

## COPE moves forward

The Committee on Publication Ethics (COPE) was formed in 1997 by a group of medical editors who were struggling with cases of publication and research misconduct. Many felt dissatisfied with the standard response of rejecting a manuscript when there was clear or suspected evidence of research misconduct. The extremely limited powers that editors have to investigate suspected misconduct, and anecdotal experience which suggested that the employing authorities of authors under suspicion were often unwilling to “grasp the nettle,” only added to the frustration.

Since 1997 COPE has considered 56 cases of possible publication and research misconduct, 15 of which are still under consideration. Common problems include redundant publication and ethical issues, many of which involve failure to obtain appropriate ethics committee approval or informed consent. But COPE has also considered several cases of disputes among authors, some of which threatened to amount to professional misconduct. Among the five cases of research fraud COPE has assessed, one was proved and resulted in a retraction; it emerged that the first author had already been struck off the General Medical Council Register. Other problems have included failure to declare a conflict of interest, dual submission, and a request to publish a “sensitive” paper anonymously.

We know that research misconduct is not just endemic in the UK. Earlier this year the US Office of Research Integrity (ORI), which deals only with research funded by the US Public Health Service, released a review of over 1000 allegations of scientific fraud, investigated between 1993 and 1997. The review, *Scientific Misconduct Investigations 1993–1997*, shows that falsification and fabrication, but also plagiarism, were the most common findings. Junior members of staff were far more likely to be found guilty than staff at

senior levels, despite associate professors attracting the highest numbers of allegations of misconduct.

Most of the whistleblowers identified in the ORI review were senior academics, who, the evidence shows, often lose their professional standing and risk their livelihoods. It will be interesting to see whether the UK Public Interest Disclosure Act 1998, which came into force July 2 this year, and which applies to all those in employment apart from the armed forces, the secret service, and the self employed, will ensure adequate protection for whistleblowers, and make it easier for them to come forward.

Over the past year, the members of COPE have also become increasingly aware of a need for guidelines to help editors deal with cases of research and publication misconduct, which might also act as an aide memoir for investigators and authors. This year's *COPE Report* includes guidelines on good publication practice which attempt to define the issues and advise on how to investigate suspected cases and apply sanctions to those committing the misdemeanours.

COPE has no statutory powers and does not make formal recommendations about the management of individual cases, nor does it endorse or ratify sanctions against miscreant authors. Ultimately, it is the editor's decision as to how to deal with a particular situation. Nevertheless, editors have found it useful to share their problems on publication misconduct, and to obtain the views of others before finally deciding how to deal with a particular case. It is in this spirit that the guidelines have been produced. Although COPE consulted widely on their content, we anticipate that they will evolve over the coming months as they are put into practice, and will be revised on an annual basis.

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Chairman of COPE  
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# BMJ

## Dealing with research misconduct in the United Kingdom

After years of inactivity over the problem of research misconduct in the United Kingdom, there is now an enthusiasm and drive to do something. But how should medical fraud be tackled? Representatives from medical journals (both British and American), the Medical Research Council, a medical school and a medical charity, and a member of the Danish Committee on Medical Dishonesty give their views on this important topic.

## An American perspective on research integrity

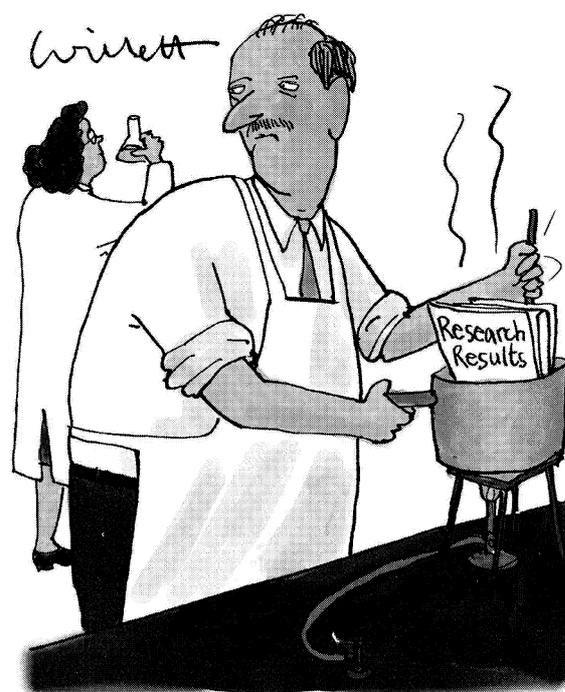
Drummond Rennie

An allegation of scientific fraud can ruin the careers of both the accused and the accuser, divide faculties, bring a research institution's functions to a halt, provide a field day for the media, and, when the scientific establishment is unprepared, result in a loss of confidence in the entire research enterprise. Yet, despite repeated demonstrations that this is the case, scientists are still reluctant to face up to such an unpleasant problem. Three years ago, at a meeting on research misconduct held by the *BMJ*, I warned that many extremely embarrassing incidents at a variety of institutions would be required before anyone took any action in the United Kingdom. This seems to have been borne out. At a meeting organised by the Committee on Publication Ethics (COPE) in London, I was depressed that so few seemed to have paid the slightest attention to the rich, well documented and instructive experience of the United States, where an energetic attempt to face up to the problem has been made. Such parochialism may doom the UK to repeat the many mistakes already made by others.

To the American observer, the news from the UK about incidents of misconduct in research is, as baseball's greatest philosopher, Yogi Berra, remarked, "déjà vu all over again." I began to be seriously concerned about the problem in 1979 when, as deputy editor of the *New England Journal of Medicine*, I had to help sort out a serious case of fabrication and of plagiarism during review.<sup>1</sup> In the next few years, several other cases, for example, that of Darsee, involved that journal.<sup>2</sup> The US Congress reacted to the media attention to these and many other cases with more than a dozen highly publicised congressional inquiries, the first in 1983 under then Congressman Al Gore.<sup>3</sup> The response of each research institution varied but was only too often characterised by circling the wagons, denial, and cover up. Under the eyes of the press, each institution would hurriedly patch together its own process, assembling ad hoc panels, sometimes with glaring conflicts of interest. The results were frequently

slow, bungled, idiosyncratic, and unfair to almost everyone.<sup>3</sup>

Against this background, several meetings were held in the 1980s, jointly arranged by the American Association for the Advancement of Science and the American Bar Association, to frame some rational response to the growing public perception that fraud in science was rife. Senior scientists kept insisting that this perception was false, but since their assertions were made in the absence of evidence they appeared self serving and unscientific. In 1989, federal regulations were issued governing research sponsored by the US Public Health Service and the institutions where this research was conducted. The rules provided a definition of misconduct and a process that institutions



had to follow when an allegation was made. An office was set up, now called the Office of Research Integrity, to oversee and enforce the institutions' compliance. Since the Public Health Service sponsored most publicly funded biomedical research, its definition and process became the standard adopted by research institutions in the United States.

The past nine years has seen a few high profile cases (for example, the Gallo case and the Imanishi-Kari or "Baltimore" case) thrown out, but a good many others have been concluded without too much fuss. A universal definition and a set of procedures to be applied to research conducted under the aegis of every US government agency, from the National Institutes of Health and the National Science Foundation to the National Aeronautics and Space Administration, have still not been agreed. Heated argument still continues, and is unlikely to subside when the White House committee charged with putting together government-wide procedures reports this summer. We can, however, reach a few general conclusions.

### An assessment

When the Office of Research Integrity adopted a "scientific dialogue model," evaluating cases according to the way scientists look at the evidence, judgments would be challenged and resolution would be slow and incomplete. Scientists are not trained in conflict resolution; their intuitive response is usually wrong and they tend to set up shaky ad hoc procedures that do not guarantee the accused notice of all the charges, and the opportunity to respond to all the charges and to the evidence, and a decision based on rigorous standards.<sup>4</sup> When the Office of Research Integrity changed to a more "legal" method, following the procedures of administrative law, cases would be handled more expeditiously and were less prone to challenge. A Commission on Research Integrity, of which I was a member, examined the issue. Its report in late 1995 broadly followed an earlier attempt by the National Academy of Sciences.<sup>5, 6</sup> It refined and extended the definition, basing it on the principle of telling the truth, and suggested a whistleblowers' bill of rights and responsibilities. As happened with the original regulations, the commission's definition has been widely reviled by a scientific community that still has difficulty coming to terms with the basic fact that together with the privileges of a profession come responsibilities.

All sorts of other issues remain unsettled.<sup>7, 8</sup> For example, the use by whistleblowers of a law dating back to the Civil War that permits their bringing action to recover misspent government money. However, the generally quieter tone in the United States seems to reflect an understanding that matters are now being dealt with fairly routinely and competently. It also reflects the fact that since 1992 the Democrats have been in a minority in the Congress, and Congressman John Dingell—who pursued the issue so remorselessly for so long, and kept it on the front pages of the papers—had to relinquish his powers to less interested Republicans.

### Lessons for Britain

The idea that the situation in the United States is uniquely bad rings hollow in the face of growing num-

#### Procedural criteria

- The procedure must secure the evidence
- It must guarantee prompt, fair inquiry
- The interests of all the parties involved must be protected—for example, by ensuring that the same body is not investigator, prosecutor, and judge
- The procedure must correct the scientific record
- It must provide reassurance to the press and the public

bers of cases in Britain, Germany, and elsewhere. It has not been shown that scientists in Britain differ importantly from those in the US. Institutional denial in the United Kingdom is therefore no longer a sensible option. It would help if we were all to stop registering shock and recognise that the bestowal of a scientific or medical degree is not accompanied by a guarantee of honesty. The only useful approach, therefore, is to assume that, in common with other crimes, a certain proportion of our colleagues will plagiarise, fabricate, and falsify the evidence—in other words, that scientific misconduct will occur infrequently but regularly. This routine approach requires that a definition of misconduct be agreed on and promulgated, not least because it is unfair to accuse people unless they have had the chance to know what is unacceptable. A corollary of this is that scientists must be taught about good and bad research practices and about research ethics. Courses in research ethics are proving useful in the United States, but my bet is that if senior scientists make efforts to become closer mentors to their juniors, this will raise standards considerably.

When allegations arise, research institutions must have an effective procedure in place. The requirements for such a procedure are listed in the box.

The legitimacy of institutions, whether or not they are funded by the public, ultimately depends on public confidence, and the public interest requires that the process and the resolution of cases be made public. Morale in the institution where the problem occurred can be devastated. An essential step in rebuilding trust is to show that justice has been done.

It makes no sense to leave the regulations governing research misconduct to be developed by individual research institutions, not least because some central oversight to ensure compliance is wise and necessary. The credibility of the process is greatly enhanced by having universally applicable rules, developed and supported by prestigious scientific and medical bodies. In addition, the central body, which must have the power to review cases and to sanction institutions that do not comply, or which fail to protect responsible whistleblowers, should publish their experience.

Other improvements would help. For example, we should stop being led astray by pretending we know the cause when in fact we can only speculate. We should ignore whining about the supposedly awful pressures of "publish or perish" when we have little credible evidence on what motivates misconduct, nor on what motivates the conduct of honest, equally stressed colleagues. Laziness, desire for fame, greed, and an inability to distinguish right from wrong are just as likely to be at the root of the problem. There is an urgent need to encourage investigation in this area, including confidential experimental audits.<sup>9</sup> We must

recognise that scientists have expertise in the interpretation of scientific evidence but little training in the dispassionate adjudication of cases, so we need help from lawyers. For example, we tend to absolve dishonest colleagues because their fabricated results are “correct,” even if invalid.<sup>8</sup> And we all tend to condemn as crooks those who are merely “uncollegial” and to condone the real crimes of those whom we like. We forget that the legal profession has had a great deal of practice with sorting out guilt from innocence, and they are the first people we should consult when putting together regulations to ensure that they will work and withstand legal challenge.

### Where to begin?

Implementation will take a long time, and whatever is decided on will offend some group. I would start with meetings modelled on those of the American Association for the Advancement of Science and the American Bar Association, and pay great attention to experience in the United States. Though I would model my approach on the one taken by the National Academy of Sciences and the Commission on Research Integrity,<sup>5, 6</sup> I do not presume to tell Britain what model it should adopt, whether American, Danish, or some new one. But I do know that this represents a great opportunity, and the sooner you bring

representatives of scientific and medical societies together with representatives of research institutions, commercial laboratories, pharmaceutical companies, members of the bar, and politicians, the sooner you will get a definition and procedures generally approved. And the sooner that happens, the sooner those involved will get justice; the sooner those high up in institutions will stop looking foolishly unprepared; the sooner the public will feel its concerns are taken seriously; and the sooner this initiative, started in Britain by far sighted medical editors, will be realised.

- 1 Broad W, Wade N. *Betrayers of the truth*. New York: Simon and Schuster, 1982.
- 2 Relman AS. Lessons from the Darsee affair. *N Engl J Med* 1983;308:1415-7.
- 3 Rennie D, Gunsalus CK. Scientific misconduct. New definition, procedures, and office—perhaps a new leaf. *JAMA* 1993;269:915-7.
- 4 Gunsalus CK. Preventing the need for whistleblowing: practical advice for university administrators. *Sci Eng Ethics* 1998;4:75-84.
- 5 Commission on Research Integrity. *Integrity and misconduct in research. Report of the Commission on Research Integrity to the Secretary of Health and Human Services, the House Committee on Commerce and the Senate Committee on Labor and Human Resources*. Rockville, MD: US Department of Health and Human Services, Public Health Service, 1995.
- 6 National Academy of Sciences. *Responsible science. Ensuring the integrity of the research process*. Vol II. Washington, DC: National Academy Press, 1993.
- 7 Parrish DM. Improving the scientific misconduct hearing process. *JAMA* 1997;277:1315-9.
- 8 Youngner JS. The scientific misconduct process. A scientist's view from the inside. *JAMA* 1998;279:62-4.
- 9 Rennie D. Accountability, audit, and reverence for the publication process. *JAMA* 1993;270:495-6.

## Conduct unbecoming—the MRC’s approach

Imogen Evans

Scientific misconduct is taken seriously by the Medical Research Council. In its work as an employer and substantial provider of research funding, two responsibilities are the management and training of researchers. If research is not conducted with integrity, the results cannot be trusted and the implications for the wider scientific community are both important and unacceptable. To reassure the scientific community that this message is more than a laudable intention, we have devised a specific policy and procedure for handling allegations of scientific misconduct.<sup>1</sup> The policy formally covers all staff employed in MRC research units and institutes, as well as visiting scientists, but researchers in universities and elsewhere who are awarded MRC grants will also be expected to operate under similar policies.

### MRC procedure

Having reviewed extensively the existing European and US guidelines on the management of misconduct cases, we decided to introduce a separate procedure to deal with allegations. These had been addressed previously under our normal disciplinary procedures. For this purpose scientific misconduct means fabrication, falsification, plagiarism, or deception in proposing, carrying out, or reporting results of research and deliberate, dangerous, or negligent deviations from accepted practice in carrying out research. It includes failure to follow established protocols if this results in unreasonable risk or harm to human beings, other vertebrates, or the environment and also the facilitating of misconduct by collusion in, or concealment of, such actions by others. Misconduct does not include honest error or honest differences in the design, execution, interpretation, or judgment in evaluating research methods or results of misconduct (including gross misconduct) unrelated to the research process.

We devised an essentially stepwise approach that sets out a sequence of stages for the investigation of an allegation. This procedure, which is shown in the box, was designed to achieve a number of aims, including appropriate confidentiality (particularly should an allegation prove groundless), protection of whistleblowers, and natural justice towards those who are the subject of the allegation. The director of the relevant MRC establishment normally has primary responsibility for adhering

#### MRC’s stepwise approach

- Preliminary action—to determine whether the allegation falls within our definition of scientific misconduct
- Assessment—to determine whether there is prima facie evidence of scientific misconduct
- Formal investigation—to examine and evaluate all relevant facts to determine whether scientific misconduct has been committed and, if so, the responsible person(s) and seriousness of the misconduct
- Imposition of sanctions
- Appeal

to the procedure. If he or she is not perceived as being impartial or is the subject of the allegation, however, the responsibility falls to the executive director of council.

The design of the procedure ensures that scientifically expert assessors evaluate the evidence and draw conclusions. There are also clear commitments both to inform the scientific community, sponsors, and other interested parties in the event of any proven allegation of misconduct in relation to published work and also to restore the reputations of those subject to ill founded, even potentially malicious, accusations. In this last instance, it is then a matter of principle that the MRC will pursue action against the complainant.

### Importance of good practice

Notwithstanding its seriousness, scientific misconduct is an extreme and unusual occurrence. Of greater day to day importance to the MRC is the need to

ensure that standards of good practice are maintained in our establishments. We are therefore currently preparing a guide to good research practice to be published later this year. The intention here is to provide information and guidance to staff and visitors to our establishments on the key components of the contemporary research process, including supervision and training of researchers; the scientific method; research data, including gathering, storage, and retention; and publication of results, including authorship and methods of publication. As with our scientific misconduct procedure, we plan to distribute the information widely in the hope that the MRC approach will interest the broader research community.

1 Medical Research Council. *MRC policy and procedure for inquiring into allegations of scientific misconduct*. London: MRC, 1997. (MRC ethics series.)

## An editor's response to fraudsters

Michael J G Farthing

Fraud in biomedical research is alive and well, and apparently flourishing. Despite increasing publicity during the past 25 years, its magnitude is unknown and its detection largely serendipitous.<sup>1,2</sup> Research fraud is committed by general practitioners, the young and inexperienced, and those at the very top of the profession.<sup>3</sup> Fraudsters often arouse suspicions for some time before they are detected externally or a whistleblower feels secure enough to make his or her suspicions known. The most serious cases involving doctors are drawn to the attention of the General Medical Council, and the guilty invariably lose their place on the medical registrar. In Britain, where no agency exists to deal with less serious cases of research misconduct by medical practitioners and fraud in non-clinical scientific disciplines, the fate of those who are dealt with by internal institutional review is unclear. The Royal College of Physicians made recommendations on how academic institutions might handle suspected research misconduct,<sup>4</sup> but there has been no national review of the implementation of these recommendations nor have institutions been invited to report on their activities in this area.

### What can editors do

I first came face to face with research misconduct as a part time editor of a specialist journal. I reviewed the cases detected during my first year and found examples of overt plagiarism, "salami slicing" of one piece of research to create as many articles as possible, duplicate publication, and the submission of manuscripts that had not been approved or even seen by coauthors.<sup>5</sup> It might be argued that none of these cases amounted to serious research fraud; indeed, in every case the ultimate crime was prevented since all were detected before publication.

From an editor's point of view, doing one's duty is simplified if fraudulent material is actually published.

In this case, retraction or explanation is required, the matter is in the public domain, and the offenders face public disgrace. It is up to others to decide whether there is a case to answer elsewhere, such as before the General Medical Council. The dilemma arises when there is clear evidence of research misconduct, but the information remains on the editor's desk. What is the editor's duty then? Is a standard rejection letter sufficient? Should an additional paragraph be added to explain to the authors exactly why the manuscript has



been rejected? Under these circumstances an editor would need to be extremely certain of his or her grounds to avoid the threat of libel. Or should the editor write to the head of department (often a coauthor), or a dean or vice chancellor, explaining the concerns and perhaps requesting a full internal review?

An editor has no mandate to investigate suspected research misconduct. For overt plagiarism the case is usually secure and can be quantified by calculating the proportion of the manuscript that has been taken from elsewhere. It is often extremely difficult to investigate one's suspicions about "the perfect study" in which the data presented do not seem to have been generated in a "biological system." Although the opinion of a statistician can be helpful, uncertainty often remains. Examination of original research records is usually required, and generally these would need to be obtained at extremely short notice. It is unlikely that an editor would be able to achieve this, and anyway, is it really an editor's job?

### Committee on Publication Ethics

Last year about 20 frustrated editors got together to form an informal group, the Committee on Publication Ethics (COPE).<sup>6</sup> This group had no pretensions that it was formed to stamp out research fraud—it was a "self help" group for editors to discuss some of the dilemmas raised above and to seek advice on how they should be handled. In its first year the committee examined 17 cases. These included examples of plagiarism (one case involved several examples), suspected data fabrication, a serious conflict of interest between the reviewers and authors, and ethical issues relating to human research studies. All cases are brought anonymously, although we keep accurate notes of our meetings and plan to produce an annual report which will include the cases discussed. In 1997, the committee organised a meeting for editors entitled "Research misconduct—how should editors respond?" and a second one on detecting fraud is planned later this year.

Many frustrations remain. An editor has no mandate to investigate suspected fraud and is therefore unlikely to be able to present a fully investigated case to an author's institution. There may be only suspicions. Is it right that the matter should then be allowed to rest? Members of the committee feel strongly that this should not be the case but recognise that this is not a job for the group. When the case is clear cut, editors do sometimes take the matter into their own hands and punish authors who indulge in duplicate publication by refusing to consider articles from that author for a statutory time period, say three or five years.<sup>7</sup> We believe that this will only deal with the tip of the iceberg. Research fraud should be detected and reported well before its products land on an editor's desk.

### Need for an independent agency

Is it really such a difficult problem? Other countries are actively managing research misconduct and have left Britain way behind. The United States set up an Office of Scientific Integrity in 1990. This was replaced by an Office of Research Integrity in 1992 and was soon followed by similar agencies in Denmark, Norway, Finland, and Australia.<sup>3</sup> These agencies rely on

expertise provided by scientists, clinical investigators, and other academics, but they function independently of individual academic institutions, funding agencies, or other professional regulatory bodies. Surely the time has come for the speedy establishment of a similar agency in Britain? It is absolutely vital that we act promptly if research fraud and other forms of misconduct are to be prevented and detected. All of us who are involved in the many aspects of research and publication ethics must have access to an independent agency with which we can air our concerns when suspicions are raised.

Whistleblowers, possibly the most important tool for detecting research fraud, must, at least initially, have anonymity and full protection. Since working with the Committee on Publication Ethics I have been approached by a number of whistleblowers from various institutions, each asking for advice. My experience suggests that these people are not treated appropriately by their own institution. They are sometimes discouraged in pursuing their claims and are even threatened with career disruption or dismissal if they fail to keep quiet. Similarly, editors will be reticent about making accusations to deans and vice chancellors unless the case is secure; as discussed previously, full investigation is often impossible or inappropriate. "Do we need research police?" asked Professor Geir Jacobsen.<sup>8</sup> If the policing means prevention and detection of research crime then the answer is unequivocally "yes."

