

**T**his past year has been a bumper year for research and publication misconduct. Woo Suk Hwang's faked stem cell research in South Korea has been the most prominent and perhaps the most damaging single case, but there have been several others reported in medical journals and the media, all contributing to the sense that science and scientific journals have not got their houses in order.

Two things at least are at stake: the public's trust in biomedical science and, since research feeds into patient care, the public's safety. What is COPE's role in all of this and what has it contributed in 2005?

COPE was established in 1997 as an ad hoc self help group for medical journal editors. Since then it has grown into a properly constituted international body of editors seeking to improve the integrity of biomedical publications. Its members meet six times a year to advise each other on how to handle anonymised cases that present ethical dilemmas for the editors involved. The cases and the committee's advice are posted on COPE's website, which has now become a fully searchable resource for anyone interested in publication ethics, with an extensive archive covering the whole gamut of issues from redundant publication, undeclared conflicts of interest, authorship disputes, plagiarism, and data fabrication.

From the start, COPE's emphasis has been on the misdemeanours of authors and peer reviewers. But editors behave badly too, or simply make mistakes. COPE's Code of Conduct for Editors, launched at the end of 2004, recognised the need to raise the standards of editorial behaviour by setting out broad principles of good conduct. These include:

- ▶ publishing corrections and apologies where necessary
- ▶ retracting fraudulent or erroneous articles
- ▶ publishing cogent criticisms from readers
- ▶ ensuring research articles conform to ethical guidelines
- ▶ keeping editorial and commercial decisions separate
- ▶ declaring their own and other people's conflicts of interest
- ▶ dealing properly with complaints, and, most onerous of all,
- ▶ making all reasonable efforts to ensure that allegations of misconduct are properly investigated

COPE's council thought it important to find out how close editors were to meeting these standards. Our survey of COPE members was not encouraging. Almost two thirds of respondents had no declared policies on pursuing research misconduct when it is suspected; six out of 10 had no declared complaints procedure; half had no published guidance for authors; and one in eight had no procedures for dealing with competing interests.

This confirms what most editors know all too well: that they often have few resources available to them and little in the way of back up. COPE's role is to empower editors to prioritise best practice in publication ethics as part of wider efforts to raise standards in biomedical science.

The code of conduct brings with it the offer to act as arbiter in complaints that journals are unable to resolve. This in turn made us realise the need for our own arbiter, an ombudsman, to resolve complaints against COPE, and Professor Richard Green,

honorary professor of psychiatry at Imperial College, London, and consultant psychiatrist at Charing Cross Hospital, London, has been appointed to this role.

COPE will continue to support and advise the growing number of journal editors who are joining as members. It will also continue to advocate good practice internationally in biomedical publication and to support research and education into issues relating to publication misconduct.

I hope you will find this report and the website useful. And if you are not already a member, I hope too that you will consider joining, and that you will let us know what else you think COPE should be doing to protect the integrity of biomedical publication.

Fiona Godlee

Editor, *BMJ*

Chair of COPE 2003-5



# THE COPE REPORT 2005

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**T**his report is based on the proceedings of the annual seminar held on March 11 2005, the seventh since COPE was founded in 1997. The meeting aimed to evaluate the robustness of the code of conduct for editors, and to share information on dealing with difficult cases of research misconduct.



## COPE CODE OF CONDUCT FOR EDITORS

### **Dr Fiona Godlee, editor of the *BMJ* and former chair of COPE**

COPE started life as a self help group in 1997, providing a focus for editors to share problems around difficult ethical cases. It also took on the role of a pressure group to force government to put research misconduct onto the national agenda, and in this it has been successful.

COPE published Guidelines on Good Publication Practice for editors and authors in 1999, after which it decided that editors should be able to regulate themselves, akin to the General Medical Council for doctors or the Press Complaints Commission for media editors.

### **Why was the code developed?**

Editorial misconduct tends to get ignored, with the focus on misconduct perpetrated by peer reviewers and authors. This may be because editors want to pretend that they don't commit such misdemeanours.

The code aims to:

- ▶ Set baseline standards for good editorial conduct
- ▶ Raise standards
- ▶ Stimulate debate
- ▶ Eventually move to a gold standard of behaviour

It is intended to be advisory and supportive rather than punitive. COPE has neither the mandate nor the resources to conduct elaborate investigations into editorial conduct (*BMJ* 2004;329: 1301-2)

The code urges editors to make "all reasonable effort to make sure that all allegations of misconduct are properly investigated." Instead of simply rejecting a suspect paper, editors now have a duty to pursue that allegation.

The code was agreed by the membership in November 2004, and took effect in January 2005.

### **Are editors equipped to comply with the code?**

COPE surveyed its members to obtain some information on what they currently do, and whether they already had mechanisms in place for complying with the code.

Of the 346 members of COPE, 118 journals responded, many of which were from BIOMed Central.

### **Key findings:**

- ▶ 17% had no published descriptions of peer review processes
- ▶ Over half had no declared appeals mechanism

- ▶ 9% had no letters columns, despite the importance of peer review after publication
- ▶ 9% had no mechanism for critical responses
- ▶ 16% had no policy for protecting the confidentiality of patients and obtaining informed consent to publish; in 10% the policy was unclear
- ▶ Half had no published guidance to authors
- ▶ 13% had no mechanism for handling conflict of interest
- ▶ 39% had no declared policies on advertising; 10% didn't know if they had such a policy
- ▶ 60% had no declared complaints procedure
- ▶ 28% had no mechanism for ensuring ethics committee approval had been obtained
- ▶ 64% had no declared policies on pursuing research misconduct

On this last point most respondents felt that despite the absence of a declared statement they had inbuilt mechanisms to prevent commercial decisions impacting on editorial decisions. Some didn't carry much advertising, so the picture may not be as bad as the figure suggests.

A declared complaints procedure is important for the COPE code, because complainants must have exhausted the journal's own complaints procedure first.

This could be a resource issue as much as not having thought about it, because 30% had no declared complaints procedure and 10% were unclear if they did.

Many responses indicated that membership of COPE was sufficient and therefore there was no need to have declared policies on pursuing misconduct.

### Issues for editors

- ▶ Inadequate resources
- ▶ Journals are too small
- ▶ They are not full time editors
- ▶ They don't have back up

But quite a few commented that that they wanted to raise their game and that the code provided a goal.

Areas for improvement include:

- ▶ Appeal mechanisms
- ▶ Guidance for authors
- ▶ Editorial/commercial separation
- ▶ Complaints procedures
- ▶ Pursuit of misconduct

Areas that were satisfactory:

- ▶ Description of peer review process
- ▶ Provision for corrections/apologies
- ▶ Policies for critical review
- ▶ Confidentiality
- ▶ Conflict of interest

The questionnaire is available online ([www.publicationethics.org.uk](http://www.publicationethics.org.uk)). It has also been submitted to the Peer Review Congress in Chicago (2005).

### Comments

- ▶ There were some concerns that the data might be skewed in view of the fact that 118 responses came from BIOMed Central and that the respondents were COPE "regulars."
- ▶ But Dr Godlee said that BIOMed journals had been counted as one.
- ▶ It was also suggested that conflict of interest should be unpicked because it fails to distinguish between conflicts of interest for staff, authors, and reviewers. These are all different and need to be handled differently.
- ▶ Dr Godlee said that the code will be reviewed in 18 months' time.
- ▶ One delegate wanted to know if there had been a difference in response between basic science and medical journals. Dr Godlee responded that there were currently few science journals in COPE, a deficit which should be addressed.

