

## **The COPE Report 2001**

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# **The COPE Report 2001**

Annual Report of the Committee on Publication Ethics

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## A year of growth and development for COPE

COPE was born in 1997, went through puberty towards the end of the last millennium, and is now entering early adult life. COPE has transformed itself from an informal self help group for editors to a mature organisation with a constitution and elected officers.

In March 2001 we sought nominations for a chair, vice chair and treasurer. I was delighted to be elected as chair and welcome Richard Smith as vice chair and Alex Williamson as treasurer. Anastacia Kirk will continue to act as secretary to the council, and we are extremely grateful for all her hard work. Following the elections the new council met at an extraordinary meeting on 18 June 2001 and nominated four additional members of council. I am delighted to report that Professor Lesley Rees, Dr Sabine Kleinert, Dr Fiona Godlee and Professor Ian Kennedy have agreed to serve on council for three years. We are indebted to Roger Dowsett for his assistance in advising on our constitution, which is included as an appendix to this report.

COPE has matured not only with respect to its governance procedures, but also in its membership. Our treasurer has worked indefatigably to recruit major publishing houses into the COPE network. Harcourt have signed eight of their European journals, and Oxford University Press 11 titles. And negotiations continue with Blackwell Science, Elsevier, and the Nature publishing group. Other biomedical journals have joined COPE on an individual basis.

We therefore believe that COPE now represents a substantial proportion of UK biomedical journals and is expanding into Europe. COPE's internationalisation is also recognised by its close contacts with the World Association of Medical Editors (WAME) with which we collaborate on ethics and difficult cases. COPE is therefore firmly established as a properly constituted organisation with an identifiable governance structure and an increasingly sound, independent financial base.

COPE has achieved some of its initial objectives – namely, to advise editors on the management of possible cases of research and publication misconduct and to produce *The COPE Guidelines on Good Publication Practice*. It also is committed to promoting research and education and to this end the council has decided to establish two subcommittees to pursue these objectives. As part of its educational activities, COPE organised a one day seminar in October 2001 to discuss whether the UK needs an independent national panel

to advise on research and publication misconduct. Professor Sir George Alberti opened the day with a view from the royal colleges which was followed by presentations from Magne Nylenna and Drummond Rennie, summarising the experience in Scandinavia and the USA, respectively. This was followed by workshops to consider specific issues on how a national panel might operate in the UK.

There was unanimous agreement that a national panel was required, although there was a spectrum of opinion as to whether this panel would be merely advisory or might move towards acquiring statutory powers to conduct enquiries. It was widely acknowledged that as more than two years had elapsed since the 1999 Consensus Conference in Edinburgh had recommended the establishment of such a panel, there was now a sense of urgency and a vital need to identify who might lead such an initiative.

*The COPE Guidelines on Good Publication Practice* continue to evolve and some further amendments have been made this year, particularly with respect to “ghost authorship.” An updated version of the Guidelines appears as an appendix to this report.

I and other members of COPE continue to be dissatisfied with the lack of progress in establishing appropriate procedures to deal with research and publication misconduct in the UK. Although a number of guidelines exist for individual organisations, with the exception of the General Medical Council, there is no obvious body to whom “whistleblowers,” higher education institutions, and NHS Trusts can go to for advice. And there is no central repository of cases which could begin the process to start to answer questions about the prevalence and severity of research misconduct in Britain.

Furthermore, there has been no audit as to how these various guidelines have been implemented and no indication whatsoever of the outcome of internal enquiries. The Banerjee case was finally resolved in November 2000, almost a decade after it was first published, with his suspension by the GMC for publishing fraudulent data. Since then some of us have had questions about the validity of internal enquiries that remain “in camera” and never have to report their findings to the outside world.

Professor Michael JG Farthing  
Chair of COPE  
November 2001

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

## **Does the UK need an independent review body to deal with biomedical research misconduct?**

**Proceedings of the meeting held on 15 October 2001  
BMA House, London**

### **Programme**

#### **Introduction**

Professor Michael Farthing

#### **Plans for a UK national panel**

Professor Sir George Alberti

#### **Experience in the USA**

Professor Drummond Rennie

#### **Experience in the Scandinavian countries**

Dr Magne Nylenna

#### **A framework for discussion**

Dr Richard Smith

#### **Workshops on the design of a UK national advisory panel: structure and function**

Four panels facilitated by:

Dr Peter Wilmshurst

Dr Fiona Godlee

Dr Sabine Kleinert

Professor Sir Cyril Chantler

#### **The way forward**

Professor Ian Kennedy

## Introduction

Michael J G Farthing  
Editor, *Gut* and Chair of COPE

COPE started in 1997 as a rather modest self help group for editors. It has subsequently taken on the role of an action group to try and raise awareness of, and work on the prevention of research misconduct. It also aims to draw other people into the debate of whether we are doing enough to tackle the problem.

This year COPE changed its constitution and the senior officers in the organisation are now elected. We now have an executive and a properly constituted council, with set terms of office.

We have produced annual reports and held several seminars. The first seminar was in our foundation year when we asked how editors should respond to publication and research misconduct. That was borne out of our frustration at seeing many examples of misconduct, but feeling powerless to do anything about it.

Our first report was published in 1998 after which we held a second seminar to work on our guidelines on good publication practice, published in the *COPE Report 1999*.

This, then, is our third seminar which really grew out of a consensus seminar in Edinburgh in October 1999. That meeting brought in a whole range of stakeholders from the royal colleges, the General Medical Council, the Academy of Medical Sciences, the pharmaceutical industry and many others. The idea was to draw people into the debate as to whether we needed an independent body. And just a month or so ago, the Royal College of Physicians of Edinburgh published a blueprint for a possible national panel for research integrity which will inform our debate this afternoon.

People often say that we are making a fuss about nothing. Serious research fraud is rare, they say. Minor misdemeanours can be put right by appropriate training and education; we have got guidelines already in place; and it is employers' responsibility to sort it out. End of story. But we don't know how much serious fraud there is out there. We don't know whether training and education will eliminate minor misdemeanours. We still don't know how to deal with misconduct in spite of all these many guidelines, some of which have been around for 10 or 12 years.

We do, of course, have the General Medical Council (GMC) which does a very good job. But it can only deal with medical practitioners and is already overloaded. A few weeks ago a case was eventually dismissed under the terms of European Human Rights legislation for having kept the defendant waiting for four years.

Although the GMC have promised to speed things up, looking at what is currently on their books does not bode well for the lesser forms of research miscon-

duct, which many of us feel are important, but which are currently falling between the cracks. A case that exemplifies how the British system has failed to deal with the issue is illustrated by a whistleblower who was intimidated by the institution. An internal enquiry by a London medical school found the individual guilty, but no action was taken. It took a second whistleblower to refer the case to the GMC. It was 10 years before the case was heard. And that was in November 2000.

We have got good mechanisms in place, but the culture is such that it is not always easy to get due process. We rely enormously on whistleblowers. Despite new legislation they are extremely reluctant to come forward, particularly to provide evidence for an internal enquiry. Whistleblowers have told me that when they talked to the department, or university, or institution head, they were dissuaded from taking the matter further.

**I think we have to be reminded of the basic fundamentals of honesty, time and time again. It starts in medical schools but clearly continues throughout one's professional life. Like all things laws are only made for the minority, but I do think we need enforceable laws governing research and publication conduct.**

Finally, let me draw your attention to a paper published in the *BMJ* earlier this year, which I found deeply disturbing. It was about Dundee medical students and written by Dundee medical students who asked whether tomorrow's doctors were honest. Students were presented with 14 different real life scenarios, and asked what they would do in the same situation, whether they had ever done the same thing, and if not, would they do it?

Forging a doctor's signature for an assignment was considered acceptable by 7 per cent; 9 had done it already. Seventeen per cent thought it was OK to plagiarise, and 14 per cent admitted having done it. But the most disturbing finding was that that one in four thought it was OK to write in a patient's clinical notes that a central nervous system examination had

been done and was normal, when they had not done the examination at all. Almost a third (32%) of the students questioned had already done this.

I was so alarmed by this that I talked to every year in my own medical school about this. Some of my students thought I was over reacting about the CNS scenario. It was, after all, only a student write up they said. What harm could it possibly do anyone? But it is still dishonest. So my starting point for today is that I

don't think there is anything intrinsically different about us as doctors from any other part of the community.

I think we have to be reminded of the basic fundamentals of honesty, time and time again. It starts in medical schools but clearly continues throughout one's professional life. Like all things laws are only made for the minority, but I do think we need enforceable laws governing research and publication conduct.

## Plans for a UK national panel

Professor Sir George Alberti

President of the Royal College of Physicians of London

Is there a problem? I think we wouldn't be here if there weren't. So the question is, what is the extent of it? There have been small numbers of highly publicised cases and increasing numbers of cases coming through the Association of British Pharmaceutical Industries (ABPI) who have been particularly active in this area. And there is a suspicion that it is a common problem, with pressure to publish, and so forth.

But we really do not know how common it is and I think that is one of the difficulties we face. My feeling is that minor misconduct, rather than fraud, is probably very common, and often unintentional because of poor training.

### Definition of fraud

So how do we actually define it? The answer is, with difficulty. But there have been several attempts. In 1991 the Royal College of Physicians defined it as piracy, plagiarism and fraud; alternatively, theft, fabrication and destruction. These are nice punchy definitions but with very little actual meaning when you examine them more closely.

The Medical Research Council (MRC) definition of not so very long ago, which was developed at the GMC under my chairmanship, was fabrication, falsification, plagiarism or deception in proposing, carrying out, or reporting results of research, and deliberate, dangerous or negligent deviations from accepted practices in carrying out research.

**Ambition plays a part in it. Competitiveness plays a part when it comes to minor fraud and actually major fraud too. And laziness: it is a lot easier to add a few extra numbers when you can't be bothered to do the experiments.**

It then goes on to say failure to follow established protocols and facilitating of misconduct in research by collusion in, or collusion of, such actions by others. It also includes intentional, unauthorised removal of, or damage to, research related property of another person. It includes apparatus, materials, writings, data and so forth, or any other substances or devices used in, or produced by, the conduct of research.

If we explore our experience, many of us can come up with a series of examples of probably most of these. The definition does not, however, include honest error, or honest differences in the design, execution, interpretation or judgment in evaluating research methods or results, or misconduct unrelated to the research process. The difference between misconduct and research misconduct is very important and needs to be clear. The other very important issue is plain old crummy research, which is also not included.

An aspect of publication misconduct, which doesn't come to COPE's attention so much, is failure to publish. And that may be driven by industry. It is often driven by sloth. Just how far back can you go? But undeclared conflicts of interest, inappropriate authorship, deliberate delays of competing manuscripts, false criticism, bogus data etc, are some of the many aspects of publication misconduct.

What are the causes of all of this? Professor Farthing says that it is human nature. Ambition plays a part in it. Competitiveness plays a part when it comes to minor fraud and actually major fraud too. And laziness: it is a lot easier to add a few extra numbers when you can't be bothered to do the experiments. Ignorance comes into it as well, as does failure of good supervision. And that is partly induced by the current health system where clinical academics are so busy that they no longer sit down and go through raw data with their research students.

### What is being done to combat it?

What has been done recently? A lot of people have been urging vociferously for action to be taken, but really quite a lot has been going on. The MRC issued a series of guidelines, as did COPE which has been very, very proactive in this regard. Our own report is due out shortly and the GMC has produced good practice in research guidance.

NAPAG (National Association of Professional and Academic Groups: British Academy, Royal Society, the Academy of Medical Sciences, Academy of Medical Royal Colleges and Engineers) have come to a full stop after their coordinating group decided about three years ago to tackle fraud, covering not just biomedical research. Then we have the recent joint consensus conference, the paper that has just appeared from the two Scottish colleges and the faculty of pharmaceutical medicine. The *BMJ* and *The Lancet* have also had leaders on the subject. So there is a lot of will for something to be done now; we just need to get on and do it.

What are the actions we could all be doing to minimise the problem? There is prevention, which is terribly important, and monitoring of research, with each institution having a dedicated policy. When The Royal College of Physicians surveyed the medical schools, less than half had any sort of plan. And these ranged from a 24 page document to one paragraph in the university statutes somewhere, although the situation has improved over the past three years. You need good local and national investigative procedures and we contend that you also need a national panel to coordinate all of this.

On the prevention side I think we need much, much better training, and this really hasn't happened. The supervisors or mentors need training in research supervision. It is just assumed that when you get to the point of being a lecturer or you have a new research student that you know how to do it. The new researcher needs formal training and proper supervision.

I am not sure you can ever get properly informed consent in clinical research. You can certainly tell patients or subjects what is going on, but whether they understand it is quite a different matter.

## The role of institutions

What about the institutional side? I think we need to have proper systems in place, with written guidelines, spot checks, and a senior named officer. I am not just talking here about teaching hospitals or medical schools and universities; I am talking about the entire community in which research takes place. A lot of the problems in the past, for example, in primary care research, have arisen because no one is really in charge, no one is really trying to help people do good research.

You need clear institution guidelines and this is where a central panel can help achieve some uniformity of approach. We have suggested in our own college report that there should be nominated screeners at each level. For example, a department of child health would have its nominated screener who would be the first port of call if there were a hint of a problem. They would then refer to a more senior institutional panel if they thought there was a case to answer. And they in turn would then call in external advice if it was found to be serious and could not be dealt with locally.

It is a stepwise approach, but every institution needs this sort of thing in place, and very, very few have at this time. It begins with a nominated individual, who invites a detailed written statement from the complainant. They decide whether it is justified, or if uncertain, they refer to the panel. The person about whom the complaint is being made is informed and then either the senior officers of the institution are informed and call for external advice, or the matter is reported to the GMC, or local action is taken. This is

what was outlined in the 1991 RCP report and I don't think that it necessarily has changed very much. It is just a pity that nothing has happened in the past 10 years.

## Format of a national panel

There is a lack of consistency in approach; there is no major coordinating source of advice; and there is a lack of coordination, overall, so I think there is a very strong case for a national panel.

What should its role be? The following are the sorts of things that we have suggested in our own report and which are not dissimilar to the very good Edinburgh statement:

- producing and revising guidelines;
- advising institutions on prevention and detection;
- coordinating advice from the many other bodies who are involved.

It is very important to provide a list of people who could go on rapid response teams. That will require training; it is real work, but without that a national panel becomes yet another talking shop. This panel could also keep a simple record of what is going on and produce annual reports, etc.

What I have called the Scottish model comes out of the Edinburgh report. This emphasises the education of researchers and supervisors, the development and maintenance of standards and audit, with a coordinating function for allegations or suspicion of misconduct.

What about membership? We suggested representatives from the major bodies, people from the legal profession and pharmaceutical industry who are very important players here; the Human Genetics Commission because a lot of things revolve and will increasingly revolve around the genetics arena; government/NHS and patient associations.

