

# THE LANCET

## Will the UK COPE?

*The Lancet* has been threatened with legal action on two occasions during the past month or so. Since none of our editorial staff seem especially keen to go to court, let alone see the inside of a jail cell, the precise circumstances of our alleged transgressions must remain, for the time being anyway, confidential. However, both instances concern potential wrongdoings by investigators. And presumably because we have challenged them, they or their employers have bitten back as aggressively as they can. Editors have long reflected on these issues and how they might deal with them (alone usually).<sup>1</sup> In the UK, the problem is that there is no forum for discussion of how editors should handle alleged incidents of publication or research misconduct. At least, not yet.

It is not only *The Lancet* that is struggling here. Since the *BMJ*<sup>2</sup> and ourselves<sup>3</sup> joined forces with Stephen Lock and Frank Wells<sup>4</sup> last year to draw attention to the problem of scientific misconduct, there has been a string of widely reported new cases.<sup>5-7</sup> And on July 17 the UK's General Medical Council removed the registration of a physician who had falsified clinical trial data.

Yet, despite the efforts of many to encourage British professional organisations—e.g., the Royal Colleges—to give a lead and create a committee on research integrity, the response has been lamentable. Barbara Altounyan has summed up the situation well:

"The United Kingdom currently monitors research by a series of badly publicised ad hoc and piecemeal guidelines and recommendations which by definition exist on a voluntary basis within individual research institutions and universities. Needless to say each institution or university has a vested interest in keeping any allegation of fraud or misconduct firmly hidden from the discerning eye of the public and government, lest it should lead to a cut in funding or loss of reputation."

When Michael Farthing became the new editor of *Gut*, he did not have scientific misconduct high on his agenda. But during his first year he faced four such cases.<sup>8</sup> These events prompted him to raise again the idea of a central committee to help editors with issues of publication ethics. The editors of *Gut*,

*BMJ* (which also draws attention to the committee this week), *The Lancet*, *British Journal of Anaesthesia*, *Journal of Bone and Joint Surgery*, *Annals of Rheumatic Diseases*, *Pre-Hospital Immediate Care*, *Journal of Clinical Pathology*, and *Journal of Medical Screening*, together with Prof Ian Kennedy from the Department of Law and Ethics at King's College, London, have now had three exploratory meetings to discuss a UK Committee on Publication Ethics (appropriately contracted to COPE).

We plan to hold our first open gathering—Research misconduct: how shall editors respond?—on Nov 4, 1997, chaired by Michael Farthing. At that meeting we will have case-based discussions on fraud and plagiarism, confidentiality and patient consent, whistleblowers, duplicate publication, and media interest. The day is designed for those with an interest in the ethics of the publication process, although disentangling these matters from research integrity will be difficult. Because COPE has no legal standing it cannot itself inquire into allegations of misconduct but it can offer advice to journals who face these challenges, ensuring at the very least that editors are no longer working alone. For those pondering the importance of this task, perhaps sceptically, one might recall the words of Lock when writing about Malcolm Pearce's fall from grace in 1995: "The profession here has failed its responsibilities to the community".<sup>9</sup> Nov 4 may be the day when we start to put these failures behind us.

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- 1 Horton R. Revising the research record. *Lancet* 1995; **346**: 1610-11.
- 2 Smith R. Time to face up to research misconduct. *BMJ* 1996; **312**: 789-90.
- 3 Editorial. Dealing with deception. *Lancet* 1996; **347**: 843.
- 4 Lock S, Wells F, eds. *Fraud and misconduct in medical research*. London: *BMJ Publishing Group*, 1996.
- 5 Marshall E. Fraud strikes top genome lab. *Science* 1996; **274**: 908-10.
- 6 Abbott A. Fraud claims shake German complacency. *Nature* 1997; **387**: 750.
- 7 News in brief. AIDS "cure" researchers guilty of misconduct. *Nature* 1997; **388**: 112.
- 8 Farthing MJG. Research misconduct. *Gut* 1997; **41**: 1-2.
- 9 Lock S. Lessons from the Pearce affair: handling scientific fraud. *BMJ* 1995; **310**: 1547-48.

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# BMJ

## Research misconduct: how should editors respond?

*The Committee on Publication Ethics (COPE) is formed*

Misconduct in research momentarily rose high up the agenda of the British medical community after Malcolm Pearce, an obstetrician and gynaecologist, was found in 1995 to have forged a series of papers.<sup>1</sup> The case made the front pages of the newspapers and led to the downfall of a president of a royal college. Despite calls for action on research misconduct,<sup>2,3</sup> the issue has not been tackled. Now Britain has another high profile case,<sup>4</sup> and perhaps the profession will be awakened from its torpor. In the meantime, editors—who are regularly confronted by cases of possible misconduct—have decided to help themselves. We have set up the Committee on Publication Ethics (COPE).