- ▶ Then treasurer Alex Williamson said that this issue had been debated long and hard when COPE was first set up. Inevitably, the journals tended to be at the clinical rather than the basic research end of the spectrum. Although the problems were different, it was difficult to have a code that covered the entire spectrum.



## DEALING WITH EDITOR MISCONDUCT

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### Small group discussions

#### Case 1: Adding references after final proof

When their paper is published, the authors of a study are surprised to see that changes have been made that were not in the final proof sent to them before publication. A comment has been added to the introduction, emphasising a view contrary to the article's premise, and two references have also been added, both of which are to review articles written by the editor of the journal. The authors complained to the editor.

In his response, the editor says that he did this because the article was insufficiently balanced. The references he added were to comprehensive reviews of the subject that were published recently in the journal of which he thought readers should be made aware. The journal in question belongs to COPE.

- ▶ Does this represent editorial misconduct?
- ▶ What should the editor have done?
- ▶ If you were the subcommittee invited to deal with this case in the light of the COPE code, what would you do (step by step) and what recommendations would you make?
- ▶ What problems, if any, do you foresee in implementing the code?
- ▶ What do you think the outcome will be for the author, editor, and for COPE?

#### Comments

- ▶ Editors may want to make substantial editing changes as part of acceptance, or suggest ways in which the manuscript can be improved, including additional references. But the way in which this has been done is wrong.
- ▶ The editor should have cleared the sentence and the references with the authors before acceptance, although how much an editor can influence authors before acceptance and how much authors could feel pressurised to accept the suggestions is a rather murky area.
- ▶ If the article is insufficiently balanced, a better process would be for the editor to have invited a commentary posing the opposite view. Why wasn't it brought up during the peer review process or at least independently of the editor?
- ▶ Could this be construed as massaging the impact factor as the review article has been written by the editor of the journal and published in the journal?
- ▶ The authors should go back to the journal, then the journal ombudsman, then to COPE. If the editor is found to be in breach of the code, COPE could ask for an explanation. If none was forthcoming – no apology published for example, the authors should go straight to owners/publishers of the journal.
- ▶ The code says that editors should be responsible for everything, but it neglects the responsibility of authors. If published in an author's name, the author is ultimately for what it says; the editor only monitors the process, and this case illustrates why the editor can't interfere with judgments made by the author.
- ▶ The responsibilities of authorship are outlined in the Guidelines on Good Publication Practice.
- ▶ Where would the author stand if the journal inserted a couple of sentences in the author's name that provoked litigation?
- ▶ It is important to publish a correction as well as an apology that would link back to the original paper. The authors could also decide to retract the paper.

#### Case 2: Changing decision after acceptance

An author whose paper had been accepted for publication by a journal receives a letter from the editor saying that the journal has too many papers to publish and that he is no longer able to publish it. The author complains, but the editor stands firm. The author refers the case to COPE.

- ▶ If the journal is a COPE member, what should COPE do?
- ▶ Conversely, if the journal is not a member, what should COPE do?

### Comments

- ▶ This represented a fundamental problem of misconduct. But it's possible that the editor may have discovered something else and used this as an excuse. But it is not acceptable behaviour.
- ▶ The guidelines refer to investigation of members of COPE. But COPE could still apply pressure to have the decision reversed.
- ▶ There could be good publishing reasons for not going ahead, for example, allegations that consent had not been obtained from all the authors, and the authors responding that the paper has already been accepted so they are not duty bound to do anything further.
- ▶ Could publication threaten the journal's financial future? This is unlikely: surely it should just be a matter of delay and increasing the journal's backlog?
- ▶ Journals should always have a conditional clause, whereby they stipulate that acceptance is subject to no other issues arising. In a recent COPE case a paper clearly duplicated something that had already been published. It was therefore rejected at a late stage. It had been accepted subject to compliance with peer review changes.
- ▶ Journals' commitment to authors should always be phrased in such a way so as not to represent a binding contract.
- ▶ The implication in this case, however, is that there is no other reason for turning down a perfectly good paper, other than space or money.
- ▶ Papers can be withdrawn after acceptance, if, for example, the same paper has been published elsewhere, or an editorial board member has uncovered fraud, because the author has then broken the agreement between him/herself and the editor.

### Case 3: Publication bias

An editor receives complaints from readers that the journal is biased in the papers it publishes relating to a specific issue. It has published only those reflecting one point of view. One author has written 14 review articles over the past five years, the most recent of which makes the same points as the previous one, and cites mainly work from that author and the editor of the journal. A reader refers the case to COPE. The journal is a member of COPE.

- ▶ What should COPE do?

### Comments

- ▶ This is not a case of editor misconduct. The readers may well have a legitimate complaint, but they should write a letter to the editor or the editorial board, but the editor has not done anything wrong.
- ▶ If the editor does not have a letters column, the readers should write to another journal, or still write to the board.
- ▶ The code deliberately tries to steer clear of decisions about content, because that's the responsibility of editors.
- ▶ Let the reader decide. If it's such a biased journal, people will stop buying/subscribing to it.

### Case 4: Massaging the impact factor

An editor of a new journal wants to boost the impact factor, and discovers that one technique being used elsewhere is to ask authors to include references to papers already published in that journal. The editor in chief questions this approach, but the editor is adamant that his competitors are doing it, so he should be allowed to do it too, if the journal is not to be unfairly disadvantaged. The editor in chief refers the case to COPE.

- ▶ What do you think of the editor's approach?
- ▶ What issues does this case raise?
- ▶ What should COPE do?

### Comments

- ▶ Would we feel same way if the editor had asked the author to strip out references to another journal? The process was dishonest, and the paper would be skewed by adding references so scientific content. The reader suffers.

- ▶ COPE should write to ISI and request that self referential citations should be discounted, and the editor in chief should recommend that this practice be stopped.
- ▶ Is it inappropriate to bring to authors' attention, relevant references that have been published in that journal? Because they happen to be in that journal does not undermine their validity, and it could be laziness on the author's part.
- ▶ There is a difference between that and demanding that publication is dependent on including at least 25% of references from that same journal. But many editors would not have the time to trawl through MedLine, looking for other valid references.
- ▶ Would the addition of these references necessarily skew the article? Conversely, editors can't monitor everything the author decides to include.
- ▶ It is unethical to selectively point authors to references in one journal if there are equally good references in others, but editors do tend to be more familiar with their own journals.
- ▶ The integrity of the journal and the quality of the material should be the decisive factors, not where a reference is published.
- ▶ A peer reviewer who is expert in the field should be able to advise the author on the relevant research, and not just what has been published in the journal.
- ▶ Peer reviewers should be required to look at the references and suggest ones that might have been missed; it is their job, not that of the editor.
- ▶ What happens if the peer reviewer recommends acceptance, providing the authors cite two papers that have been written by the peer reviewer? And if the authors refused, would the article be rejected?
- ▶ This would constitute a deliberate attempt to massage the impact factor, and is a clear case of unethical behaviour.
- ▶ Citing a paper is not an editorial question; it's a scientific question. If there are no scientific reasons, it should not be cited, irrespective of where it has been published. Rogue citations are a problem. Steering citations partly depends on the country in which the reviewer or editor live, so it's important to prevent that bias and give examples of publications that authors have missed.
- ▶ Should editors take responsibility for ensuring balanced citation? Citation is biased anyway, but editors should do all they can to prevent it. Requesting a reference should only be done after checking PubMed for something better first. On smaller journals, editors tend to act as surrogate peer reviewers, so blurring the roles.
- ▶ Courting publicity through electronic tables of contents and press releases increases the visibility of the journal, which could be construed as massaging the impact factor. An editor might feel the need to do this because the journal is not issuing press releases and if it can't compete, will struggle in terms of revenue/supplements, etc. That could have major consequences for a small journal.