### Part of public health

Some would argue that this is all a fuss about nothing. Most research misdemeanours are minor and cause no harm other than adding a few inconsequential inaccuracies to the biomedical literature. I would argue that the preservation of research integrity is just another aspect of public health. We have a drinking water inspectorate to protect domestic water supplies. We are about to have a food standards agency, an independent watchdog to ensure that the food we buy and eat is safe. Surely public concern about the entry of erroneous material in biomedical publications on health and disease is at least of equal importance. Fortunately, the regulation of clinical trials of new drugs is generally of high quality, but doctors still try and fudge the data, usually for pecuniary gain; and there is always the risk that an ineffective or possibly dangerous drug might be used to treat patients for many years before its lack of efficacy is detected. Similar concerns might surround the dishonest reporting of the safety of new surgical procedures by selectively discounting the cases that did not go quite so well, and inflating the efficacy of new diagnostic test, again by data selection.

Although editors may be regarded as custodians of biomedical publication, their ability to preserve the nation's research integrity is limited. There is an urgent public need for an independent agency to formalise the maintenance of research standards and the detection and prosecution of fraudsters. Clearly such an organisation would need to work closely with other bodies that are responsible for maintaining professional standards such as the royal colleges and the General Medical Council. One way forward would be for the government to commission a report along the

lines of the James report on food standards<sup>9</sup> and then use similar mechanisms to establish an independent Research Standards Agency perhaps with a parallel structure to that proposed for food.

1 Kohn A. *False prophets*. Oxford: Blackwell, 1986.

2 Lock S. Misconduct in medical research: does it exist in Britain? *BMJ* 1988;297:1531-5.

3 Lock S. Research misconduct: a resume of recent events. In: Lock S, Wells F, eds. *Fraud and misconduct in medical research*. London: BMJ Publishing Group, 1996. Royal College of Physicians of London.

4 Royal College of Physicians. *Fraud and misconduct in medical research*. London: RCP, 1994.

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

6 Smith R. Misconduct in research: editors respond. *BMJ* 1997;315:201-2.

7 Doherty M. The misconduct of redundant publication. *Ann Rheum Dis* 1996;55:783-5.

8 Jacobsen G. Do we need a research police? *J R Coll Physicians Lond* 1997;31:8-9.

9 James P. *Food standards agency report*. London: Cabinet Office, 1997.

## Deception: difficulties and initiatives

Cyril Chantler, Shireen Chantler

That fraud and misconduct occur in research is not in doubt.<sup>1</sup> Nor is there any question that they continue to pose a problem, despite recommendations to detect and eliminate them. The General Medical Council is clear that research misconduct is wrong and, in most cases brought to its attention, amounts to serious professional misconduct.<sup>2</sup> Nine of the 10 doctors who appeared before the conduct committee in the past five years have been suspended or removed from the medical register.<sup>3</sup> We do not know, and it is probably impossible to know, how prevalent research misconduct is. Relatively few cases are reported in relation to the increase in medical research, though there are suspicions that it is more common than these cases suggest.<sup>4</sup> But this is to miss the point: every single case reduces public confidence, abuses the use of public and charitable funds, and causes insult and frustration to the vast majority of careful, honest workers.

### Recognising the difficulties

Firstly, we need to recognise the difficulties. Much research in medical schools and the NHS is carried out by people who are not members of the medical profession, and many are not accountable to a regulatory body. Routine audit of scientific activity by internal or external mechanisms would be difficult. The scope of inquiry is so great that a large panel of experts would be required, the expense would be great, investigators would be removed from their prime endeavours, and the efficacy would be doubtful. Even financial audit does not prevent fraud.

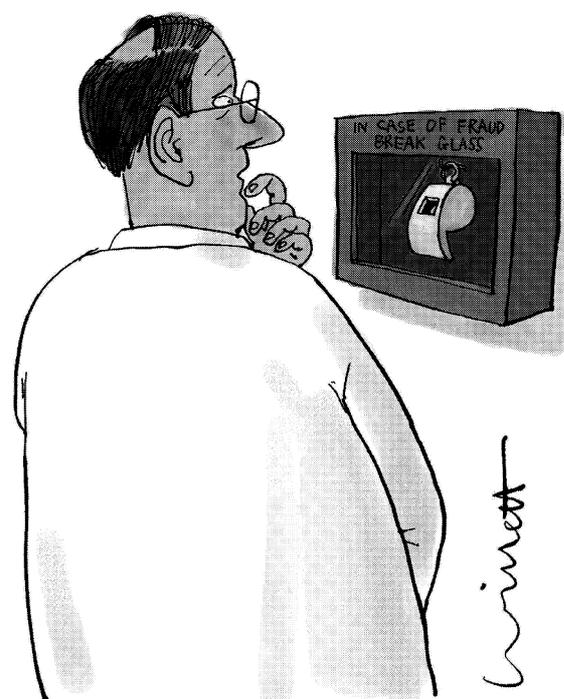
Suspecting a case of misconduct or fraud is different from providing evidence to prove the case beyond reasonable doubt to a regulatory body, to a university inquiry, or to the courts of law. Often the circumstances are not clear cut and depend on the interpretation of actions alleged to have taken place. When an investigation is started under the institution's disciplinary procedures, the miscreant may resign before the process is completed. If the individual then applies for another post, the suspicions may not be passed on to the new employer because of the risk of legal action. Thus, some individuals may move to another department, where the process may be repeated.<sup>5</sup>

### Guidelines

Guidelines for the prevention and investigation of complaints were published by the Royal College of Physicians of London in 1991.<sup>6</sup> This report defines scientific misconduct as including piracy, plagiarism, and fraud and provides a description of each. It includes guidelines for investigators in scientific research that were prepared by the Harvard Medical School and guidelines on authorship drawn up by medical journal editors. Guidelines also provide students with information on plagiarism.

### GMC initiative

The GMC, aware of the widespread concern about research fraud that was reflected in editorials in the *BMJ* and *Lancet*,<sup>7,8</sup> convened a meeting with representatives of the medical royal colleges and heads of medical schools to discuss a way forward. As a result of that meeting, a committee has been established. It has set in train a review of the Royal College of Physicians' guidance, drawing on advice from medical editors and



others, with a view to producing clear advice supported by the colleges, universities, and the GMC. All university medical schools are being asked to submit their procedures to this committee so that best practice can be recommended. It is likely that those schools which have faced problems will tend to be the ones with the most developed procedures, but all should be encouraged to review their procedures now. Certainly all should have a named person or persons to whom a complaint can be addressed, in complete confidence, and whistleblowers must be respected and protected. Doctors have a responsibility to take action if they feel a colleague's conduct, performance, or health may place patients at risk, and a similar responsibility to report concerns about scientific research has been placed on them in the review of good medical practice recently undertaken by the GMC.

### Good practice

Clear guidelines on good practice in the conduct of scientific research should be available to all who undertake it. All should receive formal education on ethics and good practice in research, and the fact that they have done so should be recorded and audited. Some commercial organisations require all primary data to be recorded in bound volumes (not loose leaf volumes) with numbered pages. All alterations and deletions have to be signed and dated, and the printout results from scientific equipment have to be pasted into the books. The books have to be inspected and signed off regularly by the head of the research group (who has to be knowledgeable about the work), and when they are complete they are securely stored. Obviously, this requirement is necessary for patent and commercial reasons, but it does establish a clear audit trail. The lack of such a trail can impede investigations into misconduct and the investigators are left to choose between the veracity of different accounts and the different perceptions of the same event.<sup>6</sup>

### Editorial input

The editors of medical and scientific journals, who have done much to draw attention to the problem, could perhaps do more to help eliminate it. Rather than simply rejecting articles they find suspicious, they should be encouraged to express concerns to the author or contact the named designated person in the organisation (see above) that employs the lead author, or both.

### Investigation and inquiry

After a complaint has been received, the responsible individual to whom the complaint is addressed should invite the person making the allegation to submit a detailed statement in support, while guaranteeing his or her anonymity. If the allegation is frivolous, unsustainable, or unfounded, it should be dismissed and the person making it informed accordingly. However, the nature of the complaint and the action taken should be recorded, and steps should be taken to ensure anonymity. If there is prima facie evidence to support the complaint, or there is insufficient information, an inquiry should take place.

It has been suggested that an office for investigating scientific fraud should be set up, as in the United States. As noted above, the wide scope of scientific inquiry would require a large bureaucracy of uncertain efficacy to support this, but obviously it is a suggestion that merits consideration. An alternative view is that the responsibility for dealing with complaints has to rest on the employer, be it a pharmaceutical company, university, hospital, or whatever. Each organisation should be required to set up a scientific misconduct committee with external representation. If, as the first step, the responsible person decides that the complaint is trivial and no further action is to be taken, the committee should review the decision and record that it has done so. Where there is a case to be answered, the committee would undertake this task, and all cases must be concluded, even when the individual about whom the complaint has been made has left the organisation.

### National audit

A small national body could be established for audit purposes. All organisations undertaking medical research would be required to report regularly all complaints received and the action taken. The national office could then audit this information—in other words act as the agency for quality assurance in this area. It could also act as a resource for advice on good practice and how to deal with specific complaints where necessary.

### Repercussions

Finally there is the problem of what to do when misconduct has been proved. Presumably gross misconduct will lead to dismissal from employment and, in the case of doctors, referral to the GMC. For non-medical scientists the problem is more difficult to resolve. Information on those found guilty of misconduct could be kept by the national office and employers could check with the office before offering employment to non-medical scientists.

### Other initiatives

There is an increasing willingness now to do something about research misconduct. As well as the deliberations of the college of physicians' committee, the National Academic Policy Advisory Group led by the Royal Society is also undertaking a comprehensive review of the problem and will make recommendations. These initiatives are welcome and no doubt will lead to further debate which, hopefully, will not be protracted. We need to develop systems that inspire public confidence, protect the integrity of medical research and of individual researchers but are not overly bureaucratic and intrusive.

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## Honest advice from Denmark

Povl Riis

The United Kingdom faces the same problem as a number of other European countries. The responsibility for unmasking and preventing research misconduct within medical science has been, and still is, part of the remit of a number of administrative, political, and scientific bodies. As a consequence, the natural law of shared responsibility comes into force, according to which the sum of shared responsibilities rarely or never amounts to the whole.

The latest figures from the Nordic countries, which have social structures and resources similar to Britain, show that 1-2 cases per million inhabitants are referred to their national systems annually. For Britain this would mean 60-100 cases each year, which is not a frightening prospect, especially since the more serious cases represent only 20-25% of the total. In addition, it must be remembered that one serious case of misconduct not dealt with fully, or at all, by a national system creates a media explosion that damages severely not only relations between society and biomedical research but the atmosphere within the scientific community.

### Independent national system

Not surprisingly, my suggested solution is the creation of an independent national system covering all health sciences—medicine, dentistry, pharmacy—and the drug industry and agencies. Such a national committee would be detached operationally, but not by membership, from the universities and other research institutions, thereby breaking away from the concept of total self government of institutions.

The committee should have a judicial chairman, for instance a High Court judge. Scientific misconduct most often takes place in the grey zone between legislation and unwritten guidelines for good scientific standards. The rules and guidelines of the system must be able to secure fairness for whistleblowers and accused scientists alike. Furthermore, experience suggests that the prestige associated with having a judge as chairman reduces the likelihood of subsequent court trials.

Members of the national committee should represent bodies such as the universities, scientific societies, research ethics committees, and government research institutes. The membership must be kept low, at eight to 10, and substitution of members should be possible. Membership could be considered a professional duty and consequently non-salaried, except for the chairman and vice chairman.

Whistleblowers should be able to contact the committee directly, not through the governing body of the university or the research institute. If the committee takes up the case, the institutions will obviously participate in the inquiry and the identity of the whistleblower will become known. I would not recommend a procedure whereby a complaint has to be made through the institutions at which the alleged misconduct has taken place. There are all too many examples of undue biased involvement by institutions.

Furthermore, local resistance may well be strong in some academic circles, as was the case when research ethics committees were introduced.

### Procedures

A national committee should divide its procedural operations into two phases—the inquiry and the investigation. Decisions on whether or not an investigation is required depend on the results of the inquiry. Ad hoc investigative committees can be internal to the independent national body or partly external, with an internal chairperson and an added number of independent experts accepted by both whistleblower and the accused person. The final report from the national committee should contain the committee's own conclusion, based on the premises of the ad hoc committee.

Punishment is best left to the institutions employing those found guilty of misconduct, but these should be obliged to report back to the national committee. However, the weight of reprisals should be determined centrally to avoid too heavy a punishment being meted out by an institution that wishes to demonstrate its commitment to purity.

### Creating a committee

In creating a national committee all interested parties—the Medical Research Council, the Royal Colleges, the universities, the Department of Health, the professional associations, and the hospital authorities—should hold preliminary discussions. Even if one group should refuse to participate, the others must press on. A UK committee on scientific misconduct will need administrative offices and a secretariat—perhaps in one of the royal colleges, the MRC, or the Department of Health. The budget could be covered by joint funding for a pilot period of, say, three years.

### Support for “authorship”

In addition to securing general prevention of fraud, a UK committee could create the necessary support among scientists for the endeavours of medical journals to restore authorship to its original position and validity. In this way such a committee could tackle the most prevalent “crime” in the dishonesty spectrum.

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# THE LANCET

## Coping with fraud

It is 10 years, to the month, since Stephen Lock, then editor of the *BMJ*, published the results of a personal survey, "Misconduct in medical research: does it exist in Britain?" Of 80 senior academics "over half of the correspondents knew of some instance of medical misconduct—most encountered first hand, although a sizeable minority were well authenticated secondhand instances—and there were a few rumours as well". Lock concluded that research fraud was flourishing in Britain and that action should be taken to tackle the problem by establishing an agency like the Office of Scientific Integrity in the USA "to allay professional and public alarm".

Although the UK General Medical Council has been busy with fraudsters since Lock threw down the gauntlet, editors of biomedical journals know that the GMC sees only the tip of an iceberg, the magnitude of which is quite unknown. However, 1998 witnessed a notable gearing up of activity in relation to publication ethics and research fraud, much of which was driven by journal editors. Early in the year the *BMJ* ran a series of articles on "informed consent in medical research". The Committee on Publication Ethics (COPE) published its first report, which included the proceedings of its first meeting "Research misconduct: how should editors respond?" and synopses of 22 cases that were being considered by the committee. To date the committee has considered 41 cases of suspected research misconduct. The report attracted attention in the daily press on both sides of the Atlantic, including a substantial piece in the *New York Times*. To coincide with the publication of the COPE report, the *BMJ* published a further series of articles on "Dealing with research misconduct in the UK". This included views from experts in the USA, Denmark, the UK, and a view from the Medical Research Council. Some authors favoured a move to set up an independent agency to investigate cases of suspected fraud whereas others were more cautious. As always, sensitivities about intrusion crept into the debate, together with concerns about the loss of professional self-regulation. There is a sense among editors that the available approaches to self-regulation are not working and that alternatives must be sought. The GMC, for example, has no jurisdiction over non-clinical scientists.

As the summer progressed, the temperature continued to rise with a volume of *JAMA* being devoted to the proceedings of the Prague Congress on biomedical peer review. The ethics of authorship, conflict of interest, bias, and quality of peer review were all debated. Retraction of papers was also considered. A search of Medline from 1966 to August 1997 revealed that 235 articles had been retracted, 86 of which were deemed to be due to misconduct. It was alarming to learn, however, that these 235 articles had been cited 2034 times after the retraction notice had appeared—old dogs never die! The *BMJ* retracted a paper in June 1998, five years after it had been published. This paper "Evidence of unmet need in the care of physically disabled adults", had influenced the development of services for the disabled and had been used in the part I examination of the Faculty of Public Health Medicine. One of the authors became concerned when he learned that his co-author had been struck off by the GMC. Having failed to confirm that a series of interviews, integral to the study, had taken place, he felt compelled, unilaterally, to request retraction; the action has not been contested by his co-author.

What hopes is there for the future? Last year, the UK Medical Research Council published its procedure for enquiring into allegations of scientific misconduct. This year, the GMC convened a meeting with representatives of the medical royal colleges and heads of medical schools to discuss how to proceed. COPE continues to meet on a regular basis and will publish its second report in 1999. COPE will also publish guidelines on publication ethics which it hopes will set a framework for researchers, authors, and editors which should improve the quality of research published in Britain. COPE has decided to be more responsive when the scientific integrity of submitted papers is in question, following Sir Cyril Chantler's comment on perceived pacificity of editors: "The editors of medical and scientific journals, who have done much to draw attention to the problem, could perhaps do more to help eliminate it. Rather than simply rejecting articles they find suspicious, they should be encouraged to express concerns to the author or contact the named designated person in the organisation that employs the lead author, or both." COPE has

every intention of following through on his suggestion.

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## Review

### Handling of scientific dishonesty in the Nordic countries

*Magne Nylenna, Daniel Andersen, Gisela Dahiquist, Matti Sarvas, Asbjørn Aakvaag, on behalf of the National Committees on Scientific Dishonesty in the Nordic Countries*

Despite a widely recognised need, most countries still have no coherent system to deal with scientific misconduct. Committees have been established by the national medical research councils in Denmark (1992), Norway (1994), and Sweden (1997), and by the Ministry of Education in Finland (1994), to deal with scientific misconduct—ie, to initiate preventive measures, to investigate alleged cases, or both. Each committee includes both scientifically and legally qualified members. The employing institutions are responsible for possible sanctions or punishments. So far, 47 cases have been accepted for investigation, the majority (25) being Danish. Disputed authorship was the most frequent reason for investigation. Junior researchers made complaints in only three of the investigated cases. Investigations have been completed in 37 cases; in nine cases, dishonesty was revealed—two of them were related to the same researchers. Cooperation between the four Nordic committees has shown close agreement on specific issues and cases, despite minor differences in definitions, organisation, and procedures.

Scientific dishonesty in medical research has received increased attention over recent years. A survey among 274 medical scientists in Norway showed that 22% knew about cases of serious misconduct, and 3% were aware of falsification or fabrication of data. 9% of the respondents had themselves contributed to one or more incidents of misconduct.<sup>1</sup>

The first reaction of denial within the scientific community has gradually been replaced by a recognition of the need for systems to handle this problem. These systems may include guidelines for good scientific practice and promotion of scientific integrity, definitions of dishonesty, procedures and bodies to prevent, detect, investigate, and punish misconduct when it occurs, and even research into this field.

The international scene has been reviewed by Lock and Wells.<sup>2</sup> The first systems to deal with scientific misconduct were established in the USA in the 1980s.<sup>3</sup> Later on, recommendations were also made elsewhere, but most countries still have no coherent system even though the need for one is widely recognised.<sup>4,5</sup> National funding agencies

and research bodies have a special responsibility for setting standards and establishing systems to deal with scientific misconduct.<sup>6</sup>

In the UK, editors of medical journals set up the Committee on Publication Ethics (COPE) in 1997 as a forum for discussion on how to deal with breaches of research and publication ethics.<sup>7</sup> In its first yearly report, COPE strongly recommended the establishment of a national body in the UK.<sup>8</sup>

Denmark, Finland, Norway, and Sweden established national committees on scientific dishonesty during the 1990s, whereas Iceland, the fifth Nordic country, still has no such body. The Nordic experiences and results so far are presented in this paper.

#### Setting

The four Nordic countries (Denmark, Finland, Norway, and Sweden) have a total population of about 23.5 million inhabitants. During 1996, the Nordic countries spent 2.22% of their gross national product on research. The mean value for countries belonging to the Organisation for

	Denmark	Finland	Norway	Sweden
<b>Committee established</b>	1992	1994*	1994	1997
<b>Committee members</b>	Eight members: a High Court judge (chair), seven senior medical researchers. From 1999, only four medical researchers in the subcommittee for the health sciences.	Twelve members: one university chancellor (chair), six professors (two MDs, two jurists, two philosophers), one theologian, and four civil servants representing agencies of higher education, research funding, or animal protection.	Eight members: five professors (three MDs, one dentist, one psychologist), one medical director of a drug company (MD), one judge, and one medical journal editor.	Eleven members: one judge (chair), six medical experts, two lay individuals, one representative of the Swedish Drug Agency, one Representative of the National Board of Health and Welfare.
<b>Definition of dishonesty</b>	Intention or gross negligence leading to falsification or distortion of the scientific message or a false credit or emphasis given to a scientist (1992)	Presentation to the scientific community of fabricated, falsified, or misappropriated observations or results and violation against good scientific practice (1998)	All serious deviation from accepted ethical research practice in proposing, performing, and reporting research (1994)	Intention distortion of the research process by fabrication of data; theft or plagiarism of data, text, hypothesis, or methods from another researcher's manuscript or application form or publication; or distortion of the research process in other ways (1997)
<b>Procedures</b>	Centralised. Cases are submitted directly to the committee. The principle of contradiction is firmly adhered to. The decision will be presented to the accused scientist's institution in case of proven dishonesty. No appeal mechanism.	Decentralised. Suspicion or accusation of dishonesty is filed to the rector or director of the research institute involved. This person is responsible for the initial inquiries and investigations. A second opinion can be requested from the National Research Ethics Council which may propose additional investigations.	Centralised. Committee investigates the case upon agreement with the employer of the accused person, and reports findings to the employer and to the two parties. No appeal mechanism.	Decentralised/centralised. After an initial inquiry within the faculty, a centralised investigation should be requested by the local rector. A centralised investigation is made by an expert group chaired by a judge. The decision by the expert group is forwarded back to the local rector who decides on sanctions. No appeal mechanism.
<b>Number of cases received</b>	45	7	9	7
<b>Number of cases investigated</b>	25	7	8	7
<b>Investigations completed</b>	24	5	4	4
<b>Dishonesty disclosed</b>	4	2	0	3†

\*The Finnish Committee was established in 1991 but did not deal with specific cases of dishonesty until 1994. †Two of the Swedish cases were related to the same researchers. Dishonesty was disclosed in both cases but for different reasons.

Table 1: **National committees on scientific dishonesty in the Nordic countries**

Economic Cooperation and Development (OECD) is 2·16%. There were, however, substantial differences between the four countries: Sweden spent the most (3·02%), and Norway the least (1·72%). Clinical medical research has a strong position in the Nordic countries: 406 clinical research papers were produced per million inhabitants in 1996, compared with the OECD average of 197. The average number of citations per paper was also higher than the OECD average: 4·20 versus 3·76.<sup>9</sup>

The Danish Medical Research Council initiated a report on scientific dishonesty and good scientific practice in 1991.<sup>10</sup> On the basis of recommendations in this report, the Danish Committee on Scientific Dishonesty was established in November, 1992. From 1996, this committee reported directly to the Ministry of

Research. In January, 1999, three subcommittees were formed, and the committee's area of function was extended to all fields of research.