After consultation the government should nominate an individual to lead the panel, who must nevertheless be independent of government. The issue affects not just the NHS, but universities as well. We have got enough "hit teams" emanating from the Department of Health so I think independence will be very, very important.

Accountability is a difficult issue. One suggestion has been that NHS Research and Development should be the accountable body, but research misconduct is an issue that goes beyond the NHS. Parliament, an independent quango, and the GMC have all been suggested, but again we are not just talking about medically qualified people on the register. The GMC may be a partner, but should not be the final accountable channel.

So my feeling is that it should be an independent quango, and that is the view of one or two people in government with whom I have discussed the matter. I believe we have an absolute need for a national panel to get our national act together to make sure that institutions behave sensibly, that whistleblowers are looked

after, be they mischievous or otherwise, and to train impartial experts, protect subjects and researchers.

To summarise by quoting from two of our organisers today, Richard Smith and Michael Farthing “While

our leaders are fiddling, the research enterprise may be starting to burn. Please, men and women in gowns, do something.” I think we should rise to that challenge now.

## Experience in the USA

Professor Drummond Rennie  
Deputy Editor of *JAMA*

I stopped being interested in research misconduct six years ago when I stepped down from a commission established by the US government to look into this. The fact is that in the United States the whole business of research misconduct is old, boring, and above all, routine.

I'm not here to tell you that you should adopt the US system. But what you should aim for is something that is routine. For example, if there is an allegation of theft, the administrators of the institution don't have to scurry around trying to invent a wheel that deals with theft. There is a whole system: police, magistrates, lawyers, courts, prisons and so on. There is a routine for dealing with theft and what you should aim for is a routine for dealing with allegations of misconduct.

In the States there has been almost no media coverage since this became routine. And I suspect you will hear exactly the same has happened in Scandinavia. It has become routine; people have moved on. That is one very good reason for doing something because the handling of misconduct in the UK is not routine. It is very clear that dealing with misconduct here is very unroutine and everybody has their own ideas about it.

### Why should editors be involved?

I used to be the deputy editor of the *New England Journal of Medicine* and within a very short time I saw gross cases of scientific misconduct coming in, and allegations of completely plagiarised or false research. Like everybody else I couldn't believe it could happen. And then I watched all sorts of officials and senior academics falling over themselves, bumping into each other in the dark, and so on, as they fouled things up. And the media had a field day with every eruption that occurred. And that is more or less what is happening here now in the UK.

Editors see it because when work is submitted to a journal it is the first time that work is fully outside the institution, and the allegations start coming in when it is published.

### The role of government

Politicians got involved early: there were 13 separate congressional hearings on this, the first of which was started by Al Gore when he was a congressman. He poured scorn on senior members of the scientific establishment who were adamant that it was very rare while case after case after case appeared in the newspapers. Eventually the American Association for the

Advancement of Science, an umbrella organisation for all scientists, got together with the American Bar Association, among others, and held a series of meetings.

And this was justified not in moral terms; it was justified by "following the money." Most of the money for research, certainly in biomedicine, comes from the government: the National Institutes of Health (NIH) and the National Science Foundation. The NIH dish out about US\$25 billion a year, the National Science Foundation about \$7-8 billion.

What the congressmen said was that the government had every right to come in to every institution that had signed a contract with it, and if anything other than good research was being done, it would want to know why. The Office for Scientific Integrity was set up in 1989. It came up with a definition for research misconduct, which is the single most important thing you should do first. Because you certainly can't accuse people of doing something wrong when you have not defined what is right and what is wrong.

So first of all there came a definition: fabrication, falsification and plagiarism and other conduct, which is spectacularly out of line and deliberate, and a process was decreed. And numerous cases were tried, and I mean tried, because very soon lawyers got involved. And the lawyers rapidly started showing scientists that we didn't know about things like standards of evidence. Were we talking about reasonable doubt as you see in a murder case or were we talking about a preponderance of the evidence? What was to be the standard of proof?

The definition and process were slightly modified and expanded to include more and more disciplines, and then this last November both were applied to encompass all science so that a mathematician, an astronomer, a clinical researcher—everybody—would be covered by the same rules. No exceptions at all. They had to abide by the definitions and they had to abide by the process. And the process was as follows: an initial enquiry; then a full investigation; then a report to the Office of Research Integrity, as it subsequently became, and so on, and built into that was an appeals process.

The government process became *de facto* what everybody abided by in their institution. Everybody is now governed by the same rules in the United States, if their institution gets any government money at all. And since there isn't a single institution in the United States that doesn't get some government money, it's the same for everybody.

The commission I sat on in 1994 and 1995, set up

by the public health service, held 15 meetings all over the country, and interviewed about 300 to 400 people in public. We made all sorts of suggestions, including ones for the protection of whistleblowers. Those were rejected almost entirely by the scientific community, which does not, I can assure you, want whistleblowers to be protected. They said there was sufficient protection already. But there aren't.

So the system, good and bad, in the United States, is built on a huge experience, with reports published every year. Everything is done at the institutional level, which reports to the government. Why is there that reporting? Because you can't trust professional bodies to self-regulate.

It is the same with all of us—All the advantages of a profession without the responsibilities is what we most like about being in a profession.

**If there is an allegation of theft, the administrators of the institution don't have to scurry around trying to invent a wheel that deals with theft. There is a whole system: police, magistrates, lawyers, courts, prisons and so on. There is a routine for dealing with theft and what you should aim for is a routine for dealing with allegations of misconduct.**

## How should a national panel work?

What you have to ask about a proposed national panel for research integrity is: does it have a clear workable definition? The Edinburgh definition is a joke in that it includes conduct that is both intentional and unintentional. If you leave your thesis on a train by mistake, or some of the data fall into a canal and you leave them out, is that intentional? No. Is it a case of misconduct? Clearly not.

Next you need to ask, does it have a clear workable process? Who do you phone if you've got a problem? Who deals with the appeals all the way through? Who does the initial investigation? How do you keep

conflict of interest out of the panels that deal with this? Who are those panels? Do they include external people? Are they just experts in the field, or what?

To make the process stick, you have to involve all the stakeholders. Otherwise you'll find that three of your researchers are covered by your regulations and the fourth isn't, and you'll have a shambles on your hands. People really have to buy into this. And by that I mean everyone really has got to feel that this is worth while.

Then you have to ask yourselves: is it legal? The process must satisfy legal standards, and here we have to be extremely humble because we have a lot to learn about the law and we will find that most things that we suggest are illegal, improper, and unfair. The law has had a lot of practise at dealing with just this sort of thing, so it is worth listening to.

Forget the causes. No one has a clue about the causes of research misconduct. For example, the "pressure to publish" argument is a nonsense. The papers on this all show that the cause isn't the pressure to publish, although people keep talking about it. And indeed there are several examples, starting with John Long in 1978, who pleaded this, but once found guilty, said that he had said it only to get a lighter sentence.

Why do we have any regulations at all? Public trust in research: that's the single most important one. But there are others. There's preserving the research record, getting all the retractions; accounting for the money, to which I will return; and preventing these embarrassing explosions in the press.

Restoring morale is enormously important, as the few cases of misconduct that occur are very destructive to morale, especially to those whom they involve. A lot of (particularly young) people will get out of the business altogether when they see bad people getting away with murder. Doing the thing speedily is also very important: justice delayed is no justice at all. Trying to stop the destruction of two careers by protecting the whistleblower is also critical.

All of this may be pre-empted by the Wellcome Trust. About 20 per cent of research institutions are funded by the Wellcome Trust, which isn't nearly as much as the US government, but the "following the money" principle is the same. The Wellcome system is a pretty good system, with definitions and process all defined, requiring both institution and researcher to sign on before the money is allocated. My bet is that this will become the general standard in just the same way that the government money forced the general standard in the US. So it may be that the bold action of the Wellcome Trust may force the issue.

## Experience in the Scandinavian countries

Magne Nylenna

Editor, *Journal of the Norwegian Medical Association*

The Scandinavian countries have had systems, or bodies, working for a few years now. The Danes were certainly the pioneers, with Professor Povl Riis, Professor Daniel Andersen, and a few others leading the way. They set up the Danish Committee on Scientific Dishonesty in late 1992. Drawing on the Danish experience, Norway set up a national committee in 1994 and the Swedes followed a few years later. Some of these establishments were fairly controversial, less so in Denmark than in Norway, but let me start with the experiences so far.

### Definitions and mandates

Here we differ from the US because, from the very beginning, all the Scandinavian countries chose their own definitions. All are slightly different, but all three are wide definitions, unlike the explicit American ones. Formal definitions have never been regarded as critical in the Scandinavian countries as we think that we have to rely on some sort of sound judgement.

The mandates for committees in all three countries were two-sided. On the one hand they should handle or investigate alleged cases of dishonesty. On the other, they should also adopt pre-emptive measures. Guidelines have been produced, but sanctions have been left to employers. The committees were purely consultative bodies that gave advice, and that is one of the reasons why there are no formal appeal mechanisms within those committees because appeals must come after sanctions. Of course you could appeal a consultative judgment but what really matters to individuals are the sanctions and these are taken care of by the institutions concerned.

Our experience in Denmark, now nine years, and seven years in Norway, shows that we have investigated few cases, and even fewer cases of dishonesty have come to light. On average, the three Scandinavian countries have investigated about eight cases a year, and about one in five has come to be regarded as “dishonesty” according to our relatively informal definition. In most cases, dishonesty has not been disclosed and a practice over the years has developed not only to conclude on a guilty/not guilty judgment, but to describe, explicitly, in what manner even non-dishonest practice deviates from what we might call “good” practice. So we also produce a full report even in “not guilty” cases.

Things are changing, even in Scandinavian countries, and a discussion has been taking place as to whether our systems are worth while at all. Dishonesty is

revealed in only a handful of cases, given that the total population of the Scandinavian countries is about one third that of the UK, and there are, of course, relatively high administrative costs. I have been a member of the National Committee on Dishonesty in Health Care Research since it was established in 1994 in Norway. And I think that we have spent about US\$15,000 per annum.

But most of us find it rather unpleasant work. That's one of the reasons why nobody really likes to touch on these matters and why responsibility for them tends to get shifted around. Being a member of such a committee, I can really understand why. And with 14 years experience as an editor, I find it increasingly unpleasant. Never before has my competence, in every sense of the word, been questioned so many times. I can easily understand why academic institutions don't want to take matters into their own hands.

**Perhaps one important factor is simply the number of cases that may occur. In a community where a relatively small number of ethical breaches take place, perhaps an integrated body that can handle issues across scientific disciplines is needed, whereas in a larger community perhaps more specialist bodies might be desirable.**

### How research misconduct is investigated

Based on the experience so far, there have been a few recent developments, with the Danes again leading the way. In 1999, they introduced a system that involves having one body control three different committees on health and medical science, social science and humanities, and natural science, including agriculture and technical science. Each has four members. These three committees share the same chair, who is a high court judge in Denmark, as well as administrative support structures. Each of these committees will set up *ad hoc* committees to investigate individual cases.

In 1999 they obtained a legal basis for this work,

founded on the Danish Act on Research Advice and they additionally came to a new definition: “action or omissions in research such as falsification or distortion of the scientific message, or grossly misleading information or actions regarding a person’s effort within research.” It is still fairly wide, but perhaps more limited than the definition initially used in 1992.

The two important aspects of this change are that there is a system that incorporates all aspects of science, and there is now a legal basis for it. In Sweden the current thinking is to form a wide interdisciplinary committee instead of the one limited to healthcare research and, like Denmark, a legal basis for this committee has been recommended. Sweden also operates slightly differently to Denmark and Norway at the moment in that it has a two-tier system. Possible breaches of ethics are investigated at local level first before being referred to the national committee when appropriate. In both Denmark and Norway only the national level currently exists.

Norway is considering a move to the Danish-style multidisciplinary approach, where a panel of nine members would preside. This would include a judge, a

layperson, and representatives from different branches of science. It is not yet certain if Norway will adopt this approach, but it will be making changes to its current system. One of the principal drives behind this move is that non-medical branches of science have also recognised that there is a need for this kind of body. Norway is unlikely to introduce a legal basis for this body, instead relying on the kind of “agreement” system currently in place, for which the employer’s permission is needed before an investigation can take place. Clearly, this restriction would not apply with a legal base.

There are many issues involved here. Perhaps one important factor is simply the number of cases that may occur. In a community where a relatively small number of ethical breaches take place, perhaps an integrated body that can handle issues across scientific disciplines is needed, whereas in a larger community perhaps more specialist bodies might be desirable. In the more integrated model there is a danger that the body will move away from the scientific community. Clearly judicially based bodies would take parliamentary time to amend their constitution, but “agreement” based systems offer a more flexible approach.

## A framework for discussion

Richard Smith

Editor, *BMJ* and vice chair of COPE

There are three broad questions to tackle:

### 1 *Do you think that Britain needs some sort of national body to respond to research misconduct?*

There may be a whole lot of people out there who think that the answer is clearly “No,” but I suspect that that is not the majority view here. None the less I think there ought to be some quick discussion about this.

### 2 *What might this body look like?*

#### **How might it function?**

It might just provide broad leadership. It might be a discussion forum. Would it advise employers? If it is to have some sort of investigative role, how will it do that? Will it do it by legal right? Should it conduct hearings? Should it be in the business of sanctions? Should it be auditing what's going on? Should it be about prevention, education? Should it be doing research? Should it produce an annual report? Should it be some kind of clearing house, collecting data?

#### **What should its scope be?**

Should it cover all research, including the humanities? Should it be restricted to scientific research? Or biomedical research? Should it just be research done by doctors? Should it cover Britain or Europe or beyond? Should it cover England or the UK?

#### **Who should own this body?**

Should it be part of government? Should it belong to the academic bodies? What should be its link to the NHS? Should it belong to patients in some way?

#### **What should its legal status be?**

Should it be created by acts of parliament? Should it be a part of government, or like the GMC, report to the privy council? Should it predominantly act on behalf of other bodies by their consent? What might its governance be like?

#### **How would it be funded?**

#### **What might it be called?**

### 3 *How are we going to make this happen?*

Who is going to do what, with whom, when, where, and how?

#### **Workshop sessions**

##### **Group 1 facilitated by Dr Peter Wilmshurst, Royal Shrewsbury Hospital**

##### *Is a national body needed?*

Everyone agreed that a national body was required, but the term misconduct needed to be defined. The body should be national, not European because of different legal systems, and should include Scotland and Wales. The panel should look to Commonwealth countries whose law is more like that of the UK, rather than the EU.

To gauge the scope of the problem, a survey could be undertaken or the government could commission a report to investigate data from the stakeholders, decide on a model, and then report to a minister. Every time an internal enquiry was undertaken this should be notified to the national body. The participants thought that the yellow card system was not very effective.

