

## **The COPE Report 2002**

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# **The COPE Report 2002**

Annual Report of the Committee on Publication Ethics

*Edited by*

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## COPE's fifth year

COPE is now 5 years old. Having started in 1997 as an informal self-help group for editors, it is now an organisation with a constitution, elected officers and a membership which includes many UK publishers and more than 170 journal editors.

COPE's primary function is to offer a forum for editors who are struggling to manage cases of possible research and publication misconduct. This continues to be an important part of the Committee's work, although the number of cases has fallen over the past year. This could indicate that COPE has been successful in providing advice for a cohort of editors who are now coping well. It might also indicate that the number of cases of publication misconduct have decreased, possibly because of the increased awareness of authors of the importance of reporting their work honestly and with integrity.

Since 1997 COPE has organised four seminars, the first of which, on how editors should respond to publication misconduct, set the scene for our future work. It drew on expertise from Europe and North America and one of the important messages to emerge was that when concerns arose, editors would not be fulfilling their editorial responsibilities if they just rejected the manuscript.

COPE then set about developing a set of guidelines for *Good Publication Practice*. In 1999 the second seminar on "Setting a new agenda for Good Publication Practice" considered a draft guidelines document. Following a series of workshops, the first guidelines were subsequently published in the 1999 COPE report. Since then, these Guidelines have been updated on several occasions and will continue to evolve over the years.

In October 1999, there was a joint consensus conference on "Misconduct in Biomedical Research" at the Royal College of Physicians in Edinburgh. Many important stakeholders were represented, including the General Medical Council, the Royal Colleges, the National Health Service, the Faculty of Pharmaceutical Medicine, the Association for British Pharmaceutical Industries, publishers and journal editors.

The consensus panel agreed a broad definition of research misconduct, made suggestions as to how to promote good research, and finally recommended the establishment of a national panel. The panel's task would be to co-ordinate a national effort to document cases of research misconduct, to advise on the investigation of alleged cases, and to develop preventive strategies.

Regrettably, little action occurred until early 2002, when at a meeting of stakeholders convened by the President of the Royal College of Physicians London, it was decided that the Academy of Medical Sciences, under the leadership of its President, Sir Peter Lachman, should take the lead in developing a framework for such a national panel.

Some progress has been made, as outlined by Sir Peter in his recent address at the 4th COPE seminar, "Promoting integrity in research and publication," which took place in October 2002. This report includes an account of progress so far, but there are major concerns that this panel will have insufficient commitment and authority to make a real difference. Yet again, the UK seems to be lagging behind North America and other European countries in this regard.

In the 1998 COPE report, objectives were set for COPE's future work. COPE has advised editors on the management of possible cases of research and publication misconduct and will continue to do so. In its seminars and in the day to day working of the Committee and its Council, it has considered many of the broader issues in publication and research ethics, including authorship, confidentiality, editorial freedom and media relations. The Guidelines have already been mentioned, and the website bears testimony to the annual reports ([www.publicationethics.org](http://www.publicationethics.org)).

But earlier this year the COPE Council decided to establish two subcommittees, one for research in publication ethics and the other to develop educational strategies, to enable us to fulfil our other objectives: to offer teaching and training about research and publication integrity.

There are still many unanswered questions in the field of research and publication ethics. Every journalist wants to know how common it is. Embarrassingly, in the UK we are not able to answer this question. We still do not have a clear idea as to why people commit research misconduct nor do we know whether there is a progression from minor misdemeanours to the more serious aspects of research fraud.

Our experience as editors suggests that there continues to be a level of ignorance as to what constitutes research and publication misconduct. This may reflect poor training and supervision, but it may also indicate changing attitudes in society as to what constitutes economy with the truth. It is clear, however, that research misconduct is not limited to biomedicine, following the devastating revelations of research fraud committed by Jan Hendrik Schön in the physical sciences in Bell Laboratories, New Jersey.

COPE continues to be concerned about the apparent tardiness of British academia and others to give research and publication misconduct an appropriate priority rating. Fraudulent research can damage patients. We have agencies to ensure food and water quality, and these are now regarded as an essential component of public protection. Why should we not expect the same standards from our research?

Michael JG Farthing  
Chair, COPE  
November 2002

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## Membership of Cope

Acta Paediatrica	Taylor & Francis	Archives of Disease in Childhood	BMJ Publishing Group
Acta Physiologica Scandinavica	Blackwells	Asia Pacific Digestive News	Blackwells
Age & Ageing	Oxford University Press	Asia Pacific Family Medicine	Blackwells
AIDS	Lippincott Williams & Wilkins	Asia Pacific Journal of Clinical Nutrition	Blackwells
Alcohol and Alcoholism	Oxford University Press	Australasian Journal of Dermatology	Blackwells
Alimentary Pharmacology & Therapeutics	Blackwells	Australian & New Zealand Journal of Psychiatry	Blackwells
Allergology International	Blackwells	Australian Journal of Rural Health	Blackwells
Anaesthesia	Blackwells	Australian Occupational Therapy Journal	Blackwells
Anatomical Science International	Blackwells	Australasian Psychiatry	Blackwells
Animal Science Journal	Blackwells	Australasian Radiology	Blackwells
Annals of Occupational Hygiene	Oxford University Press	Autonomic & Autocoid Pharmacology	Blackwells
Annals of Oncology	Oxford University Press	Biochemical Journal	Portland Press Ltd
Annals of the College of Surgeons, Hong Kong	Blackwells	Biochemical Society Transactions	Portland Press Ltd
Annals of the Rheumatic Diseases	BMJ Publishing Group	Biomed Central	Current Science Group
ANZ Journal of Surgery	Blackwells	BJU International	Blackwells
APLAR Journal of Rheumatology	Blackwells	Brain	Oxford University Press
		Brain Research Bulletin	Elsevier



British Journal of Biomedical Science	Institute of Biomedical Science	International Journal of Mental Health Nursing	Blackwells
British Journal of Clinical Pharmacology	Blackwells	International Journal of Nursing Practice	Blackwells
British Journal of Dermatology	Blackwells	International Journal of Urology	Blackwells
British Journal of Haematology	Blackwells	International Journal of Experimental Pathology	Blackwells
British Journal of Ophthalmology	BMJ Publishing Group	Journal of Obstetrics and Gynaecological Research	Blackwells
British Journal of Oral & Maxillofacial Surgery	Churchill Livingstone (Harcourt)	Journal of the European Academy of Dermatology and Venereology	Blackwells
British Journal of Plastic Surgery	Harcourt	Journal of Antimicrobial Chemotherapy	Oxford University Press
British Journal of Sports Medicine	BMJ Publishing Group	Journal of Bone & Joint Surgery	Society owned
British Medical Journal	BMJ Publishing Group	Journal of Clinical Pathology	BMJ Publishing Group
Bulletin of the World Health Organization	WHO	Journal of Cosmetic Dermatology	Blackwells
Carcinogenesis	Oxford University Press	Journal of Endocrinology	Blackwells
Cell Proliferation	Blackwells	Journal of Epidemiology and Community Health	BMJ Publishing Group
Cellular Microbiology	Blackwells	Journal of Gastroenterology and Hepatology	Blackwells
Cephalgia	Blackwells	Journal of Hospital Infection	WB Saunders (Harcourt)
Chinese Journal of Digestive Diseases	Blackwells	Journal of Internal Medicine	Blackwells
Clinical & Experimental Pharmacology & Physiology	Blackwells	Journal of Medical Ethics	BMJ Publishing Group
Clinical & Experimental Allergy	Blackwells	Journal of Medical Genetics	BMJ Publishing Group
Clinical and Experimental Dermatology	Blackwells	Journal of Medical Screening	BMJ Publishing Group
Clinical and Experimental Immunology	Blackwells	Journal of Neurology, Neurosurgery and Psychiatry	BMJ Publishing Group
Clinical and Experimental Ophthalmology	Blackwells	Journal of Paediatrics and Child Health	Blackwells
Clinical and Laboratory Haematology	Blackwells	Journal of Sleep Research	Blackwells
Clinical Endocrinology	Blackwells	Journal of the National Cancer Institute	Oxford University Press
Clinical Medicine	Royal College of Physicians, London	Journal of the Norwegian Medical Association	Norwegian Medical Association
Clinical Microbiology and Infection	Blackwells	Journal of Viral Encephalitis	Blackwells
Clinical Oncology	Harcourt	Medical Education	Blackwells
Clinical Otolaryngology and Allied Sciences	Blackwells	Medical Humanities	BMJ Publishing Group
Clinical Physiology and Functional Imaging	Blackwells	Medical Hypotheses	Churchill Livingstone (Harcourt)
Clinical Radiology	Elsevier	Molecular Human Reproduction	Oxford University Press
Clinical Science	Portland Press Ltd	Movement Disorders	John Wiley New York
Colorectal Disease	Blackwells	Mutagenesis	Oxford University Press
Cytopathology	Blackwells	Nephrology	Blackwells
Diabetes Metabolism Research and Reviews	John Wiley & Co Ltd	Nephrology, Dialysis & Transplantation	Oxford University Press
Diabetes, Obesity & Metabolism	Blackwells	Neurogastroenterology & Motility	Blackwells
Diabetic Medicine	Blackwells	Neuropathology	Blackwells
Digestive Endoscopy	Blackwells	Neuropathology and Applied Neurobiology	Blackwells
Diseases of the Esophagus	Blackwells	Nursing and Health Sciences	Blackwells
Dutch Journal of Medicine	Bohn Stafen Van Loghivm	Obesity Reviews	Blackwells
Emergency Medicine	Blackwells	Occupational and Environmental Medicine	BMJ Publishing Group
Emergency Medicine Journal	BMJ Publishing Group	Occupational Medicine	Oxford University Press
European Journal of Clinical Investigation	Blackwells	Paediatric Anaesthesia	Blackwells
European Journal of Gastroenterology & Hepatology	Thomson (LWW)	Parasite Immunology	Blackwells
European Journal of Immunogenetics	Blackwells	Pathology International	Blackwells
European Journal of Neurology	Blackwells	Pediatrics International	Blackwells
European Journal of Orthodontics	Oxford University Press	Postgraduate Medical Journal	BMJ Publishing Group
European Journal of Public Health	Oxford University Press	Practical Neurology	Blackwells
European Journal of Surgical Oncology	WB Saunders (Harcourt)	Psychiatry and Clinical Neurosciences	Blackwells
Eye	Royal College of Ophthalmologists	QJM	Oxford University Press
Family Practice	Oxford University Press	Quality and Safety in Health Care	BMJ Publishing Group
Foot and Ankle Surgery	Blackwells	Reproductive Medicine & Biology	Blackwells
Fundamental and Clinical Pharmacology	Blackwells	Respiratory Medicine	WB Saunders (Harcourt)
Geriatrics International	Blackwells	Respirology	Blackwells
Gerontology	Karger	Reviews in Clinical and Experimental Hematology	Blackwells
Gut	BMJ Publishing Group	Reviews in Medical Virology	John Wiley & Co Ltd
Gynaecological Endoscopy	Blackwells	Rheumatology	Oxford University Press
Haemophilia	Blackwells	Scandinavian Journal of Immunology	Blackwells
Heart	BMJ Publishing Group	Scottish Medical Journal	Hermiston Publications
Heart Lung & Circulation	Blackwells	Sexually Transmitted Infections	BMJ Publishing Group
Helicobacter	Blackwells	The British Journal of Aesthetics	Oxford University Press
Histopathology	Blackwells	The Journal of Hand Surgery	Churchill Livingstone (Harcourt)
HIV Medicine	Blackwells	The Journal of Infection	Harcourt Publishers Ltd
Human Reproduction	Oxford University Press	The Journal of Pathology	John Wiley & Sons
Human Reproduction Update	Oxford University Press	The Lancet	Elsevier
Immunology	Blackwells	Thorax	BMJ Publishing Group
Immunology and Cell Biology	Blackwells	Tobacco Control	BMJ Publishing Group
Injury Prevention	BMJ Publishing Group	Transfusion Medicine	Blackwells
Internal Medicine Journal	Blackwells	Tropical Medicine and International Health	Blackwells
International Journal of Andrology	Blackwells	Ultrasound in Obstetrics and Gynaecology	Blackwells
International Journal of Dermatology	Blackwells	Vox Sanguinis	Blackwells
International Journal of Epidemiology	Oxford University Press		

## Introduction: COPE moves on

Michael J G Farthing  
chair of COPE and editor of *Gut*

It's now five years since COPE was founded as a self help group for editors, struggling with ethical issues in their publications. COPE has since taken on the role of an action group, the primary objective of which has been to call for an independent body to monitor research ethics and publication misconduct in biomedicine.

COPE has also published guidelines on publication ethics, which have been well received, and continue to be updated on an annual basis. And it has run three seminars—another very important part of our activities.

The first, with contributions from the USA and Europe, was held in our foundation year in 1997, to set the agenda and to begin to benchmark our responses. The second, in 1999, took the form of workshops to draft our guidelines.

Last year's seminar was directed particularly to determining whether there was a need for an independent body to deal with biomedical research misconduct. The answer was yes. And in our subsequent annual report, we published some ideas for useful ways in which that could be taken forward.

COPE now has a constitution, with elected officers. This has enabled us to further our original agenda, by creating two subcommittees to look into how we might foster research on publication ethics and offer education and training on the issues.