In September, 1994, the Norwegian Medical Research Council established a similar national committee mainly based on Danish experiences.

The National Research Ethics Council of Finland, which was established in 1991, and which covers all branches of science, also deals with scientific dishonesty and, since 1994, has reviewed specific cases of fraud and misconduct.

In Sweden during 1996, the Committee for Research Ethics within the Medical Research Council suggested the formation of a national expert group to deal with dishonesty in medical research. In January, 1997, the Expert Committee was instituted.

All the committees have both scientifically and

legally qualified members. Characteristics of the Nordic national committees are given in table 1

### Definitions

In the USA (the country with the longest and most extensive experience of handling scientific dishonesty in a systematic way), the definition of dishonesty became a major issue at an early stage. The main question was whether to use a narrow or a wide definition. The former defined scientific misconduct as fabrication, falsification, and plagiarism in proposing, performing, and reporting research, as suggested by the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.<sup>11</sup> The wide definition, as suggested by the National Science Foundation and by the Public Health Service, includes a statement saying that scientific dishonesty also includes other serious deviations from accepted research practices.<sup>12</sup> Schachman has argued that such an open-ended definition “breaches an important principle of due process, the right to know in advance those activities that are proscribed”.<sup>13</sup>

In the Nordic countries, formal definitions have never been considered critical or even feasible, since dishonesty is regarded as ranging from minor deviations from good scientific practice to obvious misconduct. Scientific dishonesty has therefore been broadly characterised, and the establishment of a verdict relies on sound judgment rather than rigorous definitions.

The definitions of dishonesty used by the Nordic committees are given in table 1. Important for the judgment of dishonesty is whether the deviation from good scientific practice is serious or intentional. The Finnish guidelines initially defined scientific dishonesty narrowly, but the amended guidelines now have a wider scope.

### Procedures

The mandates of the Danish, Norwegian, and Swedish committees are fairly similar and, in principle, two-sided: to investigate alleged cases of misconduct, and to initiate preventive measures. In Sweden, cases cannot be referred directly to the national expert committee; instead, this body offers the medical faculties a centralised inquiry in response to a request from the dean or rector. The inquiry is a two-step procedure. Within a month, an initial inquiry decides whether there is reason to undertake a complete inquiry. A complete inquiry then takes 3–6 months, and determines whether dishonesty, according to the definition, can be verified or not. The inquiry group collaborates actively with the Medical Research Council’s

Alleged misconduct	Number of cases*
Disputed authorship	16
Manipulation of data	8
Wrongful use of data	8
Plagiarism	5
False description of methods	3
Twisted statistics	4
Theft of data	6
Fabrication of data	5
Other†	8

\*Each case may include more than one kind of alleged misconduct.

†Conflicts of interest (economical vs scientific), manipulation of experimental set-up, suppression of unwanted data, presentation of research to the general public without scientific publication.

Table 2: Specification of cases according to accusation (n=47)

coordinating Committee for Research Ethics in developing guidelines for good medical research practice and other preventive strategies.

In Denmark, cases can be referred directly to the committee without initial institutional inquiry. Anonymous complaints are discouraged, but can be accepted under special circumstances. The Norwegian committee can investigate cases only after agreement with the relevant institution, and anonymous complaints are, in principle, rejected.

The Finnish Research Ethics Council has adopted an approach different from those of the other Nordic countries. The National Council in Finland does not itself investigate cases of suspected misconduct, but, in 1994, produced guidelines for prevention, handling, and investigation of misconduct and fraud in scientific research. According to these guidelines, universities and research institutes are responsible for preventing all forms of scientific misconduct, and for investigating suspected or alleged cases of dishonesty. A suspicion of misconduct is reported to the rector of the university or the director of the research institute; consideration of cases without a filed suspicion may also be given. The investigative procedure includes an initial inquiry followed, if necessary, by a full investigation by a specially appointed committee. The Council is informed of all inquiries and investigations, and receives the final report on each case. If not satisfied with the investigation, the researcher involved, or the informant, can request an opinion on the procedure or the final report from the Research Ethics Council, which can recommend additional investigations by the university or the research institute.

The national committees of all the Nordic countries may use external experts when investigating individual cases. Full reports of the cases, together with the decision of the committee, are sent to the person who made the complaint, the accused, and the employing institution, which is

responsible for possible sanctions. The Nordic committees take on any case, irrespective of funding.

### Experience

In Denmark, the establishment of a national committee on scientific dishonesty was met with approval by scientists, institutions, and professional and lay press. In Norway, there was some resistance, primarily from the unions of physicians and researchers, but also from some prominent scientists. In Sweden, planning for the establishment of a national committee started in 1993, but responses from the medical faculties during this period were extremely slow (which may be interpreted as a kind of passive resistance), and the process was delayed. A media debate about the honesty of several members of the Medical Research Council itself (which led to a complete renewal of the Council in 1995) accelerated the process of establishing a national committee. In Finland, there was much concern about fair and due process, and ill-founded stigmatisation, and this was one reason for the narrow definition of misconduct established in the first place. In some faculties, there was initially doubt as to whether fraud is a significant problem.

As of February, 1999, 68 complaints had been received by the Nordic committees (including seven cases from clinical or biomedical research of a total of 14 cases reported to the Research Ethics Council in Finland). Most cases (45) were reported in Denmark (table 1). 21 cases were not investigated, mainly owing to lack of substance, obsolescence, or because they were referred to other countries or authorities.

47 cases were accepted for investigation. Disputed authorship was the most frequent reason for investigation (table 2). The most common complaints were made by one senior researcher about another. Junior researchers complained about senior researchers in only three of the investigated cases. Ten of the 47 cases are still pending. In nine cases, dishonesty has been revealed, of which two were related to the same researchers.

*Case 1*—The author of a paper published in a Nordic journal discovered an abstract in MEDLINE with an identical title and data. The abstracted paper originated from a foreign journal. Plagiarism was established, and the paper was retracted. Later on, more than 20 papers were found to have been plagiarised by the same person, who was dismissed from his professorship.

*Case 2*—A senior registrar published research

results from his work at a clinical department without the permission and knowledge of his superiors, and he included them as authors without their knowledge. The registrar was dismissed.

*Case 3*—An American information company offered a Nordic expert the authorship of a completed review paper recommending a certain drug. The company was wilfully dishonest since it attempted to give the impression that the review was impartial, and because it broke the rules for authorship (ghost authorship). The name of the company was disclosed in the committee's yearly report.

*Case 4*—A registrar had stated, in a published paper, that he had done a masked evaluation of a new diagnostic method. Perusal of the clinical records proved, however, that an open evaluation had been done. A correction was published in the journal. No further action was taken.

*Case 5*—Two clinical scientists (a professor and a senior lecturer) had distorted their research results. The number of reported patients was larger, and the reported follow-up period was longer than what could be reconstructed after work-up in several independent registers of patients. The case was reported to the relevant journals, and the researchers were withdrawn from their honorary positions at the university.

*Case 6*—A senior researcher had selectively excluded several patients in a long-term multi-centre clinical study of a new therapeutic method. The distortion resulted in unreliable scientific publications. In addition, several counts of violation of good scientific practice were found, including grossly inadequate research plan, lack of ethical evaluation, and insufficient supervision of the project by the administration of the clinical institutions involved. There was no information on sanctions.

*Case 7*—A researcher in a biomedical research laboratory published a paper on a study in which material received from another laboratory was used. The material was used in breach of a mutual agreement between the researchers. The report of the case pointed out that there were no internal guidelines for good scientific practice in the institute. The researcher left the institute before sanctions were taken.

*Case 8*—A senior researcher had distorted data to make better the results of a new modification of a surgical procedure developed in collaboration with a research student. The senior researcher had also published the results as a single author. The

senior researcher was prevented from tutoring research students, and from receiving grants as a main investigator.

In most cases, no dishonesty has been confirmed, and in several of these cases, the committee's most important task has been to acquit the accused. In a widely published case, the vice-chancellor of a Nordic university was accused of scientific fraud, which, it was claimed, had been committed 20 years earlier at an American university. After a thorough examination involving several international authorities and site visits, the vice-chancellor was cleared.

The national committees publish yearly reports on their activity. The Danish committee has published five sets of guidelines covering presentation of research protocols, data documentation, rights and duties in using and storing scientific data, authorship, and agreements between researchers at the beginning of cooperative projects.<sup>14</sup> Further guidelines are under production by the Norwegian committee on scientific dishonesty. In Sweden, this work has been done by the coordinating Research Ethics Committee. Education of researchers is an important part of prevention, and the national committees are involved in courses and seminars, including three Nordic conferences.

## Discussion

The fact that the notion of scientific dishonesty is inexact makes the question of definition elusive. The delineation of the concept therefore requires an element of judgment, and several cases to serve as illustrative examples. In the Nordic countries, scientific dishonesty is described in slightly different terms—"serious deviations from good scientific practice" (Norway), "intentional distortion of the research process" (Sweden), "violation of good scientific practice" (Finland), and "acts which falsify or distort the scientific message" (Denmark). The definitions include a wide range of acts (eg, fabrication of data; plagiarisms of data, text, hypotheses or methods; and dishonest selection of data). Intention to deceive is considered of major importance in all four countries, but Denmark also includes gross negligence. Whether or not an act is defined as dishonest will depend more on the culture in the research communities than on the precise wording of concepts. Experience from a Nordic conference dealing with this subject, and from discussions of mock cases, has revealed almost complete agreement despite differences in definitions between the four countries.

The reason for the high number of cases referred to the Danish committee, compared with the other national committees, is unclear. The general approval of the committee, and lack of resistance to its establishment from the scientific community in Denmark may be important, as well as the fact that the Danish committee was established earlier than those in the other three countries. The Danish Committee on Scientific Dishonesty has published a series of national reports,<sup>15</sup> and has probably been more visible and active than any of the other Nordic committees. In contrast to the procedures in Sweden and Finland, cases can be referred directly to the Danish committee without initial institutional inquiry, and no agreement with the involved institution is needed to initiate investigation, whereas it is in Norway. Even anonymous complaints can, under special circumstances, be accepted in Denmark. Thus, it may be easier to make complaints in Denmark than in the other Nordic countries.

In three-quarters of cases investigated, dishonesty in the strictest sense was not disclosed by the investigative bodies. In some of these cases, however, deviation from good research practice was revealed. Many researchers might feel that the committees should confine themselves to giving their judgment on whether dishonesty had taken place or not. However, experience has shown that such constraint does not work. If the responses from the committees are dichotomised into "black or white", no indication will be given of whether the committees find the practice completely free of reproach or whether they find it deviating from good scientific practice to a greater or lesser extent. The decision "no dishonesty" may be interpreted as an approval from the committees. For this reason, and to increase the educational and preventive value of the decisions, a practice has developed within the committees not only to conclude on a dishonesty/non-dishonesty judgment, but also to describe explicitly in what way a non-dishonest practice is found to deviate from good scientific practice. Experience also suggests that dishonest acts at all levels of severity should be dealt with by a unified set of guidelines and procedures. Disputed authorship is increasingly frequent among medical scientists.<sup>16</sup> It is an alleged misconduct in a third of investigated cases; this high proportion reflects the importance and extent of authorship as a problem in research ethics. The addition of specifications of each author's contribution to a paper<sup>17</sup> to the Vancouver Group's definition of authorship<sup>18</sup> might prove useful, but as long as bringing credits to authors

has become one of the main tasks of scientific publishing, unethical practice in this field must be expected. The concept of authorship should be further discussed among researchers, editors, medical schools, and funding agencies. International guidelines should be developed and, most importantly, followed.

The lack of complaints from younger researchers is probably due to fear of sanctions.<sup>1,19,20</sup> 47 of 68 “whistle-blowers” reported negative action as a result of their revelations in an American study.<sup>21</sup> Lower-ranking faculty members, and students and fellows in basic science departments were most likely to have experienced such negative action. An American Commission on Research Integrity in 1995 suggested a whistle-blowers bill of rights and responsibilities “intended to encourage institutions to treat good-faith whistle-blowers fairly, shield them from retaliation, and to articulate the responsibilities of any individual who accuses another of research misconduct”.<sup>22</sup>

Anecdotal evidence, also from the Nordic countries, shows that younger researchers are particularly reluctant to bring cases of suspected dishonesty before a national committee because of fear of retaliation. Michael Farthing, chairman of the Committee on Publication Ethics (COPE) has written: “I have been approached by a number of whistle-blowers from various institutions, each asking for my advice. My experience is that these people are not treated appropriately by their own institution”.<sup>23</sup>

Experience from the Nordic countries shows that national research councils can set up appropriate bodies for handling of misconduct in medical research. These bodies can be an integrated part of a broader ethics system including all branches of science and scholarly activity (Denmark, Finland), or separate committees for medicine and health sciences (Norway, Sweden). Inquiries in the first instance can be made within the faculty or institution (Finland, Sweden), or cases can be referred directly to the committee (Denmark, Norway). Even though the Nordic countries define scientific dishonesty in slightly different ways, the national committees’ judgment of individual cases is similar. The main difference between the four countries seems to be the conditions under which a committee can start an investigation.

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## Commentary

### Scientific misconduct: exaggerated fear but still real and requiring a proportionate response

The overlords of research probity have secured a firm place among science policy-makers, but not without blood being spilt. The process began in the USA in the 1980s, when over-enthusiastic investigators from the Office of Scientific Integrity blundered into laboratories to investigate several celebrated cases of alleged misconduct. After the agency was reborn as the Office of Research

Integrity (ORI), these armies of auditors adopted a more careful strategy, one that has seen their efficiency rise as their caseload has fallen.<sup>1</sup> The ORI is now more respected than reviled.

A Danish Committee on Scientific Dishonesty followed in 1992, and it succeeded from the start in being not only visible but also credible. Its guidelines on good scientific practice<sup>2</sup> make recommendations about protocol development, data documentation and storage, and authorship. France established a committee on scientific integrity in 1998 and Germany is linking eligibility for research funding to provision of institutional procedures promoting good scientific practice. In the UK, although there is a case for establishing a central agency to review alleged instances of misconduct,<sup>3</sup> the creation of an informal advisory body, the Committee on Publication Ethics (COPE), to which possible breaches of good publication practice can be referred, has been left to editors.<sup>4</sup>

The review in today's *Lancet*, by Magne Nylenna and colleagues, shows that national committees for handling scientific dishonesty are not only feasible but also highly efficient and effective. Norway (1994), Finland (1994), and Sweden (1997) have followed Denmark in establishing their own committees, and together they have received 68 complaints, the commonest being disputed authorship (34% of referrals). Fabrication of data accounted for far fewer cases (11 %). These agencies were able to set standards, offer training and education, provide guidance during investigations, and act as an institutional memory for this case-experience.

Nylenna and colleagues draw the following conclusions. First, despite differences between the four Nordic countries in the definition of misconduct, "the national committees' judgment of individual cases is similar". Protracted wranglings over definitions seem unnecessary; even if misconduct is hard to define precisely, scientists recognise it when they see it. Second, although most cases of alleged dishonesty were not proven, "deviation from good research practice was revealed". And third, "dishonest acts at all levels of severity should be dealt with by a unified set of guidelines and procedures".

Given the great publicity research misconduct has received, there were surprisingly few cases of serious scientific dishonesty. Is the prevalence of scientific misconduct exaggerated? On current evidence, yes, although this conclusion may be premature. Nylenna has considered why so few cases have been submitted to the Norwegian national committee.<sup>5</sup> Potential complainants may

hesitate to report cases, the committee may not enjoy the confidence of scientists, the existence of the committee may not be well known, or there may indeed be no more misconduct to be found. Which of these explanations is true is not known.

Yet the pressure for even greater oversight of research is increasing. A Swedish parliamentary committee has recently recommended that each of the country's universities should create an ethics team composed of equal numbers of scientists and lay people to scrutinise all human research, private and public.<sup>6</sup> In the USA, the Office of Protection from Research Risks (OPRR) raised its profile by closing down 2000 research projects at Duke University for 4 days in May this year.<sup>7</sup> OPRR's budget and staffing are likely to be increased soon to enable it to extend its work.<sup>8</sup>

A backlash is developing. Researchers are concerned that excessive regulation and the threat of public witch hunts<sup>9</sup> will deter investigators from doing important research. According to Richard Peto and colleagues, for example, new regulatory constraints, "however well-intentioned, may well do more harm than good to patients". Peto has criticised the editors of the *New England Journal of Medicine* and *JAMA* for their "inappropriately harsh editorials" that seemed to jump on the misconduct bandwagon after allegations were made against the cancer trialist, Bernard Fisher. The issues at stake are serious:<sup>9</sup>

"... intrusive, time-wasting audits that treat those who organise trials and those who collaborate in them as potential delinquents might well divert or discourage clinical research workers from organising as many trials as they could otherwise have done, and could deter many of the thousands of practicing doctors who might otherwise have offered their collaboration. This would mean that life-or-death questions will not be answered as quickly or reliably as they should be".

Failures of due process lie at the heart of this concern. Barbara Mishkin, a US lawyer specialising in scientific integrity, has written that, "the greater the potential effect on an individual's reputation, freedom, or livelihood, the greater must be the due process afforded". Procedural justice demands, as a minimum, that there be published rules and procedures, that the charge be precisely framed, that innocence be presumed, that the institution be distanced from the investigation, that the accused has full access to the evidence, and that the opportunity exists for full cross-examination of that evidence. Those are the lessons learned by ORI, most painfully after the

spurious allegations made against Thereza Imanishi-Kari and David Baltimore,<sup>10</sup> lessons that have yet to be learned by some fledgling national committees.

Given the wide US and European experience with research misconduct, what next? First, editors could do more to raise awareness about good research and publication practice. As Debra Parrish has argued, the “Fisher case brought attention to how disconnected journal editors have been from the scientific misconduct process”.<sup>11</sup> Editors must be more explicit in their approach to research error, intentional or otherwise.<sup>12</sup> The Nordic experience, and that of COPE,<sup>4</sup> should help to prevent the grotesque abuses perpetrated against scientists when misconduct investigations go wrong.

Second, researchers should distance themselves from instances of misconduct. John Budd and colleagues reported that 235 research papers retracted between 1996 and 1997 were cited 2034 times after the retraction.<sup>13</sup> Should retracted research be better sequestered from the searchable scientific literature? Third, policy-makers must design a proper research agenda to discover, for example, whether “low-level” misconduct (minor authorship disputes) leads to major misconduct (outright fabrication of data). The ORI has made a welcome start in this direction.<sup>14</sup> And finally, editors must pool their international experience and agree on procedures, norms of due process, protection for whistleblowers, and sanctions. They must also rethink their approach to publication. Many instances of error either go unnoticed or become the subject of unnecessary dispute because of failures by authors to disclose in sufficient detail what they did. Stephen Lock has proposed “a new philosophy of encouraging the longer and better article at the expense of the shorter and meretricious one”.<sup>15</sup>

Is there a danger that editors are over-reacting to the threat of scientific fraud? If editors write rigid regulations for researchers to follow, over-train the institutional muscle of agencies responsible for scientific oversight, or impose

wider-ranging sanctions against scientists found to commit minor misdemeanours, they should not be surprised if Peto’s predictions come true.

But to ease back now and let recent injustices stop efforts to raise the standards of research and publication practice would be a mistake. “Doctoring the evidence”, “Not worth the papers they are written in”, “Fraudulent research a threat to patients” are recent headlines that may eventually persuade the public to withdraw its trust from doctors still further. The chain of trust that links patient to doctor and doctor to researcher is fragile. Research evidence strengthens this chain, whereas fraud weakens it. The review by Nylenna and colleagues should help to reinforce that trust in Nordic countries, an outcome that researchers and editors everywhere are likely to applaud and draw important lessons from.

*Richard Horton*

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## JAMA

### Biomedical Peer Review (July 15 1998)

The following is a summary of a selection of the contents of the July supplement published last year. This included papers on authorship, the quality of peer review, conflict of interest, bias, editors and their journals, and solutions for when things go wrong.

#### Overview

In a paper on freedom and responsibility in medical publication, Drummond Rennie, deputy editor of *JAMA*, outlines four systems, which, he believes, would promote greater openness and responsibility, and which would enhance the ethical climate of the publication of research.

These comprise the:

- abolition of authorship in favour of contributorship, with the work done by each of the contributors listed for all readers to see
- change from anonymised to open peer review
- assumption of full responsibility by scientists for the aftercare (updating) of their papers
- enablement of readers to assume the responsibilities of reviewers as a result

Dr Rennie suggests that keeping the names of the reviewers from the authors is a "perfect example of privilege and power," and that it reflects a lack of accountability to the fellow scientist who wrote the paper. In any event, he says, in up to half the cases it is impossible to successfully mask the identity of the reviewer.

There are glorious paradoxes in a system that permits authors' names to be disclosed to the reviewer, thereby behaving as if anonymity does not matter, and then preventing authors from knowing the names of reviewers, and so behaving as if anonymity mattered very much indeed.

"Justice is ill served by secrecy," he writes, and suggests that openness would strengthen the link between power and accountability, because when reviewers know their names will appear at the bottom of their reviews, they are likely to do much more constructive and thorough assessments.

Dr Rennie goes on to suggest that postpublication peer review will enhance accountability for the writers. In this way published articles could be altered in response to criticism from readers who then act as potential reviewers themselves. This should be more feasible, as electronic publication becomes more widespread, he suggests, and cites the *Medical Journal of Australia* which is experimenting with posting articles on the Web for criticism from the entire readership,

and subsequent revision, before they are accepted and published.

For responsibilities to be openly shared in scientific and medical publishing, contends Dr Rennie, contributors, editors, reviewers, and readers must be prepared to be held accountable (280:300–2).

Other steps towards greater accountability are discussed in a study on the disclosure of financial interest, which the authors believe, best serves the scientific community and the public (280:225–6), and another on the appointment of a journal ombudsperson, a practice established by *The Lancet* in 1996. Twenty complaints were received in the first 18 months, 11 of which were upheld, and these did not concern editorial decisions which were felt to be outside the ombudsperson's remit. Benefits extend well beyond the issue of complaints, drawing an editor's attention to the importance of efficient and courteous journal processes, the author concludes (280:298–9).

#### Authorship

Several papers tackle the thorny issue of authorship, including one from the ombuds office at Harvard Medical School. It shows that author disputes have more than quadrupled from 1991–2 to 1996–7. The study concludes that: "Institutions should increase enforcement of published authorship standards and place more emphasis on managerial skills for laboratory and research department heads." (280:216–7).