Ethics committees could take a larger role. They already have a role in preventing unethical research from going ahead, but they are not properly constituted nor do they have the power or ability to look at fraud. Most ethics committees are very overworked as it is and only cover medical research.

##### *Scope*

- education
- policing research
- investigating fraud

The new body should be proactive and include training, for example, on how to supervise, with certification on completion. It was considered the duty of institutions to undertake this.

Fraud or misconduct are not viewed as criminal offences in the medical community as they would be in a commercial environment. There would need to be different grades of offence with corresponding fines/sanctions. There could be guidelines for institutions, for which legislation would not necessarily be required.

Define penalties and policy from the start. The body should span biomedical research, and all types of

research, if national. There could be an overarching panel with subpanels. If limited to biomedical research, the new body must include non-clinical scientists. It could act as a model for others to use in other fields.

A good idea would be to look at the US and Scandinavian systems and cherry pick after proper appraisal.

#### *Status*

It should be a GMC type regulatory body. One function would be to promote research integrity. Powers would compel an employee to co-operate or, when required, deploy an investigative team. A lot can be achieved without legislation, so the new body could start without statutory powers but with an advisory role. It could collect data on the number and type of complaints logged, encourage participation, and then see if the next step should be to formalise. But it must be totally independent from government, with a lay person to run it: there had already been too much posturing by the colleges and everyone wanted to be in charge.

#### *Governance*

Parliament or a minister should oversee the body. This would involve co-ordination with the Department of Health, DTI, DEFRA and Department for Education. It should also include representatives from the MRC, NHS, Wellcome, universities, members of public, and include an ethicist.

#### *Funding*

It would primarily be funded by central government, with each institution also paying a membership fee. It could operate along the same lines as the quality control scheme for laboratories where each institution pays an annual fee. This could be levied as a direct cost against each research grant or as a percentage of the amount of research being done. Institutions may find that money is more difficult to get for research if they haven't signed up. There would have to be benefits. It will be both expensive and time consuming to police and investigate misconduct. Fees could be charged for training courses, which could be a lucrative source of revenue.

It must have individuals experienced in this type of investigation.

#### *Possible name*

Research Standards Agency

#### *Summary*

- A body is necessary for British institutions to cover dishonesty and serious scientific fraud.
- This should cover biomedical research to begin with and expand later.
- Could develop two models: one statutory and one non-statutory.

- Governance should come from institutions, possibly a quango.
- Money should also be contributed by funders of research and all stakeholders. Names of those who could possibly run it: Michael Farthing, national audit office, charity commissioners, Ian Gibson MP (also a scientist), Minister of Health, Lord Sainsbury.
- It must be independent of government.
- Local action at institutional level may not be enough and difficult to apply sanctions etc if not statutory.
- A clear definition of research is needed, and very good evidence of misconduct.
- Membership should be voluntary.

### **Group 2 facilitated by Dr Fiona Godlee, Biomed Central**

#### *Need for a national panel*

There were mixed feelings about whether a panel was needed, and whose problem this really was. The government does not own science. But it's important to publish science, otherwise there is no influence, so funders have an interest in making sure the research is credible.

The difference between deliberate undesirable practice and ignorance needed to be defined. This would depend on the severity of the sin, of which there are degrees: sending a paper to two journals is annoying, but not sinful. The seriousness of the crime would be dictated by the consequences to some extent.

#### *Scope*

This will depend on how much the panel will be dealing with non-medical and non-UK authors. Covering scientific sins by people employed only in British institutions ignores the fact that we operate in a global environment.

It was felt that the panel should cover all research aspects, including plagiarism and research grant applications. But it was much too ambitious to begin with an all inclusive set up; rather, starting with medicine and building from there would be preferable. But there was no logical reason for ultimately not including all of science. That must be the primary goal.

Its focus should be dishonesty, rather than all bad research, and it should concentrate on obvious rather than minor cases of misconduct, otherwise it risks being swamped.

#### *Function*

It needs to:

- Encourage whistleblowers and afford them some protection

- Structure the way research employers deal with misconduct
- If there is disquiet and reasonable grounds for concern, provide somewhere for people to go that is outside the institution, otherwise they have to rely on the integrity of employers who are not impartial and often have a vested financial interest.

A suggested scenario for bringing a case to book might start with the institution:

- To ask if there is a prima facie case
- If so, a nominated person to approach
- If there is a case to answer, a task force should have a dialogue with the institution
- Call in other people needed to give evidence

But it was felt that the institution might not take on this role, and how would pharmaceutical companies proceed?

#### *Sanctions*

Most crime does not get punished, so it would be unwise to expect this panel to do more. But it should publish an annual report in which it names names and implements heavy sanctions. Care would be needed to avoid libel, and so the standards of evidence should be beyond reasonable doubt.

What about whistleblowers on the receiving end of actionable insults, but who can't afford to sue? Whistleblowers should not be immune from libel because they could be motivated by malice. Should there be legal indemnity to protect the whistleblower/government/drug company? It should be remembered that anonymity could be hidden behind.

#### *Ownership*

Universities could take up voluntary accreditation and would have to submit to audit and quality control. They would have to be strong moral support from funding bodies

There could be a code of good practice published, a report written and action taken if they were revealed to be lacking. But that still leaves out commercial organisations, and they should be included.

Another suggestion was a no fault system with education as the prophylactic and random audit to prevent being scrutinised all the time. Any organisation signing up to it would know that they had a responsibility to investigate allegations. There could be a central body with an independent appeals court.

#### *Accountability*

- Wellcome
- NHS Research & Development
- MRC

Researchers could be answerable to them, and fun-

ders could apply sanctions if the recipients failed to comply. Any investigations, including the outcome, would be filed in a public report.

#### *Funding*

Institutions could price it into their funding applications or the MRC could levy a small tax.

#### *Statutory powers*

The new body would need strong statutory controls to have any teeth. These could be under the aegis of the Secretary of State/Office of Science and Technology/Office of Fair Trading/Department of Trade and Industry.

Membership should be periodically renewed.

It should be some sort of quango with statutory powers and central funding. It could be a special health authority for stakeholders in other fields. It could be developed along the lines of the National Cancer Research Institute (NCRI).

#### *Name*

- Committee for Research Integrity (CRI)/ Council on Research Integrity
- Serious Research Misconduct Office

#### *How are we going to make this happen?*

First steps:

- Public involvement
- Get the following to sign up:
- Council of deans and medical schools
  - Principals and vice chancellors
  - NHS R&D
  - All major employers and research funders

Signing up to it would not mean membership. Local research ethics committees should be kept informed.

The chair of COPE could pull everything together into a consortium that would include Ian Gibson MP, who is also a molecular biologist, Lord Hunt, and Lord Sainsbury, to build up a broader action group of movers and shakers.

Look at different models of bodies who could help action it:

- National Audit Office
- Audit Commission
- Research Councils
- NCRI

#### **Group 3 facilitated by Dr Sabine Kleinert, *The Lancet***

The overall feeling was that there should be a national panel, but that it must have an impartial adjudicator.

Institutions can't or won't deal with research misconduct. But current libel laws could cause problems.

#### *What might it look like?*

There should be one body to deal with all institutions. Its role would be to:

- Provide leadership
- Produce guidelines in training and research
- Educate
- Boost morale

And to be effective, everyone would have to sign up to it, including groups like the forensic pathologists, for the peer pressure effect. If its investigations have legal powers an Act of Parliament would be required.

#### *How would it work?*

The panel should be tried out on a voluntary basis first, and if that fails, then it should be given legal teeth. It could have a rapid response team comprising independent investigators, but what would their remit be and who would fund them? COPE stops short of investigations, but surely the institution should have someone to call on. But would institutions pay for this?

Could it be run along the lines of a counter fraud office within the NHS?

The body should have a list of independent investigators who could be called on, if required. A report should be published which the institution would not be able to buy.

The report and its consequences should be dealt with in secret by human resources.

There would be a contractual relationship between researcher and institution and the funder, and if this were flouted, this would constitute breach of contract, and would be part of NHS research governance.

#### *What about sanctions?*

There should be a framework from minor to major breaches; human resources can also get involved

#### *Scope*

It would be better to start small with biomedical research and then widen it out to include humanities, engineering, etc. And it should be applicable only to the UK.

#### *Ownership*

The government should not own it. This could be undertaken by funding bodies like the NHS, Wellcome Trust, the MRC etc, but all stakeholders must be involved

#### *Governance*

This was not a job for the royal colleges, and it would be too complex to leave to one.

#### *Funding*

- Subscriptions
  - Centrally funded
  - Would individuals sign up to it or learned societies?
  - All stakeholders should go into the funding pot
- Institutions would call in investigators; perhaps funders should get involved. But what about whistleblowers? Protecting them is very difficult.
- Would insurance premiums cover this type of investigation for an institution?

#### *Name*

UK Biomedical Research Standards Council

### **Group 4 facilitated by Sir Cyril Chantler, Guy's, King's College, and St Thomas' Hospitals Medical and Dental School**

It was unlikely that a national charity, such as the Wellcome Trust, could take on the role of a national body, as it could not act both as a funding agent and deploy governance. Care must be taken to ensure that bureaucracy does not get in the way of research. The new body must not be just a mass of red tape.

There was some debate about whether the research misconduct was confined to medicine only or whether the rest of science needed to be included. And some felt that the stimulus for the panel came from embarrassing stories in the press.

#### *Function*

The new body should step in when an institution can't or won't do so. Initially there should be a voluntary agreement to work to agreed rules set out by the new body rather than handing responsibility over to it completely. Once critical mass had been achieved, then things could proceed to an audit body, and then to a more formal legal footing, if needed. But the issue was who would pay for such a body?

Many institutions have no guidelines at all and those that do have ones that are wide ranging. And guidelines do not necessarily mean that there are procedures in place. The new body could help standardise these and set up a process in the institution with things achieved through consensus. The new body could kitemark through audit.

Research misconduct should be built in by the funder and become part of current governance.

There needs to be a place for whistleblowers to go outside the institution, which must have teeth. The institution should have a named independent person within it.

#### *Investigations*

Employers or sponsors could do these, although most

sponsors would not have the money. Or the new body could do these either wholly or in a supervisory role for internal investigations. But it was felt that many institutions did not have the competencies to carry out investigations, and it was feared that if an institution were not compelled to call in the new body, it might not do so of its own accord.

#### *Audit*

The new body could become the auditor and audit year on year. But the institution must report any complaints to it, and once started these should be followed through even if the transgressor left and moved on elsewhere. Audit was thought to be a good idea but this should be anonymised unless the case was proven. It should be borne in mind that some people will call in legal advice once they leave employment.

#### *Register*

Some kind of register was needed. There is the GMC register, but the GMC is unlikely to make this public as they do in the US. And scientists who are not doctors would fall through the net.

There would need to be some kind of legal framework for it. Employers could search the register before hiring anyone. But what about European human rights legislation and protection of privacy? It was felt that it could become public on the grounds of public interest.

The problem is the retention of names rather than publication of "guilty parties." A register leaves the onus on the employer to get the references. Could this be under the auspices of the Commission for Health Improvement?

#### *Sanctions*

These should be applied by according to gravity of the offence. But where to draw the line between minor and major offences? And should the accused lose his or her job over major misconduct? If the panel is to be about prevention and advising on best practice, it is important to look at minor offences as these form the bulk of misdeeds.

How can sanctions revert to the funder or employer? The new body could let the institution know whether its sanctions are reasonable as part of its advisory and audit role.

The new body could be similar to other bodies such as the Association of British Travel Agents (ABTA) or the Association of British Pharmaceutical Industries (ABPI) to which organisations could voluntarily belong. The new body could have the power to remove the kitemark from institutions failing to adhere to guidelines. Funding bodies could use membership as a deciding factor for granting monies.

#### *Ownership*

- Owned by members as a mutual model
- Government?

- Royal Society if it is to go beyond biomedicine
- It should be seen to be evolving model where employers and researchers are members.
- Funding bodies need to be linked in as well as royal colleges.
- What about patient/lay membership?

#### *Funding*

Multiple sources are best. Fees could be proportionate to the means and size of the institution. Funding bodies could chip in.

#### *Scope*

The membership model would allow for expansion outside the field of medicine. But it should start with biomedicine and include non-medics.

#### *Legal status*

It would be acting on behalf of others who have legal responsibilities; therefore the legal framework lies with the employer.

It should just advise, audit, and produce reports, but it may need to form extra legal requirements.

Its strength should come through its mutuality: it's legitimate rather than having legal status.

Members should be drawn from legal, medical, pharmaceutical, genetics, government and public entities.

#### *Name*

Council of Research Integrity

#### *How do we make it happen?*

We have to get members to see that it is in their best interests. The Academy of Medical Sciences should take the lead. Wellcome's guidelines are on the right track; research councils should be shaken up as well. All universities should be on line by the end of the year. But we need to build on that momentum

## **Feedback from group sessions**

### **Group 1**

We thought that the new body should be called the Research Standards Agency.

We spent a lot of time talking about whether this body should be voluntary or statutory and, in the end, came to the conclusion that it would be best to work two models in parallel and then decide what was most suitable. We felt that it would be a good idea to look at the existing systems that have been developed, and cherry pick from those.

Whether this should be a statutory body or not seems to be very dependent on how long it would

take for legislation to be passed. Professor Kennedy advised that it would be very easy for legislation to enact this, and just as easy to change it once it had become law.

If it wasn't set in law, we needed a total cultural change, because it seemed to us that it was a sort of mindset equivalent to the development of ethical criteria in the eighties. We thought that clinical governance might need to play a part.

We thought that there were two main roles for the body: an investigative and an educative/data collector/advisory role. And there was some discussion as to whether we might need separate bodies.

A concern is that we actually don't know the scale of research misconduct and maybe before we can start, we need to do some research on this.

As to the breadth of the body, we felt that there should be some kind of overarching committee along the lines of the Scandinavian model in the biomedical sphere. We thought that government should set it up and partly fund it. We were quite keen that there ought to be funding coming from both above and below with the possibility of the institutions being affiliated with the Research Standards Agency and paying a fee for that privilege.

What we do now is talk to the Department of Health, who should appoint a minister.

## Group 2

We weren't entirely sure that we did a national panel but most of us thought so. And most of us thought that it should deal only with British researchers or employees of British institutions. Despite the fact that our journals receive all sorts of problematic research from around the world, we felt that it was going to be very difficult to deal with any other than our own.

But we think the issue goes beyond publication. It's not just what is published, it is what is done. Other areas where it could be picked up would be people stealing ideas, or grant applications.

We thought it should cover dishonesty, scientific dishonesty. But we were aware that only about 2 per cent of crime is detected so we felt it should concentrate on serious scientific fraud. There are all sorts of misconduct that you are never going to stop and you are never going to catch.