We will hear more about these later today, and part of this afternoon's presentation will include an exercise to test out how some of these ideas might work in the future.

Over the past year, discussions have focused on whether publication ethics should cover medicine, biomedicine, or extend more widely into other sciences and the arts, and this will be the focus of first presentation.

We will then consider the work undertaken by the Academy of Medical Sciences in driving forward the establishment of an independent review body for research misconduct. In 1999 the Edinburgh consensus came up with a broad definition of misconduct and several suggestions for promoting ethical research.

The most important outcome of this meeting was the proposal for national body akin to those in the USA and Scandinavia. Three years later we are still waiting.

COPE has now published in excess of 150 cases that have been reported to the committee, although interestingly, the numbers submitted have fallen over the past year, and we really don't know why.

It could be that COPE has helped editors, and we've all learnt how to deal with cases of research

misconduct, and don't feel the same need to bring everything to the committee. Perhaps there has been a real decrease in the numbers of offences. Or maybe we've given authors a warning shot over the bows, and they know that editors are becoming more robust in their handling of such cases, and are reporting authors to heads of institutions.

**“Those of us who are journal editors, or who head up faculties or institutions, are accountable. We need to know what our staff are doing and we have to be accountable to the public. And at the moment, we are simply not able to do that.”**

But the truth is, we don't know if misconduct really is on the decline or, indeed, what's going on in the rest of the UK.

Why does any of this matter? Those of us who are journal editors, or who head up faculties or institutions, are accountable. We need to know what our staff are doing and we have to be accountable to the public. And at the moment, we are simply not able to do that.

### SESSION 1

Chair: Richard Smith

Editor *British Medical Journal*, vice chair of COPE

I used to believe that integrity was something you were born with, and that unless you fell into wicked ways, it continued. But now I've realised that integrity is something you have to work at every day, and that it is very easy to stumble.

Let me give you a couple of examples. The satirical magazine *Private Eye* pointed out that the reviewers used by the *BMJ* to rebut their MMR exposé, Professor David Elliman and Dr Helen Bedford, have ties with vaccine manufacturers. The magazine said that the *BMJ* forgot to mention this, claiming it was an oversight.

Because the piece was in our Medicine and the Media section, we did not ask the authors to declare competing interests. If it had been an editorial, we, of course, would have done so.

I've just had an article rejected from the *BMJ* because we failed to get prior ethics committee approval. A dozen of the 150 or so reported COPE cases fell into this category.

So you see, it is very easy to stumble into wicked ways. And we shouldn't think that we are the virtuous few, looking out at the horizon trying to spot monsters, because some of us are those monsters.

Journalists regularly ask me why all the fraud cases seem to be concentrated in biomedicine, and not in physics or astronomy or biochemistry. Is it that we are uniquely wicked?

It could be that there really is more fraud in biomedicine. It could be a denominator problem in

that there is more research in this field. It could be that there is a lot of pharmaceutical company money around. It could be that biomedicine is full of amateur researchers. Or it could be that it is not true at all and there is just as much going on in other areas of science.

But when I get asked: 'why does it happen?' my response is: why wouldn't it? Every area of human endeavour is shot through with wicked behaviour. Casinos operate on the premise that everyone is wicked and trying to get away with something, so there are cameras everywhere. But academic science does exactly the opposite, so it's not surprising that wickedness is rather easy to perpetrate.

## Does research misconduct extend beyond biomedicine?

Ritu Dhand

Chief biological sciences editor, *Nature*

Research misconduct has been with us since Galileo Galilei, founder of the scientific method. Colleagues had difficulty reproducing his results. The boy genius Isaac Newton introduced the “fudge factor” to magnify the predictive power of his results. And the geneticist Greg Mendel’s results were deemed too good to be true.

Misconduct in the biological sciences can start with the “tidying up” of experimental data, through to the fudging of statistics, and the invention of entire experiments. There are some striking examples, such as the Gupta Files in 1989.

Gupta recycled “Himalayan” geological fossil specimens by assaying fictitious locations with foreign materials once housed in museums and other people’s laboratories. He managed to work with 60 co-authors for more than 25 years, and he was not found out until a fellow palaeontologist questioned the striking similarity of the so called Himalyan fauna with those found in Wales.

In 1997 Brach and Hermann produced work on multi-drug resistance in cancer treatment. They had mixed and matched computer images to produce new data. They were eventually rumbled when colleagues, who suspected that they had fabricated their results, consulted the university dean.

**“Research misconduct has been with us since Galileo Galilei, founder of the scientific method. Colleagues had difficulty reproducing his results.”**

In 2000 a new species of Chinese bird fossil, the archaeoraptor, was discovered, which explained the link between dinosaurs and bird evolution. But the tail came from a different species and had been glued on to the body. The findings had been published in a journal that did not use peer review, but the error became obvious once exposed to public scrutiny.

In 2002 Jan Hendrik Schön claimed to be able to create transistors from single molecules using nano-electronics. He published 80 papers in two years—one paper every eight days. Seven of them were published in *Nature*. Fabricated data were found in 16 of the 24 cases examined.

The fraud came to light only when researchers failed to replicate the results and found that the graphs

in three separate papers were identical. But it’s easy to see how he eluded detection because the same technique was applied to many different modalities and the graphs were always going to look similar.

### So why does scientific misconduct exist?

There is an enormous pressure to publish, largely because of its impact on career prospects. This is one of the few disciplines in which scientists are graded, not on personal merit or how good they are at their job, but by the number of papers they publish—hence “publish or perish.”

Added to which, we are all fighting for the few grants available, and the numbers of top jobs are limited, with a huge bottleneck at postdoctoral level. To get these jobs, a fantastic publication record is required. The competition to publish quickly is enormous, with authors who have taken three or four years to complete a piece of research petrified of being scooped within days.

Publishing large volumes of work can also achieve fame and recognition. In some areas authors are encouraged to publish regardless of the quality. It’s the volume that counts.

Another reason is money. In China fossils regarded as national treasures cannot be sold legally. This has led to a thriving black market, in which the more different the species, the higher the price is likely to be. A US curator bought the archaeoraptor for US\$150,000.

In the biomedical sciences the profits to be gained by pharmaceutical companies for developing drugs and vaccines sometimes drive the creation of positive results in basic research.

Misconduct is also easy to do. There is a fine line between manipulating digitised images to clean up data and creating completely new data, as in the cases of Brach and Hermann and Schön.

But one of the most compelling factors is trust. We trust co-workers to do what they say they are going to do, which is why Gupta went undiscovered for so long by his 60 colleagues. People are deemed innocent until proven guilty, and despite the gossip, it’s often a long time before a formal inquiry is instigated. And in Europe there is no unified approach to this.

What is the punishment? Embarrassment, withdrawal of funding, blacklisting by journals and loss of scientific integrity are all likely. But formal inquiries resulting in job loss or severe punishment are rare.

## Who is responsible?

First and foremost, co-authors must take responsibility. They contribute to, and read, the paper. At *Nature*, all authors must give consent before the paper can be published. But once again, it is difficult for co-authors to cross the line of trust and question each other's integrity. It is deemed insulting not to trust a data source. We need to change the culture before this becomes acceptable.

Peer review has a major role. Editors peer review work to ensure that it is technically sound. But do they pursue glamour, and as such, undertake short cuts, over-rule hostile referees, and select sympathetic ones? Ultimately, no editor wants to publish something that is wrong and which they will have to retract.

Do the referees responsible for the technical review need to be more critical, spend more time, and take the initiative to look beyond the paper?

**“... one of the most compelling factors is trust. We trust co-workers to do what they say they are going to do ...”**

Funding agencies, universities and institutes also have a role. Fraud doesn't just happen at the stage editors see it. These agencies see it at various stages before publication. Should they carry out spot checks on unpublished work? Should they follow up on any gossip? Should they insist on internal peer review of work that is about to be published, and do more to encourage the teaching of good laboratory practice?

## What next?

In Europe we have nothing equivalent to the US Office of Research Integrity, set up in 1989 to monitor allegations of misconduct in biomedicine. In 2001 127 were reported to the Office of Research Integrity (ORI). But even this system relies on scientists reviewing scientists, and this takes time, for which there is no pay.

The American Chemical Society talked about setting up a committee to develop policy in 2000, but nothing has happened so far. In physics there is no such committee as yet, because no one feels the need for it. But the example of Schön shows that perhaps there is.

## Discussion

A delegate pointed out that if he wrote a paper suggesting that the Golgi apparatus was an artefact and

sent it to a world expert, it would be rejected on the grounds that to accept it would invalidate all previous work. “There's an inbuilt system whereby people who question established thought don't get a fair referee.”

Dr Dhand agreed that getting a balanced review on papers that question literature spanning decades was indeed very difficult. For that reason, she said, such a paper would not be sent to one referee who was unlikely to agree. “Our job is to find the people who would agree, and we go out of our way to do that.” She added that *Nature's* policy was to ask authors to suggest reviewers for and against their work.

Richard Smith commented: “It's a human problem. Beethoven's music was accused of being just noise and Van Gogh's paintings just daubs. If you come up with something truly original, the world is not going to be able to cope with it.”

One delegate pointed out that any co-author shares an equal intellectual responsibility, but authors are also responsible for the integrity of any papers quoted in support of their work. But most people don't accept this, he said.

Did the peer reviewers in the Schön case have the responsibility to review not just the papers in question, but all the papers the author had ever written, as suggested by the *New York Times*, suggested another?

Dr Dhand said that from the referee's point of view, the technique was already established. Papers on it had been published widely throughout the physical sciences, and it was the application of the technique that was critical. “With hindsight, it's easy to look at numbers and say how could this have been missed? But in reality the raw data have become so large they can't be reviewed. You have to look at data that has been worked on and analysed.”

Discussion ensued about whether catching a fraudster in two years was a success story, considering the thousands of papers out there, or whether some alarm should have been raised at the sheer volume being written.

The problem, said Dr Dhand, was that it was one method applied to different systems. “If it had been a biological principle you could ask how could seven papers on one principle go unnoticed? But this was a technique.”

Various comments were made about how easy it is to commit fraud when there is no licensed degree to throw away and no prospect of losing your job. Richard Smith pointed out that in biomedical science people often had their license to practice removed.

Did Dr Dhand think biomedicine should adopt the “casino” approach? “Trust is a factor that allows misconduct to go undetected. But I don't think most scientists are fudging data. And in science you could argue that you would be found out because as soon as you publish, people will try and replicate your data.”



## The Research Integrity Initiative: progress report

Professor Sir Peter Lachmann  
President, Academy of Medical Sciences

The initiative is based on a NAPAG (National Academies Policy Analysis Group) inquiry. NAPAG is made up of four learned academies in this country: the Royal Society; the British Academy; the Royal Academy of Engineering; and the Academy of Medical Sciences.

The remit of NAPAG was to discuss:

- Fundamentals of good practice and definitions of research misconduct and fraud
- The scale of the problem
- Whether there are factors in the current organisation and funding of research that promote research misconduct
- Procedures for dealing with fraud and misconduct in the UK and elsewhere
- Proposals for improvements, if appropriate, in such areas as good practice and audit
- Perceptions and concerns among policy makers and the public
- Education and training
- Prevention
- Legal aspects and a code of practice

A full report was not published, but the proceedings can be obtained from the Academy.

### Definitions

There are no generally agreed definitions. The headings of fraud, deceit, and theft (Drenth, 1999) are probably a good place to start. The intent to deceive is probably essential for a definition of major misconduct.

But NAPAG felt that financial fraud is a separate issue. If invented patients are included in trials to obtain money, that's a clear case of commercial fraud and a matter for the criminal courts. No sophisticated education is needed to tell people not to do that.

We also felt that publication misdemeanours, such as gift authorship or publishing the same data in two papers, are best dealt with by the journals with whom contributors have contracts. Major theft of ideas is, of course, a different matter.

### Extent of the problem

We were not convinced that there were any reliable data on this point, and the reported incidence figures lack denominators. Effectively, we are dealing with anecdote.

In the Nordic countries, the feeling is that there are one or two cases per million of the population,

including all science and the humanities, of which 20 per cent are considered to be serious (Riis, 1999). Most of their investigations conclude that there was no basis to the allegations.

If these figures are applied to the UK, that would suggest a total of 60 to 100 cases every year (Riis, 1999), of which 12 to 20 would fall into the serious category.

It's worth comparing this with the data from the NHS Counter Fraud Directorate, which investigates financial malfeasance in the health sector. In 2001 they investigated 22 hospital doctors, 126 GPs, 35 dentists and 122 pharmacists (Hangartner, 2001). There is still more financial fraud than any other category, and British insurers suggest a considerable degree of minor misreporting.

**“But it is quite unrealistic to believe that this trust culture can be replaced in any way at all by an accountability or audit culture. The scientific enterprise simply wouldn't work if people felt the need to check up on everything ...”**

### Why is research fraud important?

Research fraud undermines the scientific enterprise and corrodes trust both among scientists and between scientists and the public. That is enormously important because science relies on credibility.

But it is quite unrealistic to believe that this trust culture can be replaced in any way at all by an accountability or audit culture. The scientific enterprise simply wouldn't work if people felt the need to check up on everything, and it would simply become corroded by suspicion and mistrust.

Second, it damages careers. Even allegations of fraud tend to ruin people's careers, and the damage can go on for decades whether the allegations are proved or not. They damage the careers of those against whom the allegations are made and they can also seriously damage the careers of the people making them. Malice may be behind some allegations.