A Dutch study points out that the criteria for authorship are poorly known, even if most authors seem to be complying with the terms set out by the International Committee of Medical Journal Editors (Vancouver Group) (280:217–18). Yet a further paper points to a worrying increase in the number of authors given for any study, with a significant rise of authorship among professors and department chairpersons, (280:219–21) while another shows how a substantial proportion of peer reviewed medical journals show clear evidence of honorary or ghost authorship, particularly for review articles (280:222–4).

#### Peer review process

Several studies address the effect of open and closed peer review. One study shows that blinding reviewers to author identity or revealing the reviewer's identity to a co-reviewer made no significant difference to review quality, reviewers' recommendations, or time taken to review (280:234–7), while another declares that the optimal time to peer review a manuscript for a general medical journal seems to be a maximum of three hours. (280:231–3). A further study points out

that reviewers who did not know authors' identities were less likely to recommend rejection than those who did know. But requiring them to sign their reports did not improve the detection rate of errors (280:237–40).

*Publication bias*

Research that produces non-significant results is likely to take much longer to be published, or may not even be published at all, shows a study on passive smoking data (280:250–3). The average time to publication for non-significant results was five years compared with three years for significant findings. Positive outcome also seems to affect the acceptance of research abstracts at scientific meetings and their subsequent publication.

Study design and quality did not appear to be the governing criteria (280:254–7).

*Retraction*

A study of MEDline articles from 1966 to 1997 showed that 235 articles had been retracted. Error was the reason in 91 retractions; inability to replicate the results in 38; misconduct in 86; and no clear reason in 20. Of these 235, 190 were retracted by some or all of the authors; 45 by another organisation. However the 235 articles were subsequently cited 2034 times after the retraction notice, and in only 19 of 299 of these subsequent citations was any mention made that the article had been retracted. The remaining 280 treated the retracted article as valid research (280:296–7).

# **Committee on Publication Ethics (COPE)**

## **Setting a new agenda for good publication practice**

**Proceedings of the meeting held on 27 April 1999  
St Bartholomew's Hospital, London**

### **Programme**

#### **Publication misconduct and how editors should respond**

Professor Michael Farthing

#### **A view from the General Medical Council**

Sir Cyril Chantler

#### **A view from the Royal College of Physicians**

Professor Stephen Tomlinson

#### **Debate**

Chaired by Dr Richard Smith

#### **Breakout sessions to agree content of guidelines**

Study design and ethical approval; data analysis

Facilitated by Professor Michael Farthing and Dr Stephen Evans

Authorship; conflicts of interest

Facilitated by Dr Richard Smith

Peer review

Facilitated by Dr Sandy Goldbeck-Wood

Redundant publication; plagiarism

Facilitated by Dr Philip Fulford

Media relations; duties of an editor

Facilitated by Dr Richard Horton

#### **Debate: Use of editorial sanctions**

Chaired by Dr Richard Horton

#### **Summing up**

Professor Michael Farthing

## Delegate list

- Ms Barbara Althoungyan, London  
Dr J Andrews, *Gerontology*  
Mrs Susan Austin, *European Journal of Orthodontics*  
Dr M Bakowski, Solvay Healthcare  
Professor K Bartlett, Newcastle University  
Dr B Bentley, *Radiology*  
Professor J Bligh, University of Liverpool (Medical Education)  
Dr Joseph Chamberlain, *Journal of Pharmacy and Pharmacology*  
Professor Sir Cyril Chantler, GMC  
Dr Anne Cockcroft, *Occupational and Environmental Medicine*  
Dr F Cox, *Parasitology*  
Dr Ron Davis, *BMJ*  
Professor Sandy Davison, *Nephrology Dialysis Transplantation*  
Dr Tony Delamothe, *BMJ*  
Professor Michael Doherty, *Annals of the Rheumatic Diseases*  
Dr Steve Dunnett, *Brain Research Bulletin*  
Dr R Dybowski  
Mr Stephen Evans, *BMJ*  
Professor J Farndon, *British Journal of Surgery*  
Professor Michael Farthing, *Gut*  
Dr Philip Fulford, *Journal of Bone and Joint Surgery*  
Professor John Garrow, *European Journal of Clinical Nutrition*  
Dr Sandy Goldbeck-Wood, *BMJ*  
Mrs L Grayson, *British Library*  
Professor A B Grossman, *Clinical Endocrinology*  
Professor Terry Hamblin, *Leukaemia Research*  
Dr Hilary Hearnshaw, University of Warwick  
Dr R G Hendrickse, *Annals of Tropical Paediatrics*  
Dr H Hillman, *Resuscitation*  
Dr P N Hirschmann, *Dentomaxillofacial Radiology*  
Mr Frank Horan, *Journal of Bone and Joint Surgery*  
Dr Richard Horton, *The Lancet*  
Dr Rory Howlett, *Nature*  
Dr J Hunter, *British Journal of Anaesthesia*  
Dr N James, Sigma Metrics  
Mrs Alison James, *Journal of Physiology*  
Professor A Johnson, *AIDS*  
Professor David Katz, *International Journal of Experimental Pathology*  
Dr S Kleinert, *The Lancet*  
Dr C Livingstone, *Clinical and Experimental Immunology*  
Dr Fraser McDonald, *European Journal of Orthodontics*  
Dr D McNamee, *The Lancet*  
Professor Alan McNeilly, *Journal of Endocrinology*  
Mr Peter Medawar  
Dr G J Misiewicz, *European Journal of Gastroenterology and Hepatology*  
Mr Dominic Mitchell, *BMJ*  
Mr N Parkhouse, *British Journal of Plastic Surgery*  
Professor P Pharoah, *International Journal of Epidemiology*  
Professor John Pickard, *British Journal of Neurosurgery*  
Dr E Power, *Colorectal Disease*  
Dr S Richard, *Medical Science*  
Ms G Romano-Critchley, Medical Ethics, BMA  
Dr J Rothwell, *Brain*  
Dr Mohsen Shahmanesh, *Sexually Transmitted Infections*  
Mr D Sharp, *The Lancet*  
Ms Jill Shepherd, Press Office, BMA  
Professor T Sherwood, *The Lancet*  
Dr A Silver, *Journal of Physiology*  
Ms Jane Smith, *BMJ*  
Dr Robert Smith, *International Journal of Pharmaceutical Medicine*  
Dr Richard Smith, *BMJ*  
Dr M Stack-Dunne  
Dr G Steel, *International Journal of Radiation Biology*  
Ms Josie Stephenson, *BMJ*  
Professor Michael Stock, St George's Hospital, Tooting  
Dr E Sumner, *Paediatric Anaesthesia*  
Professor P K Thomas, *Journal of Anatomy*  
Dr R Tiner, Association of the British Pharmaceutical Industry  
Professor Stephen Tomlinson, Royal College of Physicians  
Dr Peter Toner, *Journal of Pathology*  
Professor E G D Tuddenham, *Blood Coagulation*  
Dr R Wakefield, British Library  
Professor M J Walport, *Clinical and Experimental Immunology*  
Dr P Watkins, Royal College of Physicians  
Ms C White, *BMJ*  
Dr A White, Department of Health (Scottish Office)  
Mr H Whitfield, *British Journal of Urology*  
Mrs Alex Williamson, *BMJ Specialist Journals*  
Dr Peter Wilmshurst, Royal Shrewsbury Hospital  
Dr Rolf Zetterstrom, *Acta Paediatrica*

# Publication misconduct and how editors should respond

Michael J Farthing  
 Editor, *Gut* and Chairman of COPE

## Aims of the meeting

About a quarter or third of all UK medical journal editors are represented here today, primarily to look at some draft guidelines on good publication practice. These have been put together by those of us who regularly attend COPE meetings, with the hope that, as a group of editors/publishers, we might develop guidelines that could be adopted by most UK biomedical journals and perhaps even further afield.

One of the particular points for discussion is the action that we might take, as editors, should we discover research or publication misdemeanour. Ultimately, I think this will help us as editors, because it isn't always clear as to how we should proceed. I believe guidelines will help us do our job better.

A secondary objective is to try and interest more of you in the workings of this committee. It's an extremely informal group with no constitution and no fixed membership. We get together primarily to help each other—a self help group for editors.

## The difficulties editors face

COPE is not in any way usurping or competing with the important role of the General Medical Council, or the Royal Colleges, or with any other bodies who have responsibilities in this area; COPE is primarily concerned with the problems that face editors. When we detect research or publication misconduct, how should we respond? COPE has been trying to answer these questions over the past two years.

Last year Sir Cyril Chantler threw down the gauntlet when he said:

“The editors of medical and scientific journals, who have done much to draw attention to the problem, could perhaps do more to eliminate it . . . Rather than simply rejecting the articles they find suspicious, they should be encouraged to express concerns to the author, or contact the named designated person in the organisation that employs the lead author, or both.<sup>1</sup>

In other words, if you find something you don't like, report it immediately to the institution concerned. I suspect that actually most of us don't do that. Most of the time, the easiest way to deal with suspicions of misconduct is to reject the manuscript, exactly as Sir Cyril said. Many editors have been reluctant to get involved, and even if they feel that there is something mischievous going on, they actually don't really have the powers to investigate it in any depth. Often an editor is uncertain as to whether there's a problem, but feels uncomfortable, so gets rid of the paper.

The other issue is retraction. The *BMJ* retracted a paper last year<sup>2</sup> whose senior author was Cameron Bowie, emeritus director of public health, Somerset. The paper was retracted because grave doubts emerged about its content and how the data had been obtained. Cameron Bowie commented: “I could find no one who could remember being telephoned, and only a third could remember the original home visit.”

Retraction serves the immediate purpose of unburdening the editor, and, at the same time, punishes the perpetrator because it puts a researcher into the public domain to face criticism from his/her peers. But retraction is often ineffective: a study published in a peer review supplement to *JAMA* last year<sup>3</sup> looked at the reasons for retraction, and citations of publications after they have been retracted. A Medline search for retractions published between 1966 and 1997, found 235 articles that had been retracted. In 91 there was probably a genuine error, or they said there was a genuine error; in 86, there was evidence of misconduct; and in 20 they could find no reason. But the 235 retracted articles were cited over 2000 times, and only in 6% was there an acknowledgement at the time of the citation that there was anything wrong with the study.

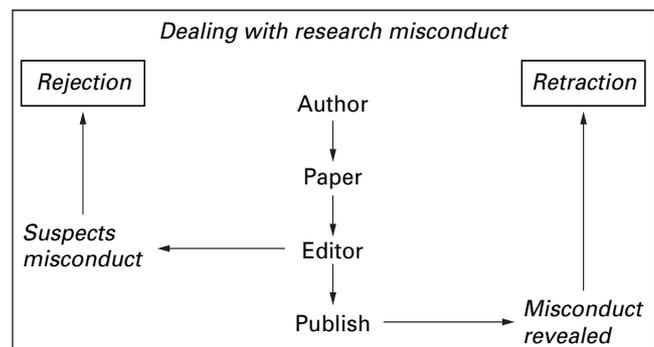
### Phenomena of retraction

#### MEDLINE 1966–97

Articles retracted n = 235	Error n = 91	Misconduct n = 86	No reason n = 20
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- 235 retracted articles cited 2034 times
- Only 6% acknowledged retraction

So although retraction has an immediate response, it exposes the author(s), and unburdens the editor, the study is still out there in the public domain, waiting to be read, digested, and re-quoted.



## Background to COPE

COPE grew out of a small group of part time editors, who usually have very little training for the job, and one or two full time editors, to try and decide how to manage some of these difficult situations. We discuss the anonymised cases submitted to us, and then we advise the editor as to what they *might* do; not what they *should* do. We recognise that we have extremely limited powers to investigate any particular issues that come up.

We also consider other issues, including authorship, editorial freedom, peer review, redundant publication, and a range of topics which come under the umbrella of publication ethics. We publish an annual report, and plan to promote research, and consider offering teaching and training about publication ethics.

Over the past couple of years we've discussed 56 cases submitted by editors:

### COPE cases 1997-99

■ Completed	41
■ Under consideration	15
<b>Total</b>	<b>56</b>

## Misdemeanours assessed

What sort of misdemeanours have we looked at? Redundant publication tops the list, but we've had a number of papers that we've regarded as being unethical. For instance, should you publish a paper on commercial organ donation from a country where methods of obtaining the organs are not known? Author disputes are common. Often, there may be one or two, or even three misdemeanours that have been committed at the same time. Failure to declare conflicts of interest on the part of a reviewer occurred when a reviewer assessed a paper, but clearly there was a major conflict between him and the authors concerned—it wasn't just academic competition. Dual submission, where the same paper was sent to the same journal at the same time, has also been reported to us.

We've also dealt with breaches of confidentiality—publishing data that you have agreed not to. One group wanted to publish their paper anonymously because they were afraid it might destabilise their local health services or that they might lose their job. Then there was the case of an editor who had been sacked for fraud, but continued to function as an editor.

We've also dealt with four major cases of plagiarism—and five possible or probable cases of fabrication or falsification of data. One was a letter signed by somebody who had forged another's signature. We've had one obvious fabrication/falsification that led to retraction and reporting of the case to the GMC. Another fabrication/falsification case was also complicated by the fact that the authors were attempting to silence the whistleblower.

### COPE cases 1997-99

Misdemeanour	n*
■ Redundant publication	18
■ Unethical	20
Failure to obtain—ethics approval	9
—informed consent	7
Other	4
■ Author dispute	10
■ Plagiarism	4
■ Fraud	5?
■ Failure to declare conflict of interest	1
■ Dual submission	1
■ Breach of confidentiality	1
■ No ethics committee	1
■ ? publish anonymously	1
■ Failure to obtain reviewer's consent	1
■ Co-editor sacked for scientific fraud	1

\*Some cases involved more than one misdemeanour

### COPE cases 1997-99: fraud and suspected fraud

■ The case of the fraudulent letter	97/11✓
■ Fabrication/falsification GMC	98/11✓
■ Fabrication/falsification (whistleblower)	98/17?
■ Falsification	98/25?
■ Fraud and an editor	98/29✓

## What action can be taken?

The question is, what can we do? And just how suspicious should you be? How much evidence do you need to alert the dean, or vice chancellor, or the heads of other institutions? Plagiarism is relatively easy to detect because you can look at blocks of text that have been taken from one paper to another and add it all up and, say, if more than 10% of the paper's been plagiarised then that's a misdemeanour. Redundant publication is also fairly easy to spot—if you've got two papers that look very much alike, one's published in one journal and one's in another, there isn't much to argue about.

- How suspicious should you be?
- How much evidence do you need?
- Plagiarism ✓
- Redundant publication ✓
- Falsification?
- Fabrication?

The difficult ones are where you suspect falsification or fabrication, but you don't have the evidence. So, what do you do under these circumstances? What action should be taken? How soon do you respond? Do you begin an investigation to obtain more evidence? What sanctions would need to be taken—a written warning to the authors, or withdrawal of publication rights? The editor of the *Annals of the*

*Rheumatic Diseases* made it very clear what he would do if he detected redundant publication in the journal,<sup>4</sup> but most of us don't have such clear statements in our Instructions to Authors.

- **What action should be taken?**
- **When should action be taken?**
- **What sanctions are appropriate?**
- **A written warning?**
- **Withdrawal of publication rights?**
- **Report suspicions to higher authority?**

I have problems with reporting to higher authorities when they involve the host institution. What's in it for a dean of a medical school to reveal a colleague as a fraudster, and then to sack them? I believe that there

**Report to higher authority: Problems**

- **No action**
- **Conflict of interest**
- **Limited internal enquiry**
- **Reluctance to reveal a colleague as a fraudster**
- **Reluctance to initiate a sacking**

have been several examples of internal enquiries suppressing evidence of research misconduct to avoid embarrassing the institution and senior colleagues.

The Medical Research Council (MRC), for instance, have extremely well documented procedures for dealing with prospective fraud within the unit,<sup>5</sup> but what if the internal enquiry comes first and is led by the director of the same unit in which the fraud is suspected? It's extremely difficult to investigate a colleague under those circumstances and is unlikely to open up a case further. Suggestions to involve other directors from other units could be met with protestations about their lack of knowledge of the local culture or the people within that unit. We simply don't have in place a satisfactory way of dealing with research and publication misconduct, as editors, nor can we be totally confident that when we've handed it on to somebody else, it will be dealt with appropriately.

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## A view from the General Medical Council

Sir Cyril Chantler

Dean, The Guy's, King's College, and St Thomas' Hospitals' Medical and Dental School

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.<sup>1</sup>

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.<sup>2,3</sup>

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."

# A view from the Royal College of Physicians

Stephen Tomlinson

Dean, University of Manchester, Faculty of Medicine, Dentistry and Nursing

## Genesis of action

That is a need for action, and a feeling of discomfiture in the academic community, and certainly in medical schools, that not enough is being done to ensure that all research coming out of medical schools is valid and of value.

There is no definition of fraud and misconduct which covers the whole spectrum of activity. Misconduct is perhaps the best all embracing term to use for activity which ranges from plagiarism through to deliberate deception for personal gain, involving fabrication or the production of fraudulent data.

### Need for action

- **Definition of “fraud and misconduct” not widely known**
- **Not all medical schools have clear procedures**
- **No guidelines for doctors in NHS**

A survey was undertaken by Councils of Heads of Medical Schools of the 25 medical schools in the UK. Eighteen responses were received; only 10 of them had written procedures which could be followed in the event of an allegation of fraud or misconduct in research.

The committee chaired by Professor George Alberti, President of the Royal College of Physicians, for the GMC, could not just focus only on medical schools and universities because this problem can involve those working outside universities and medical schools, and specifically those who work in the NHS. The stakeholders in ensuring that research is of high quality, is not fraudulent, and not produced in any way which might have derived from misconduct, comprise a wide ranging group. The ensuing report from Professor Alberti's group will therefore attempt to try to define the range of misconduct, from the relatively trivial through to deliberate deception for personal gain.

## Elements of good practice

In all institutions which undertake research, there should be a manual of good practice which ensures that both supervisors and those people who are going to be involved in research know what is expected of them, and what the relationships are between supervisor and supervised, and among different researchers in a research group.

The supervisor has a key role, and manuals of good research practice can offer guidance to both those who are supervising and those who are going to be supervised: there should be induction courses for researchers. Having established a graduate school in science, engineering, and medicine in Manchester, generic courses for all those undertaking research in that graduate school are available, so that a culture of scientific integrity is promoted. Undergraduates need to be exposed, right from the start, to principles of good research practice, to prevent the slide down the slippery slope which can end in deliberate deception.

Good research practice includes:

- access to raw data
- availability of statistical analysis/advice
- fostering a culture of scientific integrity
- eliminating the practice of gift authorship

### Action

- In response to allegations, all organisations where research is undertaken should publish legally valid guidelines for dealing with allegations of fraud and misconduct.
- Organisations should review the contracts of all employees, to ensure that procedures are binding, whatever the source of funding or the location of the research.
- Those involved in screening and investigating allegations should be appropriately trained.
- Investigations should include representation from outside the institution where the alleged misconduct has taken place.
- Investigations should involve a two-stage inquiry, beginning with an internal enquiry, and then a formal enquiry involving outside experts.
- A time limit should be set for the initiation and completion of the process.
- An appeals process should be in place that is independent of the screening and formal inquiry stages.
- Most organisations have limited experience of, and expertise in, dealing with allegations of fraud and misconduct in research and its consequences for those involved, so there should be a national body or panel of experts to whom organisations can apply for advice and guidance.
- Once an allegation has been proved, action should be taken by:
  - the appropriate professional body
  - grant awarding body
  - relevant journal editor
  - possible revocation of a degree/fellowship
  - disciplinary proceedings

- A central register of incidents involving deliberate deception in research for personal gain of any kind should be maintained, covering all research institutions, and funded by the participating bodies.
- The data on the register should be accessible, with appropriate safeguards, to named officers in the institutions where the research is undertaken.
- Data on the proposed register should be available to professional authorities, such as the GMC.

## Debate

Chair: Richard Smith  
Editor, *BMJ*

Richard Smith outlined the aims of the session—understanding, clarification, to examine what could be done that is currently not being done. Suggested questions for discussion included:

- How big a problem do we have?
- Are editors facing up to the problem?
- What should editors do when faced with possible misconduct?
- Do editors have the legitimacy and means to manage misconduct?
- Do we need a national body to help with research misconduct?
- How can editors help prevent misconduct?
- Do editors have a responsibility to help with education on misconduct?
- How can we respond to misconduct among authors who do not belong to an institution?
- What should editors do about editorial misconduct?

On this last point, Richard Smith commented: “Editors are one of the most unaccountable groups left. You can still create all kinds of havoc as an editor—it’s very difficult to do anything about it.”

for that person’s future professional career. Conversely, you can have malicious whistleblowers who do fantastic damage to perfectly good people. So I hope we can form some idea of providing appropriate incentives to people who blow the whistle genuinely, of how to protect against victimisation, and some sort of sanction against people who allege misconduct which subsequently is shown to be quite untrue.”

Stephen Tomlinson responded: “It is a cause for concern that it’s considered that the anonymity of the whistleblower must be preserved at all costs, up to the screening stage. But if you then move on to a formal investigation, natural justice must tell you that the anonymity must be lost and the accused must be able to respond to the accuser.”

Edward Tuddenham said: “If the whistle is blown somebody has to consider whether it’s being blown mischievously or not, and if they think perhaps not, then an audit is held. And what we’re auditing is, do you have the data to support the interpretations that you have published? If not, too bad. If you can’t produce the data there doesn’t have to be a loss of anonymity for the whistleblower.”

**“Editors are one of the most unaccountable groups left. You can still create all kinds of havoc as an editor—it’s very difficult to do anything about it.”**

A show of hands revealed that none felt that they had witnessed satisfactory outcomes to allegations of misconduct in terms of a proper investigation, due process, and resolution.

The policy in the *BMJ*, said Richard Smith, was to reject a dubious paper because 85 per cent are rejected anyway, but over the past two years he’s reported four authors to the GMC, one of whom had already been struck off, and including one case each to the Indian Medical Council and the South African Medical Council. He also referred two cases to the chief executive officers of NHS Trusts “who always want to know what they should do with this information.”

### Whistleblowing—in the UK and overseas

A register assumes that people are going to get on to it, and the main route by which they get on to the register is on someone’s say so, pointed out John Garrow. “The experience of everyone is that it does nothing whatever

One delegate suggested: “It’s fine putting in a police force in the UK. We have to tackle the big question of how we sort out what’s happening on an international scale. And in terms of whistleblowers particularly, the one case of whistleblowing to the journal that I’ve dealt with was an anonymous complaint about data fabrication that came from India.”

