply with them for whatever reason, they may be required to justify non-compliance to their peers.

The standards developed by the Council, although always in accordance with the law, consider the moral duties of the doctor, so in many instances, place a duty on doctors which is higher than simply meeting legal requirements. An example of that would be our recent advice about consent.¹

The legal standard for consent is what's required to prevent us from being charged with battery, and based on the information that a responsible body of medical opinion acting as an expert witness might provide. Many people now say that it is inadequate and that it should be what a reasonable person would expect to receive; the Medical Defence Union has now adopted the reasonable person standard. It's likely that judges will begin to interpret the Bolam rules differently because there is now guidance—through publications on good medical practice, confidentiality and seeking consent, which can be taken to represent the standard taken by the profession.^{2,3}

When the new guidance has been developed by the Alberti Committee, the Council itself will want to consider it, and decide whether to issue its own advice on research misconduct.

Current issues

There are perhaps five problems that we might discuss.

1 Multiple agencies

Medical research is carried out by many different agencies, and the main responsibility, to ensure good practice, to detect misconduct and to eliminate it, rests with the employers. These include:

- universities and medical schools
- hospital trusts
- health authorities

- primary care groups
- the pharmaceutical industry
- private providers
- government or local authority agencies
- researchers who are self employed

We need to develop systems which cover all these different circumstances and which are sufficiently comprehensive to ensure that any individual who is guilty of poor practice or frank misconduct is not able to move from employment to employment without being identified and subjected to appropriate discipline.

I know of a case of a scientist who had been recruited with satisfactory references and no mention of research misconduct. He then became the subject of, or was mentioned in, an article by an investigative journalist who proved that this individual had moved from place to place, but always managing to move faster than the investigation. Therefore, whenever he moved, the process had been stopped and had never been brought to completion, and people would never allude to this anxiety for fear of legal action.

2 Researchers who are not registered with the GMC

The individual I mentioned previously was such a person, so whatever systems we set up, need to deal adequately with non-medical scientists and people who move from place to place.

3 Training about good practice

The Wellcome Foundation had very strict rules about how research had to be recorded. For example, all research had to be documented in bound volumes which were numbered, not on loose bits of paper, and all primary results coming off machines had to be pasted into the book. The principal scientist had to go through the books of all the people in the team and sign each page, and when the book was finished it was taken away and locked in a safe. The process was concerned with commercial confidentiality procedures, but it also ensured a clear audit trail which could be followed.

We don't yet ensure that all our researchers, including medical students at BSc stage, get good advice on how to carry out research in this sense, or on the ethics of research misconduct. Similar training is required for supervisors, and should include not only good practice in research, but also how to detect and deal with it.

All institutions need to have properly approved procedures, and both the procedures themselves, and the action taken in relation to them, need to be audited on a regular basis.

4 Role of scientific journals

Editors of the main journals have done much to stimulate awareness of the problem and the need for urgent action. When I was an editor, I submitted a case to

COPE, and found the advice extremely helpful. The article, which we rejected, was published eventually in an American journal which has at least as big an impact factor as the journal I edited.

But perhaps you could do more: rather than simply rejecting a suspicious paper, you could raise your concerns with the authors, and if dissatisfied with the reply, contact the named designated person in the organisation that employs that author.

5 National register and audit

I don't think that research misconduct of a serious nature is all that common, but that doesn't mean it's not important—it's very important. We should avoid setting up a process which is too complicated and too bureaucratic, to satisfy legitimate public concern. I am therefore not in favour of an office of scientific integrity as a government sponsored body or as a quasi legal institution. But there is a case to be considered for a national office which might be set up by bodies that already exist, perhaps the Medical Research Council or the Wellcome Institute, and such an office could perform several functions.

Firstly, it could be a source of advice, rather like COPE is for editors. It could maintain a register of all those who have been found guilty of research misconduct, so that prospective employers could check before offering a post to an applicant—similar to the General Medical Council, which maintains a register of all doctors which could be used by prospective employers. It could also maintain a register on an annual basis of cases that have been raised in every institution, and their resolution. And it could, if necessary, also conduct audits of institutions, to ensure that their processes were appropriate and working adequately.