Third, it's extremely costly—not just to investigate, but to go over all the science again and unbutton all the consequences of any fraud.

## What needs to be done?

We must promote high research standards by example and by teaching. There is no good evidence base on how this should be done, but it's not clear to me how giving graduate students courses in good research conduct is going to be much more helpful than having them work for supervisors whose own standards are high.

It's essential to establish the extent of the problem, as well as robust and fair procedures for dealing with allegations of misconduct. And the interests of whistleblowers and of those against whom allegations are made must be protected.

The Academy of Medical Sciences proposes to maintain a database of allegations and their outcomes and it will collect experiences with procedures, to provide robust guidelines for dealing with fraud and misconduct.

Guidelines written round a committee table, when subjected to the messiness of real life, often turn out to be inadequate and sometimes to do harm. This problem will not be solved by more experienced people devising even more guidelines, but by sharing experiences and explaining what did and didn't work. This will allow us to produce a template for proper procedures.

Finally, the Academy will provide employers with independent expert help in the early phase of an investigation, when impartial views from outside the institution are critical.

What it will not do is to police research conduct, or sit in judgement, or act as a national "fraud busting" committee. We have no doubt that the responsibility for investigating misconduct rests with the employer with whom the research worker has a contract. Unless there is a contract with the person under investigation there is very little that can be done except by a statutory body.

There is a further reason why a body such as the ORI wouldn't work in the UK: the patenting system. In America patents are issued on first discovery whereas in Europe they are issued on first filing, and as a consequence, the whole attitude to record keeping is entirely different.

In order to establish first discovery, a research notebook has to be signed off every evening. It must be in non-loose leaf format and information contained in it must not be altered. This is counter cultural to Europeans. No one does this except industries wishing to patent in the USA. Until we adopt this approach we won't have the kind of records on which the ORI depends.

## Proposals for the database

Information will be solicited from employers and other relevant bodies, such as the Royal Colleges, including those of nurses, midwives and vets, the GMC and journal editors. Information on the nature of the

allegation and the outcome will be essential.

The consent of parties involved will be sought, although exactly what will happen if it is refused is not clear. It will probably still be possible to obtain the data in anonymised form.

The database will have to be registered with the Information Registrar whose regulations will have to be followed. The database will be held on a secure computer that cannot be accessed from the web, with back-ups kept in a safe.

An anonymised annual report will be supplied to subscribers to the initiative.

## The template for good practice

We would like information from anyone who undertakes investigations. They can also choose to remain anonymous.

Experiences with existing guidelines will be distilled. Most of these are unenforceable because many of the actions they recommend are not written into employment contracts. Employers will therefore have to be advised on what they should include in contracts to enforce good practice.

Most universities have not yet written into their contracts of employment clauses that give them the right to oblige people to hand over their research records.

Preliminary assessments are particularly difficult. They require robust and fair procedures that adhere to rules of evidence, right to representation, and conflict of interest, although we do not envisage the need for lawyers.

The consent of the parties to be investigated will normally be required. We will have to see how often this is refused. If those involved can't agree whether the Academy should be involved in this, they may have to leave it to their employer.

The assessors are legally required to be competent, to act in good faith, and to have no conflict of interest. They may therefore need training and they might need a contractual relationship with the Academy to ensure this.

The Academy itself will need insurance or indemnity from employers against any possible legal actions, probably the former. And the output will be limited to a report to the employer, with the conclusions restricted to what can be drawn from the evidence available to the panel, and nothing more.

The details will need to be drawn up by a lawyer and we will have to persuade the Council of the Academy to go along with it.

It was suggested that we should provide a conduit for whistleblowers, but we have decided against this following discussions with Public Concern at Work, which has long and considerable experience of dealing with whistleblowers.

## How it will be run—probably

I say probably because there are several contingencies that have to be met. We will probably recruit a management board to run the initiative, including a lawyer and experts in relevant areas.

It is absolutely dependent on the NHS, universities, and others employing research workers subscribing to the initiative, because funds are required to run it. Whether the major research charities or journals wish to sign up, has not yet been explored.

We haven't yet worked out the budget sufficiently carefully to propose subscription costs, which will, of course, depend on how many people come on board. HEFCE, the NHS Research and Development Directorate, and the GMC have already contributed funds towards the costs of setting up the initiative.

**“... papers should be published only for their scientific merit, and not to attract media attention and raise impact factors. Several popular journals have published papers, which they know to be wrong.”**

## “COPEing” with misconduct

Some journals are sometimes part of the problem rather than part of the solution.

- 1 Editorial triage is practised by journals that consider themselves to be very popular. This is not peer review in any sense of the word and actually subverts the process. It has undesirable effects on the research enterprise because it focuses effort on what the journals think will appeal to popular interest. How the triage is done is often not clear.
- 2 Editors don't always keep to COPE guidelines. One of these is that papers should be published only for their scientific merit, and not to attract media attention and raise impact factors. Several popular journals have published papers, which they know to be wrong.
- 3 COPE states that all significant contributors should agree to publication, nevertheless there was a notable case in the *Lancet*, which published a paper despite the editor having received a letter from a major contributor disassociating himself from the work.
- 4 Publication bias against negative findings certainly still exists. And there is an obsession with bibliometrics, which has done no favours to science at all. The whole business of citation indices and impact factors is corrupting. The fact that people judge work on where it is published rather than on what the paper says is highly damaging.

The media has a dangerous obsession with maverick science, illustrated by the following examples.

- Jacques Benevise's theory of extreme dilution and memory in water to explain homeopathy
- Peter Duesberg's studies on HIV not causing AIDS
- Alan Ebringer's assertion that bovine spongiform encephalopathy is an automimmune disease and therefore not contagious
- Arpad Pusztai's research that genetically modified potatoes poison rats
- Andrew Wakefield's study showing that MMR gives rise to autism and colitis.

## Discussion

How should editors bring out controversies was the first topic for discussion.

Sir Peter was clear that peer reviewed publication in the scientific press was not the way to do it. “If people wish to have meetings about controversies, that's fine, but to publish something in what is considered to be a reputable journal gives it to the public prematurely which is damaging.”

The publication of the Pusztai paper in the *Lancet* was followed by comments that if it was published in the *Lancet*, the editors must believe it to be true, he said.

But truly innovative science is almost always controversial, countered Richard Smith. “Are you saying that if it's controversial it should not be published?” he asked.

Sir Peter agreed with the COPE guidelines. If it is of scientific merit, it should be published whether it's controversial or not, he said. But this was different from publishing material that was known to be untrue and where there were obvious flaws in the science, the statistics were wrong, and there were no controls, etc.

One of the ways in which patients get information is from conference abstracts and proceedings which are not peer reviewed. Should we steer clear of this, suggested another delegate?

More and more publications will be put on the web without peer review. Some scientific groups communicated in networks on the web all the time, responded Sir Peter.

He added that he had once surveyed the content of FASEB abstracts, and found that a substantial proportion never reached the literature. “It's people publicising preliminary results which they hope turn out to be true and which establish priority, but which, if they don't work out, then disappear. Anyone can write exciting sounding abstracts, but the data don't always stand up.”

Sir Peter was asked if was right that publication conferred a standard or stamp of approval to a piece of work, in the scientific community and if not, then how should work be judged?



Publication was essential, he said. “It doesn’t matter where it’s published as long as it’s peer reviewed. Since citation indices came in, and to avoid having to read the work, people assume that a history of appearing in high impact journals means that the work must be good. Scientific papers are meant to be read, not to be counted.”

Richard Smith wanted to know if Sir Peter agreed that scientific papers were not truth, but provisional truth? Many of them turned out ultimately to be wrong in some sense.

Yes, said Sir Peter, but in interpretation only. The data should be relied on. “You certainly don’t have to rely on how people interpret them. And that’s how science progresses.”

There was some discussion on the difficulties of improving the peer review process for journals with a low impact factor. Sir Peter felt that the society journals, which often fell into this category, had a peer review process that was probably as rigorous as any. This was because they expected to have all the technical information and were not being asked if the study was of interest to a general body of readers. It was also mentioned that *Nature* and the *Lancet* were considered to be better journals before the introduction of citation indices.

**“It doesn’t matter where it’s published as long as it’s peer reviewed ... Scientific papers are meant to be read, not to be counted.”**

Sir Peter disagreed with the assertion that the whole peer reviewed process was biased towards the best journals. He suggested that a retrospective review of different journals would not reveal any difference in the quality of referee reports.

Richard Smith felt that there was plenty of research showing what a deeply flawed inadequate process peer review is. But Sir Peter said: “Peer review is to science what democracy is to politics. It’s not the most efficient mechanism, but it’s the least corruptible.”

Michael Farthing suggested that without the numbers, researchers would still know what the hierarchy of journals was. “The only way to get rid of this is to abolish the journals and put everything up on PubMed Central and go through the laborious process of peer reviewing everything we read ourselves.”

He then went on to say that he doubted financial fraud was more common, but that it was easier to detect because it was audited both internally and externally. “The problem with research is that we have no audit process. Shouldn’t we be aspiring towards

much better record keeping and some sort of internal and external audit? Why is scientific research any different from financial probity?”

**“Peer review is to science what democracy is to politics. It’s not the most efficient mechanism, but it’s the least corruptible.”**

Sir Peter said this went back to the difference between a trust and an audit culture. The case of Enron undermined the assumption that audit picked up fraud. “I’m sure the amount of undetected financial fraud is also quite high; there’s no reason to think it isn’t.”

“The disadvantages of substituting hyper-accountability and audit for the trust culture is a very high price to pay. You should look at the consequences this will have on the way that science is done just as it has had consequences on the way the health service is run.”

Michael Farthing countered: “We used to trust doctors, now we audit their practice.”

Sir Ian Kennedy pointed out that the Nordic countries and the UK were not comparable, in terms of the number of pharmaceutical companies and universities. He also said that the case of Enron demonstrated that if you had a system there would always be criminals. That’s the reason to have criminal law rather than to abandon the idea, he said.

Sir Peter agreed that the UK and the Nordic countries were not entirely comparable. In which case, responded Sir Ian, the notion that fraud misconduct was not common was unsustainable.

That was precisely why there was a need for a database, said Sir Peter. “My own view is that we have no satisfactory data. I personally suspect that serious fraud is uncommon. It exists, but since there are no denominators there is no way of establishing one way or another. But there is no reason to believe that the accounting and finance agencies are any better regulated than science is without them.”

He said that the engineers believed there was quite a lot of commercial fraud but that this was dealt with internally and never actually reached the public domain. In the other sciences, such as the hard physical sciences, fraud was also a feature, but because the research was much easier to replicate, it was probably easier to get found out. There was fraud in the humanities, too, but the general public didn’t take this seriously whereas research fraud was a disaster, he said.

A delegate pointed to the importance of impact factors are incredibly important, and the attendant pressure from funding bodies and institutes to publish in the top impact factor journals. Editorial boards

round the world thought about how to attract high quality authors to raise the impact factors, he said.

“You’re right, but it’s a tragedy and a corruption of science. And one should fight against it,” commented Sir Peter.

Tim Albert thought the Academy’s proposals to have a committee of eminent people, who have written many papers, to sort out a register in retrospect was a “very British solution. The world I inhabit is full of young researchers who are confused about what ethical standards are and get all kinds of conflicting messages,” he said. Were there any plans to inculcate proper ethical standards among these people?

Sir Peter said that some guidance was possible, but he disagreed with the assertion that confusion was rife. “I don’t think anyone has any real doubts about the ethical standards of science, and they should learn them from their supervisors. If there is a problem, then it will have to be addressed. When people fabricate data or falsify controls, they know what they are doing.”

Richard Smith was not convinced. When the next high profile scandal of fraud in biomedicine occurred, would Sir Peter be able to confidently say, ‘you really don’t need to worry, because the Academy has got a very well considered response to this and we’re on top of the problem?’

Sir Peter responded that the essential function of dealing with misconduct belonged to employers. The

Academy was there to help them sort things out. But Richard Smith suggested that this has always been the case, and there were plenty of examples of universities burying these problems.

Sir Peter said this used to be the case 30 years ago, but that the situation had improved. It was a case of seeing how the procedures worked and being patient. The answer was not to have a national fraud-busting committee that chased fraudsters.

“I don’t think it will work and it is deeply counter cultural in this country. I think the US examples are horrifying, and the examples in Scandinavia suggest that they are putting a great deal of effort into relatively little,” he said.

But Richard Smith wanted to know why the Academy took a different line on a national body from all the other members of the consensus panel in 1999, including the colleges, the GMC, the MRC, the Wellcome Trust and members of the public? Sir Peter said he believed the Academy’s view to be widely shared.

Sir Peter said that the Academy was already carrying out one investigation, to inform future procedure. Meetings with Universities UK and the NHS R&D Directorate were planned, after which final approval would be sought from the Academy Council. But he warned that if no one signed up to the scheme, it would die through lack of funds.

# COPE sets out an agenda for research

Fiona Godlee

Editorial director (Medicine), Biomed Central

We have set up a committee, the remit of which is to encourage research into publication misconduct by all parties in the publication process: authors, hidden authors in industry and elsewhere; funders; editors; peer reviewers; advertisers; and publishers. It excludes publication outside peer reviewed biomedical journals.