Sir Cyril Chantler commented: “You have an absolute duty to conduct all research in honesty and integrity. You have a duty to report evidence of fraud or misconduct in research to the appropriate person or authority. One of the problems the GMC faces is doctors who misbehave in one country and hotfoot it to the UK. There was a case just before Christmas, of an individual who was working in Canada. He was suspended and immediately came over here and took a locum job. He was struck off the register and is no doubt busy practising somewhere else. So one of the issues for the GMC over the next year is to establish some sort of fraternal relationship with other countries around the world to make sure we can deal with this.”

Peter Wilmsbury, of the Royal Shrewsbury Hospital,

cautioned: "A whistleblower who is malicious is not necessarily wrong. Whistleblowers will often blow the whistle after they have got into an argument with the person responsible for the wrongdoing, after having tolerated their fraudulent behaviour for a long time. The fact is, it doesn't mean they are wrong, it means their motives are wrong."

Anne Cockcroft, Editor of *Occupational and Environmental Medicine*, said: "Whistleblowers may not start off paranoid but they often end up paranoid, particularly if the person they are complaining about is somebody senior to them, and in institutions where perhaps the head of the institution might be the person responsible for the misconduct."

Michael Farthing felt that some perspective on this problem was called for: "I seem to remember Drummond Rennie (Editor of *JAMA*) said he's interviewed over 700 whistleblowers, of whom only 5% were malicious and wrong. So this is probably a very small minority, whatever the number is, compared with the people who have a genuine complaint."

Richard Smith warned: "The evidence is that almost all whistleblowers end up damaged. Unless you have some kind of legal protection for whistleblowers that applies to any kind of whistleblower anywhere, it's very tough to actually guarantee that they are protected."

"There's an absence of whistleblowers when it seems highly likely that fraud has taken place. There doesn't seem to be any investigation in the institution concerned as to why results published in journals, which are totally unrepeatable, and after several attempts, were ever published," commented Terry Hamblin, Editor of *Leukaemia Research*. "In many institutions abroad you've got the priesthood of medicine and the science of medicine. The priesthood is by far the stronger. One of the worst things is that in order to get promotion in almost any university influenced by western thinking, you've got to publish. The result is some publications in which some fact is merged with myth, and so forth, but if they don't publish they die. To some extent, we the journal publishers are at fault here because this has become the lodestone for everybody worldwide."

Anne Cockcroft explained that *Occupational and Environmental Medicine* takes quite a lot of papers from abroad, "but I also do quite a lot of work abroad myself—community surveys and so on. The interesting thing when working in different countries is that the norm is that people don't believe the results of surveys because, depending on who has done them, they are fudged in one way or another—often for political reasons."

"It seems to me there is a crucial question as to how much "we," a sort of amorphous group that goes under the heading COPE, should concern ourselves with international activities, and how much we should concentrate on getting our own house in order here," commented Richard Smith. "But there are things we could do—for instance to we could give the guidelines to the European Association of Science Editors for their meeting, and the Council for Biology Editors in the States. We could give them to the World Association of Medical Editors. We could present them to the International Committee of Medical Editors of Vancouver. Alternatively, we could say that probably the majority of our papers come from outside Britain and therefore we have to think globally."

Ultimately it was felt that employers who should take responsibility for pursuing the sanctions and investigation. "We can't solve that here. We particularly can't solve that internationally, but as editors we do have to work out ways of handling those issues for all submitted manuscripts, and not just for those coming from the UK," suggested one delegate.

Mohsen Shahmanesh, Editor of *Sexually Transmitted Infections*: "There's nothing we can do to change the situation in other countries. What we can do though, is to do something we did some years ago and that's to reject the paper."

Mr Whitfield of the *British Journal of Urology*, disagreed and felt that it was important to tackle the issue on an international basis. "We probably all receive more redundant publications than fraudulent reports and this is where international editors can get together and make it known that editors in a particular subspecialty are on the lookout for it."

Philip Fulford, Editor of *Bone and Joint Surgery*, agreed:

**One of the worst things is that in order to get promotion in almost any university influenced by western thinking, you've got to publish.**

Frank Cox, Editor of *Parasitology*, pointed out different cultural perspectives which can make it difficult to adopt a universal approach: "If we report someone in England, or Australia, or the United States, it can be up to the departmental level. If we report something in China or some parts of the Middle East these people can actually end up in prison. How do you decide what level of action you should take against particular people in different parts of the world, bearing in mind that cultures are so different?"

"I think that because English has become the international standard language in science and medicine, and because the Internet is 80% English, we have a duty of education, let alone punitive action, outside our own country."

### Submission of raw data

Stephen Evans, statistical adviser to the *BMJ* suggested that European practice should be taken into considera-

tion. "In terms of the guidelines we've got to be aware of good clinical research practice which is already a guideline in European law. The single thing that can make a big difference is for journals to demand the right to the data." However, he felt that this approach is not without its difficulties. "It can take a statistician an enormous amount of time to prove that the data are fraudulent—if you're going to make a case, it's got to be proof beyond reasonable doubt. The resources required for this are considerable. In my previous experience with other journals, quite often the papers just go away. In some instances they send you the data, you can reproduce the answers in their equations absolutely imperfectly, and all their statistical significance totally disappears, but they then go and publish it somewhere else."

It was suggested that a condition of publication should be that authors are prepared to produce their raw data for editors if they are queried, and if they refuse, the paper won't be considered.

Kim Bartlett, of Newcastle University, wondered what people thought constituted raw data, bearing in mind that much of it is in electronic form, many machines will edit or smooth data, or enhance it in some fashion, and how should it be stored?

Stephen Evans responded that it was both easier and reasonable to have it on disk. The raw data that comes out of the machine, even if it's processed, he said, is still raw data and a good statistician should be able to detect when it has been smoothed.

Alan McNeilly, Editor of the *Journal of Endocrinology*, explained how he had recently submitted a paper to an American journal, one of whose reviewers felt the photomicrographs were "too good to be true" What he was saying, was that all data, not only numbers, but particular visual images can be smoothed by various computer distorting mechanisms—for example, gels, and it is very difficult nowadays to say what is truly raw data.

Peter Pharoah, Editor of the *International Journal of Epidemiology*, commented: "Surely raw data is data that hasn't been cooked. When I think of my raw data, it's in a filing cabinet on paper. The act of putting that on to a computer is possibly cooking the data, and you can cook it at any stage you like. The raw data is the paperwork from which you get the data."

Michael Farthing agreed that raw data is often the patients' notes themselves. "But they often get lost as they disappear into the database, and unless you have built in systems to know when people enter and exit on the database, and what changes are made to it at a particular time, you can end up with what is apparently raw data in electronic form. To go back to a thousand sets of notes would be extremely difficult."

## Redundant publication

Richard Smith outlined how redundant publication is something for which there are good data. Around 20% of papers are published more than once in substantially the same format, he said. "It's an incredibly common endemic problem."

It was pointed out that papers published in the native language were often submitted in English unbeknownst to either editor, which was very difficult to detect. Perhaps 'This must not have been published before, even in another language,' should be included in Instructions to Authors? "I don't even mind republication in English of important foreign papers, but the editors must know that it's going on. When this happens we can write to the other editors of the journals in the same field: frauds hardly ever do it once."

Richard Smith warned of the dangers of such an approach: "This is actually one of the things that people who know a lot about research misconduct will tell you—doctors playing lawyers can go horribly off the rails. You have to be very careful about sending out names of people all round the world unless you've got pretty solid evidence that whatever they did you could prove, to the extent of being in a libel court where the onus would be on you to prove the case."

Charles Livingstone, Editor of *Clinical and Experimental Immunology*, felt that editors should be much more concerned with actually trying to identify what is the harm that flows from a particular piece of misconduct and that very little harm flows from a duplicate publication if the data are absolutely correct and it's a solid piece of work.

Richard Smith suggested that "a keen systematic reviewer would say that a lot of harm potentially flows from publishing the same thing more than once because when naive people—most of us—do a systematic review we end up thinking that a drug perhaps is a lot more powerful than it actually is. And the other side of redundant publication is not publishing negative results which a lot of people are guilty of too."

It was also suggested that a person involved with duplicate publication was also likely to be involved in other fraud and that relatively minor misdemeanour might lead to more serious misconduct, such as fraud.

The *Journal of Bone and Joint Surgery* have arranged to have papers of interest to French researchers translated and published "under licence" in a French journal.

Richard Smith felt there was no problem with duplicate publication as long it was openly acknowledged and the author's permission had been obtained. It was only when it was hidden, that it was a problem, he said.

It was suggested that some scale of wickedness was needed to maintain a focus on the serious and ensure proper procedures, rather than getting bogged down with the fact that all of us are wicked. Scientific methodology is flawed, said the speaker. "I think it very rare that a piece of research as published is going to be completely correct. It may be that the wrong statistics have been applied wilfully, or it may be that they have been applied by accident, and yes, we have to improve the exercise of methodology, but we actually have to define precisely what we mean by misconduct."

## Defining misconduct

Frank Horan's definition (*Journal of Bone and Joint*

*Surgery*): “Misconduct is cheating, it’s as simple as that. A paper signed by the professor of the department who has never seen it, is cheating too. I think you have a climate of cheating because people are allowed to get away with it. At the end of the day, my view is that it comes down to the editor. It’s our job.”

“A lot of people think that there is this really horrible stuff—the Malcolm Pearce type stuff—and then

have already published it once, is deliberate deception and it’s for personal gain.”

“Then you would have to qualify what deliberate deception is, and it seems to me that it’s fraud. If you produce fraudulent data, that is deliberate deception,” retorted the previous speaker.

“In terms of scales of wickedness, you seem not to have mentioned the silent impact of what some of

**“Misconduct is cheating, it’s as simple as that. A paper signed by the professor of the department who has never seen it, is cheating too. I think you have a climate of cheating because people are allowed to get away with it.”**

there are all these arguments around duplicate publication, authorship, conflict of interest. We don’t really know, it seems to me, we don’t have evidence to tell us,” suggested Richard Smith.

A delegate said that it was impossible to deal with everything: “We can’t produce a procedure which actually covers the whole spectrum because there are degrees of wickedness. The procedure that has been written for handling allegations of fraud can’t be used to handle incidents of minor wickedness.”

“So if you put your name on a paper where you’ve done almost nothing, probably true of 20% of papers in the medical literature, where is that on that scale?” asked Richard Smith.

The previous speaker retorted that we shouldn’t be so interested in intentions to be wicked, but in effects.

these papers might achieve, and that is on the patients. So in my scale of wickedness, forget financial gain and an extra £10,000 a year, or an appointment in academia. What to me matters, is whether the patient at the end of the day suffers, by either not getting a treatment or getting a treatment which is inappropriate and could be fatal. I think we’re all being very sanctimonious about levels of wickedness and forgetting perhaps what we really want to be looking at, which is the end result of research misconduct,” commented the former editor of *Cancer Treatment Reviews*.

Peter Medawar (author on scientific integrity): “Article 1 of the Japanese penal code says, more or less ‘harmony is more important than justice’ and I think probably the same goes for truth, and it applies far beyond Japan. The second point is about the distribu-

**... forget financial gain and an extra £10,000 a year, or an appointment in academia. What to me matters, is whether the patient at the end of the day suffers, by either not getting a treatment or getting a treatment which is inappropriate and could be fatal.**

Retractions don’t make work disappear. Acknowledgements that papers have been retracted, are rare, he said, the work is repeatedly cited.

“This is a bit like saying, how do we respond to hypertension?” suggested Richard Smith. Clinicians and public health doctors approach it differently, he said. “We really don’t have a very good fix on what this scale of wickedness is, nor do we have any very good agreement, nor do we have a sense of how it’s distributed.”

Many activities fall short of deliberate deception for personal gain, it was suggested. “Even duplicate publication and gift authorship, people would say, are less wicked than deliberate fabrication of research results.”

Perhaps this was playing with words, said Richard Smith. “When you use the phrase ‘deliberate deception for personal gain,’ getting a paper published a second time in a journal without telling that journal that you

tion of what we call wickedness and I wonder if this test isn’t too high? Instead of slamming wickedness, we should be more concerned to promote propriety.”

“Everybody is capable of being wicked, given the right circumstances, and one of the reasons perhaps why people behave worse in other countries, is that they have actually got different incentives,” suggested a delegate. “We’ve been talking about the outcomes here, but if we want to do something about it we need to talk about causes. At the moment, a lot of the incentives are towards being wicked, or fudging things, or twisting things a little bit at the edges.”

### Possible actions

George Misiewicz, Editor of the *European Journal of Gastroenterology and Hepatology*, said that editors have enormous power because everyone who has done good

research wants to publish in English. He felt that the message of the guidelines would percolate worldwide and have an effect.”

It was suggested that COPE could write to universities and ask them to confirm that they have procedures in place for dealing with allegations of fraud in research. Chief executives and NHS Trusts should be included.

Peter Wilmshurst said that writing to the deans about whether they have protocols in place would mean nothing unless they were used. “I can think of five London teaching hospitals where the heads of the medical schools failed to take action against research misconduct this year.”

Richard Smith felt that it wasn’t just a question of having procedures, but whether they were any good or not.

The editor of the *Journal of Pathology*, Peter Toner, suggested that COPE could set up an incident reporting system outlining just the nature of the problem, to obtain some statistical data on how many incidents are happening and being reported among the 250 journals published in the UK?

Richard Smith said that COPE is already doing that, to some extent. “Some of the cases presented to COPE are very clear, but it’s surprising how many of them throw up issues that many of us had never thought of before, and which advance our understanding. The idea behind that is to sort of get a taxonomy. I suspect that most of the cases COPE receives come from few journals. Most journals at the moment, do not send us their cases; they deal with them in their own particular way. One reason to send us a case is not to get advice, but to get a fix on the problem.”

The incident reporting system was pursued further with a suggestion that it should be at two levels: request for a detailed presentation and discussion of the case, or simple notification on a postcard that a problem has been encountered without the need for discussion.

Stephen Tomlinson suggested writing to the deans to forewarn them that if they haven’t got procedures in place they aren’t eligible to receive any grants from the NIH or any other public health service.

Peter Hirschmann, Editor of *Dentomaxillofacial*

*Radiology*, said: “It seems to me that as far as NHS Trusts are concerned, this is a clinical governance concern. It is part of the way in which staff employed in trusts behave in relation to standards, and if trusts are going to have mechanisms in place to deal with doctors that harm patients, then may be this comes under the same umbrella.”

The editor of the *British Journal of Surgery*, John Farndon, wondered if journals could be encouraged to make joint statement, using the yellow card system? “One of the things we found on the international scene is tremendous enthusiasm in Western Europe to issue a joint statement.”

Michael Farthing said that was because of the tremendous fear of being sued. “I don’t think you’ll get US colleagues on board for this sort of networking.”

Sandy Davison of *Nephrology Dialysis Transplantation*, suggested that deans and the chairman of trusts could decide to limit the number of publications that could be cited when applying for a post. This, he said, would significantly reduce the number of publications being submitted and it would also make it possible to actually look at their merit. “We could start by cutting this out as part of the criteria for employment and grants.”

This already happens in Hull, and for some senior lecturer and chair posts, where candidates are asked to pick out the five publications that they want to highlight as their most important.

Many grant applications also now insist that a maximum of five most recent relevant papers.

“Rename the yellow card system an orange system, somewhere between red and yellow,” said Stephen Tomlinson. “And also emphasise that it should be anonymous so we might get the Americans in, because we are interested in doing this to assess the prevalence of the problems rather than identifying individual cases.”

Hilary Hearnshaw, from the University of Warwick, suggested that one of the drivers behind misconduct is because somebody gains from it. “One of the major gains is the CVs, and when you change that culture, that will be much more effective than any punishment or sanctions. Let’s go for removing the rewards from misconduct.”

## Break out session reports

Chair: Anne Cockcroft

Editor, *Occupational and Environmental Medicine*

The various groups reported back on their amendments to the draft guidelines, point by point. Only those issues which provoked extensive discussion are reported here.

### Study design and ethics; data analysis

Facilitated by Professor Michael Farthing and Dr Stephen Evans

Discussion was generated on the ethics of animal research in different countries. A case in point was the example of a British referee suggesting that a paper should not be accepted in a British journal because the way of taking blood from the mouse would not be acceptable in the UK. "We can't really expect people to adopt regulations that are not relevant to their country," commented Michael Farthing.

The analogy was drawn out further by a participant asking if a paper that reported on experiments on people in China, which would not be acceptable in Britain, would be published. "If you would not do that, why should you publish a paper that describes experiment on rats that would not be allowed in Britain?"

It was agreed that the standards adopted for publication should be those currently adopted in the UK. But it was suggested that international journals, which receive papers from Asia and in particular China, would not be able to apply this and may have to publish findings that would not be published had they originated from a United Kingdom base.

"We publish in terms of UK copyright law perfectly happily so why should we behave any differently about UK ethical law?" commented one of the delegates. Another suggested that such a paper on transplantation pointed out the dangers of what happens to people being transplanted under those circumstances—extraordinarily useful in an international community. This would never have surfaced had this ruling been applied.

"You don't want to talk about compliance but what you want to emphasise is that practices which would be patently unacceptable in the host country are the ones you might consider not publishing," said Michael Farthing.

### Authorship; conflicts of interest

Facilitated by Dr Richard Smith

#### *Authorship*

It was felt that most difficulties with regard to authorship could be resolved by disclosure of individual contributions.

The *British Journal of Radiology* asks authors not only to demonstrate their contribution, but actively to identify that contribution, on the basis that the part contributed might be requested, it was noted Anne Cockcroft commented that might be difficult for somebody whose contribution covers a bit of everything.

A fear was expressed that the same people can get away with gift authorship by putting their name to contributing in some vague sort of way, by reviewing the final version of the debate, for example, when they really had nothing to do with it.

Richard Smith suggested that the section on authorship really boils down to "we're confused, so it's all right for you to be too. It's actually a terrible mess at the moment. But the section is a step forward in the sense that if it said 'Terry's contribution was to turn up every so often and tell us a good joke,' it's better than including Terry as one of the authors with the suggestion that he had done as much as everybody else."

"It's one thing for the authors to declare to the editor, but if the paper is published, are they going to give different type size to the different percentage of contributions. How are the readers going to know?" queried another.

#### *Conflicts of interest*

When conflicts of interest are declared to the journal what should the journal then do about it?

Because so many journals are doing such different things, it was felt that it was impossible to be prescriptive about this. If they are declared to the editors, the implication is that the editors can decide.

Should editors publish in their own journals? Yes and no. Editorials only, said some, but they know their subject so well, responded others. A show of hands showed that most present thought it was acceptable.

Comments included:

"I think it's very important that editors, when publishing in their own journal, send it out for a peer review."

"I regularly publish in my own journal. It's totally independently peer reviewed and totally independently decided on. It seems to me that if you do it that way it's OK, and I've had papers rejected."

"My unwritten policy was that the lead editor and the deputy editor would not publish research papers in our own journal. The senior editors and associate journals would be free to do so. I think the issue of the editor in chief excusing himself from the editorial review process is not a cut and dry issue, because there is a question of the bias of whoever you sign over the decision of the process to. There is still a question of

them being favourably biased towards accepting a paper because their editor in chief is the author of that paper. It requires a lot more debate.”

“I think there is no reason why an editor shouldn’t publish in their own journal but it obviously shouldn’t be processed by him/her.”

“If you do it, I think you should declare at the end of the article the process you used to review it, and not leave it to the readers to assume that you used an entirely fair process.”

“I think the same argument should apply to the editorial board. It’s very unfair to penalise the board just because they may be working on what you consider the best journal.”

“If you have a decent editorial board you hope you have some of the best brains in the specialty. To exclude them from the journal seems a bit like shooting yourself in the foot.”

“I refereed something for an editor in his own journal, and along with the other reviewer, recommended rejection. The editor published it, and so I replicated it, or failed to replicate it in a study four times as large. He refused to publish my paper.”

## Peer review

Facilitated by Dr Sandy Goldbeck-Wood

Journals could declare whether or not they propose to grade reviewers, and if they do, to tell them. It may not be acceptable to keep information on people that you’re not willing to reveal to them.

It was noted that the Data Protection Act is shortly to be extended to written documentation beyond the present conditions of the 1984 and 1987 Acts for access to computer records. There may not be any choice or flexibility. Someone may ask to see the name of confidential referees held on written records in editorial offices.

It was felt that there were exemptions within the body of the Act which would preclude serious problems *vis à vis* authors wanting to know who had refereed their paper, and for information on that referee.

*Brain Research Bulletin* sends anonymised papers for review: “We’ve done that regularly for the past five years and I don’t think it changes the outcome of the peer review process one iota. It does increase the confidence of some less self confident authors, by getting a fair review that they may not have otherwise. So I think it’s more of a perception to authors of fairness rather than any change in the fairness.”

Comments included:

“I don’t think it’s made any difference to the fairness of the review process except that it enables reviewers to show off and say it’s obvious that this comes from so and so, because they are the only people doing this work, etc., so we are paying lip service. It’s helpful but not essential.”

“There was one small randomised controlled trial published in *JAMA* which suggested that blinding the

reviewers to the identity of the authors improved the quality of the review. We then did two much bigger randomised controls trials, one of which we did at the *BMJ* and one of which was a multi journal trial in the US, and neither of them found any benefit whatsoever in the quality of the review. The outcome measure was a validated measure of the quality of the review.”

“The quality is slightly dependent on how long you take to review. A very short time to do it and a very long time means poor quality, and the optimum is between that—about 3 weeks or so.” Other experience indicated that 3 to 4 weeks gave reviewers time to read it once and then go away and think a bout it and come back a do a more careful review.

A show of hands indicated that the delegates were more or less equally divided on the issue of whether open peer review was a good idea.

## Redundant publication; plagiarism

Facilitated by Dr Philip Fulford

### *Redundant publication*

It was felt that it is justifiable to publish in other languages because not everyone speaks English. Similarly, important research published in languages other than English needs to be widely disseminated.

How disclosure should be made also provoked considerable discussion. Disclosure form at revision stage? If authors were to sign this, the onus of truth rests with them. If they do not comply, they would be guilty of a deliberate attempt to deceive, and would make it clearer to interpret their behaviour as ‘with intent’, and to then institute action.

It was agreed that reviewers/referees couldn’t always be relied on to spot problems.

There are legal copyright obligations to seek permission to use or reprint text/figures, but these are hard to enforce.

### *Plagiarism*

Caution is required for plagiarism referring only to published work because rejected papers have been plagiarised. People also plagiarise grant applications that are not published material.

“If you announce your ideas and discuss them in public, they’re in the public domain and you can’t patent them.”