## NEW UK PANEL FOR RESEARCH INTEGRITY

**John Pritchard, senior planning and policy advisor at Sheffield Hallam University on secondment to Universities UK**

The health committee of Universities UK was involved in the early thinking on the establishment of a UK panel for health and biomedical research integrity.

### Background to the proposals

In many respects the UK is out of line with many other countries in continental Europe and the USA, which have had national bodies for some time.

At the joint consensus conference at the Royal College of Physicians of Edinburgh in October 1999, general agreement was reached on:

- ▶ Developing/promoting models of good practice for local implementation
- ▶ Providing assistance for the investigation of allegations of research misconduct
- ▶ Collecting, collating, and publishing information on instances of research misconduct

For various reasons, this agreement failed to materialise, and it was not until January 2004 that Universities UK took on this initiative, in recognition of its role as the employers' body for one of the largest sectors where instances occur.



Project approval was granted through to September 2004. Professor Michael Farthing was appointed to lead the project on account of his expertise in the field and as former chair of COPE.

One of the first tasks was to survey the membership to look at the nature and prevalence of research misconduct.

Seventy per cent of the membership (86 members) responded, 40% of whom reported instances of research misconduct within the previous five years.

And 44% of them reported allegations in the area of health and biomedical sciences.

This confirmed this initial thinking that this was the area of greatest need. There has been some debate in UUK as to whether the areas should be broader, but we need to start with the area of greatest need first, expanding to others if we can clearly demonstrate the usefulness of such a move.

Of the 66 allegations reported, a prima facie case was established after a stage I investigation in 35 cases, and in 19 cases, the allegations were upheld in full.

Contact was made with the Department of Health at an early stage. It was clear that they had been thinking along similar lines. In July 2004, the Chair of the Health Committee, Janet Finch, and the chief executive of UUK met with the then health ministers, John Hutton and Alan Johnson, who indicated support for the project.

### **Key functions of the panel**

The health committee was clear that it was important to build in good practice and prevention rather than just set up a body advising people what to do when things go wrong.

It was decided that the panel should additionally have a:

- ▶ Guidance function, offering a programme of advice and support to staff and employers in the NHS and university sectors
- ▶ Programme of training and staff development
- ▶ Public information agenda, including records management
- ▶ Whistle-blowing role

### **Good practice**

The main purpose of the agency will be to promote models for good practice, governance, management and general conduct of general health and biomedical research.

Clearly, as part of prevention, the agency should encourage institutions to think about what they might do to avoid problems arising and to have general standards that are clearly understood. This will be much more effective than mopping up mistakes.

An early priority will be to draw up a set of national guidelines. The agency will aim to draw together all the best elements of the wide range of policies, frameworks, and codes of conduct currently in use into a single set of national guidelines that would command respect, and be widely understood and applied across the NHS and university sectors.

This will be a significant challenge and is likely to take up the first year's work of the panel. We need to take care not to cut across what other people are doing, and ensure that the guidance will be integrated and user friendly.

The guidelines will not be mandatory, but we would expect their usefulness to encourage employers to take them on board and want to be seen to be doing so. This would ensure greater consistency across both the university and NHS sectors, and at the interface of other sectors.

### **Advice**

The panel will have an important role in offering advice, and the guidelines will provide a framework. But specifics may not be covered, so organisations will need access to expert advice, should they need it.



It's important to strike the right balance. The advisory role recognises that the primary responsibility rests with employers to take action, so that must not be undermined.

We will establish a panel of expert advisors. These will be people who can respond and advise on specific queries, in relation to the guidelines or other areas.

They should be available to join a local enquiry panel, but only at the employer's request.

The nomination of the advisors will be open, so that people are not appointed on the basis of established networks, but for their practical expertise.

### **Training and staff development**

There will be a UK wide programme of road shows and staff development days on site to raise awareness of essential elements of research integrity as well as providing practical advice on employment law and the workings of enquiry panels.

### **Public information and records management**

The agency will provide useful information to a whole range of stakeholders, which will be available to researchers, employers, government bodies, sponsors and the general public on its website and through the publication of an annual report.

Records management will be managed carefully and sensitively.

### **Whistleblowing role**

There are benefits to having a recognised third party, which could act as a clearing house for employers. But this will be an impartial, advisory role. The agency will not take on responsibility for investigating whistle-blowing allegations, but will pass the query onto employer, with a request for them to investigate. The intention is that this will have a catalytic effect and lead to early resolution of cases.

But the agency will clarify its legal liabilities before taking this further.

### **Governance**

The agency will initially run for three years, after which its value and effectiveness will be assessed before possible renewal.

The project board will have equal representation from the University and NHS sectors, as well as other stakeholders. The board chair will be an independent appointment. The position is likely to be filled by someone who is not affiliated to either sector, and probably with a legal background.

There will be a small team, with two main posts of a project director and a project officer. These will be open appointments.

Universities UK is the preferred operational base, using existing facilities and resources.

### **Funding**

An application for funding will be made to the Department of Health and The Higher Education Funding Council of England, who are regarded as the primary sponsors. The Association of the British Pharmaceutical Industry has also indicated some interest in becoming a subsidiary sponsor. But funding in the long term will need to be considered.

### **Stakeholder consultation**

Informal contact has been made with a range of bodies, who were formally invited to a meeting in January 2005.

There was widespread endorsement for the establishment of a panel. No one disagreed with the stated aims and objectives, but there was some concern that the primary responsibilities of the employer should not be compromised.

### **Next steps**

If the project plan is approved in April, this will provide the basis for a funding application, and the process for nominations to the project board and register of advisers will be considered.

Throughout May and July detailed operational planning will get under way, to include the legal footing and human resource issues, practicalities and logistics. Another meeting of the stakeholders and possibly the shadow advisory board will be held.

October is the target date for the establishment of the panel.

### Comments

- ▶ Dr Godlee welcomed the plans. Everyone was very glad to see it becoming a reality at last after so much effort had been made, she said.
- ▶ Peter Wilmschurst asked whether the 19 cases of fraud had resulted in anyone being dismissed or their research retracted. Five years on, the University of London had not retracted the master of surgery qualification awarded to Banerjee, which was falsified, despite repeated requests.
- ▶ He also queried the composition of the stakeholders, who, he said, comprised those who have a stake in maintaining a low profile on such matters and keeping research fraud under cover. The panel's stakeholders should be those interested in dealing with fraud, not those whose record is about consistently covering it up.
- ▶ John Pritchard explained that the survey had merely intended to gauge the level of activity. But he acknowledged that the point about public representation had been made by other respondents, and that it would be considered carefully and seriously.
- ▶ Jeremy Theobald wanted further explanation about the openness of the records. If these involve cases of research misconduct, will the names of the accused and the investigators be available to the public, or will everything be anonymised as in COPE?
- ▶ John Pritchard explained that there was an essential tension between the need to protect the confidentiality of whistle blowers, for example, and the need for transparency. How exactly this would be resolved had not yet been decided.
- ▶ Fiona Godlee wanted to know if the agency had been modelled on a body already in existence, to which John Pritchard responded that it was broadly in line with the Scandinavian and US models.
- ▶ Iona Heath questioned how sponsorship from the ABPI squared with public confidence in the independence of the new body? The Health Select Committee had recently pronounced on the pharmaceutical industry, so perhaps this was not the right time to be cozying up to it.
- ▶ John Pritchard explained that it would be advantageous to involve the ABPI as they clearly are a stakeholder and have an influential role. It could be a missed opportunity to exclude them.
- ▶ Iona Heath responded that engaging in the process and accepting substantial funding were two completely separate issues.
- ▶ John Heath said that although there was a clear body of activity in biomedicine, the same issues applied to a wide range of health related disciplines.
- ▶ All the stakeholders were medical: had toxicology and epidemiology been considered?
- ▶ Jeremy Theobald pointed out that there were already guidelines for good laboratory and clinical practice for toxicology in the commercial sector, which were subject to quality assurance audit.
- ▶ The panel of experts would be drawn from among the stakeholders. An invitation would be sent to NHS Trusts and vice chancellors of universities, explained John Pritchard.