The committee's task is to identify and prioritise key areas for research. We plan to encourage and facilitate research by raising awareness about the need for it, contacting potential sources of funding, providing other resources, such as bibliography and case reports, and helping to disseminate the results.

## What are the key issues?

I conducted a web survey of the virtual organisation the World Association of Medical Editors (WAME). I asked members what issues relating to publication misconduct most concerned them? There were 13 responses, categorised under two headings: authors behaving badly and reviewers behaving badly.

The following themes emerged for authors behaving badly:

- Redundant meaning duplicate publication/duplicate submission/salami slicing, also known as disaggregation in the USA
- Undeclared conflicts of interest
- Poor methodology, defined as methods that can't answer the study question
- Badly done randomised controlled trials, with selective and incomplete reporting/biased or inappropriate analysis/undisclosed protocol amendments
- Overstated conclusions, leading to misleading press coverage (such as the MMR study) and potential harm to patients
- Non-publication of negative or small studies
- Non-peer reviewed matter from conferences getting into the literature
- Plagiarism
- Fabrication
- Serious fraud

Concerns about reviewers were as follows:

- Unfair or rude reviewing
- Poor quality or lazy reviewing
- Reviewers misappropriating the data
- Undeclared conflicts of interest

From this, the research committee came up with the key issues for research:

- Duplicate publication
- Conflicts of interest/relations with industry
- Failure to correct the scientific record
- Publication of poorly done or overstated research
- Non-publication
- Unfair or unethical review
- Authorship misconduct
- Falsification, fabrication, and plagiarism

## Conflict of interest

For this meeting, I conducted brief literature searches on two of these issues—conflict of interest and duplicate publication—hoping for signs of progress up the evidence tree from anecdote and hypothesis generation to hypothesis testing. I also wanted to see if there was any evidence on the epidemiology of misconduct, including definitions, incidence and prevalence, impact of specific outcomes, and effects of interventions.

I began by looking into conflicts of interest and relations with industry. A Pub Med search, using the terms conflict(s) of interest in the title or abstract, and a related paper trail, uncovered a total of 506 items. Almost all of these were opinion pieces or policy statements, declaring what a bad thing this was and urging action.

There were some original articles on the links between clinicians and the drug industry, and there were 18 articles on conflict of interest in research and publication.

The first of these looked at journal policies:

Krimsky S, Rothenberg LS. Conflicts of interest policies in science and medical journals: editorial practices and author disclosures. *Sci Eng Ethics* 2001; **7**: 205–18.

This was a survey of editors of highly ranked journals. Among the 1396 respondents, 16% had conflict of interest policies, three quarters of whom routinely publish disclosure statements. But less than 1% of articles published in journals with policies contained any disclosures.

Either links with the industry are very limited, or there is a poor response to requests to disclose links, or editors are not making enough efforts to capture that information.

It would be interesting to research what the effect of declaration of conflicts of interest is on readers, reviewers and editors? Should reviewers be denied this information because it might influence them?

Other articles related to the prevalence of links to industry among academics:

Boyd EA, Bero LA. Assessing faculty financial relations with industry: a case study. *JAMA* 2000; **284**: 2209–14.

Jellinek M, Lazare A. Relations between academic departments of psychiatry and pharmaceutical companies. *Am J Psychiatry* 1979; **136**: 827–9.

It would be interesting to look at exactly what links are acceptable. Is it OK to be paid for one lecture or to be an employee when it comes to research?

The effects on the conclusions of the research were covered by:

Davidson RA. Sources of funding and outcomes of clinical trials. *J Gen Intern Med* 1996; **1**: 1550–8.  
Clifford TJ, Barrowman NJ, Moher D. Funding source, trial outcome and reporting quality: are they related? Results of a pilot study. *BMC Health Services Research* 2002; **2**: 18.

The second of these, a small pilot study, found no effect. The authors looked at 100 randomised controlled trials from five high impact factor journals, and found that over two thirds favoured the new treatment. But this was not associated with the funding source.

The effect of conflicts on the conclusion of reviews was considered in:

Stelfox HT, Chua G, O'Rourke K, Detsky AS. Conflict of interest in the debate over calcium channel antagonists. *N Engl J Med* 1998; **338**: 101–6.

This was also a systematic search for articles on the controversy over the safety of calcium channel blockers, mainly reviews and letters. These were classified as neutral, supportive, or critical. The study asked authors about their financial relationships with the drug manufacturers of these and competing products.

**“The only factor associated with concluding that passive smoking was not harmful was whether an author was affiliated to the tobacco industry.”**

“Supportive” authors were significantly more likely to have links with calcium channel blocker manufacturers and to have a financial links with any drug company. Most people had a conflict of interest,

but it was only disclosed in 5%.

Barnes DE, Bero LA. Why review articles on the health effects of passive smoking reach different conclusions. *JAMA* 1998; **279**: 1566–70.

This was a systematic search for review articles on the health effects of passive smoking. For 106 articles, the outcomes examined included quality of the article, conclusions, and author affiliations to the tobacco industry.

The only factor associated with concluding that passive smoking was not harmful was whether an author was affiliated to the tobacco industry. Whether the paper was well written or not made no significant difference.

A couple of papers looked at the impact of conflict of interest on clinical practice guidelines:

Papanikolaou GN, Baltogianni MS, Contopoulos-Ioannidis DG, *et al.* Reporting of conflicts of interest in guidelines of preventive and therapeutic interventions. *BMC Med Res Methodol* 2001; **13**.

Choudhry NK, Stelfox HT, Detsky AS. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *JAMA* 2002; **287**: 612–17.

The first of these looked at 191 clinical practice guidelines and found that only seven mentioned any conflict of interest, all of which had been published since 1999. Only 18 authors disclosed 24 potential conflicts.

The second was a cross sectional survey of 192 authors of 44 guidelines. The response rate was 52%, and showed that 87% had some interaction with pharmaceutical companies. On average, the authors interacted with 10.5 different companies, and 59% had relations with the drug company whose drugs were considered in the guidelines. Another 55% said there was no formal process for declaring conflicts of interest.

One in five thought that their colleagues' judgment was influenced by these conflicts, but only 7% thought their own judgment was affected.

There may be some UK data out there, but equally, there may not, and that is one of the things that the committee should look at.

## Conclusion

In summary, there was quite a lot on the nature and extent of the problem, with evidence of substantial links between researchers at all levels.

It was clear from the research that relations with industry do affect the conclusions of research and review articles. And few journals and clinical practice guidelines have policies or mechanisms for disclosure.

Circumstantial evidence suggests that rates of disclosure and adherence to disclosure are low. But

there was heavy reliance on author declarations, either in print or when surveyed afterwards, with the exception of the tobacco industry.

But the high rates of links with industry among academics as a whole would suggest that low rates are actually due to low disclosure.

There is no research on whether disclosure affects readers' perceptions of what they are reading, and the next step will probably be to look at whether editors and reviewers are affected by disclosure.

## Discussion

Richard Smith declared that the *BMJ* Publishing Group was just about to post on its website all the competing interests of all its editors and editorial board members. It had taken over two years to gather all this information using exactly the same forms as are used for authors. This, he pointed out, reflected the fact that people are always interested in accountability except where they are personally concerned.

Dr Godlee said that declaring a conflict of interest could be helpful because at least it forced people to lie, if that was their intention, and that was progress of sorts.

Richard Smith pointed out that when the *BMJ* used a general form of conflict of interest, few people declared any, but when financial conflicts were specifically asked about, almost everyone did. "People don't think of themselves as having a conflict of interest, but when you ask people whether they have ever given a lecture paid for by a pharmaceutical company, then of course almost everyone has."

He went on to describe some research carried out at the *BMJ*. This involved sending out a paper to reviewers, half of whom received a version containing a conflict of interest statement. They were asked to rank it for several measures, including interest and relevance.

The expectation was that the conflict of interest would lead to lower marks. But those reviewers receiving papers with declared conflicts of interest ranked the paper low on all counts.

## Duplicate publication

I did a brief literature search on duplicate publication using the same methods, using the terms duplicate or redundant publication in the title or abstract.

There were 119 items, almost all of which, once again, were opinion pieces or notices of duplicate publication. There were two case studies and four prevalence studies, all of which were article based.

The case studies looked at the effect of duplicate publication on the results of meta-analysis of randomised trials of anti-emetics. Where those duplicate publications were used in one meta-analysis, the conclusions as to the effectiveness of the anti-emetic went up by around 23%. That answers the point about whether duplicate publication is important.

A study on duplicate publication in the surgical literature found that almost one in six original articles in three leading journals represented some form of duplication.

**"People don't think of themselves as having a conflict of interest, but when you ask people whether they have ever given a lecture paid for by a pharmaceutical company, then of course almost everyone has."**

In conclusion, the prevalence studies all used the same article based methodology. They suggest that the amount of duplication in the literature has not changed, but that the frequency of disclosure has increased. I found no studies looking at:

- Causation or attitudes and knowledge among researchers and authors
- Prevalence, using questionnaires or interviews
- Barriers to journals tackling the problems
- Effectiveness of educational initiatives, better detection, stricter reinforcement or heftier penalties for non-disclosure

The committee has now developed a preliminary action plan, which will include:

- Quick reviews in all key areas to identify relevant questions and throw up gaps in the research
- Suggesting systematic reviews
- Identifying funders
- Commissioning a programme of research
- Developing resources on the COPE website, such as bibliographies and case studies

## Discussion

COPE could help define exactly what is meant by duplicate publication.

Michael Farthing pointed out that a drug company intended to publish an entire poster from a conference, which would constitute the complete data set from a forthcoming paper and put it on the company's website. This, in effect, would be tantamount to full publication.

Richard Smith pointed out that this was acceptable, providing that it was declared when it came to subsequent publication. He said that the *BMJ* had given up on refusing to accept papers that had had some sort of previous airing because of the amount of research done on behalf of the government, etc, which meant that it had already been seen or discussed before its publication date.



Dr Godlee canvassed delegates about what they considered to be their primary concerns. These were:

- The scale of the problem for each element
- The reasons why they happen
- Does minor lead to major and can education prevent this?
- The distorting effect on citation
- Unethical research, using animals for example
- Roles and responsibilities
- Slow unresponsive reviewers
- Journal policies
- Training and the qualifications to do the job
- Information and guidance

## Comments

In the US, schools that receive federal funding are required to teach research ethics courses. It was suggested that this should be applied in the UK. People know how to do the methods in the laboratory, they don't know how to write up their research, because this is not taught, on the grounds that it is intuitive.

People assume that biomedical publishing is more ethical than other forms of business, stated a delegate. "Once we realise that this is just like any other activity, then we'll start to make some progress," he said.

Michael Farthing said that his clinical work and his teaching were audited, but not his research. "In many ways this is the most vulnerable aspect of my work." Richard Smith pointed out that clinical trials for drug companies intending to submit their results to the US Food and Drugs Administration, have to be monitored.

By next spring anyone carrying out research on patients using NHS data will have to have a contract with the health service, commented a delegate.

Michael Farthing said that there was currently no audit to check that what it is written in the lab book ends up in the final publication.

Any author should be made to keep their data for at least seven years, which would enable any checks to be carried out, it was suggested.

"It's very difficult to do research into publication ethics without funds, and in general, people are not much interested in funding this type of work," said Richard Smith in his concluding remarks.

## SESSION 2

Chair: Professor Sir Ian Kennedy

Emeritus Professor of health law, ethics and policy, University College, London

## COPE takes a role in education

Faith McLellan

North American Senior Editor, *The Lancet* and joint chair, COPE Education Committee

Sabine Kleinert

Senior Editor, *The Lancet* and joint chair, COPE Education Committee

### Workshops: Peer review dilemmas for editors, authors, and reviewers

Dr McLellan began by introducing the various members of COPE's Education Committee, including trainer Tim Albert. He mentioned progress on a first draft of document for young researchers on the meaning of authorship.

Hooman Momen, editor of the *Bulletin of the World Health Organization*, said that the WHO had sponsored a workshop of about 15 African medical editors from 10 different countries in Geneva. Part of that workshop, led by members of the COPE Education Committee, included analysing cases reflecting COPE issues.

Our committee has been charged with developing educational programmes that will be useful to COPE members and others. In order to obtain the best idea of what we should be doing, we want to have some feedback on:

- What audience should we be trying to reach?
- What are the most important issues?
- How will we do this?

### Audience

- Medical and biology students
- Investigators
- Supervisors
- Editors
- Pharmaceutical companies
- Funders
- Reviewers
- Ethics committees
- Publishers
- Authors
- Government
- Patient groups (to build trust and educate about scientific process)

- Health journalists
- Newspaper editors
- Statisticians
- Librarians

### Issues

- Implementation of policies
- Intellectual honesty
- Duplicate publication: what do we mean by it? (Lot of focus on research end but little focus on publication end)
- Authorship
- Publication and research ethics (they go together)
- Integrity of scientific enterprise
- Data analysis including data management
- Peer review: not only how to do it, and whose responsibility, but also, is it a shibboleth whereby establishment creates its own establishment?
- Correcting the research record
- Ethics vs etiquette
- Access to the literature
- Whistleblowing: prevention and treatment
- Competing interests

### How?

- Mentoring (but by trained mentors)
- Sharing experiences
- "See one; do one; teach one"
- Learning by doing
- Case finding to provide clues that something is amiss
- Web based approach including discussion groups and distance learning

## Scenario cases

Delegates were divided into groups to analyse cases and asked to consider each case along the following lines:

- Briefly summarise the problem
- Think of all the parties involved, including the invisible parties, such as patients, the public, and readers
- What further information is needed to resolve the case, if any?
- What resources can help you decide?
- What ethical values are at stake?
- What are all the possible courses of action?
- Which of these is the best, and why?