“Surely it’s a moral issue rather than a legal one. If I had a brilliant idea here and announced it to all and sundry which someone else claimed as their own, surely that’s a moral argument?”

“This is important issue because we’re all used to discussing with colleagues from institutions, different ideas and so on.”

“What tends to happens at conferences is that people will only present either an accepted version or what has already been published, and so very frequent-

ly at conferences you get a 'proceedings of' which consists of stuff which is entirely dual publication. They are not usually in *Index Medicus* but they are cited by *Current Contents*, for example, and they just appear and appear. I think it probably ought to be stopped."

What about the web? The *New England Journal of Medicine's* line is that if an abstract at a meeting has been posted on the web or published on a CD in relation to the meeting then that will not constitute primary publication. It was suggested that even if something has been published in full on the web it will be increasingly difficult for journals to say they won't publish it.

## Duties of an editor; media relations

Facilitated by Dr Richard Horton

### *Duties of an editor*

Even if something happened in a journal years ago, the editor would still have a responsibility in terms of making it public, it was suggested.

"Editors will always have opinions about topics and they can therefore influence the review process unofficially. They can write to reviewers saying 'am I making a terrible mistake if I publish this paper, or I'm planning to reject this paper, so do you think I'm making a terrible mistake?' and you're expected to review along those lines. That surely should not be happening."

There was no resolution to the problem of what happens to the editor of a small journal if he is being questioned for a possible allegation of misconduct? There may be nobody else in a proper position to do that.

Privileged information also came under discussion. Should editors who have access to that, publish it? If of merit and relevance, why not, but what about the publication of articles that are relevant to materials that might be being prepared for biological warfare?

Who should editors confess to?

- Consortia or COPE, using the orange card system advocated earlier.
- Relevant publisher
- Learned Society
- COPE could widen its remit to deal with complaints against editors
- If editors sign up to COPE, they agree to abide by its rulings.
- An ombudsman, a readers' watchdog, such as is operated by *The Lancet*.

### *Media relations*

It is not just authors who need to give a balanced account but journals as well, because the larger ones have media relations staff who proactively put out press releases and hold press conferences.

When authors reach out to the media they have a certain obligation to work with the journal and the editor on how they are communicating to the media; similarly, the journals that want to proactively communicate with the media need to keep authors informed of what they are doing.

It was felt that it is sometimes difficult not to supply journalists with additional data when they want to know what has happened one year on, and that sometimes additional data have to be supplied to clarify the science.

## Use of editorial sanctions

Richard Horton  
Editor, *The Lancet*

“The greater the potential effect on an individual’s reputation, freedom, or livelihood, the greater must be the due process afforded.”

Barbara Mishkin, US lawyer specialising in scientific integrity.

The Danes have been officially dealing with research misconduct for some years, and it would be useful to invite them, together with their colleagues in Norway, Finland, and Sweden, to attend COPE meetings and relay their experiences about how they have handled allegations of fraud. These countries have dealt with 41 cases since 1993, and authorship issues top the list of misconduct inquiries.

### *The Danish experience*

	93	94	95	96	97	Total
Cases	15	5	2	10	9	41

### *Issues of misconduct in Danish scientific publications*

Authorship issues	10
Suppression of unwanted data	4
Unauthorised use of data	4
Plagiarism	3
Flase description of method	3
Distorted statistics/conclusion	2
Theft of data	2
Construction of data	2

In the USA research misconduct was brought into stark relief by the Fisher case which showed how widely disconnected journal editors had become from the scientific misconduct process. As Parrish commented, “there are different expectations regarding the obligations of authors, research institutions, and federal agencies about informing the relevant journals when an allegation of scientific misconduct is made about a publication in its pages.”<sup>1</sup>

Should there be a national body to deal with research misconduct, and what should it be responsible for?

The following could be priorities it might adopt:

- Institutional memory
- Training and education
- Setting standards
- Investigation
- Securing public confidence

How do we define fraudulent research? According to Peter Medawar, a scientific paper is a fraud “in the sense that it does give a totally misleading narrative of the processes of thought that go into the making of scientific discoveries.”<sup>2</sup> Once research misconduct has been defined, due process must seen to be done; there must be access to the evidence, and the opportunity to refute allegations.

Due process is perhaps best summed up by a quote from David Sharp, Deputy Editor of *The Lancet*, in 1991: “Most medical journal editors who have had to face allegations of fraud in their own pages will have realised the need for fairness to all, for ‘due process’ or ‘natural justice’.”

How we deal with fraud as editors ranges from the private—beginning with a letter of explanation to the authors—to the public—beginning with retraction, and the reasons for so doing—to a mixture of the two, including banning submissions and reporting individual doctors to the GMC.

### *Editorial sanctions (so far)*

<b>Private</b>	Letter of explanation Letter of warning Letter to institution/funding body
<b>Public</b>	Publication of notice: retraction, redundant publication ... Editorial, explaining full details
<b>Private/public</b>	Ban on submissions: individual, unit, institution Report to GMC

But retraction does not have a particularly good record. A Medline search for the years 1996 and 1997 showed that there had been 235 articles retracted, yet the citations after retraction amounted to 2034.<sup>3</sup>

**“Editors have done too much to encourage articles that are short rather than long enough to be able to report and discuss all the findings in a single paper . . . hence I would suggest a new philosophy of encouraging the longer and better article at the expense of the shorter and meretricious one.”**

**S Lock (1996)<sup>4</sup>**

**“We must end this ludicrous emphasis on authorship as a goal in itself, the obsession with having one’s name on as many articles as possible.”**

**S Lock (1996)<sup>4</sup>**

## ISSUES TO CONSIDER WHEN DECIDING ON MISCONDUCT

<b>Issues for editor</b>	<b>Author intent</b>
<b>Etiquette</b>	<b>Intentional malpractice</b>
<b>Ethics</b>	<b>Negligent practice</b>
<b>Error</b>	

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### Debate

#### *Role of education*

It was suggested that the principles of academic honesty should be included in medical students' courses, and that a policy of "zero tolerance" should be adopted in this respect.

It was thought that sanctions early on would prevent the occurrence of major fraud. If COPE allowed editors to publish the guidelines and use the sanctions appropriate to the misdemeanour, that these would help educate and deter. "It is important that the due process should be as much educational as punitive," commented Anne Cockcroft.

It was agreed that journal editors have considerable leverage because authors want to publish, and that means that editors can have a significant impact on the culture of science.

#### *Thresholds for involving the author's institution*

Richard Smith reiterated the importance of pushing back the concern to the institutions, because editors don't have either the legal legitimacy or the means. He felt that the institutions would then discover that they don't know how to handle these things and consider whether they should have an institutional policy. It would also create a climate whereby people will demand some kind of national body, he said, because they won't be able to manage without one. "And the corollary of that is we should have a fairly low threshold of involving the institution—authorship, for example. If I had reported those four people I mentioned this morning on the grounds that I was confident that this was misconduct and they should be struck off, then I wouldn't have dared do it. All I'm doing, is saying to the institution is there are enough

signs and signals here that I am confident that somebody ought to look hard at this, somebody who does have due process, somebody who does have legitimacy. If after you've looked at it, you come back and tell me that it's all fine then all well and good. But if you discover there's a problem, I will publish it in the journal."

Richard Horton confirmed that going back to the institution with a reasonable letter was very helpful. "I've done this three times. Twice at least I've had a really grateful letter expressing gratitude for pointing it out, and hoping that the sanction of non-acceptance of any further studies for two years would not be applied. They did do something about it, which suggests that somewhere nearer to zero tolerance is probably a good idea, feeding back material all the time."

It was felt that feedback to institutions, as well as having the effect of making them confront the issue, like clinical complaints, would make people think about the whole framework in their institutions for prevention. It's not just the quality of patient care, but the quality of everything that the NHS or university does, and research is an important part of that. Extreme mechanisms might be needed for handling extreme cases and normal governance for handling the minor misdemeanours.

What is the threshold for referral to an institution? Do we think that we should handle anything internally, such as dual submission, redundant publication, a little bit of plagiarism? Do we feel that as journals we shouldn't apply any sanctions at all? asked Michael Farthing. "There's a tremendous danger of crying wolf and starting to send everything to institutions.

Ron Davis, North American Editor, *BMJ*, suggested that if there was an allegation of manufacturing data the editor must go back to the institution, "but in the case of redundant or duplicate publication I don't see why in most cases, in fact all cases, the journal editor couldn't handle that by him or herself, perhaps consulting with the editor of the other journal where the duplicate publication might have occurred."

Richard Smith said that another reason for going back to the institutions is where something minor turns out to be much more serious, when the data are assessed: "I know that the institutions most of the time don't have a clue what to do. Some kind of investigation process is not the kind of thing that deans know about, not the kind of things that editors know about."

**...All we're doing is refusing to do as we used to do, and to effectively allow malpractice to continue by the fact that we don't take any action; and it's not for us to judge if it's fraud or not fraud, but pass it to someone who can decide."**

“What’s really happening,” said a delegate, “is that there’s a suggestion of some impropriety over which we as editors cannot finally be the arbiter and that we’ve got two choices, either it stops with us, and the information goes no further, and nothing happens, or we allow ourselves to be a channel for that problem to land on the desk of somebody who potentially is in a position to do something about it. I feel that it’s not about crying wolf because that would imply we’re delivering a sanction or punishment. All we’re doing is refusing to do as we used to do, and to effectively allow malpractice to continue by the fact that we don’t take any action; and it’s not for us to judge if it’s fraud or not fraud, but pass it to someone who can decide.”

It was suggested that a low threshold should be adopted because it would then become routine and lead to greater openness. But it was also suggested a low threshold of naming and shaming people before an investigation had taken place, would be like publishing the name of an alleged murderer in the newspaper. “You don’t make an allegation. You raise question marks,” was the response.

At Southampton a system has been introduced where every division in the medical school has a responsibility to review what is being done scientifically. “We are going to take two publications a year and have an independent group of three people review the raw data. It will be done randomly so everybody is on their mettle.”

But not everyone agreed that institutions were equipped to cope. “I have suspicions that someone might be a murderer; shall I refer them? If they might be a bank robber, should I refer them, if they park on a double yellow line should I refer them? Most of the time, and there may be exceptions, we know that, in fact, the people you complain to in medical schools actually don’t do anything, so we do need a national body that will

**... Most of the time, and there may be exceptions, we know that, in fact, the people you complain to in medical schools actually don’t do anything, so we do need a national body that will deal with this, and just putting it back in the hands of corrupt police forces is of no use whatsoever.”**

deal with this, and just putting it back in the hands of corrupt police forces is of no use whatsoever.”

Arthur White (Scottish Office) suggested that one of the most effective means of handling misconduct is to ask for the money back. “We’ve actually done this and the message gets round the institution and it gets through to people who are looking for grants.”

## Summing up

Michael Farthing  
Editor, *Gut* and Chairman of COPE

### Where do we go from here?

Those of us who have worked on the Guidelines feel very strongly that they should not be cut in stone, that they will be updated on a regular basis, and that they will evolve and change with time and experience.

We also need to consider: What is the future of COPE? By correspondence would like to try and gauge your interest in this organisation and at what level you might like to continue to relate to it. Do you think COPE should be an organisation with individual membership (editors), or is it an organisation that should be primarily journal driven—should our journals form the membership of COPE so that we ensure continuity regardless of who is editor?

I believe we have influenced the General Medical Council and the Royal College of Physicians in the way in which they're now approaching this problem. So I think COPE has helped the process. We should continue to stress the importance of the entire spectrum of research misconduct and not just research fraud. We should also promote further debate on the desirability of creating an independent agency to deal with research misconduct.

### Endorsement of the guidelines

By September, it would be good if we could have a large proportion of UK editors of our medical journals supporting the guidelines. It would show that we as a group are going to continue to push ethics in publication. I think that will bring increasing pressure to bear on the GMC and other bodies.

We should not pretend that these guidelines are a final word.

Finally, in order to make this meeting happen we had to build a database of British biomedical journal editors. This will greatly facilitate communication in the future, and, I hope, will allow us to act together in the development of COPE and the *Guidelines on Good Publication Practice*.

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# Committee on Publication Ethics (COPE)

## GUIDELINES ON GOOD PUBLICATION PRACTICE

### Why the guidelines were developed

COPE was founded in 1997 to address breaches of research and publication ethics. A voluntary body providing a discussion forum and advice for scientific editors, it aims to find practical ways of dealing with the issues, and to develop good practice.

We thought it essential to attempt to define best practice in the ethics of scientific publishing. These guidelines should be useful for authors, editors, editorial board members, readers, owners of journals, and publishers.

Intellectual honesty should be actively encouraged in all medical and scientific courses of study, and used to inform publication ethics and prevent misconduct. It is with that in mind that these guidelines have been produced.

Details of other guidelines on the ethics of research and published codes of conduct are listed in the Appendix.

### How the guidelines were developed

The guidelines were developed from a preliminary version drafted by individual members of the committee, which was then submitted to extensive consultation. They address: study design and ethical approval, data analysis, authorship, conflict of interests, the peer review process, redundant publication, plagiarism, duties of editors, media relations, advertising, and how to deal with misconduct.

### What they aim to do

These guidelines are intended to be advisory rather than prescriptive, and to evolve over time. We hope that they will be disseminated widely, endorsed by editors, and refined by those who use them.

## 1 Study design and ethical approval

### Definition

Good research should be well justified, well planned, appropriately designed, and ethically approved. To conduct research to a lower standard may constitute misconduct.

### Action

- (1) Laboratory and clinical research should be driven by protocol; pilot studies should have a written rationale.
- (2) Research protocols should seek to answer specific questions, rather than just collect data.

- (3) Protocols must be carefully agreed by all contributors and collaborators, including, if appropriate, the participants.
- (4) The final protocol should form part of the research record.
- (5) Early agreement on the precise roles of the contributors and collaborators, and on matters of authorship and publication, is advised.
- (6) Statistical issues should be considered early in study design, including power calculations, to ensure there are neither too few nor too many participants.
- (7) Formal and documented ethical approval from an appropriately constituted research ethics committee is required for all studies involving people, medical records, and anonymised human tissues.
- (8) Use of human tissues in research should conform to the highest ethical standards, such as those recommended by the Nuffield Council on Bioethics.
- (9) Fully informed consent should always be sought. It may not always be possible, however, and in such circumstances, an appropriately constituted research ethics committee should decide if this is ethically acceptable.
- (10) When participants are unable to give fully informed consent, research should follow international guidelines, such as those of the Council for International Organizations of Medical Sciences (CIOMS).
- (11) Animal experiments require full compliance with local, national, ethical, and regulatory principles, and local licensing arrangements. International standards vary.
- (12) Formal supervision, usually the responsibility of the principal investigator, should be provided for all research projects: this must include quality control, and the frequent review and long term retention (may be up to 15 years) of all records and primary outputs.

## 2 Data analysis

### Definition

Data should be appropriately analysed, but inappropriate analysis does not necessarily amount to misconduct. Fabrication and falsification of data do constitute misconduct.

### Action

- (1) All sources and methods used to obtain and analyse data, including any electronic pre-process-

ing, should be fully disclosed; detailed explanations should be provided for any exclusions.

- (2) Methods of analysis must be explained in detail, and referenced, if they are not in common use.
- (3) The post hoc analysis of subgroups is acceptable, as long as this is disclosed. Failure to disclose that the analysis was post hoc is unacceptable.
- (4) The discussion section of a paper should mention any issues of bias which have been considered, and explain how they have been dealt with in the design and interpretation of the study.

### 3 *Authorship*

#### **Definition**

There is no universally agreed definition of authorship, although attempts have been made (see Appendix). As a minimum, authors should take responsibility for a particular section of the study.

#### **Action**

- (1) The award of authorship should balance intellectual contributions to the conception, design, analysis and writing of the study against the collection of data and other routine work. If there is no task that can reasonably be attributed to a particular individual, then that individual should not be credited with authorship.
- (2) To avoid disputes over attribution of academic credit, it is helpful to decide early on in the planning of a research project who will be credited as authors, as contributors, and who will be acknowledged.
- (3) All authors must take public responsibility for the content of their paper. The multidisciplinary nature of much research can make this difficult, but this can be resolved by the disclosure of individual contributions.
- (4) Careful reading of the target journal's "Advice to Authors" is advised, in the light of current uncertainties.

### 4 *Conflicts of interest*

#### **Definition**

Conflicts of interest comprise those which may not be fully apparent and which may influence the judgment of author, reviewers, and editors.

They have been described as those which, when revealed later, would make a reasonable reader feel misled or deceived.

They may be personal, commercial, political, academic or financial.

"Financial" interests may include employment, research funding, stock or share ownership, payment for lectures or travel, consultancies and company support for staff.

#### **Action**

- (1) Such interests, where relevant, must be declared to editors by researchers, authors, and reviewers.
- (2) Editors should also disclose relevant conflicts of interest to their readers. If in doubt, disclose. Sometimes editors may need to withdraw from the review and selection process for the relevant submission.

### 5 *Peer review*

#### **Definition**

Peer reviewers are external experts chosen by editors to provide written opinions, with the aim of improving the study.

Working methods vary from journal to journal, but some use open procedures in which the name of the reviewer is disclosed, together with the full or "edited" report.

#### **Action**

- (1) Suggestions from authors as to who might act as reviewers are often useful, but there should be no obligation on editors to use those suggested.
- (2) The duty of confidentiality in the assessment of a manuscript must be maintained by expert reviewers, and this extends to reviewers' colleagues who may be asked (with the editor's permission) to give opinions on specific sections.
- (3) The submitted manuscript should not be retained or copied.
- (4) Reviewers and editors should not make any use of the data, arguments, or interpretations, unless they have the authors' permission.
- (5) Reviewers should provide speedy, accurate, courteous, unbiased and justifiable reports.
- (6) If reviewers suspect misconduct, they should write in confidence to the editor.
- (7) Journals should publish accurate descriptions of their peer review, selection, and appeals processes.
- (8) Journals should also provide regular audits of their acceptance rates and publication times.

### 6 *Redundant publication*

#### **Definition**

Redundant publication occurs when two or more papers, without full cross reference, share the same hypothesis, data, discussion points, or conclusions.

#### **Action**

- (1) Published studies do not need to be repeated unless further confirmation is required.
- (2) Previous publication of an abstract during the proceedings of meetings does not preclude

subsequent submission for publication, but full disclosure should be made at the time of submission.

- (3) Re-publication of a paper in another language is acceptable, provided that there is full and prominent disclosure of its original source at the time of submission.
- (4) At the time of submission, authors should disclose details of related papers, even if in a different language, and similar papers in press.

## 7 Plagiarism

### Definition

Plagiarism ranges from the unreferenced use of others' published and unpublished ideas, including research grant applications to submission under "new" authorship of a complete paper, sometimes in a different language.

It may occur at any stage of planning, research, writing, or publication: it applies to print and electronic versions.

### Action

- (1) All sources should be disclosed, and if large amounts of other people's written or illustrative material is to be used, permission must be sought.

## 8 Duties of editors

### Definition

Editors are the stewards of journals. They usually take over their journal from the previous editor(s) and always want to hand over the journal in good shape.

Most editors provide direction for the journal and build a strong management team.

They must consider and balance the interests of many constituents, including readers, authors, staff, owners, editorial board members, advertisers and the media.

### Actions

- (1) Editors' decisions to accept or reject a paper for publication should be based only on the paper's importance, originality, and clarity, and the study's relevance to the remit of the journal.
- (2) Studies that challenge previous work published in the journal should be given an especially sympathetic hearing.
- (3) Studies reporting negative results should not be excluded.
- (4) All original studies should be peer reviewed before publication, taking into full account possible bias due to related or conflicting interests.

- (5) Editors must treat all submitted papers as confidential.

- (6) When a published paper is subsequently found to contain major flaws, editors must accept responsibility for correcting the record prominently and promptly.

## 9 Media relations

### Definition

Medical research findings are of increasing interest to the print and broadcast media.

Journalists may attend scientific meetings at which preliminary research findings are presented, leading to their premature publication in the mass media.

### Action

- (1) Authors approached by the media should give as balanced an account of their work as possible, ensuring that they point out where evidence ends and speculation begins.
- (2) Simultaneous publication in the mass media and a peer reviewed journal is advised, as this usually means that enough evidence and data have been provided to satisfy informed and critical readers.
- (3) Where this is not possible, authors should help journalists to produce accurate reports, but refrain from supplying additional data.
- (4) All efforts should be made to ensure that patients who have helped with the research should be informed of the results by the authors before the mass media, especially if there are clinical implications.
- (5) Authors should be advised by the organisers if journalists are to attend scientific meetings.
- (6) It may be helpful to authors to be advised of any media policies operated by the journal in which their work is to be published.

## 10 Advertising

### Definition

Many scientific journals and meetings derive significant income from advertising.

Reprints may also be lucrative.

### Action

- (1) Editorial decisions must not be influenced by advertising revenue or reprint potential: editorial and advertising administration must be clearly separated.
- (2) Advertisements that mislead must be refused, and editors must be willing to publish criticisms, according to the same criteria used for material in the rest of the journal.
- (3) Reprints should be published as they appear in the journal unless a correction is to be added.

## **Dealing with misconduct**

### **1 Principles**

- (1) The general principle confirming misconduct is intention to cause others to regard as true that which is not true.
- (2) The examination of misconduct must therefore focus, not only on the particular act or omission, but also on the **intention** of the researcher, author, editor, reviewer or publisher involved.
- (3) Deception may be by intention, by reckless disregard of possible consequences, or by negligence. It is implicit, therefore, that “best practice” requires complete honesty, with full disclosure.
- (4) Codes of practice may raise awareness, but can never be exhaustive.

### **2 Investigating misconduct**

- (1) Editors should not simply reject papers that raise questions of misconduct. They are ethically obliged to pursue the case. However, knowing how to investigate and respond to possible cases of misconduct is difficult.
- (2) COPE is always willing to advise, but for legal reasons, can only advise on anonymised cases.
- (3) It is for the editor to decide what action to take.

### **3 Serious misconduct**

- (1) Editors must take all allegations and suspicions of misconduct seriously, but they must recognise that they do not usually have either the legal legitimacy or the means to conduct investigations into serious cases.
- (2) The editor must decide when to alert the employers of the accused author(s).
- (3) Some evidence is required, but if employers have a process for investigating accusations—as they are increasingly required to do—then editors do not need to assemble a complete case. Indeed, it may be ethically unsound for editors to do so, because such action usually means consulting experts, so spreading abroad serious questions about the author(s).
- (4) If editors are presented with convincing evidence—perhaps by reviewers—of serious misconduct, they should immediately pass this on to the employers, notifying the author(s) that they are doing so.
- (5) If accusations of serious misconduct are not accompanied by convincing evidence, then editors should confidentially seek expert advice.
- (6) If the experts raise serious questions about the research, then editors should notify the employers.
- (7) If the experts find no evidence of misconduct, the editorial processes should proceed in the normal way.
- (8) If presented with convincing evidence of serious

misconduct, where there is no employer to whom this can be referred, and the author(s) are registered doctors, cases can be referred to the General Medical Council.