## THE ETHICS OF AUDIT AND RESEARCH

### Iona Heath, London GP and member of the BMJ Ethics Committee

JK Galbraith wrote in *The Good Society: the Humane Agenda* (1996) "A comfortable and disciplined culture resting often on past success takes the place of innovation and change."

Research ethics committees have made a huge contribution to academic work, but there are issues around the ossification of process, how innovation and change can be accommodated, and about the perverse incentives that any bureaucratic system imposes on everyone who interacts with it.

In a recent paper in the *BMJ* (2005;330: 468-73), Derek Wade contended that both research and audit start with a question, and expect the answer to that question to change or influence clinical practice. They require formal data collection of patients, and depend on using an appropriate method of design to reach sound conclusions.

Research requires ethical committee approval; audit does not. This implies that there is clear water between the two and that it is very easy to distinguish one from the other.

But, increasingly, research is being presented as audit to avoid the need for ethics committee approval. And some audits clearly have ethical implications, so why should they be immune from ethical scrutiny?

### **Essential components of every clinical encounter**

According to Derek Wade, every clinical encounter has three components:

- ▶ The epistemic: the situation is analysed and potential actions identified
- ▶ The pragmatic: you work out what potential actions are possible
- ▶ The ethical: this identifies which of the many potential actions are morally acceptable or preferred, in other words which are most compatible with the values of society, the patient, and the clinical team

It's where those values come into conflict that provokes ethical debate and ethical scrutiny.

All clinical practice should be undertaken ethically, and that includes both research and audit. The task for society is to work out where formal ethical scrutiny should be focused where it is most needed. Derek's contention is not served by saying that only research merits formal ethical approval and everything else is exempt.

### **Levels of scrutiny**

Every investigation should be scrutinised to some extent in respect of the degree of change in local clinical practice associated with the study, particularly the:

- ▶ additional burden imposed on the patient and others by the study
- ▶ additional risk imposed on the patient directly from the procedure or indirectly from any additional data
- ▶ likelihood of direct patient benefit
- ▶ likelihood of the benefit to society, either directly from the knowledge obtained or indirectly from teaching research, stimulating better studies, contributing data to (later) meta-analysis

Current UK and international practice needs urgently to encourage some focused review of the degree of ethical problem implied within the study.

Proportionality is key. If the burdens and risks are very small, they should not be treated in the same way as an audit where these are much larger. Proportionality should also apply to consent.

Proportionality is one of the platforms of the whole Data Protection Act. But it does not seem to affect our handling of ethical problems in research.

JK Galbraith wrote: "There is no escape into ideology from thought; all depends on the specific case within the larger context." There is obviously a major continuing role for formal ethical scrutiny.

But the researchers also have a responsibility to think about the ethical implications of what they are doing, beyond just filling out the form. And the same applies to editors. It's not just a matter of ticking the boxes.

A commentary in the *BMJ* from Shirley Nurock, the London Regional Coordinator for the Alzheimer's Society Quality Research in Dementia Consumer Network and a carer of her husband, pointed out the difference in the estimation of acceptable risk between ethics committees and patients. (*BMJ* 2005; 330: 471-2)

She argued that committees may overestimate risk and underestimate patient altruism in wishing to make a contribution and find some good in the desperation of their own

situation. And she also suggested that all the focus is on the ethics of research when there is no evidence of anyone having any ethical concerns about the low standards of care in care homes, for example. Society is focusing ethical issues on politically safe areas rather than unsafe ones.

We have too many guidelines. Every GP registrar now has to do a project on some form of audit for their summative assessment. What sort of ethical scrutiny do we need for that? And what about patient satisfaction surveys? Where do you draw the line? We have hierarchies with arbitrary boundaries: there's ethical scrutiny for research, less for audit, even less for medical practice, and none for standards of social care.

Are we using ethics as a problem solving tool or just looking for a simple list of answers? Another commentary from John McMillan and Mark Sheehan suggests that ethical review might itself be accused of encouraging a bureaucratic approach to ethics. It might not be the best way to ensure that people are moral, especially given that Derek Wade suggests that ethics is concerned with the moral character of individuals as shown by their actions.

JK Galbraith states in his 1996 book, *The Good Society: the Humane Agenda*: "In the modern economic and political system ideological identification represents an escape from unwelcome thought—the substitution of broad and banal formula for specific decision in the particular case."

Ethics must be about resisting the escape from unwelcome thought.

## Comments

### Definitions

- ▶ Audit looks to see whether clinicians and practitioners have applied what research has found. For example, a patient needs to be operated on within 24 hours of fracturing the neck of the femur: an audit would want to know if that clinician had done it. But a research question might ask: does it make any difference if the patient is operated on within 24 hours?
- ▶ They both use research methodologies to acquire their information. Audit is about standards of practice and whether these are being applied; research is about creating new knowledge and understanding.
- ▶ Put another way: audit is about the application of existing knowledge; research is about the creation of new knowledge.
- ▶ Audit is not always about standards, but often about finding out what's happening. In practice, the definition of audit is much broader than the rather pure unrealistic definition that is frequently used.
- ▶ An example was cited in which patients were sent a survey to complete that had not been subject to any kind of scrutiny before despatch, because it was for the purposes of audit. It caused a great deal of distress to recipients.
- ▶ In Australia, the term quality assurance is used. This includes 10 different processes, such as process mapping. Even health service research can be applied in a quality assurance manner.
- ▶ There are some tricky issues for audit, including when one group of people collect data, and use it to comment on the standards of care of another group. When the data are shared, who owns the data, and where do they go?
- ▶ Ethics committees and COPE provide a consensus on which standards to apply. The editors' code provides an industry standard of what is reasonable behaviour to expect.
- ▶ We all do have to apply standards and we all do have to apply a code of practice to individual circumstances, but the consensus judgements are a valuable basis to work from.

### A separate code of practice for audit?

- ▶ Some research has very few ethical implications, so there is no need for a blanket rule. But it's not just a question of having a different code for audit, because some audit has huge ethical implications and should be subject to some form of scrutiny. The accretion of too many codes threatens to paralyse.
- ▶ Ethics committees are there to make those very decisions, which invalidates the application of a blanket rule or ideology. But the proliferation of codes of practice

speaks to the increasing prevalence of litigation and that is what is eroding individual responsibility.

- ▶ That doesn't make it the right thing to do; it's defensive practice.
- ▶ In the UK and continental Europe, we are going down the same route as the US in terms of litigation.