### CASE 2

A journal received a manuscript reporting the prevalence of tuberculosis in a small genetically unique population. The paper is sent for review and received favourable comments from all the reviewers. The authors revise the paper based upon the reviewers' comments, which were all relatively minor, and the paper is accepted for publication.

When the paper enters the editing process, a manuscript editor queries the corresponding author because there is no statement about informed consent. The agitated author telephones the manuscript editor and angrily tells him the research was conducted on long-stored sputum samples from patients seen in five pulmonary clinics in three different countries. It in no way posed a risk to the patients the samples were eventually going to be discarded, and so the informed consent was not necessary. The study had been approved by an ethics committee, which said nothing to him about any need for informed consent.

The manuscript editor, shaken and upset because of the author's response, reports this conversation to the editor in chief. What should the editor do now?

### Discussion

- These are samples collected over a long period from five different clinics in three different countries, so the logistics of trying to get informed consent for all of these would be virtually impossible at this stage.
- The concern would be that if these are small genetically unique populations they could possibly be identified at some stage.
- But the paper is sound and scientifically relevant, leaving the editor with the choice of publishing, but including a commentary to open up a debate about informed consent for samples.
- It should be made clear when patients are giving samples, that these could be used for research purposes. And they should have the right of refusal.

Sabine Kleinert asked what would have happened

if the problem had arisen earlier in the review process?

The authors could argue that they had done the correct thing because they sought ethics committee approval, and it could be argued that the ethics committee should have been alert to this issue.

Given the length of time involved, the samples could also have been collected long before the issues of informed consent were live.

Ethical approval should have been obtained at two levels: centrally from wherever the study was coordinated from and locally at each of the five collection points.

In many cases informed consent might be impractical, but if it's possible, it should be done.

There's a philosophical issue: can informed consent be obtained retrospectively? Informed consent relies on consenting to something that is about to happen and not something that has happened unbeknownst to you in the past.

For case studies in the *BMJ*, retrospective consent is frequently sought because the author has already written the paper but hasn't thought about consent.

Another aspect is that if these samples were used for a commercial purpose then the patients' consent should have been obtained.

There are two critical issues to consider: is this a really important valuable study, which should be in the public domain? And are these patients going to come to harm by publication of this paper?

But should you prioritise the pursuit of knowledge over and above the protection of the patients? These should be equal. And in some sense these patients were "harmed" by having their rights to consent ignored.

A website poll at the *BMJ* showed that while most doctors don't see a problem, most patients do.

Dr McLellan mentioned a famous bioethics case: people were asked whether they cared if their hair cuttings, swept up from a hairdressing salon floor, were used for some kind of scientific experiment.

The response was that it depended on the type of experiment. If it was simply acid based tests in the school laboratory, then no, they didn't mind, but DNA analysis was a different matter.

One of the tensions is: who has a stake in this? And our judgment about who might be harmed by it is not necessarily the same as that person's.

Anonymisation solves only a moral problem by rubbing the name out if a sample is taken without informed consent.

### CASE 3

A journal receives a single authored report of an observational study of self-reported quality of life issues in patients with an extremely rare disease. The patients were all participants on a ListServ of an internet site that had been set up as an electronic support group and information resource.



The researcher subscribed to the ListServ, which was unmoderated and automatically administered. At no time did he participate in any discussions on the list, he merely “listened in.” He collated participants’ responses to the ongoing discussions and categorised them according to predetermined criteria for the quality of life issues he was interested in studying. He then analysed the data and wrote the report. The manuscript included several quotations from the discussions, but did not identify the sources.

The editor who received the paper was intrigued by the paper’s findings, but was concerned that the paper made no mention of informed consent or ethics committee approval. She emailed the author with her queries, who responded as follows:

“I am utterly astonished that anyone could believe it is necessary to obtain permission to use statements people make in open forums on the internet, which is about as private as publishing your medical record in every major newspaper on the planet. Every statement available on the internet, is, by definition, in the public domain, and therefore no permission or consent is necessary. There is ZERO expectation of privacy on the Net!”

Is the author right?

## Discussion

- Quality of life is difficult to measure because there is no scientific standard. But is there an ethical difference between qualitative and quantitative data?
- It is unethical for someone to listen in without consent. ListServ is a restricted list.

Isn’t committing something to the web equivalent to publication, and the same as saying that newspaper circulation is a restricted list?

Sir Ian Kennedy disagreed. It’s more like sitting in a room and watching people passing in the street, going about their business, and then recording them in that street, adding up how many people are wearing a certain colour cloth, etc, he said.

The difference is whether they wish other people to know that they are in that street. On the ListServ, there might be people who don’t have that disease.

Isn’t it the same as walking into a support group meeting and taking notes at the back of the room, ventured another delegate?

There is a real difference. If someone is in a room who is felt not to be favourable to the environment you can ask them to leave. On the internet, unless you have some form of gate, you don’t know who is joining in, said Michael Farthing.

Someone pointed out that they had been commissioned by an editor of a well known journal to write up a meeting, and that they had not obtained consent from those present to do so.

These were not patients; these were people who were not consulting a doctor. They were discussing among themselves, and a medical eavesdropper

collected the information for a different purpose than that which was originally intended.

Sir Ian Kennedy said that if you were to put up a notice in an internet chat room that other people might be listening in and might use it for research purposes, many people would probably decide not to take part. That would suggest the use of these data by the researcher was inappropriate.

Faith said that in the institutions for which she had worked in the US, the collection of data for any purpose requires ethics committee approval even if it doesn’t require informed consent.

She added that the nature of the medium has been extensively talked about as very public, but that the people involved regard it as very private.

## CASE 4

An author calls an editor to say he wishes to submit for consideration for rapid publication a report of an unusual presentation of tularemia, which is known to be highly infectious and is currently being mentioned as a possible bioweapon.

The disease itself has not been reported for some years, and this particular presentation has never been described. The editor is excited about the paper (he has fleeting thoughts about the media attention its publication will surely command), and asks the author to email the report to him immediately.

Just before they hang up, the editor remembers to ask the author whether he has obtained permission from the patient for publication, as is the journal’s policy for all case reports.

The author sighs, and says no. In fact, he says, he asked the patient for permission and she refused, saying she simply didn’t want to be written about in a medical journal or anywhere else. The author told the patient, to no avail, and he now emphasises to the editor, and there are significant public health implications that should override the patient’s wishes.

What to do? (The patient is a lawyer).

## Discussion

- The editor should not be swayed by the possible media attention, but on the paper’s scientific merit alone.
- There should be an attempt to obtain consent and show the paper to the patient so that they understand they won’t be named.
- The editor should consult a virologist to ascertain whether the paper is really in the public interest to publish this paper.
- If it is, should it be published without consent, but by making it as anonymous as possible?

Sabine Kleinert pointed out that this issue goes beyond informed consent, because the patient has categorically stated that she does not want to be written about anywhere. So are there any circumstances in which public health issues would override patient consent?

Is there a legal or courtesy requirement involved here?

Sir Ian Kennedy mentioned that if it really is in the public interest, journal publication does not have to be the only way of dealing with it. You need not violate the wishes of the patient. The relevant people can be advised: the Department of Health, for example.

There are statutory regulations that you have to report notifiable diseases, but there is no need to publish in a journal and have it emblazoned across the pages of a national newspaper.

The issue remains, said Sir Ian, that there is a doctor–patient relationship in which the patient has explicitly said she does not want this published. The question is whether you can satisfy public interest without breaching that trust.

If the case is reported to the authorities, they would want to know about contacts so all anonymity would be lost.

Richard Smith said that he found it difficult to conceive of a set of circumstances where the public health interest was so strong that an editor would publish in direct contradiction of a patient's wishes.

Michael Farthing suggested that if a variant of HIV could be spread by aerosol and there was a fantastically well documented family study showing this, then public health interest would prevail.

If a patient is reluctant to have their case report published, are there ways of getting around the problem?

It was suggested that a leading article discussing the issues in their broadest sense would be a suitable alternative. Richard Smith pointed out that the *BMJ*, had taken this option.

## CASE 5

An associate editor at a journal commissioned a review article on a common disease for which effective treatments are newly available, based upon recent molecular discoveries.

The editor chose the author based on his publication history in MedLine, and on his affiliation with a prestigious institution in a large European city. The author accepted the commission after a series of email exchanges and gave the editor a mailing address in a country that was different from the institution's location.

When the article arrived, the editor sent it to four reviewers. Two said that the article was excellent and comprehensive and could go directly into print without revision; the third had suggestions for minor changes but recommended publication thereafter.

However, the fourth reviewer was more critical of the paper and said it should not be published under any circumstances. He said, in confidential comments to the editor, that the agency that had funded the author's research had accused him of fabricating data, and, after an independent investigating body upheld the findings, the author was banned from receiving

further funding from this group and was fired from his institution.

The associate editor was able to corroborate much of the reviewer's story in documents publicly available on the internet. He recommended at the journal's editorial meeting that the article must be rejected because publication, whatever the merits of the article, would damage the journal's reputation, as it would be publishing the work of a "tainted" author. Other editors argued that a review article is different from a report of original research, and that not to publish the commissioned article was unfair and discriminatory.

Having heard these two arguments, what should the editor in chief do?

## Discussion

- How had the review originally been commissioned? How had the author done it?
- Had there been a signed contract? The editor should discuss it with WAME/COPE and find out from other editors if they had had a similar experience.
- Trust is an important issue in this case, and who is entitled to judge? The publication should be withheld pending results of a full investigation and certainly should not be published hastily.

What about the fact that the paper had received three out of four good reviews? And the fact that this does not contain original research but opinion about what's been published?

Dr Godlee said the most useful comments were those relating to the fact that the author had been involved in fraud.

She pointed out that something similar had occurred at Biomed Central.

The approach, she said, was to very extensively peer review this person to find out if the taint was justified.

If the commissioned review relates to previously published fabricated data, it should not be published.

## CASE 9

A journal receives a report of a small clinical trial. In the methods section, the authors state that the sponsor of the trial, a medium sized pharmaceutical company, had no role in the design of the study, the analysis of the data, or the interpretation of the results, and that it had no control over the decision to publish the paper.

One of the paper's reviewers comments that he finds this statement implausible, because he had once done work for this company himself. The company had insisted on seeing his paper before it was submitted to a journal, and it was returned to him with significant revisions which affected the data and its interpretation. The reviewer had then excused himself from any further dealings with the paper (which was eventually published by the company researchers as the authors) and from any further association with the company.

Although he has no direct knowledge that the authors of the paper under review have been treated similarly, he is highly sceptical of their claims of non-interference.

What should the editor do at this point?

### Discussion

- At some point the accusations should be reported to the author, but at what point do you believe accusations made by reviewers?

At *The Lancet* they have protocols for clinical trials in which the role of sponsors is clearly defined.

Richard Smith pointed out that editors were not in a strong position to sort out authors because of the contract they have with them. In his view they were rather “well protected whistleblowers.”

Before accusations are made, strong evidence is needed. Even if these accusations were taken to the author, they could still be denied and it would still be impossible to know the truth.

All that can be done is to go to the institutions to signal to a body with legal legitimacy that something might be amiss. It is not up to the editors to conduct the investigations, he said.

Institutions are often inclined to say there is no problem even if an editor is pretty sure that there is.

Looking at the raw data is not satisfactory because it can be a lengthy job and can require independent statisticians to trawl through it, and possibly to no avail.

Do we believe the authors or start investigating on the strength of the author's say-so.

It's a difficult balance going to an author to ask him to justify himself or going to the reviewer to substantiate his claims. There could be animosity between the two.

Companies often distance themselves from small studies, and do post marketing studies which are underpowered but that they know someone will publish.

### CASE 11

One of your reviewers at the virology journal where you are editor in chief calls you to say that he fears a methods paper he is reviewing can be used as a “recipe for bioterrorism.” He strongly recommends the immediate rejection of the paper, and wants you to call the authors and demand that they withdraw it from consideration at any journal. Furthermore, the reviewer is prepared to call the civil authorities to alert them to this potential danger. Now what?

### Discussion

- The key issue is public interest, but if the editor does not publish, there is nothing to stop the author from publishing it on the web.
- Try and spread the reviewers' net wider and speak to people who are likely to know what this research is about.

- Go back to the author first, saying these concerns have been raised.

- Should editors practise censorship? The line to take would be to investigate and negotiate.

The American Society for Microbiology has formulated a policy on this very subject. If a reviewer is reviewing a paper that is not in the best interests of national security, she should notify the editor, who in consultation with the publications board, should decide whether to publish. It has been suggested in the US that such papers should be published, but excluding crucial methods.

Sir Ian said that a recent presentation given by the chair of President Bush's bioterrorism advisory group, indicated that editors have a moral responsibility to engage with their publishers.

He also foresaw that what was termed censorship might become legislation in the US to prevent publication of material that could have “dual use,” to advance science but also to make a bomb. This, said Sir Ian, would leave the internet unpoliced, which is where material of this kind would end up.

There is a resolution pending in the House of Representatives called “an expression of concern,” said Faith. But can all reviewers recognise something that is a threat to national security?