- (9) If, however, there is no organisation with the legitimacy and the means to conduct an investigation, then the editor may decide that the case is sufficiently important to warrant publishing something in the journal. Legal advice will then be essential.
- (10) If editors are convinced that an employer has not conducted an adequate investigation of a serious accusation, they may feel that publication of a notice in the journal is warranted. Legal advice will be essential.
- (11) Authors should be given the opportunity to respond to accusations of serious misconduct

### **4 Less serious misconduct**

- (1) Editors may judge that it is not necessary to involve employers in less serious cases of misconduct, such as redundant publication, deception over authorship, or failure to declare conflict of interest. Sometimes the evidence may speak for itself, although it may be wise to appoint an independent expert.
- (2) Editors should remember that accusations of even minor misconduct may have serious implications for the author(s), and it may then be necessary to ask the employers to investigate.
- (3) Authors should be given the opportunity to respond to any charge of minor misconduct.
- (4) If convinced of wrongdoing, editors may wish to adopt some of the sanctions outlined below.

### **5 Sanctions**

Sanctions may be applied separately or combined. The following are ranked in approximate order of severity:

- (1) A letter of explanation (and education) to the authors, where there appears to be a genuine misunderstanding of principles.
- (2) A letter of reprimand and warning as to future conduct.
- (3) A formal letter to the relevant head of institution or funding body.
- (4) Publication of a notice of redundant publication or plagiarism.
- (5) An editorial giving full details of the misconduct.
- (6) Refusal to accept future submissions from the individual, unit, or institution responsible for the misconduct, for a stated period.
- (7) Formal withdrawal or retraction of the paper from the scientific literature, informing other editors and the indexing authorities.
- (8) Reporting the case to the General Medical Council, or other such authority or organisation which can investigate and act with due process.

## Appendix

The Association of the British Pharmaceutical Industry. *Facilities for non-patient volunteer studies*. London: APBI, 1989.

The Association of the British Pharmaceutical Industry. *Guidelines for medical experiments in non-patient human volunteers*. London: ABPI, 1990.

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*Clinical trials and compensation guidelines*, January 1991.

*Guidelines for phase IV clinical trials*, September 1993.

*Guidelines on the conduct of investigator site audits*, January 1994.

*Relationship between the medical profession and the pharmaceutical industry*, June 1994.

*Good clinical trial practice*, November 1995.

*Patient information and consents for clinical trials*, May 1997.

*Guidelines on the structure of a formal agreement to conduct sponsored clinical research*, July 1998.

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Council for International Organizations of Medical Sciences (CIOMS). *International Guidelines for Ethical Review of Epidemiological Studies*. Geneva: WHO, 1991.

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*Consent*, February 1999.

*Confidentiality*, October 1995.

*Transplantation of organs from live donors*, November 1992.

International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. *JAMA* 1997;**277**:927–34.

Medical Research Council. *Policy and procedure for inquiring into allegations of scientific misconduct*. London: MRC, 1997.

Medical Research Council. *The ethical conduct of research on the mentally incapacitated*. London: MRC, 1991.

Medical Research Council. *The ethical conduct of research on children*. London: MRC, 1991.

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Medical Research Council. *MRC Guidelines for good clinical practice in clinical trials*. London: MRC, 1998.

Medical Research Council. *Principles in the assessment and conduct of medical research and publicising results*. London: MRC, 1995.

Nuffield Council on Bioethics. *Human tissue: Ethical and legal issues*. London: Nuffield Council on Bioethics, 1995.

Royal College of Physicians. *Research involving patients*. London: RCP, 1990.

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Delegates to the Meeting on April 27 1999

Other corresponding editors

## Update on cases submitted to COPE

### *1997 cases that have been closed:*

- 97/1 Can a scientific paper be published anonymously?
- 97/2 Should we have had author consent for a randomised controlled trial of peer review?
- 97/3 Disagreement between a reviewer and an author
- 97/4 Living unrelated (commercial) organ transplantation
- 97/5 Patient consent and non-consent
- 97/7 False memory syndrome
- 97/8 The reviewer writes comments that he doesn't want the author to see
- 97/9 A commentary on a piece of (unethical) research
- 97/10 Informed consent
- 97/11 The fraudulent letter
- 97/16 Double plagiarism
- 97/17 Not getting consent from an ethics committee
- 97/18 The perfect study but no investigational drug
- 97/19 The tortuous tale of a paper, a letter, and an editorial

### *1997 cases that remain open:*

- 97/6 Attempted redundant publication
- 97/13 Suspected fabrication of data

### *1998 cases that have been closed*

- 98/3 Unethical research undertaken by a single handed GP
- 98/4 Redundant publication

### *1998 cases that have been closed since the publication of last year's report:*

#### **Case 98/1**

### **Blatant example of duplicate publication?**

Two papers submitted and published in different journals had identical content but different reference styles, so were clearly intended for two different journals. The submission letter from the author to the first journal clearly states that the material has not been submitted elsewhere.

Both editors were advised to write to the authors inviting an explanation and saying that they are considering sanctions if they don't hear back by a certain date. It was suggested that both publications should be peer reviewed to ensure they are duplicates.

### **Outcome**

The editors of both journals simultaneously published an editorial in their May issues the following year, explaining to readers why they minded about duplicate publication. Both editors also retracted the publication and informed the author that they would not be accepting any further papers from him for two years. Nothing further has been heard from the author.

#### **Case 98/5**

### **Failing to get consent from an ethics committee**

An author discovered that a member of his team had produced a lot of fraudulent data for other studies and forged consent from ethics committees. The fraudulent researcher said that he had gained consent from three ethics committees for patients to be x-rayed when he hadn't, but this was subsequently granted by all three committees when the author approached them, on the grounds that it would be unethical to suppress these useful data because of the consent problem. The author wanted to know if we would have problems publishing this paper.

COPE agreed, with the proviso that the data collection and analysis did not go through the fraudster's hands. The author of the fraudulent data has now been struck off the medical register. It was agreed that the editor should be advised to get further assurance regarding the data and then publish the paper with a commentary explaining the history.

### **Outcome**

The paper was published, along with an explanation of its history.

**Case 98/6****The critical commentary**

A commentary was commissioned to accompany a systematic review. The authors of the commentary noticed that a particular randomised controlled trial was included in the systematic review while a duplicate version of the trial, published in another journal, was excluded because of inadequate randomisation. This was pointed out in the commentary.

The review authors said that they had excluded the duplicate version of the study not because of inadequate randomisation but because it was a duplicate.

The authors of the commentary want to make the point that the review was changed in the penultimate draft.

COPE felt that the authors' explanation was adequate, and advised publication of the commentary without the criticism.

**Outcome**

The commentary was published without the criticism.

**Case 98/7****Plagiarism**

A manuscript submitted to journal X was remarkably similar to a paper already published in journal Y. The similarities were noticed by one of the peer reviewers for journal X, and the paper rejected, but the editor informed the authors that unless there was a reasonable explanation, the dean of the relevant medical faculty would be informed.

The editor received five replies with four different excuses from the six authors. The editor was advised to write to the dean of the medical school and enclose the authors' replies.

**Outcome**

The editor wrote to the dean of the relevant medical school enclosing the copies of the five replies. A year later no reply has been forthcoming.

**Case 98/9****An author plagiarising the work of the reviewer?**

An author submitted part of his PhD thesis as a paper. The PhD supervisor was asked to review the paper and made various allegations, including no credit for one of the tests used, lack of acknowledgement of coworkers, similarities with other studies—including one of his own. The author refuted many, if not all, the allegations.

The editor was inclined to go ahead with publication and call the reviewer's bluff, but COPE advised the editor to let the University sort it out, and not do anything more.

**Outcome**

The editor informed COPE that the reviewer who had complained about the author plagiarising his work had backed down. The paper was re-reviewed in the normal way.

**Case 98/10****Unethical research**

A paper was submitted in which patients with healed duodenal ulcers were randomly allocated to receive treatment with either placebo or ranitidine. A gastroenterologist suggested that it was unethical to treat such patients with ranitidine or placebo rather than with *H pylori* eradication treatment.

The paper made no mention of ethics committee approval or informed consent. The paper was rejected on methodological grounds but the authors were asked to provide information on the ethical aspects of the study.

**Outcome**

The employers were notified, as was the relevant medical association of that country, and the International Human Rights Commission. So far, only the Commission has replied, saying that it would investigate the issue.

### Case 98/11

#### **Grounds for retraction?**

An author was worried that research he coauthored with a doctor, who was subsequently convicted of serious professional misconduct by the GMC, might also be fraudulent. The convicted doctor had carried out the interviews and was responsible for original data collection. He had also carried out a follow up telephone questionnaire without the coauthor's knowledge. No questionnaire answer sheets were available, although a list of those contacted was provided. None of the patients remembered being called for a telephone interview.

COPE advised the editor to retract the article.

#### **Outcome**

The editor retracted the article with a statement, which attracted a write-up in the *New York Times*.

### Case 98/15

#### **Questions of authorship, duplicate publication, and copyright**

In 1995 a group of nine authors published a paper in a leading general medical journal. Copyright was assigned by all authors to the journal. In 1998 the senior author received a complimentary copy of a recently published book.

One of the chapters was essentially a reprint of the original paper. The chapter acknowledged that the data it contained had been published before. However, it did not credit the other authors with authorship. Enquiries to the publisher of the textbook revealed that the sixth author had applied for, and for £60, been granted permission to use, the original article by the medical journal in which it was first published.

The editor was advised to write a conciliatory letter to the publishers and a letter of complaint to the author who had reproduced the article without permission.

#### **Outcome**

The author admitted he had made a mistake and apologised profusely.

*1998 cases that remain open:*

98/2 Disputed authorship

98/12 Possible redundant publication

**Cases submitted to COPE**

June 1998 to June 1999

Case 98/8 (published in full in last year's report)

## Redundant publication?

A double blind randomised controlled trial published in journal A found that drug x helps in condition y. The authors had published a similar paper in journal B two months before submission to journal A. There was only one new feature in the journal A paper, and there was therefore some overlap of the inclusion criteria in the two trials. The authors did not supply a copy of the journal B paper when submitting the journal A paper.

### Discussion/Advice

- The two sets of data overlap and the authors have not been explicit about this.
- The editor was advised to go back to the authors for an explanation and seek independent assessment of the degree of overlap.

Case 98/13

## Uncertain treatment of four patients following previous published experiments

A medically qualified author submitted a paper in which he described the treatment of four cases of "pesticide poisoning presented as ME." These four cases had doubtful sounding evidence of pesticide poisoning. The author treated them with a mixture of choline and ascorbic acid. He did this because:

"Between the years 1968 and 1973 I had carried out a number of unpublished experiments on patients with high blood cholesterol, including the familial form, and had found that oral administration of a choline and ascorbic acid mixture would lower the blood level more successfully than did clofibrate...the blood level of cholesterol would initially rise before it eventually fell, suggesting that cholesterol was being mobilised from the tissues into the blood stream prior to excretion. I decided, therefore, to try the same mixture on this patient as the pesticide is lipid soluble to see if it would respond in a similar manner."

All four patients seem to have shown some improvement, and all four have given signed consent for "details [of their cases] to be offered for publication in a medical journal." It was suspected that the four signatures might have been written by the author himself.

The paper will not be published, but should more action be taken? Should the author be referred to the GMC?

### Discussion/Advice

- Write to the author, asking if ethical approval had been obtained.
- This is a bizarre medical practice, which should be flagged to the GMC.
- In cases of overseas authors, or those who are not medically qualified, contact the local licensing authority.

### Outcome

The editor wrote to the author and received an unsatisfactory response.

The GMC was alerted. It emerged that the author had already been struck off the register.

**Keywords:** non-medically qualified researchers; overseas authors; GMC Register; informed consent

## Case 98/14

## Patients with vitiligo treated with anti-fungal drugs by a general practitioner

A letter was submitted for publication in which a general practitioner described how he treated patients with vitiligo “simultaneously with an anti-fungal and anti-bacterial medicament over a prolonged period.” He has done this because: “As is now known, a fungus resembles the human being genetically and there is a possibility that a fungus can hide in the melanocyte (analogically as is being done by the HIV virus) and therefore cannot easily be diagnosed by laboratory means.” The research seems to have been done without controls.

The editor wrote to the general practitioner asking whether his patients had given fully informed consent and whether he had obtained ethics committee approval. What should be done, if he has neither?

### Advice

- Write to the GMC.

### Outcome

The case was referred to the GMC.

**Keywords:** GMC; informed consent; ethics committee approval

## Case 98/16

## The missing author

In March 1996, journal A published a case report about an eye condition with two authors credited, Drs X and Y, both radiologists. Exactly two years later, one of their former colleagues (Dr Z) wrote to the editor claiming that she had been responsible for the patient’s care; she was the ophthalmologist on call the night the patient was admitted. She argued that, as the clinician responsible for the patient, her name should have been on this case report. Indeed, the clinical facts of the case were, she alleges, inaccurate.

Dr Z wants journal A to publish a full case report with additional facts about the case history. The editor of journal A wrote to the corresponding author of the original case report. Dr X discovered that the patient’s chart was missing; it had been taken out at the request of Dr Z. It turns out that Dr Z was “moonlighting” in the hospital at the time that the patient was admitted.

The clinical history remains disputed. What should the editor do next?

### Discussion/Advice

- Authorship should have been resolved before.
- The authority needs to hold an inquiry.
- The true facts or a retraction should be published.

**Keywords:** authorship; case report

Case 98/17

## **Allegations of scientific fraud and unethical conduct of experiments with attempts to silence the whistleblower**

### **The allegations of fraud**

A paper reported a radioisotope test for diagnosis of a specific, acute, neurological disease with 100% accuracy. Replication studies failed to confirm the findings and suggested that the test is positive in about half those affected and in a similar proportion of normal controls. Other publications by the same authors produced results at variance with their claims and misreported their findings. One author admitted that the data had been altered to show a better result. An earlier publication from the same department described another isotope test for detecting an unrelated disease with 100% accuracy. It was later proved to be without value for the diagnosis of that disease.

### **The allegations of unethical experimentation**

The study involved injection of a large dose of isotope into patients with acute neurological injury, in whom cognitive function was likely to be impaired. There was no mention of ethics approval or informed consent. The authors later stated that approval was not required because the test was used for clinical management. There was no previous or subsequent publication demonstrating clinical utility.

The employing authority was therefore asked to explain how the test could have been used for clinical management. They replied that it was only a preliminary study. When it was pointed out that such a study would require ethics approval, they stated that this had been obtained, although they had not mentioned this in the paper or subsequent correspondence. When asked to provide a copy of the approval form, they threatened legal action. It is believed that the institution did not have appropriate approval to administer the isotope.

### **Attempts to silence the whistle blower**

The whistleblower failed to replicate the observations and noted discrepancies in other papers by the same group. He contacted the patients involved in the study. They described events at variance with those of the published paper and produced documents to prove it. He challenged one of the authors who admitted that data had been altered to give a perfect result. The whistleblower approached the institution and asked for an investigation. Shortly afterwards he was told that an internal enquiry had found no cause for concern.

The whistleblower asked why he had not been asked for the names of the patients who disputed the events described in the paper or asked to produce documents. He was threatened with legal action and expelled from an MRC committee on which he sat. The committee chairman was one of the authors of the disputed study. The institution blocked a request from the whistleblower to use information on a national database which is managed, but not owned, by the institution: the database is theoretically open to all investigators in the field.

Having received no satisfactory response to his request from the head of the institution, the whistleblower approached the journal which published the paper, requesting that the journal publish a paper from him explaining that there had been scientific fraud and unethical experimentation, followed by a response from the authors. The editor felt that there was a case to answer and asked the authors of the original paper to respond. The editor copied the request to the head of the institution.

The head of the institution, instead, referred the whistleblower to the GMC for disparagement. The GMC investigated the whistleblower for eight months before he was exonerated and the focus of the investigation turned to the authors.

What should the editor do now?

### **Discussion/Advice**

- The institution must produce evidence of the investigation.
- The editor should refer the authors to the GMC if they are registered because there are legitimate doubts about the ethical procedures for this study.
- A copy of the referring letter should be sent to the head of the institution.

### **Outcome**

The case is still in dispute.

**Keywords:** whistleblowing; ethics committee approval; fraud; unethical experimentation

## Case 98/18

## Triplicate publication with possibly different data in each

A paper describing an outbreak of infectious disease was submitted to three journals. The submission to one journal described the index case; the submission to another included investigation and follow up of other cases and contacts in the country where the outbreak had occurred. The third paper looked at the spread of the disease into other countries.

A considerable amount of the epidemiological data had been repeated in all three papers. Additionally, the authors did not submit copies of all three papers when making their submissions to each journal. The most important problems were the discrepancies between the papers: the nationality of the patient differed; the time of readmission differed; even the final diagnosis differed. There were also inconsistencies in the details of the secondary cases.

What should the editors do?

### Discussion/Advice

- It was noted that specialist journal editors are in a more difficult position as they are part of the “community.”
- Write to the authors submitting copies of all three papers, asking for an explanation.
- Write to the heads of the institutions, submitting copies of the papers, plus the correspondence and ask for an investigation to be conducted.

### Outcome

All three editors met up and wrote to the authors (letter signed by all three). This elicited a trenchant response and elaborate explanations. The consensus was that the institution should investigate the case further and the case was referred to the chief executive.

**Keywords:** triplicate publication; manipulation of data; internal investigation

**Case 98/19**

## **The double review**

An author submitted a review to journal A in February 1997. It was accepted for publication in November, after peer review. The same author submitted a review on a similar topic—sufficiently similar that there was substantial overlap of content—to journal B in September 1997. Journal B accepted it in January 1998, after peer review. Neither journal editor knew of the parallel paper.

Journal B published its review in March 1998. The editor of journal A saw this paper and contacted the author. The author claimed that during negotiations in 1997, journal A had led him to believe that his review was not acceptable for publication. He had then contacted journal B.

In January 1998, the author, realising that he should inform journal B about the paper with journal A, sent a letter to the negotiating editor explaining that there was a similar review (which he claims was enclosed) elsewhere. That letter was received and filed but not seen by an editor. There is no record of the paper having been received. The editor of journal A has now rejected the review that he had accepted. The author believes that this editor should honour his earlier decision and publish his review. The paper, he claims, is sufficiently different to merit a separate publication. What should these editors do next?

### **Discussion/Advice**

- Journal B is at fault for failing to act on receipt of the letter from the author.
- The authors are also at fault for failing to tell journal B until much later.
- Journal B should get an independent expert to assess the degree of overlap of the two papers first, and if found to be acceptable, contact the author apologising for the administrative error.

### **Outcome**

The paper submitted to journal B was rejected.

**Keywords:** independent assessment; redundant publication

Case 98/21

## Duplicate publication and now fraud?

Two articles were published in two different journals. The articles had been submitted within days of each other, and were subsequently peer reviewed, revised, and published within a month of each other. The authors failed to reference the closely related article as submitted or in press, and the editors of the two journals were unaware of the other article.

After publication the editors viewed this as duplicate publication because of the considerable overlap of material and failure of the authors to disclose the existence of the other paper. Both editors issued a notice in their journals of duplicate publication. It was also noticed that two of the authors were only mentioned on one paper and another author indicated that he had been unaware of the submission of the article at all.

The editors have been asked by a third party to formally withdraw both articles on the grounds of fraudulent behaviour by the authors.

### Discussion/Advice

- The editors should write to the third party who has made the allegations of fraud and ask for the evidence.
- If this is forthcoming, the editors should write to the head of the institution involved.
- If a subsequent investigation proves the fraud, then the editors should take appropriate action.

### Outcome

The editors of the two journals felt very strongly that they should not be involved in investigating allegations of fraud, and that this should be the responsibility of the institutions involved, with the third party actioning this. They therefore decided to take no further action.

**Keywords:** fraud; retraction; duplicate publication

Case 98/22

## Confidentiality and conflict of interest

A paper reporting an attitudinal study was sent for peer review. The editor received a letter from the reviewer stating that as he was personally acknowledged in the paper, he felt there was a conflict of interest and so unable to review the paper.

The reviewer also pointed out that the research in question was part of a larger commissioned project with strict conditions of confidentiality. The persons surveyed were given assurance that the views expressed would remain unattributed and that the information gathered would be for research purposes only. The reviewer asked the editor to put the article on hold until he clarified whether or not the publication of part of the research findings would be acceptable, given the confidentiality agreements undertaken.

What should the editor do now?

### Discussion/Advice

- There is a breach of confidentiality here.
- The editor should go back to the first author seeking clarification of the supposed premature publication/breach of confidentiality, stating that a reviewer had brought this to his attention.
- If the reply is unsatisfactory, the editor should refer to the head of the institution.
- The reviewer should not lead this; the editor should.

### Outcome

The editor was satisfied with the lead author's reply and publication proceeded.

**Keywords:** confidentiality; conflict of interest

Case 98/23

## Duplicate publication

A paper was published in journal A which was subsequently found to have substantial overlap with a paper published in journal B. The editor of A challenged the author who gave an indignant response stating that the main focus and message coming out from the results as well as the principal points of the discussion were basically different.

What should the editor of journal A do now?

### Discussion/Advice

- An independent assessment of the quantity of overlap is required. If there is more than 50% then editor is advised to publish a notice of redundant publication.
- The independent reviewer/arbitrator should not be paid.
- COPE is minded to report all cases of redundant publication to heads of authors' institutions.

## Case 98/24

## Duplication, revision, and resubmission?

A manuscript was submitted which described the effect of a drug on cell turnover and apoptosis in a deletion mouse model of a common cancer. One of the reviewers noted that a very similar paper by the same authors had been published in another journal in the same specialty, and went to the trouble of underlining blocks of text that were identical in both papers. In one paper the authors had reported “tumour volume” whereas in the other they had reported “tumour multiplicity”—both measures of tumour mass. This was pointed out to the authors who “recognised our concern” and decided to withdraw the manuscript. However, they indicated that they would revise the manuscript and resubmit it to the journal for further consideration at a later date.

What should the editor do?

### Discussion/Advice

- The editor was advised to report this case to the head of the author’s institution.

### Outcome

The paper was rejected, but the case was not referred to the head of the author’s institution.