Last week John Anderton, a consultant physician in Edinburgh and former registrar and secretary of the Royal College of Physicians of Edinburgh, was struck off by the General Medical Council (GMC), which regulates medical practitioners in Britain, for faking data in a clinical trial (p 205).<sup>4</sup> The misconduct came to light because of an investigation by a pharmaceutical company, Pfizer, for which he was conducting the research. The company was helped by the private agency set up to investigate possible cases of research misconduct that is associated with Frank Wells, former medical director of the Association of the British Pharmaceutical Industry. Dr Wells, a coauthor of the BMJ Publishing Group's book *Fraud and Misconduct in Medical Research*,<sup>5</sup> says that his agency is constantly busy. Its main customers are pharmaceutical companies and health authorities. Since 1989 Dr Wells has reported 17 cases to the GMC, all of which have resulted in findings of serious professional misconduct. The agency has another 12 cases pending.

In May Dr Peter Nixon, a consultant cardiologist from Charing Cross Hospital, London, admitted in court that errors in scientific papers cowritten by him appeared to be "more than an honest slip of the pen."<sup>6</sup> Dr Nixon retired and told the GMC that he would not practice again. He may thus have escaped a council hearing. Importantly, Dr Nixon's admission emerged in a case in which he was the plaintiff not the defendant. He had spent three years suing a television programme for libel,

and the Medical Defence Union faced a bill of some £2m after supporting him.

We still do not know how many cases of research misconduct there are in Britain, but it is becoming increasingly difficult to argue that cases are isolated and rare. The United States has many cases because it has more effective methods for identifying them. In Britain we seem to be leaving it to pharmaceutical companies, a private agency, and the media to discover most cases. Cases that emerge from investigations held by medical schools or royal colleges are vanishingly rare.

This is shameful. As Sir Donald Irvine, president of the GMC, has recently reminded us, self regulation is a privilege not a right.<sup>7</sup> It has to be deserved, and we need to find better methods of responding to research misconduct not only to maintain public confidence in medical research but also to stop members of the public or parliament arguing that we no longer deserve self regulation. We need effective systems for preventing, detecting, and investigating research misconduct and for imposing pun-

### Work of the Committee on Publication Ethics (COPE)

The committee will:

- Advise on cases brought by editors. Cases will be presented anonymously, and full responsibility will remain with the reporting editor
- Consider cases related to advertising, authorship, confidentiality, conflict of interest, editorial freedom, editorial integrity, media relations, patient privacy, peer review, redundant publication, research ethics, and research misconduct
- Publish an annual report on the cases it considers
- Draft guidance on these issues
- Promote research into publication ethics
- Consider offering teaching and training

ishment, and it will obviously be sensible to put the emphasis on preventing.

While we wait for an adequate response from the broader profession, the editors of *Gut*, *BMJ*, *Lancet*, *British Journal of Anaesthesia*, *Journal of Bone and Joint Surgery*, *British Journal of Obstetrics and Gynaecology*, and of other journals from the BMJ Publishing Group have set up COPE. Michael Farthing, the editor of *Gut*, prompted us to take this step after he encountered four cases of misconduct in his first year as editor.<sup>8</sup> Most editors encounter problems of possible research misconduct and ethical misbehaviour, and we have had an informal network of telephoning each other to ask for advice. We thought that we might increase understanding, gather information that might be useful to the broader profession, and improve the quality of our responses to problems if we formalised the network.

COPE will serve editors rather than authors or readers, and its functions are shown in the box. It will help with ethical problems that are broader than research misconduct. We have chosen to serve editors because we have legitimacy to do that COPE cannot be a substitute for a proper body to serve the full profession, and the committee will deal with anonymised cases. Individual editors will

take whatever action they think is appropriate, but the committee will, I hope, urge editors not to take the easy (but traditional) route of simply rejecting questionable papers.

COPE is an experiment. It may not prove useful in the long term, and we will be delighted if it is made unnecessary because the international profession produces an adequate response to research misconduct. We have begun work already and will be holding a one day conference on journals and research misconduct in November. Editors everywhere are welcome to join COPE.

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- 8 Farthing MJG. Research misconduct. *Gut* 1997;**41**:1-2.

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