Richard said he had not come across anything which threatened national security, but that he had dealt with public health researchers suggesting that if the *BMJ* were to publish a certain paper hundreds of thousands of people would die.

One of the stipulations of the American Society of Microbiology is that the full methodology should be published so that others can validate and replicate the work.

### CASE 13

A manager at a medium sized commercial publisher learns through the grapevine that the editor of one of its surgical journals plans to publish an editorial that will be severely critical of the marketing practices of several major equipment manufacturers.

These manufacturers also happen to be the journal's biggest advertisers. The manager sends the editor a blistering email, telling him that he may under no circumstances publish such an editorial, as it will severely damage the journal's revenues.

Now what?

### Discussion

- Is the editorial fairly and properly written and evidence based?
- Is there a conflict of interest from the publishers' point of view and is the manager the editor is dealing with acting independently? Perhaps he has some financial interest in the journals he manages, or is his view truly representative of the publishers and the publishing board?

- What is the contractual relationship between the editor and the publishers? Are there clear statements about what oversight publishers can exert, or whether the publishers have stated policies about this kind of issue?
- The editor should commission some independent appraisal of the editorial, such as submitting it to COPE, and go to the publisher asking if the email represented the publisher's policy.
- If there is bona fide case for the evidence base of the editorial it should be submitted for publication, and rejected if it is the publisher's policy. Then it should be published through independent appraisal of the case rather than the content.

A delegate pointed out that something very similar had happened when he had his paper pulled at the last moment. The editor did not advise him of the reasons why but a member of the editorial board told him that it would destroy the advertising revenue from a surgical instrument that was widely advertised in the journal, and that this could lead to the journal's financial collapse.

Richard said that the *BMJ* published an editorial that was sceptical of COX 2 inhibitors and the manufacturers said that if the same piece was re-published in the US version, they would cancel their adverts, which, at the time, looked like it would be enough to kill the US version.

It was an easy decision to make, because it would have been completely unacceptable to have succumbed to that kind of pressure. "What's the point of having a journal if you are going to give into that level of corruption?" he asked.

Faith summarised the issues discussed:

- Paternalism
- Autonomy
- Consent
- Ethical differences between quantitative and qualitative studies
- Trust and accountability
- Commercial pressures

Sir Ian Kennedy said that it was a vain hope to think that there are right answers to all the issues raised by the day's proceedings. "There are simply less wrong answers," he said. "What we have to do is to steer a course towards the more right answers."

## Summing up

Michael Farthing said that earlier in the year he wondered whether COPE had a role in the future. But then he heard about the two initiatives discussed today, and suddenly saw what COPE was about.

COPE has an important role in developing methods to teach people to behave appropriately and instil that culture of honesty and integrity into research.

"COPE is at an interesting point at its evolution, and we all said that as soon as the job is done, it would be disbanded. But today I felt there still is a need. I don't think we're alone, it's not just biomedicine, but other areas of research in the arts, humanities and physical sciences where there are problems.

Peter Lachmann gave a well thought out presentation, including a gentle attack on us as editors.

But I won't feel secure in the future of that initiative unless we keep pushing, and so I would ask all of you, to accept that we still have a job to do. And until I see this organisation working along the lines that we would like to see it working, I think we are still needed, and we have to continue to maintain the pressure.

There's no doubt that we've published material in the columns of prestigious journals that has deeply upset some of our senior peers, and we're a thorn in their flesh. But I don't think we would have got where we are today without that level of irritation.

You are vital to this organisation and vital to the principles on which we are currently operating. But one thing you might do is see whether there is anywhere you can publish the COPE eye. The more journals we have, the wider the movement will become. We already have 170 plus journals behind our principles, and that is a great achievement."



## 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 Mrs Rachel Fetches, Secretary, COPE, BMJ Publishing Group, Tavistock Square, London WC1H 9JR; email [cope@bmjgroup.com](mailto:cope@bmjgroup.com); telephone + 44 (0)20 7383 6057; fax + 44 (0) 7383 6249.
- (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).
- (12) Actions taken by editors following advice from COPE are taken at the editors’ own risk.

## Update on cases submitted to COPE

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

### Case 99/05

#### Ethical status of author’s actions?

A paper on benzodiazepine abuse and resale on the black market, involving urine samples requested from patients requiring a prescription, did not contain evidence of patient consent or ethics committee approval.

#### Outcome

The paperwork for the case was lost, stimulating the journal to adopt a different filing system.

### Case 99/10

#### A first report, not followed by a second

In 1984, Journal X published a brief report of a randomised trial as a letter. This trial was never fully published.

#### Outcome

The research team was invited to write to the journal, but as no response was forthcoming, the case was closed in November 2002.

*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
- 00/11 The wrong standard deviations, the overstringent selection criteria, and the overt attempt at advertising
- 00/15 Clinical misconduct (?), incidentally discovered
- 00/22 Duplicate submission of a paper
- 00/33 Alleged plagiarism—has been referred back to COPE for further advice.

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

**Case 00/10**

**The hazardous drug used in an unlicensed way**

An author gave two patients a drug that is only licensed for a small number of indications. Neither patient met these criteria. It was unclear if the doctor told them that the drug was being used in this way, nor was there any indication of informed consent.

**Outcome**

The author was contacted, but the reply was an automatic receipt. The editor did not write again.

**Case 00/11**

**The wrong standard deviations, the over-stringent selection criteria, and the overt attempt at advertising**

An independent reviewer did not believe that the over-stringent selection criteria could have explained the low standard deviations in this paper, and the language of the paper adopted the style of an advertisement.

**Outcome**

Unsatisfactory; no further action was taken.

**Case 00/19**

**The dubious scientist**

A scientist wrote to a medical journal offering an editorial that criticised current HIV vaccine research. The author was the senior partner of a technology company, whose website advertised a patented toxin, which would remove the need for conventional anti-retroviral drugs.

**Outcome**

The author, who is overseas, cannot be traced.

**Case 00/26**

**The undeclared competing interest**

A letter was published on the importance of doing research on a long established drug. The author did not advise the journal that he was conducting a trial of the drug, which had been funded by a pharmaceutical company.

**Outcome**

The editor published a paper in 2001 on competing interests, highlighting journal policies on the issue.

*2001 cases that remain open:*

- 01/02 The single authored, unbelievable, randomised controlled trial
- 01/06 Doubts over the exact nature of a drug being used in a study
- 01/12 Attempted redundant publication
- 01/20 Dubious surgery

*2001 cases that have been closed since the publication of last year's report*

**Case 01/01**

**The incomplete systematic review**

A systematic review on the effectiveness of a comparatively new group of drugs omitted a Cochrane review published some four months earlier and the reviewer questioned the role of the advisory group to the study.

**Outcome**

The journal's ethics committee investigated the case thoroughly and compiled a report, concluding that the paper was muddled but that the authors had committed no outright research misconduct. The editor sent the report to the authors and requested that a copy be sent to the advisory group.

**Case 01/04****The doctor with a very strange theory**

A doctor described a very peculiar theory, which led him to treat patients with a chronic disease with nothing but a foodstuff. Concerns were raised that the doctor might be putting patients at risk, and the national regulatory agency was duly notified.

**Further outcome**

The regulatory body has now asked their disciplinary board to investigate further. It transpires that the same disciplinary board had already reproached the author over a previous breach of moral and legal rules.

**Case 01/07****Dual submission due to discordant action of two authors**

A reviewer pointed out that a paper describing pathophysiological observations in patients with abdominal symptoms had been submitted to another journal. The editor checked if all the authors' signatures had been included in the covering letter.

**Outcome**

All the authors had signed the covering letter. No further action taken.

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

Two readers advised the editor of journal A that the female component of a cohort published in the journal was identical to that in a paper published in journal B earlier that year.

**Outcome**

A notice of duplication and reply from the authors were published in the August 2001 issue of Journal A.

**Case 01/23****Inadequately supervised research?**

The first author of a piece of qualitative research into the experiences of families facing a particular illness, was both the families' main carer as well as being the researcher. This research was undertaken as part of her PhD and it was felt it had therefore been inadequately supervised. The editor wrote to the supervisor with the objections raised and referred the case to the journal's ethics committee.

**Outcome**

All the authors denied there was a problem with the research. The supervisor expressed concern that (1) the editorial committee felt it had a remit to question the adequacy of the PhD supervision; (2) that by writing directly to the student they had placed her in a difficult situation; and (3) that the allegation of inadequacy extended to the supervisor(s), examiners, and host organisation.

The authors requested that the allegations of inadequate supervision be withdrawn and they offered to submit the full thesis for evaluation.

The journal's ethics committee felt that the editor did have the right to question the adequacy of PhD supervision but the editor retracted his statement questioning the conscientiousness of the supervisor. The paper was rejected.

**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.

**Outcome**

The author involved has apologised to all of the individuals involved.





## **Cases submitted to COPE**

July 2001 to July 2002

**Case 01/05**

## **No ethics committee approval or informed consent**

A study was submitted which required the active participation of nearly 500 patients from a local hospital. The paper made no mention of ethics committee approval or informed consent by the patients, and an enquiry revealed that the authors had not obtained these. The chief executive at the hospital was alerted. Have the editors done the right thing?

### **Discussion/Advice**

- If the data came from an audit/questionnaire/survey neither consent nor ethics committee approval would have been required.
- From the synopsis of this case, however, the patients did appear to have actively participated.
- The medical director of the hospital should also be informed.
- Inform the authors that the hospital's chief executive has been contacted.
- The ethics committee should be contacted to question the lack of patient confidentiality.
- The GMC should be contacted if hospital management does not take prompt action.

### **Outcome**

The medical director replied promptly. He had met with the author and made it clear that he should have obtained ethics committee approval for his study. This message has now been transmitted to all those engaged in research in the Trust.

The medical director explained that the problem had arisen because the study had been carried out by undergraduate students, for whom appropriate protocols relating to research modules were in the process of being formulated. He ended his letter: "I have taken the view that your letter has afforded the particular clinician the opportunity to learn rather than give Trust management an opportunity to be censorious or to adopt new processes that might run the risk of stifling innovation." The editor agreed and accepted this explanation.

## Case 01/26

## Possible plagiarism in a cross over, double blind placebo controlled study

A paper was received which described a double blind cross over study investigating the effect of a drug in pruritus as a result of chronic cholestasis. Both reviewers recommended rejection on the grounds that the information contained in the paper was not new. Both cited a study published four years earlier in a high impact factor journal which essentially dealt with the same question. One of the reviewers, however, felt that the two studies were “almost identical” raising the possibility of plagiarism.

The editor sent the manuscript and the two reviews to a third reviewer to arbitrate, and in particular, to examine whether concerns should be raised about the similarities of the two papers.

What should the editor do next?

### Discussion/Advice

- The third reviewer found no evidence of plagiarism, despite the similarities in both papers. The editor did not request the original data, and the committee acknowledged that the data could have been falsified.
- The presentation of the papers was similar, but drug companies often use the same format for reporting, so they would, in fact, look the same.
- The Cochrane Group finds it acceptable to use the methods section from one paper in another, but this must be acknowledged and cited in the paper.

### Outcome

No further action required.

## Case 01/27

## Query triplicate publication?

Fourteen days after publication in a journal an email was received from a reader indicating that two closely related papers had already been published recently, one in the same month as the current paper, and one five months previously. Close examination of the papers by the editor indicated that there was considerable overlap between these three papers.

The editor sent the three papers to an independent reviewer, specifically asking for an assessment of “triplication”.

What should the editor do next?

### Discussion/Advice

- The independent reviewer confirmed that there was 85–90% overlap.
- The editor wrote to the authors who agreed that the papers were identical but thought that it was such a good study that it deserved to be read widely. However, there had been no cross-referencing of the papers.

### Outcome

A notice of triplicate publication should be published in all three journals.

## Case 01/28

### Plagiarism in a case report

The whole discussion section of a submitted case report was almost identical to the discussion section of a previously reported, similar case written up by another group of authors in another journal. The only difference lay in the patient details. While the other paper had been referenced in the case report, the authors of this case report had not indicated that the whole discussion was identical to the previously published paper.

What should the editor do?

### Addendum

The editors wrote to the chief executive of the author's institution. He investigated the matter and agreed that each additional case concerning the same topic as that previously reported, had to be explained in a different way.

He agreed that the authors had clearly made a mistake and asked that the case report be withdrawn. He also stated that in future any similarities (such as the discussion provided in the case report) would be avoided by members of his institution when publishing scientific material.

### Discussion

- This case provoked a great deal of discussion, but it was concluded that the chief executive had conducted a thorough investigation.
- But what was not clear was whether the editors had asked the authors to explain themselves before alerting the chief executive, which COPE feels they should have done.
- There are different cultural understandings of how duplicated material is handled.

### Outcome

No further action required.

## Case 01/29

## Revised version different from original version submitted

A paper was submitted and reviewed by one referee, who recommended that the paper be revised and then refereed again. The authors submitted the revised version which went back to the initial reviewer. In his second report the reviewer raised concerns that the revised version was fundamentally different from the first paper. The number of patients and the inclusion criteria had changed.

This was put to the authors, who explained that the studies were of two different non-overlapping patient populations that they were investigating at the same time. They had intended to send only the second study in their original submission, but inadvertently submitted the first one by mistake. This was realised at the point of revisions, so they submitted the second study with an explanation in the covering letter.