Should it just cover biomedical research? We feel that as it is all who are represented here, we have no voice to speak about other types of science. But I suspect that we should start small try and expand later. Today biomedical; tomorrow social services; and then the world!

We really felt that in order to have any authority, it had to grow out of the whole idea of research governance, which is something that should come from the institutions where research is being practised. Things are moving in that direction already. Research will be governed by proper accreditation and subject to a cer-

tain amount of quality control. Whistleblowers might go to their institution but they would also be able to go to this body if they were afraid or unwilling to do so.

Where would this quango get its authority? Principally from the funders of research, so people like MRC, the research charities, and the Wellcome Trust need to be on board.

Sanctions would principally be by publication, by just "spilling the beans." This would expose non-compliance by the institutions that failed to impose their own sanctions on miscreants.

How are we going to get it moving forward? That would be a job for the chair of COPE.

It might be set up through the MRC, via some kind of governance, or the National Audit Office, or charity commissioners who fund a lot of research. And there are certain influential people we need to lobby. Remember, in America it was a congressman who made this thing happen. We thought of Ian Gibson MP, who is a scientist himself and very keen on scientific research, Philip Hunt, the Minister of Health, and Lord Sainsbury.

## Group 3

We had a minority view that said that the case was not proven. We thought the principal issue to justify having a national body was that most important local actions were not consistent. And local could mean within a branch of bioscience.

The view was that the panel should provide leadership, looking at the basics and providing guidelines. If it were not based in statute, would it actually be able to do any investigation or make any decisions? And that might also lead to practical and monetary problems, although we thought NHS research governance could help there.

We also thought it should cover the British biomedical community and one of the yardsticks we thought of was anything that had ever had to go through an ethics committee was medical research. This would mean that it might cover sociologists and psychologists, and other allied professions and not just doctors.

Who would own it? Definitely not government. We need independence to buy in from the set of bodies we have mentioned already, with the addition of the higher education funding councils of the UK, the postgraduate dentists, and others.

In terms of the governance, we thought that it was too detailed at this stage to say how it would actually run. To ensure funding was from all stakeholders and protecting whistleblowers was going to be very, very difficult. Even if we have legislation in the end whistleblowers will always be vulnerable and there's nothing much we can do.

We wanted the name to include the words biomedical research rather than just research standards.

#### Group 4

We all agreed that such a body was required but there were a couple of “buts” the main one of which was that it wasn’t a hammer to crack a nut or too heavy-handed. We thought “regulations with a light touch” was appropriate.

What should it do? It needs to offer a definition of research misconduct, and we can offer no such definition. We also thought that protecting the whistleblowers was essential. We saw it working with the expectation that investigations would take place at an institutional level, but if the institutional were unable to do it—a small trust, for example—then it could go to the body. Or if the national body felt that the result of the investigation was inadequate, it could take steps itself to do an investigation, subject to the caveats just mentioned.

We also wondered how whistleblowers would approach the national body if they felt uncomfortable in their own institution? Clearly there needs to be some provision for that and something for editors, people who set up conferences, and those who peer review to

alert the national body to problems.

We favoured a membership, rather than a statutory model, with higher education institutions, trusts, and so on, linked into the organisation with a very strong lay representation. The Wellcome Trust or the Academy of Medical Sciences should possibly boost it, but funded by research payers and researchers, for reasons of self-interest that have already been discussed.

We thought that we should start with biomedical research and expand later.

We thought it would be seen to be legitimate by virtue of its membership, but might require more formal legal status on another occasion and we were hazy on research governance.

There are several things that might make this happen. One is that the Academy of Medical Sciences has already produced a report supporting such a national body. The new GMC report might also act as a catalyst, but leadership will be of great importance.

What should we call it? We tried to think of an acronym but the best we could manage was CORI, the Council on Research Integrity.

## The way forward

Ian Kennedy

Professor of Health Law, Ethics, and Policy, University College, London

### Do we need a national body?

The first question is the question of need and I detected some reservation as to whether you felt the need was there. I would suggest that this largely comes from a degree of uncertainty and insecurity. The notion of another body looking at what we do is always unwelcome initially.

But there are ways of getting around that problem, which were referred to by the various groups. Namely, you could start by having some less formal body and then move on to a more formal mechanism. On the other hand, we have been reminded today that this is often the resort of those who want to slow things up.

### Formal vs informal

The Americans have written into legislation what are called “sunset” clauses. This allows something to be set up and funded for a limited period of time, such as five years, at which point it is re-examined. That would not be impossible in the UK. For example, the US President’s Commission on Bioethics was funded for only a certain amount of time after which it had to come back to congress for more funding. This was refused.

So either move from the informal to the formal model or think about a limited lifespan. But you do have to solve the problem of need, if you are going to go to government, and persuade them to even take this issue seriously.

### Evidence first and foremost

The very evidence you need to establish whether or not there is a problem is the evidence that doesn’t exist, because we are talking about fraud and misconduct. But the Department of Health, and certainly the Treasury, would need to be persuaded very seriously that there was a problem before government embraced the idea and committed funds.

Therefore, I would suggest that you should start with some very senior civil servants. And you will need evidence to substantiate your claims. Any public policy to be made by government depends on good, reliable data, and if good reliable data are not available from commercial sources or from evidence of misconduct, then government is rendered that bit more insecure in its making of public policy.

### Who will take the issue forward?

The next question is: who are you talking to here? To

whom is this seminar addressed? Put another way: who is to take this issue forward? You may be talking to government, as it were, through senior civil servants; you may be talking to yourselves, as interested professionals. You have to decide who is going to be the standard bearer to take the messages from here elsewhere and to whom they are going to be directed.

There seemed to be quite considerable disagreement. A lot of you just wanted to talk amongst yourselves—you are all professionals who all understand one another. Then there are some who feel that if you talk amongst yourselves you’ll be doing it for a very long time, and that’s what you’ve done already, and now is the time to talk to the movers and shakers. I happen to agree with that stance, and I think that senior civil servants ought to be engaged very soon.

### What is the scope going to be?

The next question is, what are you going to talk to them about? What is the scope of the enterprise that you have in mind? I completely agree with the idea that if you have got to start somewhere you ought to start small and relatively well contained. And then if the argument is seen to be a sound one, you can always extend into science as a whole. You can begin with biomedicine without too much difficulty. Of course, there are always going to be arguments at the edges as to whether something constitutes biomedicine, but that’s in the nature of all these issues.

It was clear to me that although you all thought it was a very good idea to have something, you weren’t at all sure what the something should be. And there was a certain professional insecurity about being overseen by someone who isn’t “one of us.” I hear the word “lay” often used, to define those who would otherwise presume to comment on what we do.

We are talking about misconduct in dealing with volunteers in a healthcare system and so we all have a vested interest in it. It isn’t a professional matter alone. And even if you tried to make it so people would resist that. And if you believe this is important isn’t it important for all of us? And you have to say that it’s important or you won’t get it through the door of the civil servant.

We have moved on, we are in the twenty first century. We don’t leave things to cartels or to professional groups we want to get engaged. So I think you just have to recognise that there will inevitably be tension between the ideas of “professional corporatism” and the involvement of the citizenry at large.

## Accreditation vs self regulation

It wasn't quite clear how this independent body might emerge. Would it be a membership model, through the process of accreditation by the institutions? Or would it be a kind of looser confederation of professional and other interested groups and institutions?

I can see weaknesses in both, because both hinge on voluntary participation. And you will have to find a way around this if you want an independent body with the teeth to require membership and compliance. But it means ensuring that all those institutions feel that the requirement isn't imposed but collectively agreed. Membership should include all those institutions involved in research and also those who are volunteers in research, with requirements laid down for proper conduct. The Wellcome Trust is doing it; the Department of Health is doing it. Overarching clinical guidance or clinical governance are the ways forward

I have recently become a member of a council concerned with forensic practitioners. There is a body that accredits anybody giving evidence on fingerprints or toxicology, for example. It is currently an internal self-regulatory body, but will no doubt extend further in due course. That is a way in which you can begin to take steps to regulate or accreditate.

## Funding

I have already said that all funding decisions made by government are mediated through the Treasury, who largely demands that everything they fund should be cost neutral. That will be a difficult case to argue unless you can persuade the NHS research and development budget to fund you. I happen to agree with Richard Smith that multiple funding is a very good idea. If the institutions, the research foundations, the government perhaps the royal colleges, etc, all contribute all the various stakeholders themselves will be committed to the welfare of this institution. They don't resent paying for all of it, but they will feel that as part of it they can have their say, and it won't cost them more than they can afford.

## Powers

What powers and duties should this new body have? Here the devil really is in the detail of these powers and equally the reciprocal duties. You seemed to be discussing at least three models.

One is the maximal model of an independent body that is not only reactive to allegations of misconduct, but also proactive. It would have an inspectorate arm, a training arm, and a guidance arm. That option is going

to be more expensive and more onerous to launch from scratch.

The minimal model is simply to liaise with the institutions and employers to encourage them to disseminate information about research guidance and governance and to get people to agree certain standard forms.

The middle way is to insist that all institutions sign up to a certain constitutional form, which binds everybody involved in research. That contract gives you the power to discipline any improper deviations. And it provides guidance that is national and overarching. This model keeps things close to the institution, close to the employer, and close to the funding. This would seem to be the best course to adopt, with a view to developing further with guidelines, etc, as the need arises.

## National vs international

What reach should this body have? I think that the tendency here was to start small and make it applicable only to the UK. But the problem with this as Michael Farthing will tell you, is that a lot of research is submitted from all over the world and you need to have some powers to deal with that. My own view is that you should think very much in terms of internationalising through, for example, the Council of Europe.

The Council of Europe has several international conventions on biomedicine. And, in fact, they have just produced an international convention on research. It would not be too late even now to try to make some representation as regards the conduct of research. Forty three European countries now embrace the Council of Europe. It is a way forwards that is less narrow than pursuing an entirely UK based system.

## Accountability

Lastly, how should such a body be held accountable because whoever pays for it must be accountable, and must be seen to be accountable? I would have thought that one mechanism, irrespective of whether it is created by legislation or not, should be that it reports annually to a select committee within the House of Commons. This could be the select committee on science and technology or on health. The new body should also produce an annual report, to be circulated to all the institutions concerned.

All of us think that this is a very good idea but translating that idea is very hard because there are divisions within this room, and there will be divisions outside. I think the way forward is to now sit down with pivotal people within the relevant government departments and with people from the Wellcome Trust, and others, to move on to the next stage.

## Debate at the Royal College of Physicians, London, 5 November 2001

### Research fraud in Britain

### “This house believes that Britain should be ashamed of its response to research fraud and take action at once”

#### **Richard Smith, Editor of the *BMJ*, organiser and chair of the debate**

I would like to dedicate this debate to Stephen Lock, who has been talking and writing about this for ages, but considered by many to be mad for having done so. But he has, of course, now been vindicated.

In the introduction of the third edition of his book on fraud and misconduct in biomedical research, co-authored with Michael Farthing and Frank Wells, he writes that it has been 30 years since the paradigm shift in the unthinkable idea that research misconduct might happen. Ancien Regimes, such as Britain and France, have been less resolute, with no formal system in place despite the continuing evidence that the problem is no different from that in other countries where the issue has now been taken seriously.

The exception might be the Royal College of Physicians, who in 1990 set up a commission to look in to the matter, which produced a report the following year.

But there was no press conference to mark its publication. Postgraduate deans did not even know about it.

Stephen Lock writes: “Would that a fourth edition will not need to include again a plea for creating a system in the UK and a few other countries, but can instead be devoted to sharing worldwide experiences of success. However we remain sceptical.”

#### **Professor Michael Farthing, Chair of COPE and Executive Dean and Professor of Medicine, Faculty of Medicine, University of Glasgow**

It was once said that the British were fast to talk, but slow to act. And in this case it is not because they have not written or thought about it. There just is not an adequate process for dealing with the full spectrum of research misconduct in 2001.

Among the many high profile cases, there are well respected medical figures who say that publication misconduct is not a big problem, serious cases are rare; the issue is overblown. There is no need to use a sledgehammer to crack a nut, they say.

But many of the people who pontificate about research misconduct, don't see this problem at the grass roots. Editors have been vociferous about it because we see it. And much of it remains unresolved because we have limited powers.

Banerjee's case took over a decade to be resolved. There was an internal inquiry and no action was taken. This case should make us ashamed. It took an external whistleblower to make it happen.

At the centre of it all is integrity or honesty. And there's a spectrum of misconduct, from minor offences which encompass errors of judgment or poor design, to misdemeanours which leave out inconvenient data, right through to fraud and fabrication.

As far as publications are concerned, there are author disputes, dual submissions, and salami publishing, through to reviewers and editors with conflict of interest, who breach confidentiality. But how frequent are the serious offences? Do misdemeanours at the “safe” end of the spectrum lead to serious fraud? We don't know the answers. We have no database, no repository of information.

Stephen Lock first asked the question as to whether it existed in 1988 in the *BMJ*. The Office of Research Integrity in the US published its report for 1993–97 detailing more than 150 cases of fraud. In addition, there were more than 1000 allegations where no action was taken because of inadequate primary evidence or a mischievous whistleblower.

The Royal College of Physicians' report in 1991 states that there is no reason to believe the problem is rife, but there are no data on its prevalence. That was 10 years ago. I believe it is now time for Britain to follow the example of the ORI.

It is true there have been some efforts to tackle the problem. The Wellcome Trust will not fund grant applicants unless they sign up to their guidelines. But last year Sir Richard Peto said that he felt a national body would do more harm than good.

Peter Wilmshurst catalogued some cases of misconduct from 1988 to 1997 in *The Code of Silence* in *The Lancet*. It was not a reassuring picture. And COPE is the only repository of information on cases of research misconduct other than the GMC.

There was a potential turning point at the Edinburgh

Consensus Conference in 1999, which concluded that action was needed to establish a national panel, and a blueprint has been produced by the Royal College of Physicians of Edinburgh. But the Americans established their panel in 1989, renamed in 1992. The Fins, the Danes, the Norwegians, Swedes, the Germans, and most recently, the French, have all established national panels.

A sample of Dundee students reported in the *BMJ* earlier this year showed that almost a third of them had written up in the case notes that the CNS was normal when they had not undertaken this investigation. We have to send a powerful signal to the medical profession that dishonesty is totally unacceptable.

The struggle that Pappworth had to set up ethics research committees in the UK is similar to what we are going through now. The response from some senior doctors at that time would now be considered deplorable.

### **Professor Sir George Alberti, President of the Royal College of Physicians**

Is this a real problem or a witch-hunt? Let's step back a pace and ask: who is responsible? Why is there a problem?

It is human nature to be dishonest. People are honest unless put under pressure. And editors are the prime culprits. They love dramatic stories. They want press releases and to up their citation index. So authors produce them.

Solid, boring, negative result studies won't get published, they know. So they tweak them. Professor Farthing complains about salami publishing, but what about all those letters from editors saying that the manuscript is too long?