**Keyword:** redundant publication

## Case 98/25

## Surprising results and a new area of research for a senior author?

A paper described an unusual approach to disease modulation in an experimental animal model. The apparently clear cut findings were somewhat surprising. The authors also seem to have used high and low power photomicrographs of the same tissue sections to illustrate completely different experiments within the study. This occurred twice in the paper. Furthermore, this particular area of study was a complete departure from the previous work of the first and senior authors.

The editor wrote to the authors pointing out that the photos were the same. He received a garbled response, saying that computer photomicrographs got muddled up. There were 15 authors, all of whom were faxed. The first author responded immediately.

### Discussion/Advice

- Need to pin down author responsibility and responsibility for data collection.
- This is either an author muddle or fraud.
- Editor should ask to see the raw data.

### Outcome

Further correspondence took place between the editor and the corresponding author, and two further sets of figures were received for consideration. The editorial team were unsure as to whether this constituted fraud and rejected the paper on the grounds that they “had lost confidence in the data.” The rejection letter was sent to all the authors.

**Keywords:** raw data; fraud

**Case 98/26**

## **Partial disclosure of redundancy?**

A reviewer detected that a paper received for review was almost identical to a paper published by the same group three years earlier in a journal of a different specialty. The paper concerned clinical and investigative aspects of a disease that crossed two specialties. Although the authors had included their previous paper in the reference list, the title of the paper had been changed from that in the other journal. References to this in the introduction and discussion were brief in the extreme and did not indicate in any way that the authors were re-studying, or re-reporting the same patients or data set.

### **Discussion/Advice**

- The paper was openly deceitful in the reference list, but the work was not discussed and the title in the reference list had been changed.
- The editor was advised to seek clarification from the authors, and to refer the matter to the head of the author's institution.

### **Outcome**

Further clarification was eventually forthcoming. The corresponding author accepted that there had been an error in the title of the paper in the list of references, but strongly refuted the suggestion that there was redundancy.

The editor requested an independent review of the two papers by an expert reviewer who confirmed that there was major redundancy.

A response from the authors is awaited.

**Keywords:** disclosure; redundancy; independent review

## Case 98/27

## Attempted dual publication

A study by Japanese authors was submitted to specialist journal A. The manuscript was sent to three reviewers, including expert X. After two weeks, expert X contacted the editorial office to say that an identical manuscript had been sent by the competing specialist journal B to expert Y in the same unit as expert X. Expert X and expert Y had compared and discussed both manuscripts. Expert X said that the Japanese authors were clearly attempting dual publication, were therefore completely unethical, and should be reprimanded severely.

As editor of journal A, what should be done about:

- 1 The issue of apparently simultaneous submission to two journals?
- 2 The breach of confidentiality by expert X (and also expert Y, commissioned by another journal B)?

## Discussion

- Journal B doesn't state that reviewers should maintain confidentiality.
- The editor wrote to authors and received a garbled response saying that they meant to withdraw the paper from Journal A. There had also been a letter from the head of the institution saying that the "authors were considering their response." It seems that this may be a genuine mistake because of sickness. This story was corroborated by all the authors.
- As to reviewer confidentiality, journals vary in their practice. Breaches of confidence may be justified "in the public interest."

## Outcome

The paper was withdrawn from both journals. The head of the institution formally apologised to both journal and gave sufficient explanation to make it apparent that a genuine mistake had obviously been made. He also added that he felt the corresponding author, as well as all the others, had learnt from this mistake.

The breach of confidentiality was discussed by the editors of both journals involved. Expert X admitted that he had not read the instructions to referees, and had not been aware of this particular aspect of peer review. He undertook to reform his ways. He is still being used as a reviewer for journal A.

**Keywords:** confidentiality; dual publication; peer review

Case 98/28

## Redundant publication

A paper was submitted to journal A which was published as a rapid communication. It was subsequently discovered that the major US journal in this specialty had published other findings from the same set of patients, and that the paper had been considered by them at the same time. The messages of the two papers are closely related but different, but either one could have been amalgamated into the other for one publication.

All of this came to light when the authors submitted a further paper to journal A about the same patients. This time they used a new technique to expand on their studies which seemed perfectly reasonable; what is strange is that they did not acknowledge that the samples they analysed were taken from patients whose cases had been used and published before. Indeed, neither of the two previous papers acknowledges the other.

A letter was sent to the senior author, asking for an explanation. The senior author responded by saying that her submission letter to me stating that none of the work had been published elsewhere was a proforma letter and the signature was an oversight.

### Discussion/Advice

- There is no problem in using the same samples for different assays, but it is very important to be explicit.
- The head of the institution should be informed: non-disclosure is always a reason to inform the head of the author's institution.
- This should have been one paper.
- A statement of redundancy should be published in all three journals and the authors should be blacklisted but the editors' responses should be consistent.

### Outcome

The editors have informed the authors that they have been blacklisted for two years. One of the authors who is head of department wishes to appeal and the editor has directed him to apply to COPE. The editor of the second journal blacklisted the authors permanently.

**Keywords:** sanctions; redundant publication; disclosure

Case 98/29

## Overseas editor dismissed from university for fraud

An international specialist medical journal has editors in the UK and abroad who function independently. An issue of a scientific journal in 1998 reported that the overseas editor had been dismissed from a university professorship because of scientific fraud. This had been documented in three published research papers. The report highlighted a particular paper, in which 27 references cited indicated the editor was the author or coauthor of 19 of the papers. Laboratory notebooks detailing the research had disappeared.

The university committee stated that the study falsely presented data, and that these had been manipulated to produce the desired statistical results. The editor stated that there had been honest errors and that the laboratory staff had used poor research methods. The editor is attempting legally to overturn the university's action.

The UK editor wrote to the journal asking whether the incident discussed affects the editorial arrangements for the journal. Is there anything else the editor should do and does the problem affect his own position as an editor working in parallel with the overseas editor, as neither one is accountable to the other?

### Discussion

- The overseas editor hired the staff who were subsequently criticised.
- The publishers are awaiting the results of an appeal by the overseas editor, and COPE feels that the editor should stand down or be suspended, pending appeal.
- If the overseas editor refuses to do this, the other editors should tender their resignations.
- The publishers must face up to their responsibilities.

### Outcome

The overseas editor resigned from the journal. It is understood that the overseas editor has not appealed, to date, over the dismissal by the university.

**Keywords:** fraud; manipulation of data; appeals process

## Case 98/30

### A falling out

A research letter was submitted from a team of investigators, A, B, C, and D. In their covering letter they reported that:

A was involved in planning the study, collecting patient samples, and in writing the manuscript;

B measured IL-10 polymorphisms and analysed the results;

C was involved in supervising the measurement of polymorphisms and in writing the manuscript;

D was involved in planning the study and writing the manuscript.

The letter was peer reviewed and published. The corresponding author was D. Ten days later a letter was received from B and C who work at a different institution from D, inviting us to publish an erratum. Their substantive corrections were noted, together with the comment that “in addition, we wish to point out that B and C contributed equally to the content of this report.”

C also enclosed a copy of a letter to D stating that he was very unhappy about the fact that the others had never seen the proofs so that the mistakes, as shown enclosed, could have been corrected. C considered it unethical not to show coauthors the proofs. Further strong comments about the breakdown of the research collaboration followed.

D replied “surprised and saddened.” He argued that in the collaboration “the idea for this research was therefore entirely generated by us.” Furthermore, he said, B and C “saw and agreed to all the changes in the short manuscript and the final version that was submitted to the journal with all our signatures.” He went on: “I had to review the proofs within 24 hours and fax them back. There was no time to send this to the other authors for their approval (and we do not do this routinely in our department as it is usually the responsibility of the corresponding author). I am very concerned that you have sent off a letter to the journal without the courtesy of letting us see it beforehand. This is most unusual behaviour and can only have a damaging effect. The erratum is curious as these changes should have been made in the original manuscript.”

What do we do about the alleged and apparently disputed erratum?

Should journals have a clear policy about authors (all, some, the senior, or only the corresponding) seeing galley proofs? If so, what should the policy be?

### Discussion/Advice

- There is responsibility to ascertain if there really is an error. The editor thinks that if there is, then it's an interpretive rather than a substantive error.
- The authors did not see the edited manuscript.
- It was agreed that it is the corresponding author's job to clear changes with other authors.
- D removed B and C from the collaboration.
- This whole situation is not the fault of the journal, but the authors themselves.

The editor should:

- **either:** invite B and C to write a letter to the editor and show it to A and D for comment. This way, the editor can ventilate this problem as a duty to readers;
- **or:** go back to the authors' institution and have them resolve the dispute.

### Outcome

The dispute continues.

Case 98/31

## Retrospective ethical approval?

A paper reported a questionnaire study of patients' views on their preferences between minimal access and open access surgery. The questionnaires had been given to patients attending two types of clinic. The paper made no mention of ethical approval and the author was asked to clarify. He responded that he had not obtained ethical approval but that he had spoken to the chairman of the hospital ethics committee who would consider giving this retrospectively.

A subsequent email from the chairman of the ethics committee to the journal expressed doubt about the value of retrospective approval, pointing out that when a study was reviewed prospectively it was possible to suggest changes to the protocol, which obviously could not be done when it was viewed retrospectively. The chairman added that "it is certainly not a foregone conclusion that we would have passed this study."

The internal editorial committee considered this case in particular, and the general issue of retrospective ethical approval, when the authors have simply forgotten or not thought of obtaining it. They were unanimous in deciding that retrospective ethical approval was not acceptable and that this paper must be rejected, explaining the reason.

### Discussion

- The editor was advised to inform the head of the author's institution that the study had gone ahead without ethics committee approval.

### Outcome

The paper was rejected, and the editor informed the head of the institution concerned.

**Keywords:** ethics committee approval; retrospective approval

Case 98/32

## Redundant publication by an editorial board member

A specialist journal received a paper for review. An editorial board member was one of the authors. The paper was sent out for review and one reviewer replied quite favourably. A few days later the reviewer sent the editor a copy of a paper seen in another journal that was very similar to the one under consideration, and by the same authors. It was the same population and the same study, just a slightly different aspect of the paper. No mention of this study had been made in the paper submitted to the specialist journal.

The editor wrote to the board member, who replied saying that there are some important differences between the papers, and that the one submitted to the journal is intended to be the main paper that will be cited, with further reports published in due course. The board member acknowledged that the previous paper should have been cited.

What should happen about the specific paper? There clearly was a lack of transparency and it is hard to believe the board member was really so naive as to overlook the need to mention the previous publication. And what should be done about the board member?

### Discussion

- Both the editor and the co-editor have been through the paper; there is a lot of duplication. The editors should write back to the authors and the head of institution saying that they are treating this as a case of redundant/salami publication.
- The board member has a further two years to serve, but he should be treated as the other authors, and the institution head informed.
- He should also be sacked from the editorial board.

### Outcome

The editor received a long and informative letter from the board member. There were two papers being prepared by two groups who had been working on the population in question, he explained. One (the one they sent to this journal) was rejected by the first journal they sent it to and another was accepted rather quickly by a different journal. The editor thinks that the duplication between the submissions arose because of the different groups concerned.

The board member and his team did a lot of hard thinking and have made arrangements to ensure that this sort of thing cannot happen again. The editor is convinced that this was a case of poor control and communication between teams rather than a deliberate attempt to deceive.

The board member offered his resignation, but the editor invited him to stay which was accepted with gratitude. In fact, the editor suggested that he should collaborate on a piece for the journal about publication misconduct and what editors are doing about it.

**Keywords:** editorial board member; redundant publication

Case 98/33

## The author who wasn't an author

A paper was submitted crediting three authors. The paper was sent to one of the journal's regular statistical reviewers without noticing that she happened to be the second author. She wrote back to say that she had not been involved in writing the manuscript, nor had she seen this paper before. She did say, however, that she had supervised the computer input of the questionnaire data and that she had provided some general advice on the simple statistical presentation of the data.

Should any action be taken against the corresponding author, or should we simply explain what we mean by authorship and contributorship?

### Discussion/Advice

- The editor should write to the author and take up the points raised by the statistical reviewer outlining the concerns about attribution of authorship

### Outcome

The editor wrote to the author, enclosing a copy of an editorial on the differences between authorship and contributorship. The author responded, apologising for the mistake and attributing contributorship to the reviewer. The paper was published.

**Keywords:** authorship; peer review; contributorship

Case 98/34

## “Inadvertent” duplicate publication

A paper submitted for consideration in March 1997 was peer reviewed, successfully modified, and accepted for publication in June 1997. In January 1998 the paper was prepared for publication, and a commentary sought from an expert in the same field, scheduled for publication in the same issue.

The expert drew the editor's attention to the fact that a similar paper (albeit in shortened form) had been published in another journal in November 1997, after the paper to this journal had been accepted. The editor of the second journal had no knowledge of the paper being submitted to this journal.

The papers were examined and the following conclusions drawn:

- 1 The sample size, methods, and results were identical for both papers.
- 2 The discussions were similar, although reworded slightly.
- 3 Additional data had been added to the paper for one journal which had been omitted for the short report in the other journal.

### Discussion/Advice

- Could this be ignorance of process rather than bad behaviour?
- Both journals should make their position clear with regard to duplicate publication
- Both journals should look at their own processes for dealing with it.

### Outcome

The authors were asked to explain, especially as both papers had been submitted without either editor being advised of the other submission, and without a reference to the other journal in either paper. The authors claimed that the paper to this journal was a full report for the readers (one health profession) while the short report was to inform the readers of the other journal who comprised a different health profession. This explanation was regarded as insufficient grounds for the lack of information and the paper was not published.

Interestingly, had the authors kept both editors informed and credited and referenced the original paper in the second, then it is unlikely that a possible case of duplicate publication would have been considered and both would probably have been published.

**Keywords:** duplicate publication; authorship

## Case 99/1

## A lost author and a new hypothesis

A paper was published in January 1998, and seven authors were credited. B was thanked for his contribution in the acknowledgements section. One year later B wrote to the editor, outlining two alleged incidents related to this paper.

First, the cohort reported in the January 1998 paper was one that B had been working on since the early 1990s. In 1992–3 he sought collaboration with another research group. A grant was applied for and granted. At that time B, who was a co-signatory on the grant application, moved abroad but the grant specifically included money for him to travel back to his home country to continue the collaboration. Moreover, all the collaborators agreed that he would be a co-author of all subsequent papers.

As the collaboration proceeded, B felt he was being edged out of the group. A senior colleague in his home country felt the same way and eventually resigned from the collaboration. B was unaware that a paper was being prepared for publication from this study. The first time that he saw the paper was after publication. He only contacted the editor after several colleagues urged him to bring the matter out into the open. Not only was he not included as a full author on the paper, but his permission had not been sought for acknowledgement, in direct contravention of the Vancouver Group guidelines.

The second allegation concerning this paper is that the hypothesis subtly shifted between the grant application and the published paper. The hypothesis as stated in the grant application is different in an important way from that stated in the introduction to the paper. The results of the research support the hypothesis as cited in the paper, but directly contradict the hypothesis as cited in the grant application. B alleges that the research group concerned has indulged in post hoc hypothesis generation so that the results fit their beliefs about the meaning of the data rather than their pre-specified hypothesis.

Another paper from this research group, in which B is cited as an author, again without his permission, is currently being held by the editor of a specialist journal pending the outcome of this particular case. All of the co-signatories and collaborators on the original grant application have been asked (with B's permission) for their view on the allegations. A further complication is that although the grant awarding body has a procedure for dealing with allegations of misconduct, one of the authors of the paper is one of their unit directors.

### Discussion/Advice

- The editor was advised to inform the grant awarding body of this case and tell them that he had referred the matter to COPE.
- The editor should also urge the grant awarding body to act with some urgency and, that given the circumstances, the initial investigation cannot be referred to the unit director.
- The editor should await responses from all collaborators and authors and then show them to B.
- It was agreed that editors should not get involved when authors fall out but the fact that the paper is published has involved the editor.

### Outcome

The editor heard from all of the authors that the individual making the allegation knew about the work all along and they refute his allegations.

Their response to the editor's challenge about the hypothesis change was that that was the nature of scientific progress. However, from the responses, it is clear that there has been a major falling out between the two sides of the collaboration. However, this team did not agree with the allegations either.

The senior author now feels that the editor is "destroying" the collaboration and that all parties should get together and discuss.

In addition the editor has now been contacted by an editor of another journal who has received a paper from the same stable which has problems around authorship.

## Subsequent advice

COPE advises that the editor should now:

- Go back to the person who made the original allegations and get his response to the above.
- Discuss this with the grant awarding body.
- Involve the journal ombudsman.
- Invite a representative of the grant awarding body to attend a COPE meeting so that the case can be considered in its entirety.
- Inform authors and heads of institutions and research council that COPE are considering this case. This gives a line of accountability.

## Outcome

The journal ombudsman felt that there was nothing further the journal could do.

Two representatives of the grant awarding body attended a COPE meeting. They agreed to instigate an investigation and to raise additional questions about the change in hypothesis with the authors.

The grant awarding body has clear procedures and guidelines for research misconduct and they will be revising these to clarify the issues of authorship.

**Keywords:** grant applications; authorship; journal ombudsman; research misconduct guidelines

Case 99/2

## The manipulated contributor list

A paper was published for which the authors' contributions were as follows:

A and B had the original idea and planned the study.

A was also responsible for collecting the samples and patient data.

C established the database and participated in planning the clinical trial.

D developed the enzyme linked immunoabsorbent assay and analysed all the samples.

E and F were responsible for the statistical analyses of the data.

The paper had been written jointly by B, G, D, H and A.

A and B were guarantors of the study.

D complained to the Danish Committee on Scientific Dishonesty, arguing that the contributor list had been altered from what had been agreed by the authors. The Committee upheld this complaint and the journal agreed to publish a correction to the contributor list, as follows:

A and D took the initiative to the investigation.

A collected the clinical material.

F updated and validated the clinical data, which was initially registered and arranged by C. F and D analysed in cooperation the samples for PAI-1.

F and E conducted in cooperation the statistical analysis.

F, B, D and A interpreted the statistical results.

A and B wrote the first draft of the paper and were in charge of the final manuscript.

All authors actively participated in discussions regarding the conduction of the work and in preparation of the final manuscript.

The findings of the Committee have subsequently been disputed.

**Keywords:** authorship; complaints procedures

Case 99/3

## Plagiarism

A paper by five Turkish authors was submitted to journal A. The paper was virtually the same as one published in the equivalent US journal B of the same specialty, but with different authors. The paper submitted to journal A seems to have been plagiarised from the paper published in journal B.

The editor has written to the deans of the faculties of medicine to which the authors are attached. What more should he do?

### Discussion

- It was agreed that the editor should have written to the authors for an explanation first.
- Only if a satisfactory reply was not forthcoming should the editor have contacted the deans.

**Keyword:** plagiarism

Case 99/4

## What happens when there is no local ethics committee?

A paper from Taiwan was reviewed and accepted for publication. However, one of the reviewers raised the question of ethics committee approval. When the editors checked with the authors, they responded that there is no ethics committee at their university and they were therefore not able to seek ethical approval.

What is COPE's view on this? The study was fairly straightforward involving a questionnaire, some simple lung function, skin, and blood tests.

### Discussion

- Can we verify that there is no ethics committee at this University?
- Taiwan does have ethics committees and the authors should know that they need such approval. It must be made clear to investigators that their work will not be published without ethics committee approval.
- The editors should contact the authors and tell them that their paper cannot be considered for publication.

**Keyword:** ethics committee approval

Case 99/8

## Publication of misleading information and publication bias

I analysed the results of a randomised controlled trial that had just been completed by some of my colleagues. The trial compared an oxygen radical scavenger with a placebo in patients with acute myocardial infarction. One of the major outcome measures included infarct size, as measured by nuclear imaging.

My analysis showed that there was no significant difference between groups for either of these parameters, but statisticians from the pharmaceutical company involved concluded that the treatment provided significant clinical benefit. The main difference was that they had performed within-group analyses, which showed a significant reduction in infarct size in the treatment group. The study had already been presented at conventions using this analysis.

I maintained that the within-group analysis was not only inappropriate, but misleading, and even unethical. I suggested that because of the small sample size (around 60 patients), they should be happy that the results leant towards a benefit for treatment, and what they really needed was a larger trial. Unfortunately, the study contract forbade publication without the drug manufacturer's permission.

I contented myself with the thought that I had prevented the publication of wrongful claims, and we continued to lecture that there was insufficient evidence for the use of this drug in coronary artery disease. To date, the drug continues to be a best seller.

The story then hit the headlines, when it was published in a journal. The concession to its publication had been the inclusion of some statements pointing out that the conclusion was based on within-group analysis. I was appalled. How could they purposely publish a misleading claim, and ignore all references to alternative analyses?

The problem is compounded by the following:

- The principal instigator is a senior cardiologist, professor emeritus in our college, and a leading figure in heart associations.
- He sits on many committees that approve funding for projects (some of which are mine).
- He has lectured far and wide that the drug is actually effective.
- The editor is a good friend of his.

What should I do?

### Discussion/Advice

- This is not within COPE's remit as the case was not submitted by an editor.
- Suggest that the complainant submit a letter to the editor of the journal concerned.
- A systematic review of published studies would expose the flaws.

**Keywords:** data analysis; randomised controlled trial; drug efficacy

Case 99/9

## Redundant publication and change of authors

A paper was submitted to journal A with a covering letter stating that it was entirely original. However, when the editor looked at the references he found considerable overlap with a paper already published in journal B about the same infection outbreak, but with a completely different set of authors bar one.

A comparison of the papers showed that there was considerable overlap. When challenged, the authors of the journal A paper defended themselves by saying that their study describes the clinical aspects whereas the paper in journal B describes epidemiology and control. They also state that they were completely transparent about the existence of the earlier paper in journal B.

There are several points which concern the editor:

- There are inconsistencies between the two papers.
- The authors did not send a copy of the paper from journal B with their submission to journal A and the covering letter stated that the work was original
- It is not clear that this particular infection outbreak had been described before. Admittedly, there is some expanded clinical information in the paper for journal A and the authors did refer to the microbiology and epidemiology being described in a previous paper in journal B.
- The journal B paper contains a lot of clinical material and it is surprising that only one of the authors is on both papers.

### Discussion

- Arguments about the degree of overlap might never be resolved.
- The editor should seek independent assessment of the degree of overlap.
- Real key here is the degree of disclosure/transparency about the existence of the earlier paper. If the authors were explicit about this, then there is no problem.
- COPE would like to hear the editor's assessment of the degree of transparency.

**Keywords:** redundancy; authorship