References

- 1 General Medical Council. *Seeking consent: the ethical considerations*. London: GMC, 1999.
- 2 General Medical Council. *Good Medical Practice*. London: GMC, 1998.
- 3 General Medical Council. *Confidentiality*. London: GMC, 1995.

Questions and comments

Preservation of original data

The importance of imposing a duty on authors to preserve their data was highlighted by the case of a PhD thesis which was only confirmed to be fake when the original data were submitted.

Need for a national office

A national office might be of much more value if it included grant applicants. Losing the ability to apply for grants would be a means of self selecting potential fraudsters out of position and influence.

Delegates wanted to know: What body should be responsible for such a register? And who should have access to it? Should it be public so that everybody can go up and look at what cases are now under investigation?

Commented Sir Cyril: "It should be open to public scrutiny to fulfil its function. I think what it shouldn't do is contain the names of people about whom complaints have been made, but not proved. The case itself should be recorded as part of the audit procedure for that body to deal with, but that information should be confidential. But where a case has been followed to completion and proved, it should be part of the public record."

Speeding up complaints procedures

When Peter Wilmshurst registered a complaint about research which appeared to be fraudulent and unethical, because of an apparent lack of approval or informed consent, he found himself reported to the GMC for disparagement by the employing authority. The enquiry took eight months before he was exonerated and an investigation of the authors began.

"These processes have to be conducted very carefully," responded Sir Cyril, "but there is a need to speed up the fitness to practice procedure and the GMC is actually addressing that."

Investigations need to be completed

The difficulties of failing to complete investigations were highlighted by the case of a medical person suspected of fraud subsequently employed in the UK. The original alleged fraud had actually taken place in Harvard, where an investigation had been set up but not completed. The employers were not aware of the allegations, nor the fact that an investigation had been started. The problem is still not resolved.

It was suggested that the pharmaceutical industry are the only ones who are really any good at pursuing these cases.

How do editors approach reasonable doubt?

One editor was not convinced that "beyond reasonable doubt" could be applied to suspicious cases: "A misconduct case would go to the GMC if the parties concerned were sure beyond reasonable doubt, but editors are often not sure beyond reasonable doubt, but they are sure, from their interpretation of the data presented, which are either too neat, or which lack outliers, or because there is some factor that indicates 'this isn't quite right.' That isn't beyond reasonable doubt, and it's very difficult to prove. Where you draw the line before somebody's name appears even confidentially or openly in a national register."

Sir Cyril responded: "The processes would have to be very clear, and the standard of proof would have to be beyond reasonable doubt, because of the effect of being found guilty, which, as a doctor, will certainly mean an appearance before the GMC and probably the loss of your livelihood. This would equally apply to scientists if we had this national register. If those processes weren't clear, given the seriousness of the consequences, they would be subject to judicial review."

Onus on editors to provide clearer advice to authors

Sir Cyril explained that during his tenure as editor of *Paediatric Nephrology*, somebody from America pointed out that some of the results in an Italian paper had already appeared in an American paediatric journal. The author's response was 'yes, but this study went much further than that,' but the head of the institution in Italy to whom Sir Cyril had copied his letter, pointed out that this was standard practice. In their culture that was perfectly reasonable because the author was taking the argument forward. "So there is a need for more clear advice from editors."

Prevention of fraud

"I was recently asked to pronounce on research in relation to somebody's promotion from a university," commented a delegate. "It became quite clear that this person had been a subsidiary in several investigations, and that the same data had been used by different sets of people for the same research grant. The papers were not only duplicated, but their databases were changing by 5 or 10 people a year. I wrote an absolutely scathing report to the university, but what do I do about the publication, and the journals that these false papers were published in?"

"Write to the journal editors," responded Richard Horton. "If it's been published in our journal, it's then our responsibility to protect the reputation of that research and our journal, and if there is a challenge to the integrity of the data that has come out in our name, then it remains our responsibility to investigate."

Breaches of confidence

The terms under which any assignment is accepted, have to be clear, said Sir Cyril. "This has come up recently in relation to the pharmaceutical industry where it was brought to our attention at the GMC, that cases being settled out of court put a duty of silence on complainants, and that might place patients at risk. You have a responsibility to break confidence when patients might be at risk, and that runs throughout the GMC's advice. When there is a serious risk of harm to patients, then duties of confidentiality have to be reassessed."