And then there's the Research Assessment Exercise which requires many publications, and in high impact factor journals. And there's the pharmaceutical industry offering easy money, grants and trips.

And what about egos, ambition, and prizes? Look at exclusive institutions like the Royal Society. And people get destroyed by not winning the Nobel Prize. Let's tackle these first. Let's get rid of this exclusivity.

The assumption is that nothing has been done, yet Michael gave a good account of what has been done. There's a big emphasis on training and an immense amount has been done at the educational level. The NHS R&D programme has published a massive document on research governance. Scottish colleagues have proposed a council, so something is happening. This motion would have been a lot more credible five years ago.

Over the past few years this country has had a knee-jerk reaction. One case in the media and a new gestapo is set up to deal with it. Yet another surveillance body will put people off, and most people are doing research in their spare time so we shouldn't be discouraging them.

### **Peter Wilmshurst, Consultant Cardiologist, Royal Shrewsbury Hospital**

I agree with Professor Alberti's quote in *Hospital Doctor* in which he said that current standards for dealing with research misconduct were "shambolic" and there was a lack of clear guidance on what to do.

I have blown the whistle. I was the person who reported Banerjee and Peters to the GMC because I was dismayed that they had not already been reported.

In that case we know that three colleagues refused to be coauthors on their work because they had no recollection of it having taken place. Seven colleagues complained to Peters that Banerjee was fabricating data. When confronted with the evidence, Banerjee was forced to admit some fabrication in 1990.

An internal inquiry in 1991 concluded that much of Banerjee's research data were at best unreliable "and in many cases spurious." But the documentary evidence was shredded and the whistleblowers threatened. The funding bodies were neither informed nor refunded their grant monies.

A thesis on the same research was submitted to the University of London, but despite being alerted by a whistleblower to the fabricated research, Banerjee was still awarded a Master of Surgery degree.

He was also awarded a Hunterian Scholarship to present his falsified research at the Royal College of Surgeons, although senior fellows of the College knew of the doubts about its honesty.

When Banerjee resigned from King's he took with him a good reference. He received further research grants and published more papers. He became a consultant surgeon.

He was suspended seven months before his GMC hearing for unrelated serious allegations which included charges of dishonesty. Yet even while under investigation, he was nominated for Fellowship of two of the three UK Royal Colleges of Physicians.

Sir George was right. The current standards for dealing with research misconduct are shambolic. The institutions to which we look for guidance failed in this case, as in many others.

In 1986 I went to *The Guardian* about a pharmaceutical company doing unethical research. It had tried to bribe and pressurise investigators into altering data and had prematurely terminated trials with unfavourable trends. The GMC, the CSM, the ABPI, and various others all failed to take action. *The Guardian* published, and the company did not sue.

The MDU was consulted and they informed a senior physician at my hospital who pressurised me to drop the matter.

I subsequently reported concerns about other trials involving senior British cardiologists and cardiac surgeons, in which patient mortality data had been falsified.

Eventually my position became untenable. I was told

that if I didn't leave the hospital it would manufacture a reason for my dismissal.

However, the most serious threat to me came from the GMC, who investigated me for eight months for disparagement of an author who had published research. I was convinced that his research contained fraudulent data, and managed to persuade the editor of this. We reported the matter to the GMC, who received a counter charge from the author.

The GMC did not start to investigate this case until it had exonerated me, and it is still investigating my allegations some four years later. Is disparagement of one doctor by another more serious than research misconduct? It seems that way. The GMC was used to intimidate a whistleblower.

I truly believe that Britain should be ashamed of its response to research fraud and take action at once.

### **Sir Donald Irvine, President of the GMC**

In four or five years a lot has been done to reverse these trends. And I must pay tribute to Richards Smith and Horton for their joint editorials four years ago which led the GMC to take action.

We feel that honesty and integrity apply to all things that doctors do. Bad research damages the integrity of the profession. And it damages patients. The GMC has clearly set out sanctions. Since 1995 there have been 11 cases of serious professional misconduct; two have been suspended; eight erased from the register. The message is: you do it; you lose your licence to practise.

There is various guidance and many clinical guidelines in place, but clear explicit guidance is needed from the GMC. And after wide consultation, on Wednesday that will be in the public domain. It will leave people in no doubt about the link between conduct and registration.

But what do you do locally? And how do you deal with non-medical scientists. There is no really consistent approach.

In research the lessons and solutions are remarkably similar to clinical work. We back a national body. We want it to happen. But let's not confuse ourselves by saying that nothing has been happening. Standards will be out there on Wednesday. This motion is misplaced.

### **Comments from the floor**

#### **Stephen Evans, Medicines Control Agency:**

Peter Wilmshurst does make us ashamed. Are we going to take action?

#### **Dr Sinclair, self professed "elderly physician":**

I was chair of a research ethics committee in a teaching hospital for several years. It's the local committee that looks at research very carefully. They should be on the ground in each institution. Local people all know.

#### **Mrs Jean Robinson, Occupational and Environmental Diseases Association, Enfield:**

Allow patients/research subjects to get involved. They want to see original research protocols and they are always refused, because they are told it's confidential.

The ethics committees are told what the researchers are going to do, not what took place.

Richard Smith commented that editors support calls to publish research protocols. It was pointed out that the GMC paper does give patients the right to get involved.

Mrs Robinson continued: How do we get a central body? We do need one. We should hold the institutions to account and ensure that they have proper provisions. It can't be the GMC because that excludes non-medical researchers. Could it be the government, the Wellcome Trust or the Academy of Medical Sciences? Someone needs to volunteer.

#### **Frank Wells, MedicoLegal Investigations, Ltd, Knebworth:**

The government must be involved. It is not right that pharmaceutical companies have to rely on commercial bodies such as us.

The University of Oklahoma had a research unit shut down by the OHRP. This is what we can, and should do, here. I urge the Physicians and all other royal colleges to meet with the government to take this forward.

#### **Dr Marks, London:**

The real failure is not to investigate the cases of people who have been "pressurised" to do harm.

#### **Roger Goss, Patient Concern, London:**

In the end it doesn't matter how trust is breached. The end result is always a nibbling away at public trust in medical mores. We should support [the motion]. Anything less is an insult to anyone suffering as a result of any kind of fraud.

#### **Professor Roy Pounder, Royal Free Hospital:**

The MRC and the Wellcome Trust don't appear to audit anything they commission. And they should do.

#### **Dr Richard Tiner, ABPI, London:**

We do audit clinical research. Those who don't as rigorously as pharmaceutical companies may have to address that.

### **Summing up:**

Professor Alberti said that there was a need for training, but patient involvement was already happening in some places. There was a need to re-emphasise that things have been happening, even if this was only recent.

He had received an endorsement from Sir John

Pattison, head of NHS Research & Development, who also said that he would be happy to facilitate a discussion.

There needed to be local mechanisms for training, he said. “I feel enormously strongly about having mechanisms in place, but not setting up a major investigative organisation because that will put people off.”

Professor Farthing agreed that things had changed but “too little too late.” He reiterated that education was at the heart of all this. But he was utterly dissatisfied with the lack of protection for whistleblowers. Editors were targets for them, he said, because it was unsafe for a whistleblower to report his or her own institution. Internal reports were buried, he said.

Many local enquiries were carried out by people too inexperienced—because they did not see enough cases—to be carried out competently, he added.

“Things have been moving towards a universal agreement about the need for a national body, but they have been hampered by institutional rivalry.” The royal colleges had provided different responses, and the Academy of Medical Sciences was only interested in education, he said.

Leadership should come from within higher education and NHS institutions, the major employers. An independent leader was needed.

A show of hands indicated that the motion was carried and that some doubters had been won over.

# Fourth International Congress on Peer Review in Biomedical Publication, Barcelona, Spain, September 14–16, 2001

## Plenary session abstract

The Work of the Committee on Publication Ethics (COPE)

Mike Farthing<sup>1</sup>, Richard Horton<sup>2</sup>, Richard Smith<sup>3</sup> and Alex Williamson<sup>3</sup>

The Committee on Publication Ethics (COPE) is an informal group founded in 1997 as a response to growing anxiety about the integrity of authors submitting studies to medical journals.

Founded by British medical editors, including those of the *BMJ*, *Gut*, and the *Lancet*, the committee had five aims:

- (1) To advise on cases brought by editors. Cases are presented anonymously, and full responsibility for action remains with the reporting editor. The committee has so far considered 103 cases. In 80 cases there was evidence of misconduct. Several cases have been referred to employers and to regulatory bodies like Britain's General Medical Council. The commonest problems were undeclared redundant publication or submission (29 cases), disputes over authorship (18), falsification (15), failure to obtain informed consent (11), performing unethical research (11), failure to gain approval from an ethics committee (10), and fabrication of data.
- (2) Publish an annual report describing the cases it considers. The committee has published three annual reports and established a web site ([www.publicationethics.org.uk](http://www.publicationethics.org.uk))
- (3) Draft guidance on these issues. The committee drafted guidelines and after extensive consultation published them in 1999 (available on the web site). They have been adopted by many journals.
- (4) Promote research into publication ethics. Little has been achieved so far.
- (5) Consider offering teaching and training. The committee has run two seminars, and individual members of the committee have lectured and taught on research misconduct.

COPE has also been concerned to ensure that the scientific community in Britain responds to research misconduct. Britain has now had several high profile cases of research misconduct, but has yet to make a coherent response to the problem. Several bodies, including the Royal Society and the General Medical Council, are currently considering the problem, and COPE has been important both in spurring these bodies to action and in contributing to a response. COPE might have proved to be a temporary body, but members of the committee judge that its work must con-

tinue. It has thus published a draft constitution and proposes to formalise itself.

<sup>1</sup>*Gut*, London, UK; <sup>2</sup>*Lancet*, London, UK; <sup>3</sup>*BMJ* Publishing Group, BMA House, Tavistock Square, London WC1H 9JR, UK, email: [rsmith@bmj.com](mailto:rsmith@bmj.com)

## Poster session abstract

Guidelines for Good Publication Practice: The COPE Experience  
Richard Horton

**Objective:** The United Kingdom's Committee on Publication Ethics (COPE) was formed in 1997. It aims to provide a forum for editors to seek advice about allegations of misconduct. Early experience of COPE indicated that there was an urgent need for more formal guidance in matters relating to suspected breaches of research and publication ethics, and COPE set out to produce guidelines for good publication practice.

**Design:** A conference was held in April 1999 to discuss the creation of guidelines. Participation was inclusive: in addition to COPE members, the meeting was open to the UK medical licensing authority (General Medical Council) and the royal colleges. Eighty people took part, and draft guidelines written by COPE members were tabled for discussion.

**Results:** The final guidelines included sections on study design and ethical approval, data analysis, authorship, conflicts of interest, peer review, redundant publication, plagiarism, duties of editors, media relations, advertising, and dealing with misconduct. The guidelines were published in the 1999 COPE report. Since first publication, these guidelines have been republished and endorsed by 28 journals. Two revisions were proposed in 2000 about ghost authorship and contacting authors regarding alleged misconduct.

**Conclusions:** Self-organisation by editors to deal with cases of alleged scientific misconduct has led to guidelines that aim to provide a more consistent basis for decision making. In drawing up these guidelines and in securing endorsement for them, we found a large degree of unmet need and enthusiasm among editorial colleagues. A secondary effect was to stimulate statutory national bodies to take misconduct more seriously.

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## Guidance on presenting cases to the Committee on Publication Ethics (COPE)

- (1) COPE considers cases of possible research misconduct referred by editors and offers advice on what action to take. Currently the committee considers only cases referred by editors.
- (2) Cases for consideration by COPE should be sent to Ms Anastacia Kirk, Secretary, COPE, BMJ Publishing Group, Tavistock Square, London WC1H 9JR; email [cope@bmjgroup.com](mailto:cope@bmjgroup.com); telephone + 44 (0)20 7383 6602; fax + 44 (0) 7383 6668.
- (3) It is for the editor to decide what action to take. There is no obligation to follow the advice of the committee.
- (4) The cases considered by the committee are published in the annual report. They include the advice given, what action (if any) was taken, and the outcome.
- (5) Editors should present their cases as briefly as possible, avoiding extraneous detail, but presenting all relevant information to enable the committee to offer good advice. Examples can be found in the COPE annual reports available on our website ([www.publicationethics.org.uk](http://www.publicationethics.org.uk))
- (6) Cases must be anonymised to avoid problems of defamation, but without losing relevant content. The identity of the editor presenting the case will not be published in the annual report.
- (7) Editors should not give the names of journals, authors, institutions, countries, or titles of papers. They should be as general as possible about essential information. For example, refer to a “common chronic disease” rather than diabetes, if this needs to be mentioned at all, and use the term “study” rather than a randomised controlled trial unless this is critical to the case.
- (8) Editors can anonymise reports by removing information, but they should not give false information. If in doubt about the presentation of a case contact the secretary, Ms Anastacia Kirk.
- (9) Editors are encouraged to attend the meeting at which their case is to be presented.
- (10) Cases will be edited before inclusion in the final report.
- (11) Editors should feedback to the committee what actions they take and the ensuing outcomes (please quote the case reference number).

## Summary of cases submitted to COPE since its inception

Year	No of cases	“Evidence of misconduct”	“Probably no misconduct”	Not applicable
2000	33	24	9	0
2001	24	20	4	0
Total (all years)	137	106	19	12

Breakdown of problems (some cases presented several issues)	
Redundant publication or submission	43
Authorship	24
Falsification	17
No informed consent	14
Unethical research	14
No ethics committee approval	13
Fabrication	9
Editorial misconduct	8
Plagiarism	6
Undeclared conflict of interest	6
Breach of confidentiality	4
Clinical misconduct	4
Ethical questions	3
Reviewer misconduct	3
Attacks on whistleblowers	2
Deception	1
Failure to publish	1

## Update on cases submitted to COPE

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

98/8

### **Redundant publication?**

Almost identical papers submitted and published in two different journals within two months of one another; authors made no reference to published paper.

### **Outcome**

Unsatisfactory.

98/12

### **Possible redundant publication**

### **Outcome**

Unsatisfactory.

98/17

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

### **Outcome**

98/30

### **A falling out**

Authors disagreed about the final published version of a letter in terms of the contribution of all the authors, errors of fact, and refusal by corresponding author to show proofs to all authors.

### **Outcome**

The dispute has not been resolved.

*1999 cases that remain open:*

99/5 Ethical status of author's actions?

99/10 A first report, not followed by a second

*1999 cases that have been closed since the publication of last year's report:*

99/12

### **The careless surgeon**

A personal paper was published on the carelessness of a surgeon operating several years ago, suggesting that something should be done. Nothing was, and the surgeon retired. It was suggested that the article be republished with comments from others on how things should be done now.

### **Outcome**

No further action taken.