### What should be left out of ethical scrutiny?

11

- ▶ The definition of clinical science is much broader than it was 20 or 30 years ago, and much of what we do now is about patients and how to treat them. It has to be scrutinised by an ethical body. This includes audits and anything else used to measure something that is important for patients. If we include this, should we then extend it to animal research? Are protocols for patients really applicable in those circumstances?
- ▶ It's impractical to broaden it out like this. The ethics of causing harm to patients are at the sharp end, and it's people who will sue.
- ▶ How do you define harm to the patients? Banked samples may cause harm, for example.
- ▶ If animal experimentation is falsified it can have knock on effects for patients, and equally, the person who commits fraud in animal experiments could do the same in human experiments.
- ▶ Meta analysis might be regarded as audit by some of these definitions. There's a triage system, which prevents some of the audit questions coming to ethics committees. And that's part of the problem.
- ▶ Research ethics committees are set up to look at research ethics, so when they receive a proposal that is audit, they decide whether it's audit or research. People in the research arena believe that the ethics of audit should be looked at, but there is no mechanism for that. What about quality assurance? Do clinical ethics committees, which quite a few trusts have, or university ethics committees provide it?
- ▶ The enormously long form, which goes to ethics committees, does not highlight these issues. Perhaps the answer is to specialise, so that particular ethics committees look at particular questions, irrespective of whether it's research or audit. The distinction would then be made on the issues, not whether it's defined as research or audit.

### What's the responsibility of the editor?

- ▶ How far should editors be responsible for ensuring that ethical approval has been granted?
- ▶ In the summative assessment work, there's now an expectation that the authors of GP registrar audits will discuss the ethical implications against those sorts of headings. Authors must therefore prove that they have considered the ethical implications, even if they have not filled out a form. That ought to be much more common practice. That would also increase the ethical literacy of the research community if there were an expectation to do that rather than just fill out the form.
- ▶ Derek Wade has now produced a checklist based on his article, so editors can look beyond formal ethical approval to make sure that they have thought it through as well.
- ▶ There are issues in respect of submissions from international authors, where ethical standards may be different.

### Should unethical research ever be published?

- ▶ Suppose a research paper submitted was clearly unethical, such that the editor felt that s/he would have to report the individual to the appropriate body and not publish the paper, yet the answer provided by that piece of research was fundamentally important?
- ▶ It might be an unethical experiment, but it came up with a cure for AIDS? Should it still be published, because not to do so would have enormous implications?
- ▶ It's a balance of two incompatible positions. But a line has to be drawn in the sand. These are criminally collected data, and presumably there would be ways of repeating the research in an ethical way.
- ▶ There may be ways of repeating it, but the knowledge may not be there. Someone might have effectively killed a dozen people for the research, but has the potential to save millions of lives throughout Africa?

- ▶ What if someone has done something experimental in surgical practice, as a result of which there is a subtle shift in practice. What about the ethical oversight of that?
- ▶ How can we avoid paralysis of innovation? Can we still learn, change, and innovate while at the same time protecting people from abuse and harm? Both are equally important, and need to be held in the balance.

### Cultural differences in the definition of ethical research

- ▶ How can we apply our ethical moral framework to most submissions from overseas? Whose standards should we apply?
- ▶ Our journal asks for evidence of ethics approval in the relevant country. One author in an Asian country queried the importance on the grounds that the research involved “just samples from patients.” There are huge cultural difference between Europe and North America and the rest of the world.
- ▶ What is the proof of ethics committee approval? They don’t come with watermarks. It’s tough for small journals with few resources.
- ▶ We have recently started to ask people for the reference number. We don’t check it, but authors put themselves in a very awkward position if they make that up. The ethical committees are working from the Helsinki Declaration, which is a WHO document.
- ▶ Different people take different views on this. A senior lecturer at a British university was reported to the GMC for falsifying ethics committee approval forms, but the GMC only reprimanded him.
- ▶ We ask authors to state in the paper that they have ethical approval, but we don’t ask for evidence.
- ▶ It’s a system based on trust. Small journals can’t go around enforcing every part of the instructions for authors. In the same way as journals have competing interests sections, perhaps we could include an ethics approval section, stipulating the committee, the serial number, etc.

### COMMON ETHICAL AND EDITORIAL DILEMMAS OF AUTHOR MISCONDUCT: HOW SHOULD WE RESPOND?

**Sabine Kleinert, executive editor *The Lancet***

A summary of cases presented to COPE over 6.5 years up to September 2004 won’t necessarily provide solutions, but will help to raise issues and pose the questions that need to be asked in these areas.

Year	No of cases	“Evidence of misconduct”	“Probably no misconduct”	Not applicable
▶ 1997	16	11	0	5
▶ 1998	33	30	2	1
▶ 1999	27	20	3	4
▶ 2000	32	26	6	0
▶ 2001	39	30	9	0
▶ 2002	18	14	4	0
▶ 2003	22	15	5	2
▶ 2004	25*	17	7	1
▶ Total	212	163	36	13

In most of the 212 cases ( $n = 163$ ), there is evidence of misconduct; in 36 cases, there is probably none.

### Common causes of research misconduct

Two thirds of the cases relate to submitted papers rather than published papers. This is encouraging, because it means that taking action can avoid unethical publication.

### Redundant publication

Redundant publication means either salami publishing or significant overlap of data. But the crucial issue is transparency. If the authors explain in their covering letter that



▶ Duplicate/redundant/salami publication	58
▶ Authorship issues before or after publication	26
▶ No ethics approval	25
▶ No or inadequate or informed consent	22
▶ Falsification or fabrication	19
▶ Plagiarism	17
▶ Unethical research or clinical malpractice	15
▶ Conflict of interest	8
▶ Reviewer misconduct	6
▶ Editor misconduct	3
▶ Miscellaneous	39

the primary outcome has already been published elsewhere, and that this is the secondary outcome, then it's up to the editor to decide if s/he wants to publish.

But in many cases editors are not told, and find out only when the reviewer picks it up, or worse, when someone writes in after the article has been published.

Is overlap worse than salami publishing? How much overlap is too much? Those are questions for reviewers to tackle.

Is it ever legitimate—for example, if it's targeted at a different readership? If two different outcomes are being reported, the clinician has to know the whole picture. It then becomes a matter of transparency: readers can then judge for themselves if it's justified to have two papers on different outcomes or a follow up paper on a main results paper.

Is it acceptable to report mortality data in one paper and disability data in another? That's a matter of clinical judgement. But there are studies where hard outcome data are important for a general readership, but some sort of sub-study on markers would be more relevant to a specialised readership.

Does it matter? It does if there is a great deal of overlap, because systematic reviews will suddenly count double the number of patients.

An interesting viewpoint was published recently in the *BMJ*, suggesting that duplicate submissions encouraged competition among editors to reduce time to publication (*BMJ* 2005;330: 305-7).

Duplicate publication/submission is often revealed by reviewers, who happen to have seen it elsewhere or reviewed it for another journal.

Can it be incidental? It's very rare. When it is uncovered by the reviewer or the editor, and only then does the author respond, that is suspicious in and of itself. It should be the author openly declaring it if there has been a genuine mistake.

What about duplicate publication in other languages? It happens, and is acceptable if the article is cross referenced and the original journal grants copyright.

Is it enough to withdraw the paper with the authors' agreement, when the editor finds out? No. Arguably, no harm has been done, but clearly it's a case of authorial malpractice. The authors might have done it before, so the institution should be informed. If it's published, both journals will have to publish a notice of duplicate publication.