What should the editors have done?

### Discussion/Advice

- The authors added that the error had been due to the wrong email attachment having been sent.
- The editors should have asked to have seen the original protocol for the study.

### Outcome

The first paper submitted was ignored and the second paper was peer reviewed and subsequently rejected.

## Case 01/30

## Ethical standards in animal research

An author received a manuscript describing the biological behaviour of an infectious agent in an animal model. The manuscript contained new information, but the experimental procedure involved interventions that would not be permitted by UK Home Office regulations.

What should the editor do?

### Discussion/Advice

- Use of material from old data could be permitted.
- The committee agreed that this was a difficult area because there is currently no international convention that applies to all countries.
- It was suggested that the article could be published with an editorial that could potentially stimulate further discussion (unless the details of the experiment were particularly gruesome).
- It was agreed that a debate on this subject was well overdue.

### Outcome

The details of the experiment were “particularly gruesome” which meant that the validity of the data as a model for human disease was questionable.

The editor intends publishing an editorial comment relating to submissions in general, possibly in the form of a review article on some aspect of good animal practice, with an accompanying editorial.

**Case 01/31**

## **Publication of dead patient's name at the request of the family**

An author requested advice about reporting unusual ocular manifestations of a patient who died from a fatal injury. The author sought the permission of the family to report the case, but they also requested that the patient's name be added to the report in her memory.

The author has proposed to add the following in the acknowledgement section:

"The authors are grateful to the family of forename/surname for their permission to publish this case report, and at their request, have named the deceased, in memoriam."

What does the committee think?

### **Discussion/Advice**

- If the deceased patient is identifiable, then there is a breach of confidence, and confidence survives death.
- The family cannot absolve this, but if it is in the public interest, then the name could be provided.
- The editor has to be satisfied that the dead patient would not have objected to any publicity, and that no other person(s) can be hurt or harmed by the publication of her name.
- If these criteria can be satisfied then a redrafted form of words could be published—for example: "The authors are grateful to the family of forename/surname for their cooperation in the publication of this case report, and at their request have identified her as the deceased, as a memorial to her."

## Case 01/32

## Anonymous case presentations (without patient consent) on a specialist society website

A specialist society wishes to post “case of the month” on the society website. The society is not proposing to obtain patient consent from all patients, but will anonymise the case reports instead.

It has been suggested a case might be anonymised by changing details including age, occupation, or gender. It has also suggested that there is often much to learn from patients who have died, from whom consent would not be possible.

Is this approach reasonable?

### Discussion/Advice

- To do this would be in breach of the UK General Medical Council guidelines. Rendering the patients anonymous is not enough.
- If a patient has died, permission is not required, but should be obtained from the next of kin as a courtesy.
- The facts regarding age, occupation and gender could not be altered.

### Outcome

The editor was advised that patient consent must be obtained, and that patient details must not be modified in an attempt to provide anonymity.

The specialist society will inform authors that they must obtain signed patient consent before cases can be published.

**Case 01/33**

## **Redundant publication and a question of authorship**

A paper was reviewed and subsequently published in December 1999. A further publication with an almost identical title, but with different authors, was published in another journal in 2000.

It is quite clear both papers relate to the same study, and apart from some minor differences in style, which were probably requested by the editorial offices, they seem to be identical.

The editor of the second journal received a letter from the corresponding author in August 2000 saying that the authors would like the paper withdrawn, on the grounds that “the same work has been published by my senior colleague in some other journal.” The editor wrote back saying that withdrawal was impossible as the journal was now in print.

As well as the problem of duplication there is clearly another question which the authors must answer: how is it that the same work can be attributed to two apparently different groups of research workers at the same institution?

What action should be taken?

### **Discussion/Advice**

- The head of department should be informed, and a notice of duplicate publication should be published in both journals.
- Before doing so, however, the authors should be asked for an explanation.
- Whatever their explanation, the head of department should still be informed.



## Case 01/34

## Allegation of reviewer malpractice

A member of the editorial board of Journal A was approached by an overseas colleague with a strange tale.

An epidemiological study had been conducted in the community around an industrial facility, funded by a group of plaintiffs' lawyers. The study concluded that health effects in the community were related to exposures emanating from the facility.

A paper based on the study was submitted to Journal A and rejected. It was also submitted in support of a lawsuit (relating to the same plaintiffs). As part of the "discovery" process, the author, who was an expert witness for the plaintiffs, disclosed that the paper had been rejected by Journal A and he had to submit to the court the reviewers' reports. The reports were seen by the overseas colleague.

One review was detailed and critical; the other was general and positive, and recommended publication. It emerged in court that the positive review came from an individual who was working on behalf of the plaintiffs as a paid expert and who "had had a relationship with the study author for more than 10 years."

The primary question from the overseas colleague is whether the reviewer was nominated by the author or was chosen quite independently by the Journal. Bias by the reviewer and collusion seems more likely if the reviewer was nominated by the author. Journal A encourages nomination of suitable reviewers, but only uses them sometimes, and always with another one chosen separately.

The editor of Journal A is seeking legal advice about revealing whether the reviewer was nominated by the author. The Journal is also going to introduce a specific requirement for reviewers to declare any possible competing interests. This would not necessarily prevent malpractice, but it does show reviewers this is an issue that is taken seriously.

This case is submitted as a reminder that reviewers can also misbehave and to seek guidance about any further action required.

## Addendum

The positive review by the reviewer suspected of misconduct was apparently presented during the court case in support of the scientific validity of the paper rejected by Journal A.

Legal advice to the editor of Journal A is that it is permissible to reveal that the reviewer in question was nominated by the author of the paper (as is the case) but without offering any comment on the case.

## Discussion/Advice

- This is a case for the record.
- It is a salutary reminder about requesting that both reviewers and authors declare competing interests.
- Authors can pressurise editors, but they should resist such pressure.
- When reviewer comments are sent to authors perhaps they should carry a disclaimer.

## Outcome

The Editor provided a signed declaration stating the journal's practice of asking authors to suggest reviewer(s) who may or may not be used for that purpose.

The Editor's declaration stated that the reviewer in question was nominated by the authors and that no competing interest was declared by either the authors or the reviewer.

**Case 01/35**

## **Randomised controlled trial without ethics committee approval**

A paper reported a randomised controlled trial relating to a common investigational procedure.

There are two different postural positions into which a patient may be put while the procedure is carried out, and individual operators may have a preference for one or the other, but both are in routine use.

The purpose of the randomised controlled trial was to find out whether the procedure is technically more successful in one or other of the patient positions, and whether there was any patient preference. It is a clinically relevant question, and the study produced an apparently useful and meaningful result.

The paper reported that the patients consented verbally to random assignment, but as the clinical reviewer pointed out, there was no mention of ethical approval. The authors were asked about this. They replied that they had not applied for ethics committee approval, having discussed this carefully among themselves, on the basis that the only variable in the study was the position adopted by the patient, and that both positions were part of standard and established practice.

The editors felt some sympathy with this argument, but suggested the authors ask the ethics committee whether they thought that approval had been required, and if so, whether they would consider giving it retrospectively.

The ethics committee chairman replied that the project certainly should have been submitted for ethics committee approval and that it was not possible to offer retrospective review or approval. He also added that had the committee considered it, they would probably not have been satisfied with simple verbal consent and would have required this in writing, with the patients being given 24 hours to consider whether they wanted to take part.

Should the editors now reject the paper, or should they consider accepting it with an explanatory commentary about the ethical issue?

### **Discussion/Advice**

- This had been an experiment, because the subjects had been randomly assigned. Ethics approval should therefore have been obtained.
- It was, however, an important study and should be published, but with an editorial commentary, highlighting that verbal consent alone is insufficient and that ethics committee approval should have been obtained, and perhaps including the opinion from an ethics committee chair.
- The danger was that patient groups might be outraged.
- The patients should be informed that the paper is to be published.

### **Outcome**

The ethics committee of the journal felt that what the authors had done was reasonable. But the paper was eventually rejected on scientific grounds.

Had acceptance been recommended, the journal's editorial advisory committee would have followed COPE's advice to publish the paper with an editorial commentary.

**Case 01/36****Plagiarism**

The reviewer of a paper contacted Journal A to point out that a significant proportion of a review paper, on occupational stress measures, was a near verbatim copy of a longer review in a journal of a different, though related, speciality.

The editor of journal A confirmed this was the case. Not only were the descriptions of the measures lifted from the previous publication, but also comments about their usefulness, etc. The previous publication was referenced, but only for a small point, and the reference in no way indicated the wholesale reproduction of sections of the paper.

The paper comes from a respected institution and the corresponding author is a highly regarded researcher. The first author, who presumably drafted the review, is on a research scholarship to the institution. It seems likely that the co-authors are unaware of the plagiarism by the first author.

The editor of Journal A wrote to the corresponding author to point out the apparent plagiarism and to ask for an explanation.

The corresponding author replied, apologising profusely for the error and saying that he would withdraw the paper for consideration while further investigations were made.

He explained that the whole group was considered at fault for not checking the paper more thoroughly.

The author, a graduate student from another country who had written most of the paper, may have found that the language barrier made summarising findings from other papers into his/her own words difficult.

There was probably no deliberate intent to copy chunks of the text without acknowledgement as indeed reference was made to the source.

If warranted, however, the corresponding author would take action regarding present and future submissions from this author. New procedures would also be put into place to prevent a recurrence of this unfortunate event.

Finally, the corresponding author felt that a positive aspect of this incident was that it demonstrated the high calibre of the reviewers, and thanked them for doing such an excellent job. The editor was also thanked for seeking the corresponding author's views on the matter.

**Discussion/Advice**

- Plagiarism can be “accidental.”
- All authors should be willing to take responsibility for the first author's writing.
- This case again demonstrates that all authors/contributors should take responsibility for the work.

**Outcome**

The editor accepted the author's reply as a satisfactory response and decided that no further action should be taken.

#### Case 01/37

### Stolen data and omission from the authorship list

An author wrote to the editor of a specialist journal, indicating that a paper had been published without appropriate recognition of himself as an author. In his letter he stated that he had contributed more than 50% of the cases reported. The first author had “not only stolen my data and published it without my consent, but also omitted my name.”

The editor has written to the authors of the paper asking for further information, but should any further action be taken?

#### Discussion/Advice

- Under the Vancouver guidelines, simply providing cases does not constitute authorship.
- The onus was on the journal to pursue this because the paper had now been published.
- The editor should contact the head of department, but if the institution is unwilling to look at it, then it should be left as an unresolved case.
- First of all, request an explanation from the authors.

#### Case 01/38

### Difficulty in obtaining patient consent

An article describing three similar cases was submitted to Journal A. The author was asked to provide evidence of the patients' consent for their details to be used in the paper. The author replied that all the patients' personal details in the report had been anonymised and that signed consent would destroy this. Also, two of the three patients had since died and correspondence could be distressing for the relatives.

The editor explained the importance of consent and that she would be happy to accept a signed letter from the author confirming that consent had been obtained for publication of all three cases.

The author had obtained permission from the living patient and also from the relatives of one of the patients who had recently died. The relatives of the other patient could not be traced. The patient's wife had also died and there were no children. The editors accepted this explanation and peer reviewed the article for possible publication.

#### Discussion/Advice

- Legally, permission is required from the living unless they are under 16 or incapacitated.
- Relatives have no place in giving permission on behalf of deceased patients.
- The explanation from the authors was, however, deemed acceptable as it was agreed that they had gone as far as possible and had acted courteously.

#### Outcome

No further action required.

**Case 01/39****Referee with a conflict of interest**

A paper was received by Journal A in August and sent to Dr X for comment. Dr X advised that the paper was not original in the light of a publication by his own research group earlier in the year in another journal, and that furthermore, this study contained over twice as many patients as the paper the journal had sent to him to referee. The journal decided to reject the paper on the strength of Dr X's report.

Two months later Dr X submitted a paper to Journal A on exactly the same research topic, based on a combination of patient data from several research centres, but giving a much larger sample size than either of the aforementioned papers. The journal decided to reject the paper, as it did not add enough to previously published research.

The journal editors thought that Dr X had a competing interest and that the authors of the paper submitted in August might have had cause for complaint had they known the referee was about to submit a related article to the same journal.

The journal requires referees to declare a financial conflict of interest and asks referees to consider declaring other competing interests, although this is voluntary. Dr X did not mention at the time he was refereeing for the journal that he was planning to submit a closely related competing article.

Should this be taken further?

**Discussion/Advice**

- The referee should have declared his/her conflict of interest and declined to referee the paper.
- The editor should reconsider the paper, informing the authors that the referee had behaved badly by not stating his/her competing interest.

**Case 02/01**

## **New surgical technique without evidence of either ethics committee approval or patient consent**

A study was submitted in which the authors describe a new surgical technique, which includes radio frequency coagulation, to treat complete prolapse of the rectum. They say in their paper that: “in the treatment of complete rectal prolapse, no operation stands out in comparison to the others.”

The authors do not seem to have received either ethics committee approval or consent from the patients. How should the editors proceed?

### **Discussion/Advice**

- The committee assumed that the editor had already queried whether or not the authors had ethical approval and consent.
- What constitutes research in a surgical case series is a very grey area.
- How “informed” would the patient consent be?
- If the editor has any remaining doubts then he should report the authors to the head of their institution.