99/19

### **An anonymous letter in response to qualitative research**

Suggestion of fraudulent data made anonymously on the basis of interviews conducted with women whose first language was not English.

### **Outcome**

No further action taken.

99/22

### **Who ensures the integrity of the editor?**

Editor fired for acting as a whistleblower after editor in chief's behaviour contravened aspects of the International Journal Committee of Medical Journal Editors.

#### **Outcome**

No further action taken.

99/24

### **Invasive intervention without consent**

Concerns raised about consent despite local ethics committee approval.

#### **Outcome**

No further action taken.

99/27

### **Misconduct on a massive scale?**

Some 30 published articles were thought to contain fraudulent data. A journal editor, to whom several papers by the same author were submitted, conducted independent investigations. The results suggested data fabrication. As the author was from overseas and seemed to be the head of his institution, the editor took the matter up with the national bodies concerned.

#### **Outcome**

Three national bodies have now declined to investigate. The journal is currently considering publishing extensive details of the case.

99/28

### **Author dispute concerning ownership of data**

#### **Outcome**

Unsatisfactory

*2000 cases that remain open:*

- 00/08 A paper describing a case of possible medical negligence
- 00/09 The study that may or may not already have been published
- 00/10 The hazardous drug used in an unlicensed way
- 00/11 The wrong standard deviations, the over stringent selection criteria, and the overt attempt at advertising
- 00/15 Clinical misconduct(?), incidentally discovered
- 00/19 The dubious scientist
- 00/22 Duplicate submission of a paper

*2000 cases that have been closed since the publication of last year's report:*

00/12

### **Undeclared conflict of interest**

An author had not declared a competing interest in a published paper, which was subsequently pointed out by a reader who knew this to be untrue.

#### **Outcome**

The editor sent the complainant's letter to the author in question after which a statement of competing interest was published in the journal.

00/14

**The missing ethics committee and lack of written consent**

Neither written consent from the patients nor formal ethics committee approval had been obtained for a study on microbiological diagnosis of a clinical condition. The authors defended their position by saying that the chair of the committee knew of the study and to have asked for written consent from the patients would have caused unnecessary distress.

**Outcome**

The journal declined to publish the paper.

00/16

**Developing novel approaches to improve the assessment of absolute risk among patients with cardiovascular disease in routine primary care practice**

Possible dual publication of papers came to light and both editors of the journals concerned agreed to withdraw the papers from the publication process.

**Outcome**

An independent review of the paper submitted to the second journal confirmed substantial overlap with a previously published paper. The editor wrote to the author, rejecting the paper and warning him about good publication practice.

00/21

**Retrospective correction: how far back do we go?**

A case report was subsequently found to be grossly misleading and inaccurate some nine years after publication. The editor wondered whether to retract the article and publish an editorial looking at the issues.

**Outcome**

The journal decided not to retract the article, and the editorial is still pending.

00/24

**Reviewer submitting for publication material that had been removed from a paper he had reviewed**

A reviewer submitted a letter containing material removed from the paper he had assessed. The authors of the paper complained. The reviewer had not recommended omitting this material when he reviewed the paper.

**Outcome**

Agreement was achieved between the authors and reviewers and explanatory correspondence was published in the journal.

00/25

**A paper which discloses confidential material**

Author B's paper was sent to Journal Z in April 2000. The following month, the reviewer (author A) alerted the journal to the fact that the paper contained material from a paper that he had submitted to Journal X earlier in the year, but which he had sent to B, asking for advice on a reference. A had told B that the paper had been submitted elsewhere and that the material was confidential.

**Outcome**

The Journal X paper was published in December, the Journal Z paper was rejected on its lack of merit.

Author A requested that the matter not be made public as he was collaborating with author B on a research grant proposal. And he thought this might be jeopardised by a disclosure from Journal Z. The request was respected.

00/27

### **Possibly unethical plastic surgery**

A plastic surgery technique was very dangerous in the opinion of another plastic surgeon. The procedure had been carried out at a private clinic and the editor was sufficiently concerned to think about contacting the General Medical Council.

#### **Outcome**

The editor asked the original author for permission to publish something on their debate, but the request was declined. The editor now plans to raise the issue in a more general way. He did write to the British Association of Plastic Surgeons, but no action seems to have been taken.

00/30

### **Duplicate publication**

A paper was rejected on the advice of a reviewer, who suggested that it had already been published, almost word for word. The authors appealed on the grounds that the “repetition” mostly concerned quotations and amounted to only 10 per cent of the paper.

#### **Outcome**

An independent reviewer confirmed that there was substantial overlap with the previous publication (also a hypothesis), so the rejection was upheld. The editors wrote to the authors, issuing a warning about the need to maintain good publication ethics.

## **Cases submitted to COPE**

October 2000 to July 2001

## Case 00/31

### Clinical malpractice

A case report was submitted in which the authors described a patient who had a poor outcome, and where many mistakes had been made during treatment. The authors of the paper were from a tertiary care centre. The poor practice had happened in a secondary care centre.

One of the reviewers of the paper thought that the level of practice was so poor that action should be taken. The other reviewer thought the circumstances were not bad enough to report.

But the paper had already been rejected. The authors were asked whether they should do more, but should the editors do more?

### Discussion/Advice

- There are indications that something is badly wrong and possibly the likelihood that it could happen again. But is it the responsibility of an editor even if s/he is a doctor to investigate this further?
- If the editor presents the tertiary care centre with the review and questions whether there is any substance to the allegation of malpractice, would it be certain that they would have all the facts at their disposal?
- The authors should have sent a copy to the secondary care centre before submission of their article to a medical journal.
- But criticism of other people is common and making an accusation of negligence does require you to get permission first.
- Verification is needed to ensure that the information is correct and this should be done by an independent party.
- Approach the authorities of the secondary care centre to allow them to respond to the allegations made in the paper and the reviewer's comments.
- Bring the matter to the attention of the chief executives in both centres so that it can be investigated properly.

### Outcome

The editor had extensive correspondence with the senior author of the paper, who provided an acceptable explanation of what had happened. No further action was taken.

**Case 00/32****The cheating medical students**

An editorial was published on cheating at medical school. The medical school concerned had allowed a cheating student to graduate. The article attracted over 100 responses, many of them in support of the decision.

But an anonymous email response from two students claimed that an exam paper had been seen in the dean's office prior to an examination and that some 60 per cent of the students had seen this by the time they came to sit the exam. The medical school concerned was unaware of this, and a much higher proportion of students than usual received distinctions.

The two students asked if they should go public. What should the editors do?

**Discussion/Advice**

- Inform the medical school.
- The school needs to review its procedures.
- The two students should be told before this action is taken, and every measure should be taken to preserve their anonymity.

**Outcome**

The medical school was informed and responded very positively. The two students were informed that this had been done and were encouraged to contact the medical school directly.

**Case 00/33****Alleged plagiarism**

Journal A published a review paper. About a year later, the author of a paper published in 1997 in Journal B wrote to say that he had come across the paper in Journal A during a literature search.

He pointed out that parts of this paper were virtually identical with his paper in Journal B. Although the author of the article in Journal A had made one reference to his article, this was only to one specific point and the nearly identical sections had not been referenced.

The editor of Journal A wrote to the author asking for an explanation. The author of the paper in Journal B works in a faculty of law. He discussed the two papers with colleagues who agreed that this was a violation of authorship and perhaps even copyright. He wanted to know how the journal intended to remedy the situation.

**Discussion/Advice**

- The author was somewhat naïve in using a fictitious letter to start his article, but it was not necessary to declare that it was a device.
- It highlights the problem of mistaking notes taken from published material as the author's own.
- Contact the institution of the author of Journal A.
- An independent assessment should be made. If there are substantive findings, the journal should report this.

**Outcome**

The author apologised, and said that no deliberate attempt to plagiarise had been made, but the editor of Journal A contacted the author's institution. A careful review was undertaken, concluding in the end that there was no intentional plagiarism.

The editor, with consent of all parties, sent this to the author and the complainant, explaining that the journal did not intend to take any further action. Nothing further has been heard from the complainant.

## Case 01/01

# The incomplete systematic review

A systematic review on the effectiveness of a comparatively new group of drugs was submitted. The review had originally been for an independent body, so the submission was an abridged version.

A reviewer pointed out that the review made no reference to a Cochrane review and the trials it cited, which had been published some four months before submission of the paper to the journal.

The reviewer suggested that this was more than incompetence: he knew the authors were aware of the existence of the Cochrane review. He also questioned the role of the study's advisory group which had supposedly "provided peer review and advice regarding the protocol, analysis, and interpretation." He thought that the advisory group had not been involved throughout the project and had not peer reviewed the submitted manuscript. Another member of the advisory group seemed to confirm these suspicions.

What should be done now?

## Discussion

- The Cochrane Database of Systematic Reviews is designed to be used by anyone. The paper was an incomplete systematic review so it should be rejected.
- Was the advisory group aware that the authors were not submitting a complete review?
- In effect, drug companies are often the advisory group.
- If the authors are asked to revise their paper, they should describe the role of the advisory group and refer to the previous Cochrane review.
- Their findings could conflict with the Cochrane review, which could itself, of course, be flawed, but the authors should include all relevant studies if asked to resubmit a revised version, and to detail why any flawed studies had been excluded.

## Advice

- Write a frank letter to the authors asking how their review differed from the Cochrane review, and to explain the exact role of the advisory group.
- Transparency is required: ask the authors to declare any competing interests.

## Outcome

The case was referred to the journal's ethics committee and the matter taken up with both the advisory group and the authors.

The authors have not responded to all the editor's concerns, and the ethics committee feels that it is not in a position to judge whether the authors had been deliberately dishonest.

The role of the advisory group was found to be within the bounds of normal practice.

## Case 01/02

## The single authored, unbelievable, randomised controlled trial

A randomised controlled trial submitted to a journal showed that a nutritional supplement could dramatically improve one aspect of the health of the elderly. The study was a follow up to a trial reported in an international journal eight years previously.

Why had there been so much delay? Why were the results reported in this study not reported in the previous study? There was only one author and, if true, the results were extremely dramatic.

The paper was sent for statistical review. The reviewer suggested that the paper bore all the hallmarks of being entirely invented. The results were unbelievably dramatic for the kind of health problem reported.

The president of the university was asked to investigate.

### Discussion/Advice

- Some countries are less rigorous than the UK regarding research conduct.
- Show concern rather than ask for definitive evidence.
- Refer the matter to the author's institution.
- If there is no response contact the country's national regulatory body.

### Outcome

The institution had investigated and had found no problem. But the editor remained unconvinced and sent the paper for further statistical review. The journal's ethics committee also felt the results were unbelievable and suggested that the editor approach the institution again, asking for a further explanation, using the new evidence from the statistician and the ethics committee to highlight their concerns.

It was not up to COPE to question the institution's process of investigation. As the paper had been rejected the raw data could not be requested. But it was an editor's responsibility to protect the integrity of scientific publication.

The editor contacted the institution again requesting further information on this judgment. The journal is seriously considering publishing something on its unhappiness with the process.

## Case 01/03

# The incomplete retraction

A journal published a paper several years ago that subsequently had to be retracted, on the advice of the university where the work had been conducted. The university provided no further details but promised to do so.

Two years later they confirmed that the paper should be retracted, but gave no information on exactly what had gone wrong and whether anybody had been punished.

Subsequently, one of the authors wrote to the journal expressing concern that no fuller explanation had been offered. He suggested that he was innocent and that one of the authors of the paper was clearly guilty. He said that the retraction did not make clear whether all the authors were equally guilty, and he wanted a retraction published that put this to rights.

What should be done next?

## Discussion

- The problem was clearly between the author and the university and the editor was being asked to intercede on his behalf.
- It was unclear what more the editor could do; he is certainly not in a position to conduct an internal enquiry.
- How much information needs to be obtained before a paper is retracted?
- If an author had been struck off by the General Medical Council (GMC) then a notice should be published.

## Advice

- See whether all the authors had signed the covering letter on initial submission to the editor.
- Write to the head of the institution, suggesting that an internal enquiry be carried out.

## Outcome

Not all the authors appeared to be equally guilty; one had been referred to the GMC.

## Case 01/04

## The doctor with a very strange theory

A doctor submitted a letter for publication describing a strange theory. This theory included treating patients with a particular chronic disease with just a foodstuff. The letter was completely unsuitable for publication in the journal and was also rather disordered.

The editor was worried that the doctor might be putting patients at risk, and therefore notified the national regulatory agency.

Was this the right thing to do?

### Discussion

- It was the correct action to inform the national regulatory agency.

### Outcome

The editor wrote to the author who said that he wasn't interested in what the editor had to say. No reply was received from the national body.

## Case 01/06

## Doubts over the exact nature of a drug being used in a study

A journal editor received a letter from a pharmaceutical company questioning a large study reported in his journal. The study, carried out in two different countries, involved treatment with a relatively new formulation in a strength of 2%. The pharmaceutical company were concerned because the formulation was only sold in strengths of 5%, and in individual treatment packs sufficient for a single application only, for stability and sterility reasons. The company had not supplied either active or placebo preparation to the author in question.

The author refers to his version of the preparation and a placebo in one of his previous publications in which an "analogue" of the drug is mentioned.

What is the exact nature of the drug being used in these studies? Is it actually the company's drug? These concerns bring the whole study into doubt.

What should the editor do now?

### Discussion/Advice

- Ask the authors to explain. It may have been a typographical error in the paper.

### Outcome

The editor wrote to the authors, but has not received a reply.

## Case 01/07

### Dual submission due to discordant action of two authors

A paper was submitted describing observations in patients with symptoms confined to one area of the body. The paper was sent out to two expert reviewers, one of whom produced an unfavourable report and suggested rejecting the manuscript. The second reviewer, however, reported promptly to the editor that he knew this manuscript had also been submitted to another journal.

The editor wrote to the authors to confirm whether this was indeed the case. They expressed surprise, but the senior author acknowledged that dual submission had occurred and apologised. Apparently the first and second authors had acted independently of one another, and neither had indicated whether the manuscript had been resubmitted to the two journals following rejection by a third journal.

The editor rejected the manuscript explaining there had been a breach of publication ethics, and that it was the senior author's responsibility to ensure a cohesive approach was sustained throughout the publication process.

Should any further action be taken?

### Advice

- Check to see if all authors' signatures were included in the covering letter.

**Case 01/08****Suspected data fabrication**

A manuscript was received from a group of authors who had not submitted to the journal in question before. The review was extremely critical and the paper was rejected. In a covering letter the reviewer said that not only was the experimental design flawed, but he was also convinced that the experiment described had never been done.

He had scanned Medline 1997–2001 and found seven other papers with the same first author each of which had a similar protocol, but in each case had used a different nutritional supplement. All the studies had been conducted on groups of 40 subjects who were given either a supplement or control substance over a period of one year.