### Authorship issues

These are very difficult to deal with. If an author has already submitted it elsewhere, it should not be submitted to another journal until a definitive accept or reject decision has been made.

What happens when an article is published in a main journal but then published again in a supplement? An example is an article published in the *American Journal of Cardiology*, which was then published again in a supplement, paid for by the sponsoring company. Only the title was changed and readers were not alerted to its prior publication.

That's clearly wrong. But transparency is key: if that second publication had acknowledged the first, it would have been acceptable.



There is some evidence to suggest that authors repeat this offence.

Sometimes the whistle is blown on duplicate publication in a letter to the editor, and sometimes by someone with a vested interest. It could be malicious and may be untrue. The editor would always have to investigate to find out.

When and how should editors get involved in author issues before publication? Authors may declare what their role has been, but ultimately it's the authors who have to agree who is an author and who isn't. And it's their responsibility. If they can't agree, they have to seek the help of their institution.

If an author has been deliberately or inadvertently missed off the list, the record must be corrected. This is an obligation in health publications.

The issue of ghost authors is a thorny one. "Vanishing authors" are often medical writers or the drug company, and they don't appear on the paper. Gift authorship is also a well known issue.

There are huge cultural issues, and in some countries it's accepted practice that the head of a department has to be on every paper, regardless of whether they merit it.

There may be disagreement about data interpretation, and we have had to publish two different discussions on a paper, because the authors could not agree as to how these data should be interpreted.

### **Unethical research**

There is a grey area. Is a new surgical technique research or slightly changed practice? What is audit? What is normal practice, and is ethics approval needed for it? Authors claim not, but what is presented sometimes does not appear to be normal practice.

Does no ethical approval automatically mean that the study is unethical? No it does not, in the same way that ethics approval does not automatically mean that a study is ethical. Editors have a duty to judge papers for themselves. Some journals do request evidence of ethics approval.

### **Informed consent**

Is the consent truly informed? The authors often say that written informed consent has been obtained, but have the patients really been told about the risks? If that question arises, a very low threshold of suspicion is warranted, and a copy or a translated version of the consent form should be requested.

This can be done even after acceptance, if there is any doubt at all. We have done this, after seeing a consent form, which was not what we would truly regard as a consent form.

### **Clinical malpractice**

When malpractice is suspected, who should editors contact?

- ▶ Always challenge the authors first.
- ▶ Notify the institution if the response is unsatisfactory.
- ▶ When authors are in private practice or head up their institutions, approach the licensing/regulatory body of the country concerned.
- ▶ It's perfectly legitimate for two editors to talk about a case and act together.

Editors do have a duty to pursue suspected misconduct, as outlined in the editors' code.

What about defamation? Never write to an author's institution making a direct allegation of malpractice. Rather say that this particular problem has arisen, and that you have had this response from the authors. You are not satisfied with it, for the following reasons, and would that person look into it? It's then the duty of the institution to look into it. Whether they do it is another matter.

### **Fabrication/falsification**

Fabrication/falsification is another very difficult area for editors. When does it start? It is a deleted outlier? It's a gradational process, and often editors only have a vague

suspicion, because the data look too good to be true, for example. Or there's only a single author on a randomised controlled trial. These should prompt warning bells, but there is still no solid proof.

Falsification is seldom picked up by reviewers, although sometimes the statistician will detect it. Figures are one area where reviewers are better at uncovering it. Editors have the right to ask for raw data, but analysing this can be very time consuming and difficult. And what happens when the data have disappeared or the authors were only asked to keep their raw data for a specific period of time?

### Plagiarism

Extent is important. Is it one sentence or whole paragraphs? Has this been done before? Take care over co-authors, because one or two might have done this, but the other four named authors might have no idea that this has happened. Write separately to all of them.

Can it be unintentional? Sometimes there's a language problem, or phrases from another paper get used. It's easy to do, and this needs to be borne in mind.

A reviewer for a specialty journal discovered that the review paper had been plagiarised from his own published syllabus. The authors were very apologetic, and could not explain it. They made a very good case, and the paper was rejected without further action. However, the editor was contacted six months later by the same reviewer saying that the same paper had been submitted to another journal and nothing had been changed.

### Common difficulties for editors

Pursuing research misconduct is time consuming to do this, and often replies from the authors and the institutions are simply not forthcoming. Or the institution agrees to investigate, but it's barely adequate. Or there may be no institution.

Then editors can only publish notices of concern or letters, or express generic concerns in editorials.

## OUTCOMES OF EDITORS' ATTEMPTS TO INVESTIGATE RESEARCH MISCONDUCT

**Liz Wager, Publications Consultant for Sideview and member of COPE Education Sub-Committee and BMJ Ethics Committee**

When editors do decide to take action in cases of suspected research misconduct, just how successful are they? In a bid to find out, I looked at those cases published in the COPE reports (1998-2003) where editors had taken on this task.

This study includes all 79 cases that been closed. It excluded all cases of disputed authorship, but included all those of suspected author misconduct.

Type	Total	Exonerated	Impasse	Contact institute	Lastest >1 yr
▶ Redundancy	33	7	3	4	48%
▶ Unethical res.	16	5	4	7	25%
▶ Fraud	13	2	2	4	62%
▶ Med negligence	10	0	4	6	70%
▶ Plagiarism	7	2	2	2	14%
▶ Total (%)	79	16 (20)	15 (19)	23 (29)	36 (46)

In about one in five cases, the individual was exonerated. But in about 20% of cases, an impasse was reached and editors got nowhere. Usually, it was a complete lack of response, despite having tried all the different avenues.

In only about a third (29%) of cases did the journal editor contact the author's institution. Perhaps the impasse was reached, because editors had not progressed beyond attempting to contact the author.

Around half the cases lasted for more than a year, and many of them went back over decades when they started to unravel. Good record keeping is therefore absolutely essential. In some instances, the case just disappeared because the journal could not keep up with the paperwork.

### **Redundant publication**

Analysis by theme shows that redundant publication is the most common category of case reported to COPE (42 cases, 9 of which were still open). But only one case led to a formal retraction. In four cases, the enquiries concluded that there was some degree of overlap but not a deliberate attempt to deceive.

A notice of duplication was published in just six cases. In most cases, the journal decided to take no public action.

### **Unethical research**

There were 18 cases of unethical research, of which two were still open. Five authors provided a satisfactory explanation; in one case, the editor looked at it further, and realised that the author had already been struck off for similar behaviour. But in four, the editors reached an impasse.

### **Fraud/fabrication**

Fraud, fabrication and falsification comprised 15 cases of which two were still open. In a couple of cases, the editor found an appalling track record, and discovered that the author had already been suspended or struck off from clinical practice. In one case, the journal had simply rejected the article and imposed no sanctions. In one case, the journal published its concerns.

Fear of litigation prevents many journals from publishing concerns. It's a huge problem. The more serious the allegations, the greater the desire to publish concerns, but the more likely it is that the person will threaten legal action at the very least. And these threats have to be taken seriously.

The journal lost the correspondence in one case and couldn't follow it up. When the editors contacted the author's institution in another, no reply was received, and in another they were given a brush-off, on the grounds that the author was no longer an employee so it was not their concern.

### **Medical negligence**

Medical negligence made up 11 cases of which one was still open. It usually concerned unorthodox treatment or inadequate patient consent

Seven cases lasted more than a year and at least one author threatened legal action. No replies were received from the institution or the regulatory body in four cases.