### **Outcome**

The case was sent to the journal’s ethics committee as well as COPE, who disputed the authors’ suggestion that their country “did not have any ethical committee whose permission is needed to carry out any new procedure.”

The authors’ country had recently enacted research guidelines. The key issue would be whether surgical innovations would fall within the guidelines’ remit. The editor wrote to the authors including the new guidelines adopted in their country and invited a reply.

To date the editor has received no reply. It was unclear who the editor should approach as a higher authority, because the authors appeared to be working at their own organisation. The journal’s ethics committee suggested that if there is no local ethics committee, then the editor should consider writing to the relevant licensing body.

## Case 02/02

## Duplicate publication

Journal A received a letter from a reader claiming that a figure in a paper published in the journal had appeared in various guises in three other learned publications over the course of 12 years. The origin of the figure was disputed and the reader believed the original source was not the authors.

The authors of the paper in Journal A were asked to comment. They refuted the claim. The primary investigators of their institution were prepared to sign a response that stated the figures used in the authors' works were produced from original work conducted by them, and that they had documentation to support the clinical origins. They thought that any similarity between figures was a consequence of the subject matter under investigation. They requested the name of the reader in order to reserve the right to pursue legal action against him.

Although there were similarities between the figures, the editors of Journal A were unable to conclude with certainty that the original figure had been reproduced or modified for subsequent publication by the authors.

What should be done now?

## Discussion/Advice

- The figure in question is an autoradiogram, and the background material looks similar in all versions of it, but the position of the cell changes from version to version. It was impossible to ascertain whether the figures were the same or not.
- The authors should submit the original of the autoradiogram and highlight the areas used in the figure.
- If the editor felt he was still unable to judge whether the figures were the same or not, he should submit the data to two independent reviewers.
- The reader who asserts that the figure is his should be asked whether he wants his name to be released to the authors.

## Outcome

One of the other journals involved had already requested the original slide from which the figure had been prepared. The editors were not convinced that this was the original source of the published figure.

The editors sought the opinion of an external consultant, and consulted the publisher's lawyers. And on the basis that the evidence indicated that the figure was reproduced and modified from an article written by other authors, they requested the corresponding author to retract the paper.

If a letter of retraction was not received the journal indicated it would take steps to withdraw it. Journal A also asked the corresponding author whether s/he was willing to withdraw the article from Journal A.

The corresponding author was not prepared to do this, saying he would prefer to defend the case within a legal framework. The other journal arranged a visit to the author who published a similar figure 12 years earlier, in order to view any original material for the figure.

Journal A is awaiting the outcome of that visit.

**Case 02/03**

## **Duplicate submission to two journals and previous duplicate publication uncovered**

An identical paper was submitted simultaneously to two journals. Both editors had received a signed statement from the authors declaring that their paper had not been submitted elsewhere. Duplicate submission became evident only when the associate editor of one of the journals was sent the paper to review by the editor of the other journal.

The author also cited two papers within this submission, of which he was a co-author, which a PUBMED search revealed, were duplicate publications of each other.

The associate editor of one of the journals also suspected that another of the cited papers published in English was very similar to one published in German.

Both journals withdrew the paper from the review process, pending an explanation from the author for the attempt to secure dual publication.

The authors replied, apologising for the error, which had been due to “hurry and inattentiveness,” adding: “that the predicament is entirely due to circumstances beyond our intention.” They requested that the paper be withdrawn.

An explanation for the previous episode of duplicate submission was not given, although they said that they had sent a detailed letter to the editors of both journals, stating that it had not been their intention to secure dual publication.

Both editors agreed that the case could not be taken any further as the paper had now been withdrawn. It was suggested that the author’s head of department should be informed, but the head of department was one of the co-authors. The editor of one of the journals has decided to let matters lie and intends keeping a close eye on these authors in the future.

Should the matter be taken any further? A further concern is that the duplicate publications are still being cited.

### **Discussion/Advice**

- The dean or head of the institution should be informed.
- Although the author had offended on a previous occasion, he/she was continuing to attempt to secure dual publication.
- The editor had a duty to take the matter further, particularly as he was a member of COPE.
- The editor must tell the other editor what he intends to do.
- He should recommend that the institution not only look at the identified case but also alert it to the possibility that there may be others.

### **Outcome**

The editor has yet to contact the head of the institution (the web site is in German) and is trying to get a translator.



**Case 02/04****Plagiarism**

On review of a paper for Journal A, a referee recognised entire paragraphs of the manuscript from two published review articles that he himself had written. Both reviews were referenced in the manuscript with regard to particular topics, but the verbatim paragraphs were not attributed to the previously published reviews.

The editor rejected the paper and pointed out the apparent plagiarism to the authors. The corresponding author replied:

“...This review article was ‘written’ by Dr X, whom I have never met. He sent the article to Dr Z, who was on sabbatical in my institution. Because of my interest in the subject of the review, Dr Z asked if I would review the article, make some additional comments and act as corresponding author. At no point, did it cross my mind that some paragraphs copied verbatim were already present in it ...”

The corresponding author went on to say that he accepted full responsibility, would never again co-author an article with someone he didn’t know, and asked that his explanation be forwarded to the authors of the review articles with a further apology.

The editor has taken no further action, but wants to know whether the head of department, the ethics committee of the institution, or the scientific misconduct committee of the corresponding author should be informed.

**Discussion/Advice**

- The issue of authorship is a secondary problem in this case.
- The editor has an obligation to contact the head of the institution.
- It could be recommended to him/her that a document about the responsibilities of authors be circulated to employees of the institution.
- The original letter of submission should be checked to see if all of the authors had signed it.

**Case 02/05**

## **New commercial cure for a common but incurable problem**

A randomised controlled trial was submitted, showing that a new treatment, which is a combination of familiar compounds, is highly beneficial in a common but largely untreatable problem. The authors came from several different countries and included people from the company that manufactures the treatment.

The editors had great difficulty finding reviewers for the paper as many simply returned it, saying that they could not produce an opinion. The reviewer who did eventually do so said that the results were not credible and that all the signs suggested that the paper might be fraudulent.

The statistical adviser was asked for his opinion, and, although he agreed that the results were very unlikely, he was less convinced that there had been any data manipulation. He suggested that the editors request the raw data.

The editors were unsure what to do at this point. Their previous experience of asking for raw data was that it involved a highly complex and very expensive exercise. They wondered if instead they should simply alert the authors' employers—there are six different employers from four different countries—and ask them to investigate. The editors almost certainly did not want to publish the trial.

### **Discussion/Advice**

- The editor should write to the authors saying that a reviewer has expressed some concern about the data.
- Request the raw data from the authors, specifying that it should be in an electronic form.

### **Outcome**

The editors rejected the paper but also requested the raw data. The authors have submitted the raw data on CD and these are currently being analysed by a statistician.

## Case 02/06

## Late reinterpretation and a new author

Authors A, B, and C submitted a paper about the behaviour of a group of doctors. All the authors came from one institution, where the doctors' behaviour had been studied. Author A did the data collection under the supervision of author B, who was obviously responsible for the design of the study and acted as guarantor. Author C was an official at the institution.

The journal accepted it after revision, edited it, and sent out proofs. All the correspondence had been with author B. When the proofs arrived, author B (corresponding author) was on leave, and author C raised serious concerns about the paper and said it needed to be rewritten. It seemed to the journal that this was the first time that author C, who was the most senior, had properly looked at the paper, although author C subsequently denied this.

Author C submitted a revised paper a few weeks later. The general effect was to water down the negative aspects and to increase the positive aspects. In particular, author C said that the original version had misinterpreted one part of the results and that the new paper included a new interpretation. But there was no supporting evidence.

A new author had also appeared. Author D was listed as the corresponding author and guarantor of the paper. Author D's name had not appeared even in the acknowledgements of the first version.

The editor of the journal wrote to author C, asking for an explanation of the change of authorship. He raised the possibility of poor authorship practices. He asked for a written assurance from all the authors that they were happy about the revision, and he asked to see a copy of the questionnaire used and evidence for the new interpretation so that the journal could judge the changes for itself.

He also emphasised that, if the journal was satisfied with the changes and the answers on authorship, the journal still wanted to publish the article. The easiest thing for the authors would have been to withdraw the paper—but that would also best serve the desire of the institution to play down the findings.

Author C has written two holding replies, refuting the suggestion that there has been any authorial misconduct, and asserting that s/he was involved in the research. According to C, the authors are still debating the appropriate interpretation of the results of the study.

### Discussion/Advice

- The paper raises ethical issues, and it is to the credit of the institution that it studied this issue and has written it up.
- The authors should fully explain the disappearance of authors C and D's names from the author list.
- Concern was expressed that the authorship had changed and that the results had been reinterpreted.
- The paper contains important data that should be published and as the authors had all signed the copyright agreement the journal was within its rights to publish it without any further changes.
- The authors should be given a deadline to answer the questions raised above, and be advised that the editor would be contacting the head of the institution.
- The data should be published once the authorship issue has been resolved internally, but the institution should be made aware of the matter.

### Outcome

The editor reported that he had spoken with the original guarantor, author B, who had withdrawn from this position on the revised version.

Author B stated that s/he would withdraw as an author if the paper were to be published in the substantially revised form.

The editor sent the paper to the journal's ethics committee who had an extensive discussion about the paper. The editor sent the minutes of that discussion to the authors with an affirmation that the journal wished to publish the paper, providing the authorship issues were resolved.

The editor also requested a copy of the questionnaire, the interpretation of which the authors disputed and also gave the authors a deadline to answer all the questions raised. The editor also contacted author A, who was the most junior author to ensure that s/he was not being pressured into accepting the revised paper or suffering any detriment.

Author A met with the institution's vice-chancellor, who encouraged publication of the manuscript in its original form. The vice-chancellor felt that there was no need to bring in author D.

The editor is now waiting for author A to send in a final version of the paper and the questionnaire used.

**Case 02/07**

## **Consent from relatives for genetic tests**

A paper described a problem of two women who wanted their fetuses to be tested for a genetic condition, but where in both cases their partners had refused to give consent.

Should the journal publish such a paper without obtaining consent from the partners? The editors think not, but the authors are unconvinced.

### **Discussion/Advice**

- It would be impossible to completely anonymise the case even if mention was not made of the genetic condition.
- One solution might be for the case to be published in the form of a discussion and alluded to in an abstract sense, although the authors had indicated that they would prefer to leave the case reports in.
- Public interest can override confidentiality.

### **Outcome**

The journal published the article on the general subject, but with no information on the particular cases. The authors eventually agreed that it would be wrong to publish the case reports without consent from the partners.

## Case 02/08

## An unethical ethics committee?

A paper was submitted, detailing a double blind placebo controlled food challenge to a group of children.

The reviewer considered the study unethical because he was concerned consent could not have been properly informed. He believed there was a very small risk of anaphylaxis—even death—and had this been explained to the parents, they would not have consented.

The editor considered that the reviewer could well be right. The reviewer requested an independent investigation and stated that he would inform the General Medical Council about the study if the editor did not.

The independent investigator requested the ethics committee correspondence and patient information material. It transpired that the ethics committee, which was responsible for all three trusts, on submission, had recognised the potential danger and notified the lead author that it would obtain independent advice. It asked for clarification on nine points.

Six weeks later the lead author wrote to his colleagues that after discussion with the chairman of the ethics committee the latter had agreed the proposal was part of normal clinical practice rather than a clinical trial so did not require ethics committee approval. The study went ahead. Subsequent correspondence made it clear that the study had not been given an investigative reference number.

The information leaflet referred to the possibility of an allergic reaction and that a specialist registrar would be on hand at all times to deal with it. No reference was made to anaphylaxis or death.

Since the study, the responsible bodies for ethics committees, district health authorities, have been abolished. The editor telephoned the chief executive of the regional NHS office who thought he might be responsible for the committees but wasn't sure.

The editor wrote to the authors saying that the procedure was not normal clinical practice and that patients had been inadequately informed.

The editor wrote to the ethics committee chairman, expressing concern, and is awaiting a reply. The editor also wrote to two of the trust chief executives and the research and development director of the third, from whom he is awaiting responses. Curiously, the research and development director is a former editor of the journal in question.

### Discussion/Advice

- There was concern that the chairman had overruled his/her own committee.
- On receipt of the authors' response the editor should contact the chairman of the trust(s).
- He should also contact the Department of Health to inform them of the dereliction of duty of the chairman of the ethics committee and to find out what action should be taken and by whom.
- The editor must also keep the reviewers informed.

### Outcome

The editor has contacted the chief executives of the hospital trusts, detailing the allegations and requesting an investigation. The chief executive of the strategic health authority has also been contacted and asked to consider the position of the chairman of the ethics committee. The chief executives of the trusts involved and of the strategic health authority have replied, stating that they will investigate.

The chief executive of one strategic health authority has handed it to his medical director to deal with—a former editor of the journal.

# 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 arise when authors, reviewers, or editors have interests that are not fully apparent and that may influence their judgements on what is published.

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.
- (3) Editors should also consider disclosing to readers their own conflicts of interest and those of their teams, editorial boards, managers, and owners.
- (4) Sometimes conflicts of interest may be so extreme that publication will not be possible or people (for example, reviewers or editors) may have to be excluded from decisions on publication.

### 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.
- (8) Editors should ensure that the Instructions to Authors specify the need for authors to obtain informed consent from patients included in their research.

## 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

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

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

*Good clinical trial practice*, November 1995.

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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.