This implied that the authors had recruited over 300 subjects for these studies, which was hard to believe. The entry criteria for the study meant that the pool of eligible subjects was small, and the protocol was rigorous, not to say unethical, so it would have been difficult to have obtained informed consent.

What, if anything, does COPE suggest be done to investigate the suspected fraud?

**Discussion**

- As the paper had been rejected, it would be difficult to obtain further information from the authors.
- Make the authors aware that the reviewer had expressed concern and ask them to provide further evidence, but not the raw data.
- The reviewer should not be involved, and any concerns being raised should come from the editor, not the reviewer.
- In view of the seven other published papers, the editor would need to establish whether this was a *prima facie* case before contacting the other journals.

**Advice**

- Write to the authors, but if no reply is received then contact the head of the institution.
- Due to the serious nature of this case, impose a time limit, of say, four weeks, to obtain a response.

**Outcome**

No reply had been received from either the authors or the heads of their institutes. As the paper has already been rejected, and the editor has now retired from the journal editorship there is very little leverage to make them reply.

## Case 01/09

# Authorship without the author's knowledge

A paper was rejected on the reviewer's recommendation. The editor met one of the senior authors at a conference and out of politeness apologised for rejecting his paper. He was surprised to learn that the senior author had no knowledge of this paper and that the corresponding author had written papers using the senior author's name without his knowledge in the past. This prompted the editor to write to all the authors. Two others replied both saying that they had seen the preliminary draft of the paper several years ago but had not heard anything since.

What should be done now?

## Discussion

- The editor should have written to the corresponding author first asking for an explanation, although it was expected that the author would simply offer an apology. It may of, course, have been a genuine mistake or absent mindedness.

## Advice

- Refer back to the original submission letter to see if all of the authors have signed it.

## Outcome

The editor wrote to the corresponding author, giving a fairly long deadline for reply. None was forthcoming. The editor has now written to the institution and has been told that the corresponding author has indeed got a "mental illness" but is nevertheless investigating.

The editor has also informed all the other authors that the journal will not be accepting any papers from the corresponding author.

**Case 01/10****Redundant publication**

Journal A received letters from two readers pointing out that the female component of a cohort the paper published was identical with that in a paper published in Journal B earlier that year.

The two papers were sent to two independent reviewers, one of whom felt that there was a great degree of overlap between the two papers. The other agreed, but suggested that the paper submitted to Journal A had used a different statistical analysis and had looked at different problems.

Neither paper cross-referenced the other and the authors had signed copyright forms in which they had agreed that the research had not been previously published in whole or in substantial part elsewhere.

Journal A asked the authors to comment. They denied that the papers were similar. They admitted that the female populations were identical in both papers, but that the objectives, analyses, and results were entirely different. They explained that they had not cross-referenced because the two papers had been submitted at the same time, and that they neglected to reference each paper as being in press.

But the editors of both journals felt that this was a case of redundant publication, as did one of the referees; the other felt that the incident was worth a warning issued to the authors. Both editors wanted to publish a redundancy notice and to blacklist the authors for two years. They informed the authors that the issue was being referred to COPE.

What does COPE think?

**Discussion/Advice**

- Why not send both papers to an independent reviewer?
- The excuse given by the authors is inadequate; not disclosing the previous publication is misleading.
- When the journals publish a notice of duplication, publish the authors' reply alongside.
- Only one of the papers needs to be withdrawn—the paper with the later publication date, or the one that is incomplete.
- It's rather heavy handed to "blacklist" an author. Instead consider introducing a sanction such as declining to consider any submissions from the authors for three years.

**Outcome**

Both papers were sent to independent reviewers who agreed that there was a significant overlap. A notice of duplication was published in Journal B, with the authors' reply alongside.

The editor of Journal A has also privately informed the authors that his journal will not accept any papers from them for two years.

## Case 01/11

### Duplicate publication

The editor of Journal A drew the attention of the editor of Journal B to two articles published in their journals which were remarkably similar. The editor of Journal A believed that certain passages of text suggested duplicate publication of results. The dates of publication indicated that these data were accepted first by Journal A. Should it turn out to be duplicate publication, the authors would have violated the requirements of every scientific journal for the submitted data to be original.

Both editors are aware that it's possible to unwittingly accept non-original, previously published data. But what can be done when that happens?

### Discussion/Advice

- Both journals should publish a notice of duplication.
- Only the paper with the later acceptance date should be retracted.

### Outcome

A notice of duplicate publication and withdrawal of the paper was published in Journal B. This was delayed while the university sought legal advice as to whether that intention might be considered defamatory. But the dean eventually phoned to say he approved of the proposed action.

The one author who was a qualified doctor, apologised, stating that as the two papers were aimed at different audiences, he thought publication would not be duplicated. He knows better now.

## Case 01/12

### Attempted redundant publication

A group of authors submitted a paper to Journal A, but the editor noticed that it was very similar to a paper already published in Journal B. Neither paper made any mention of the other in the text, references, or the covering letter.

The editor of Journal A sent a copy of the submission to the editor of Journal B who compared the two papers and decided there was substantial overlap. More worryingly, there seemed to be different numbers of eligible patients and different numbers randomised in the two papers, although they are supposed to be from the same study.

The editor of Journal B recommended the editor of Journal A to write to the authors asking for an explanation of the differences in patient numbers and their failure to reference the previously published paper.

What more should the editors of the two journals do?

### Discussion/Advice

- The editor of Journal A should write to the authors asking for an explanation.
- A copy of this letter should also be sent to the editor of Journal B.
- If a satisfactory reply is not forthcoming then the editor of Journal A should refer the matter to the dean of the authors' institution, suggesting that an enquiry be started.

### Outcome

The editor of Journal A wrote to the authors who have not replied.

## Case 01/13

## Duplicate publication

Sixteen randomly chosen papers were examined from a PubMed search of 370 publications between 1995–2000 by the same author.

Two papers were virtually identical, differing only in the form of the introductory paragraph and the list of authors. Neither publication acknowledges the other.

Another paper reported a “second ever published case”, and two subsequent papers reported the same “second” case without reference to the earlier published paper. The text was again very similar.

Subsequently Journal A received a paper which was rejected. Apart from a change to the list of authors, it was identical to a paper that had been published two years earlier in a different journal. A paper with the same title and introduction had also been published in another journal. This could not be inspected as the journal is not available in any UK research library.

Two further manuscripts were submitted to Journal B, one in the form of a letter, and the second a full research paper. The letter was lifted directly from the paper; furthermore one of the tables was identical to that presented in the paper.

A further paper which had originally been rejected was resubmitted to Journal B, albeit slightly expanded, but with an entirely new list of authors. An independent statistician reviewed both papers and found that the content of two tables was identical except for the p values. Many of these had acquired a significance not suggested in the first manuscript.

Further to this example and the examination of just a few of the listed publications, clear cases of duplicate publication and attempted duplication were found. It's worrying that seemingly similar work can have different lists of authors, which suggests “gift” authorship. Changes in details of treatment and statistical significance throws the veracity of some of the work into question. Furthermore, the group's general failure to cite its own publications suggests a deliberate attempt to cover up duplication.

The editor of Journal B wants to inform the author that his publication will not consider any further submissions from this group. There is no guarantee that manuscripts would be original and issues of copyright are unclear. The editor would also like to alert the editors of the other journals involved.

Is this a reasonable course of action to take?

## Discussion

- A wider enquiry would have to be made; merely writing to the authors would not be enough. Independent assessment had been obtained in which the author's misdemeanours were very evident.
- This was a matter for the author's institution(s) to investigate.
- Previous cases of gross duplicate publication had been detected by simply undertaking searches on MedLine.
- The role of all of the co-authors whose names appeared on several of the papers was also questionable, although many might be unaware of their involvement due to gift authorship. It would be unwise not to consider any publications from this group until all of the authors had been approached.
- The main issues for the editors were retraction and notice of duplication of known articles and referral of the authors to the head of their institutions, raising the issue of the wider crime of fraud.
- Overseas regulatory bodies often don't reply, perhaps because they are uninterested or feel it is not COPE's business to investigate misconduct.

## Advice

- Check the submission letter to see if all of the authors have signed it.
- The editor should present a fuller version of the case presented at COPE to the corresponding author and all co-authors who were repeatedly linked to this work, asking for a response.
- If there is no reply, or only an unsatisfactory reply is received, then send a second letter asking for a response, giving them a set time limit in which to reply.
- If still no reply is received refer the matter to the authors' institution(s).

### Case 01/13 (cont)

- The journal editors should jointly publish a retraction and unravel the story in an editorial.
- A further option would be to send a letter to a national journal such as *The Lancet* or the *BMJ*, exposing the duplication.

### Outcome

The corresponding author had signed the submission letter on the other authors' behalf. In view of the large numbers of co-authors involved, the editor considered it impractical to write to them all, but contacted the editors of three other journals where there was evidence of duplicate publication.

One editor said that his journal was already refusing to consider any more work from the corresponding author. The other two editors indicated that they would take up the cases of duplication publication with the corresponding author. One of the three journals was in the process of publishing an apology, along with a fourth journal, concerning a separate case of duplication from this group.

The corresponding author had also been contacted and indicated that the cases of duplicate publication emanating from his group could have been due to insufficient care being exercised by some of his staff. After consulting the journal's editorial board the editor decided not to consider any further manuscripts from this group because they could not be confident that the work would be original.

## Case 01/15

## Duplicate submission, overlap of papers, and a referenced paper that was not in press

A paper was submitted that reported a randomised controlled trial of a treatment for a blood disorder in a group of children. Better psychomotor development was achieved in the treated group. This paper went through considerable revisions, which were requested by the editorial committee, and a revised version was finally submitted a year later.

But the revised version now included a new reference to a paper in press in another journal. No one had previously been aware that there was another paper based on this study. The authors were asked to explain this, and they replied that the term “in press” was a mistake: the paper had only recently been submitted to the other journal a few weeks earlier. A copy of this was requested and duly faxed.

There was a good deal of overlap in the methods sections of the two papers. The outcome measures looked at were largely different: the paper submitted to the journal looked at psychomotor development and the other mainly at growth and nutrition. Both reported haematological data, but these differed somewhat. The submitted paper only reported results on the subset of children who were of an appropriate age for developmental tests.

There were three concerns:

1. We had not been informed that another paper arising from the same study was being submitted elsewhere. There was no way of deducing this from the covering letter. The other journal did not seem to have been informed that there was a relevant paper submitted elsewhere, at least until the authors were prompted to do this.
2. A paper was referenced as “in press” when it was simply at the stage of having been submitted.
3. There was a good deal of overlap between the two papers. But it would almost certainly have been impracticable to try to report both sets of findings in the same paper, and if they were to be separated, some overlap in the methods sections was inevitable. It could probably have been less if both papers had been submitted to the same journal.

Should this matter be taken further?

### Discussion

- The authors should have sent a copy of the other paper and stated that it had been submitted elsewhere.
- It is misleading to claim that the other paper is “in press,” if it had only just been submitted for consideration. At least the second paper had been referred to in the revised version.

### Advice

- Obtain an independent assessment of the two papers to decide the level of overlap.
- Write to the authors highlighting what “good practice” is—that is, declaring submissions elsewhere and emphasising the difference between a paper that has simply been submitted, and one that is “in press.”

### Outcome

The authors were apologetic over what they had done and were very forthcoming about providing other information when requested.

It was clear that the two different parts did need to be presented as separate papers. The authors made clear in the final version how it related to the other paper, and assured the editors they would do the same in the other paper.

The editors were satisfied that there had been no deliberate intention on the part of the authors to mislead either journal.

**Case 01/16**

## **Undeclared conflicts of interest and potential author dispute over signed letter for publication**

A letter was published that provides guidance on prescribing a particular drug in children. There are anxieties about the use of this drug in children, and sometime back a letter from essentially the same group on the same subject was published in the same journal.

The electronic version of this original letter included a conflict of interest statement, but the paper edition did not. This was a mistake. Unfortunately neither the paper nor the electronic version of the new letter included the conflict of interest statement. It clearly should have done, not least because it seems that one of the authors of the current letter received funding from the manufacturers of the drug.

The intention is to go ahead and gather conflict of interest statements and publish them in both the paper and the electronic versions of the journal, but the lead author of the second letter seems to be opposed to this move.

The journal plans to override his objections. Does COPE agree with this?

A further issue raised by the second letter is that the third party wrote to say that three of the authors of the letter do not support everything that is contained in it. Wouldn't most people who read a piece that is signed by many authors believe that all authors support what is published unless it specifically states otherwise?

What action should be taken on this issue?

### **Discussion**

- The exclusion of the conflict of interest statement from the paper version was the fault of the editorial process. Statements were included with other published articles but not "letters."

### **Outcome**

No further action was taken.

**Case 01/17****Dual submission**

Journal A received a paper that was rejected without peer review as it was very poorly written. There was no clear evidence of original work, it seemed to be mainly a vehicle for advertising a piece of equipment/technique developed by the authors, and it was only marginally relevant to the journal's area of interest.

A month later, the first author of the paper submitted the same paper to Journal B, which happens to share an office with Journal A. The next month essentially the same paper originally submitted to Journal A was resubmitted. It was unchanged from the previous submission, but with a slightly different title. The editorial assistants of Journals A and B noted that, apart from some differences in the introduction, the two papers were identical.

Journals A and B wrote to the authors, asking for a declaration that the paper had been submitted to that journal only. Both journals received a written declaration from the authors that this was the case.

The editors of Journals A and B then wrote to the authors to ask for an explanation of this behaviour. The answer received was very poorly written, but essentially said that both submissions had been "interlaced." The authors begged the editors to continue the review process at both journals. Once the reviewers' comments had been received they would revise the manuscripts and adapt them to the individual journal's readership.

The editors of Journals A and B planned to write to the first author's institution. The other authors seem to be affiliated to something that sounds like a commercial enterprise. The editors suspect that the paper might have been submitted to other journals as well. There seems to be no way of checking this. As it happens, it is such an appalling paper it is unlikely to be accepted by any reputable journal.

**Discussion**

- How many other journals had received this paper?
- Perhaps the authors had been naïve and were possibly not serious bona fide authors.

**Advice**

- Send a letter to the authors giving advice on how to submit a paper.
- Refer to the *COPE Guidelines on Good Publication Practice* and the COPE website.

**Outcome**

This advice was followed.

## Case 01/18

### Duplicate publication

The newly appointed editor of Journal A noticed that an article he had just published in his journal bore remarkable similarities to an article published a couple of months earlier in Journal B. When the editors of both journals discussed the matter, they confirmed that they had not been told about the other article. The authors work in a well established academic department.

On detailed review, the articles were indeed very similar and came to an identical conclusion. In places, sentences had been rearranged and it was hard to escape the conclusion that this had been done deliberately. The article in Journal A seemed to be reporting the findings in a subset of subjects in the Journal B article.