### **Plagiarism**

Five cases resolved, most of them were single authored; two were exonerated, and in two the editor reached an impasse. Enquiries were begun in two, and in one case the senior author reported a junior author. With paper evidence, it's easier to progress.

### **Key points**

- ▶ In one in five cases, the matter was not resolved.
- ▶ Many authors simply don't respond.
- ▶ Many cases take longer than a year; some take more than three years.
- ▶ The responses can be disappointing.
- ▶ Journals seem reluctant to publish retractions, even when there is evidence of malpractice.

### **Comments**

- ▶ I went to the head of an institution in the UK, which held an investigation and could certify no misconduct. The case was referred to the GMC, who said no inquiry had

been held and that there was evidence of misconduct, so the head of the institution had just lied.

- ▶ Within the NHS we are being encouraged to report anything we consider to be fraud to the fraud squad, and there might be a place for referring these sorts of cases to a professional institution.
- ▶ I reported a case to the GMC involving embezzlement of money from a charitable research fund. The trust board had agreed with the consultant that if he went quietly, they would not inform the GMC or inform the police, and they would destroy the evidence. When I reported this man to the GMC, the medical director was the chair of the professional conduct committee. When I went to the NHS fraud squad they told me: “We don’t really worry unless it’s more than £15 000.”

## COMMON EDITORIAL DILEMMAS: HYPOTHETICAL CASES

Questions to ask:

- ▶ What are the main issues
- ▶ Who is involved?
- ▶ Do I need more information?
- ▶ If so, from whom?
- ▶ Who do I need to contact, and in which order?
- ▶ What possible courses of action can I take?

### Case 1

A reviewer informs you that he considers a submitted intervention trial from the UK to be unethical. This is because a possible, albeit rare, side effect could be anaphylaxis. Given the risk, he does not believe participants would have agreed to the treatment, so concludes that fully informed consent had not been obtained.

You know that the senior author had unfortunately died so make enquiries of the new corresponding author, who was his registrar when the study was undertaken. He supplies a letter showing that his senior author had sought ethical approval and that numerous concerns had been expressed by committee members, who asked for further information. However, after an informal lunch meeting between the senior researcher and the ethics committee chairman, the latter took personal action to dispense with the need for approval.

### Discussion

- ▶ There is no clear evidence of misconduct by three separate individuals. A senior author seemed to have embarked on conducting a trial under dubious conditions of ethical approval. The junior author took on responsibility to act as the corresponding author, and should have been much clearer about the ethical approval required for the trial.
- ▶ Based on the limited information available, the chair of the ethics committee himself played rather loose with ethical approval without informing his committee.
- ▶ The junior author and the ethics committee chairman should each get letters outlining concerns, and asking for clarification, and if not satisfied with responses, the editor is duty bound to raise the matter with the junior author’s employer and the ethics committee hierarchy.
- ▶ What happens if the junior author responds, saying that the senior author told him that ethics committee approval had been obtained? If the ethics committee chairman is retired and the institution doesn’t reply, should the matter be referred to the regulatory body?
- ▶ There is a question about how the doctors conducted the trial and whether the corresponding author has documented evidence of permission gained. So if these concerns were not adequately addressed, the editor would have to take it up with the employer.
- ▶ If the ethics committee chairman has retired, whoever took it on should have given proper consideration as to whether ethical committee procedures had been correctly followed.
- ▶ The junior doctor has an individual responsibility to see the ethics approval document as the corresponding author.

- ▶ Irrespective of ethics committee approval, the editor has to decide whether or not it's ethical to do the trial. The concern raised by the reviewer is whether consent was properly obtained, so the question to ask is: How did you obtain consent, and what discussion took place? A copy of the information leaflet supplied to the patient should be available, so the editor can then judge whether it's ethical on the very specific point raised by the reviewer.
- ▶ The editor who had submitted the case explained that the institution exonerated the corresponding author/registrar, on the grounds that he had acted in good faith, but they did criticise the ethics committee chairman. He removed himself voluntarily from the medical register, so no further evidence could be taken against him, but the trial participants could launch a civil case.
- ▶ The corresponding author's and the institution's defence was that this was not research, just an extension of clinical practice. The nub of the issue was the consent form, which the journal requested, but on receipt found it to be "hopelessly inadequate." For this reason, the ethics committee chairman was criticised by the investigation.
- ▶ This case took three years because the NHS had reorganised in the interim, and ethics committees had come under different governance. It proved unbelievably difficult to obtain responses to anything.
- ▶ Technically, it's assault if you do something to someone without proper consent, so such an offence should be reported to the police.
- ▶ The police are generally not interested unless someone actually dies, and the burden of proof for assault requires that you can show that a person was assaulted; absence of informed consent would not be sufficient.
- ▶ The consent form did include the warning of the potential for significant side effects, and stated that consequently a senior member of staff would be present at all times to deal with this.
- ▶ When people are involved in research, and exposed to risk, there is a duty to try and publish the study to ensure that the data are in the public domain. Is there therefore a case for publishing the research, but with a commentary to accompany it, stating that the research was unethical?
- ▶ This is a common problem: Do you want this in the public record, so you can alert people, or do you reject it, so that the authors will simply take it to another journal where the standards could be lower and not feel the need to publish a commentary?
- ▶ What are the broader ethical obligations to the trial participants if evidence that fully informed consent absent had not been obtained, but the nature of the trial might indicate some long term damage that does not manifest for some years? Does the editor have some obligation to ensure that patients are informed?

## Case 2

A reviewer, who happens to be an associate editor of another journal, tells you that a paper you sent her to review has also been submitted to her journal. Both covering letters stated that the paper had not been submitted elsewhere. Moreover, the reviewer points out that a MEDLINE search shows two references cited in the paper to other work by the author, which she considers were also duplicate publications. When you write to the author, he apologises for the error, which he states, resulted from a misunderstanding between his co-authors. He wishes to withdraw the paper from consideration. The other editor has, meanwhile, rejected the paper sent to him.

## Discussion

- ▶ The main issue is the extent to which the editor can trust the author when he apologises for the error, given the fact that he has done it before.
- ▶ It merits a letter to him and then another to his institution to say that although he explained this was an error, there is evidence that it has been done before. Somebody should look at his whole publication record.
- ▶ Whose responsibility is this? It's probably something the institution should undertake, but would they do it?
- ▶ The co-authors should be written to separately, because the corresponding author alleges misunderstanding. If he is a serial offender, how do you share that information among journals?
- ▶ Should you write to the editors of all the journals, despite the fact that this is an onerous task, outlining evidence of duplicate publication? At least write to the other editor.

- ▶ Editors cannot be responsible for the burden of proof, and this would put an editor in a very difficult legal position. But they do have an obligation to draw attention to suspected misconduct.
- ▶ An example was cited of a suspected case of duplicate publication, which prompted the journal editors to write to the authors, requesting an explanation and warning them that it might result in retraction of the paper. The request was answered with the threat of legal action, on the grounds that retraction would damage careers.
- ▶ The editors investigated and discovered that the other journal had published the paper later. The study had been published online first. The other journal applied to the permissions department of the first to reproduce the figures, and published a statement saying that the article had been previously published online. The author claimed that reporting conference proceedings made this acceptable practice, despite the fact that it said original research proceedings.
- ▶ It is important to distinguish between redundant publication of original research, which could skew a meta analysis and opinion pieces, and editorials or review articles, which might be considered as secondary publications. There is no rule against publishing your opinion more than once.