The editors wrote to the authors, who were the same for both articles, bar two additional names on the Journal A article, to ask for an explanation. They drew their attention to the COPE guidelines published in Journal B.

The authors replied, explaining that the paper published in Journal A reported preliminary findings whereas that published in Journal B reported the final results based on a larger double data set. They admitted that better communication and reciprocal information between the two corresponding authors would have avoided the problem.

### Discussion

- The reply was thought to be somewhat convenient. How could all authors have signed the copyright forms without realising that two papers on the same research were due to be published?
- There seems to be some intent to mislead and the second paper would not have been published if the first had been known about.
- A further problem was that if a systematic review was undertaken it would be assumed that two separate groups of patients had been studied.

### Advice

- Publish a notice of inadvertent duplicate publication in both journals.

### Outcome

A notice of inadvertent publication was simultaneously published in both journals.

**Case 01/19****Dual submission**

While reviewing revised manuscripts, the editor of Journal A happened across two manuscripts that looked remarkably similar. One was on the point of acceptance, pending revision of a table; one had just been revised by the authors.

The two papers were from the same institution, apparently on the same population of exposed workers, with the same measurements, and with closely related conclusions.

Two authors were common to both papers. In the revised version of the first paper, an author from the second paper was named as the corresponding author. Neither paper made any mention of the other.

The editor wrote to both corresponding authors of these papers asking for an explanation before taking action.

The editor of Journal A is feeling decidedly fed up with the number of cases like this one that have occurred over the past 12 months. Once again, this case was spotted by chance. The editor feels that there must be many more examples of duplicate publication that get through, especially when they go to different journals.

How can editors prevent these cases, rather than trying to catch them in a net with many holes in it? Is the answer to take stronger action against those that are spotted, to send out a strong signal to others thinking about indulging in a spot of duplication?

**Discussion**

- Around one in five published papers are republished in substantial form.
- A study in the 80s found that over 10 per cent did not mention previous publication, but a second study at the end of the 90s suggested this figure was around 1%.
- It takes considerable time and effort to look at all the referenced papers to see if there is any overlap and then those are the published ones, not those under submission.
- Author dispute and ineptitude could underlie this case.

**Advice**

- Write to the authors reminding them what good publication practice is and that duplicate submission is not acceptable.

**Outcome**

The editor received an explanatory letter from the authors. This seemed to confirm the impression of confusion and ineptitude among the authors. The authors referred to a third paper, accepted for publication in another journal, which seems to cover some of the same ground, and is based on the same population.

The editor rejected both of the submitted papers, but offered the possibility of submitting one paper, with full reference to the third paper accepted in the third journal. At the same time he reminded the authors about good publication practice.

## Case 01/20

### Dubious surgery

A paper was submitted, describing surgery on the sexual organs of four women. The paper was poorly written and hard to follow, but it seems that this surgery was undertaken primarily because of the unsatisfactory sexual experiences of the women's partners.

There was no mention of ethics committee approval or of the women having given consent, not only for the surgery but also for taking part in an experiment. The paper came from overseas.

The editor wrote to the author asking him to advise whether he obtained ethics committee approval and whether the women had consented on both counts.

Is this the right approach? Should this case be pursued if no answers are forthcoming?

### Discussion

- It is hard to define where clinical innovation ends and research begins. It is well known that surgeons can make changes to procedures without ethics approval, but this case raises the issue of the ethics of the surgery being undertaken.
- Informed consent was necessary, but as there was no evidence as to what this surgical procedure would do, and as it is difficult to understand any rationale for the surgery, it would be impossible to fully inform any patients undergoing these operations.

### Advice

- Refer the case to the professional regulatory body in the author's country to see if this procedure is within their realm of professional conduct.

### Outcome

No response has been received from the regulatory body.

## Case 01/21

### Bizarre treatment of viral disease overseas

A journal received an account by email from outside Britain of how 14 patients infected with a potentially lethal virus had been treated with an unusual non-pharmacological treatment.

The treatment seemed bizarre, and furthermore, there was no mention of approval by an ethics committee or of informed consent.

The author was twice emailed to ask if he had ethics committee approval and if he had obtained informed consent. There was no response.

There were no contact details apart from the email address and the name of the institution was not known.

Does the journal have any responsibility to pursue this any further?

### Discussion

- The editor is right to pursue this, but as the authors have not replied, and there is no information as to their whereabouts, it cannot obviously be taken any further.
- This is a case for the record.

## Case 01/22

## Yet more attempted duplicate publication

A study submitted to a journal was sent out for external review. The reviewer pointed out that it was essentially a shorter version of a paper already published elsewhere. The authors had referenced this paper, but did not make clear that the submitted paper was simply a summary of the other published paper. Nor did they mention the other paper in the covering letter, or include a copy of it. One of the differences between the two papers was that the original study had 17 authors, while the paper listed only 10.

The editor sent a stiff note to the authors saying that the journal regards this as poor publication practice. Should more be done?

### Discussion

- Appropriate action had been taken by the editor.
- This is a further case for the record.

## Case 01/23

## Inadequately supervised research?

A piece of qualitative research was submitted that looked at the experiences of families facing a particular illness. The first author was both the main carer for the families and the researcher. She conducted and analysed all the interviews. Nobody else seemed to have analysed the verbatim transcripts, although two senior authors did help with analysis of the data.

The reviewers and editorial committee took the view that this research used wholly inadequate methodology and worried that the first author, who had undertaken the study as part of her PhD, had been inadequately supervised. The question was raised with all three of the authors.

The editor wrote to the supervisor, who it was suspected, would probably say that the methodology was acceptable and that s/he didn't agree with the objections raised.

Was this the right thing to do? Should more be done?

### Discussion

- Many universities do not have trained supervisors nor do they provide guidance to supervisors as to their responsibilities.
- It is not only MSc and PhD students who are left unsupervised, and many lecturers are not trained to teach and often are appointed because they can attract large research grants, rather than for their teaching capabilities.
- This was qualitative research, much of which is very poor. For such a study to have any validity there must be two independent researchers.
- This case was also unusual in that the author was also the carer of the families. And the poor design of the study had not been picked up by any independent scientific reviewers at the ethics committee stage.

### Advice

- Await a response from the supervisor before taking any further action.

### Outcome

Neither the lead author nor one of the supervisors accepted that there was any problem with the research.

The case was referred to the journal's ethics committee.

## Case 01/24

### Submission of a paper by a reviewer

An editor sent out a paper to three reviewers. One of them, who gave the paper a favourable review, enclosed a research letter on the same topic, with, in his view, a better study design. He told the editor that the author of the paper had encouraged him to submit it during a meeting they both attended. He added that he thought its inclusion would make a good complementary pair of papers.

The editor sent the research letter to the two other reviewers who had reviewed the first paper. The paper's design was criticised by all three reviewers and the paper was rejected. The peer review of the research letter is ongoing but is so far favourable.

Did the editor act correctly in having the research letter reviewed as well? Is it fair to reject the paper but accept the research letter?

### Discussion/Advice

- The reviewer had abused his position by discussing the paper with the author.
- He should also have declined to review the paper due to the close association with his own research.
- A referee might review a paper badly because it is not in their interests to see similar work published before their own.
- The paper should have perhaps been sent to new reviewers, although editors often select people in the same areas to review, and if it is a small area of research the choice of referees can be very limited.
- No harm had been done as the author of the letter openly admitted his conversation with the other author and had been encouraged to submit it.
- The editor was therefore right to review the letter in the usual way.

**Case 01/25****Duplicate publication**

An author published a paper in Journal A that looked extremely similar to one already published as guidelines in Journal B. Of 48 paragraphs of text, 41 were almost identical. It has since transpired that several authors who were involved in the writing of the article published in Journal B have not been acknowledged. Prior publication elsewhere had not been acknowledged in the Journal A paper.

The editor wrote to the authors requesting an explanation. He informed them that the journal takes a strong line on duplicate publication and disclosure of related publications, and that there should also be an appropriate acknowledgement of the contribution of other authors.

The editor also wrote to the editor of Journal A asking him to look at both of the papers and to give him his views.

Has enough been done?

**Discussion**

- This is a clear cut case of duplicate publication.

**Advice**

- Publish a notice of duplication in both journals.
- The editors of both journals should also write to the head of the authors' institution, informing them of this indiscretion.
- Inform the authors that this course of action is to be taken before writing to the institution.

**Outcome**

The author of the Journal A article contacted the editor of Journal B, stating that it was an error of omission and not a deliberate attempt to deceive. The editor accepted this explanation, but intends to contact head of the author's institution, and the authors have been informed of this.

No reply has been received from the editor of Journal A, but the editor of Journal B will attempt to find some agreed form of wording that both journals can publish.

# 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) If professional writers employed by pharmaceutical companies, medical agencies, or other parties have written the paper, then their names should be included, and any conflicts of interest declared.
- (4) 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.
- (5) Careful reading of the target journal's "Advice to Authors" is advised, in the light of current uncertainties.
- (6) Authors should be vigilant about allowing their name to be used on a piece of work to add credibility to the content.

### 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.
- (7) Where misconduct is suspected, the editor must write to the authors first before contacting the head of the institution concerned.

## 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.

ABPI fact sheets and guidance notes:

*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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*Consent*, February 1999.

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Stonier P, Lowe GDO, McInnes G, *et al*. A National Panel for Research Integrity: A Proposed Blueprint for the Prevention and Investigation of Misconduct in Biomedical Research. *Proc R Coll Physicians Edinb* 2001;**31**:253–5.

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Other members of COPE

Delegates to the Meeting on April 27 1999

Other corresponding editors

# Constitution of the Committee on Publication Ethics

**1 The name of the Association is the Committee on Publication Ethics (COPE).**

**2 The aims and objects for which COPE has been established are:**

- 2.1 To provide a forum for meetings of editors, publishers, and others associated with the publication of biomedical journals.
- 2.2 To encourage and promote ethical standards in medical publications.
- 2.3 To provide guidance on publication, research, and other allied subjects to editors, investigators, and authors associated with such publications.
- 2.4 To provide guidelines and a code of practice to publishers, editors, and others in matters relating to suspected breaches of research and publication ethics.
- 2.5 To provide advice on dealing with any misconduct raised in connection with clause 2.4 and the code of practice.
- 2.6 In furtherance of such aims, to hold or arrange meetings and seminars for members, and to do all such other things as may be considered appropriate.
- 2.7 To publish an annual report for members on the work of the Association during the preceding year.
- 2.8 To receive and deal with representations from members concerning matters set out in the preceding subclauses. And in particular, with regard to allegations of misconduct, and to issue guidance and advice as to possible sanctions in respect of such matters, such guidance and advice to be in accordance with the general policy of COPE.

**3 Membership**

- 3.1 Membership shall consist of the following:
  - 3.1.1 Editors of peer reviewed biomedical and related journals based in the United Kingdom and Europe.
  - 3.1.2 Persons working in, or associated with, the publication of biomedical journals.
  - 3.1.3 Honorary members co-opted by the Council.
  - 3.1.4 Publishers who shall have group membership and shall be entitled to delegate a number of members as determined by the Council.

3.2 Membership shall depend on payment of the subscription as appropriate at any given time.

3.3 The mode and conditions of election to membership shall be determined by, and in accordance with, these articles.

**4 Subscription**

- 4.1 Every member shall be liable to pay a subscription in accordance with the initial rates set forth in Schedule 1 and thereafter as determined at the Annual General Meeting.
- 4.2 It is the intention that corporate members' subscriptions shall be based on a scale of charges determined by the number and frequency of publication of journals they publish.
- 4.3 Any member falling into arrears of subscriptions for more than two months shall be excluded from the committee.

**5 Officers**

5.1 The officers of COPE shall be:

- 5.1.1 A chairman
- 5.1.2 A vice-chairman
- 5.1.3 A treasurer
- 5.1.4 A secretary

5.2 The officers, except for the secretary, shall be elected by postal ballot at the Annual General Meeting and shall be members of COPE, or delegated representatives from corporate members, or associated with the publication of biomedical journals.

5.2.1 Officers shall normally hold office for 3 years except in the case of the treasurer who shall hold office for 5 years. Officers may stand for re-election at the end of their period of office on at least one consecutive occasion.

**6 Council**

6.1 The Council shall comprise:

- 6.1.1 The Officers.
- 6.1.2 No more than 4 members nominated by the officers.
- 6.1.3 The secretary.

6.2 The Council shall meet at least once every two months and following such meetings there shall be a general meeting of COPE.

6.3 The Council shall be responsible for:

6.3.1 The election of members and in particular the number of delegated members for corporate members.

6.3.2 The general and financial management of COPE.

6.3.3 All matters in the general interests of COPE.

6.3.4 The appointment of independent auditors.

6.3.5 The appointment of a secretary.

6.4 The Council shall present a report and audited statement concerning the finances of COPE for the preceding year at every Annual General Meeting.

6.5 In furtherance of the preceding powers, the Council shall have the power to appoint a sanctions subcommittee to make initial consideration of any such matters, in particular with regard to the provisions of clause 2 hereof, and to report its findings to the Council and make recommendations, which may include a resolution for the withdrawal of membership rights.

## **7 Annual General Meeting**

7.1 The Annual General Meeting shall be held each year on a date and at a time fixed by the Council and must:

7.1.1 Receive from the Council a report balance sheet and statement of accounts for the preceding financial year and an estimate of the receipts and expenditure for the current financial year.

7.1.2 Fill the vacancies in the Council in accordance with the results of any postal ballot, and appoint auditors for the ensuing year.

7.1.3 Decide on any resolution which may be submitted to the meeting in the manner provided below.

7.1.4 Fix the annual subscription rates.

7.1.5 Consider any other business as determined by the Council.

## **8 Notice of Business at Annual General Meeting**

8.1 Any member who decides to move any resolution at the Annual General Meeting must give notice in writing to the secretary not later than 21 days before the date fixed for such meeting.

8.2 At least 21 days before the date of any Annual General Meeting the Council shall send to all members notice of any vacancies in the Council together with a postal ballot form for election to such vacancies and requiring return of such votes at least 7 days before the meeting.

## **9 Special General Meeting**

The Council may call a special general meeting at any time for any special purpose and must do so immediately on a requisition in writing (stating the purposes for which the meeting is required) from any 10 members or one fifth of the total membership entitled to vote.

## **10 Notice of Meetings**

At least 14 days' notice of any general meeting, specifying the business to be transacted and the day, place, and hour of the meeting must be sent to every member by letter to his/her address, as given in the COPE register.

## **11 Quorum**

The Quorum for a meeting of COPE shall be at least 6 members.

## **12 Alteration of Constitution**

The constitution may be revoked, added to, or altered by a majority comprising two thirds or more of the members present and voting at an Annual General Meeting of COPE, of which notice has duly been given under clause 10, specifying the intention to propose the revocation, addition, or alteration.