### Case 3

You accept a paper, but ask for some revisions, which you consider relatively minor. The new version takes a long time to arrive, and when it does, the named authors have dropped from four to two. The corresponding author explains that his co-authors were unable to agree on the changes. You contact one of the 'disappeared' authors and suspect that she has been leant on by her head of department, a senior official in the government's health department. It appears that he is concerned that the conclusions are overstated and may result in patients stopping a safe and necessary drug, if (as is likely because of the topicality of the subject), the media quote the conclusions without a clear description of the difference between causation and association.

She and her head of department reject your offer that they should write an accompanying commentary. Having reread the paper, you are sympathetic to the government department opinion and agree that there is a chance that any ensuing publicity might mislead patients. However, the two remaining authors refuse to change their conclusions, adding that your last letter to them stated you would accept the revision if they took into account the reviewer's comments, which they have done in full.

### Discussion

- ▶ The editor has already said s/he would accept with minor revisions, which had been done. Arguably the onus is on the editor to accept this article.
- ▶ As to the two disappeared authors, was it the suggested revisions, which prompted this, or had they simply had second thoughts? We know one of them was leant on, and it may be that this paper has very important public health implications. The editor should find out why the authors have disappeared, and should seek further peer review of the paper.
- ▶ The editor should honour his promise to publish, but with an editorial comment that two authors have disappeared, and perhaps ask for a commentary by another clinician on this particular area of research.
- ▶ Considering the authorship has changed substantially and ideally the authorship contributions have also changed, arguably it is a different paper, so there is no obligation to publish it.
- ▶ But the revisions are minor, so it's not that different.
- ▶ Send it back to the original reviewer with an explanation of what has happened as well as sending it to a new reviewer, outlining concerns about the interpretation of the data, but not specifying why.
- ▶ If the changes were what the editor asked for, surely there are no grounds for rejecting it?
- ▶ But the changes did not relate to author changes as well. Whenever authorship changes it should always be investigated, because more often than not it means that there is some disagreement somewhere. And perhaps the data are unreliable, so the onus is on the editor to investigate, because there could be a serious problem with the paper.



- ▶ Don't promise acceptance after final revisions. Whether major revisions or minor revisions, the process just continues until the editor is satisfied.
- ▶ Contact the two authors who dropped out, and have them agree in writing to their deletion from the authorship credits and that they are happy about this.
- ▶ But they may have been leant on by their head of department, as is often the case with junior authors.
- ▶ Could the suggested revisions have prompted the authors to drop out? If this is the case, the editor might be wrong. The paper might not be as good as a result of the suggestions, and it may be that the authors are simply compliant because they want it published. The editor needs to know that.
- ▶ The message might be misunderstood by the press, and we have an obligation to convey the correct interpretation.
- ▶ If an editor is on the medical register, is there a conflict between the duty to publish a peer review paper and his/her duty as a doctor to act in the best interests of public health, especially if it is a safe drug and it could prevent deaths?
- ▶ That's impossible to know. Put both sides and let readers make up their own minds.
- ▶ Should the two remaining authors be attributed for all the work? If the other two authors are happy to have their names taken off, that is their decision. But if they are not happy, then there is something substantially wrong with the paper. And if they are happy, but don't want their contribution acknowledged, the editor could be publishing something fraudulent.
- ▶ When there are many authors on a paper, sometimes asking what each contributed prompts some to request acknowledgement rather than authorship.
- ▶ Creating a paper with several authors entails discussions to reach a consensus. Revisions also merit agreement among all the authors. Therefore, the paper cannot be published until the editor finds out why they have withdrawn.
- ▶ The editor who referred this case explained that all four authors agreed about the scientific evidence, but two authors had been made to withdraw. They had been told that the conclusions they had reached were not acceptable to the government.
- ▶ The two authors initially accepted the offer to publish their side of the story, but subsequently refused, presumably because they were told that they couldn't. The problem was that the paper had been accepted and all the requested revisions had been made.
- ▶ The paper was published with a long commentary, which had to adopt a cautious tone. It could not say that the editor had been contacted by government officials, merely that the authors had withdrawn for political reasons. The authors were neither named nor acknowledged.
- ▶ There was no audit trail, because everything had been done on the telephone, so it would not have been possible to publish the whole tale.
- ▶ Would it be unethical behaviour to force someone to take their name off authorship? If so, do you report the senior government official to the GMC? Would this be a case to refer to the new independent panel?

#### Case 4

You have accepted a paper which uses a case report of a rare adverse incident to highlight the author's belief that a widely practised form of therapy is not evidence based, is illogical and potentially dangerous. The author had asked for it to be fast tracked because of the need to protect patients in future, and you have agreed to this request.

Just as the proof copy arrives before publication, the author telephones your technical editor. He explains that he is appearing as an expert witness on behalf of a claimant seeking recompense from an NHS trust for alleged clinical negligence in treating her in the manner outlined. He would like to know when the paper will be published as he wishes to use it when giving evidence. The technical editor did not ask whether the case report is about this claimant, the claimant whose demographic details have been altered to preserve confidentiality, or another case altogether.

#### Discussion

- ▶ The issue here is his conflict of interest as an expert witness and whether the patient is the same one on whose behalf he is going to give evidence. Presumably it is possible to find this out from the written consent signed by the patient before publication.



- ▶ Has he been an expert witness before in this area? Was the case fast tracked so that it could coincide with his giving evidence? Did he know he was giving evidence at the time it was submitted?
- ▶ Is his fee the same whether he wins or loses the case? In which case, is there really a conflict of interest, although perhaps it would have been better to advise of his role?
- ▶ Win or lose, it is a conflict of interest. Being an expert witness should be declared, and if not declared, the editor has the right to reject the paper even at acceptance.
- ▶ Whether he acted as an expert witness is irrelevant, it is up to the court to decide what weight to give to the evidence presented in court; that's their job. Acting as an expert witness should not preclude acceptance of the paper.
- ▶ Not all journals ask authors to declare competing interests, so if he was asked, and didn't declare, he is at fault. But if he was not asked, then he is not at fault.
- ▶ What are the criteria for defining conflict of interest? This is not someone who has a contract with a pharmaceutical company, this is someone legitimately giving evidence in a court of law, and they have obligations to the court to be honest.
- ▶ As an expert witness, your first duty is to the court, not to yourself or the claimant on whose behalf you are giving evidence.
- ▶ It is naïve to assume that expert witnesses are always honest to the court. They can be pretty biased in what they say. It is a relevant competing interest because it adds to his credibility and expert witnesses can be selective in what they report.
- ▶ Why do authors want papers fast tracked? Should that be an index of suspicion? There have to be strong arguments in the public interest, and often when that is requested, the issue fades away.
- ▶ What about reviews and discussions of public data? Could these be expert witnesses attempting to have their interpretation of the data published in peer reviewed journals?
- ▶ If it's peer reviewed and scientifically sound, we publish it, regardless of the motives of the authors. But the question is: is this a conflict of interest and should it be declared?
- ▶ It's very hard to disentangle. If you write a lot about a subject, and have done a lot of research, you are more likely to be invited to be an expert witness. It depends on where your primary responsibility lies: to your peers and other professionals or to the courts? Ideally, you would hope that someone would include in their conflict of interest declaration that they are a regular expert witness for that particular case.
- ▶ If anything is published, it won't make any difference, because the court applies the medical knowledge as it was at the time, not as it appears subsequently.
- ▶ This person did have a conflict of interest and wanted to up their credibility in the eyes of the court by publishing.