The COPE Report 2000

www.publicationethics.org.uk
The COPE Report 2000
Annual Report of the Committee on Publication Ethics

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COPE moves into the next millennium

The Committee on Publication Ethics (COPE) is now three years old. This, its third report, shows that the casework continues. COPE continues to discuss a wide range of cases, from possible research fraud to the milder end of the spectrum, such as author disputes and redundant publication.

When formed in 1997, COPE's major objective was to provide a sounding board for editors who were struggling with how best to deal with possible breaches in research and publication ethics. Most case discussion has taken place during the bimonthly COPE meetings, but some editors have corresponded with the committee and advice has been offered through correspondence. The possibility of extending the work of COPE has arisen during preliminary discussions with the ethics committee of the World Association of Medical Editors (WAME).

WAME has approached COPE with a view to a collaboration. Professor Michael Callaham from the University of California, San Francisco, and Chair of the WAME Ethics Committee has put forward several proposals. These include:

- That we establish a link between the WAME website and COPE website and notify WAME and COPE members of the arrangement.
- That WAME will consider posting the COPE Guidelines on Good Publication Practice on the WAME site. WAME members can then comment directly on the guidelines and suggest modifications as and when appropriate.
- To consider organising a joint session at the Peer Review Congress in Barcelona in 2001, possibly involving case-based discussions and practical testing of the guidelines on Good Publication Practice.
- To formally establish the liaison between WAME and COPE by jointly reviewing problematic cases submitted by editors. One proposal is that COPE cases would be posted in a fully anonymised form on both websites for discussion before COPE meetings. A member of the committee might be designated to produce a short synthesis of views and suggestions for presentation to COPE members at the meeting. A summary of the discussion and proposed action could then be posted on both websites.

This could result in an important learning experience for WAME and COPE members and broaden the debate on research and publication ethics around the world.

These proposals were formally discussed at the September COPE meeting and were endorsed with enthusiasm. Further discussions will be arranged between the two committees to consider the practical implications in establishing the alliance.

COPE published the first incarnation of its Guidelines on Good Publication Practice in its 1999 report. At the time of publication, the guidelines were intended to be changed as circumstances evolved and feedback was received. Possible changes to the COPE guidelines include:

1 Dealing with misconduct
An editor has drawn attention to the point that authors should usually be informed before their employers are contacted (section on Serious Misconduct 3.11). However, we propose that this point is brought forward to become new (2) to give authors the opportunity to respond.

2 Authorship
COPE case 00/06 drew our attention to the problem of "ghost" authorship. We would suggest adding (5) authors must be increasingly vigilant of ghost-writing to which their names are appended. Ghost-writing in the scientific community should be severely discouraged.

Following this, further consultation took place and more than 200 journal editors in the United Kingdom were asked whether they would feel able to endorse the COPE guidelines and possibly publish an editorial or the complete guidelines in their journal. About 50 per cent of editors responded, most of whom felt able to give total support to the guidelines in their current form and many publicised them in their journals. BJU International even printed the COPE logo on the cover of the journal.

The core members of COPE have interpreted this response as being highly supportive and an indication that COPE now needs to move on into the next phase of its existence. We feel that the committee needs to proceed on a more formal basis with a constitution, elected officers and a management committee as well as clear operating guidelines. This report contains a draft constitution and a summary of the process by which we propose to relaunch COPE.

During the past year COPE members have contributed to a number of national and international meetings. Michael Farthing and Richard Horton were invited speakers at a session on research and publication ethics at the European Cardiological Society meeting in Barcelona in 1999. Papers summarising our work are to be presented at editors’ meetings in Washington and Barcelona in 2001, and we have been invited to organise a symposium for the United European Gastroenterology Week in Amsterdam in October 2001. Members also contributed to the 5th World Congress of Bioethics, which took place in September this year at Imperial College, London. We believe these activities are beginning to address one of our stated objectives—namely to encourage education and research in publication ethics.
Finally, one of the key events of 1999 was the Joint Consensus Congress on Misconduct in Biomedical Research held in October 1999 at the Royal College of Physicians in Edinburgh. Experts presented position papers on all aspects of research misconduct and additional evidence was provided by other invited speakers on definitions, epidemiology, diagnosis, management and prevention.

The Consensus Panel, chaired by Lord Robert Kilpatrick, considered the evidence and produced a final consensus statement under three headings: The Definition of Research Misconduct; How do we Promote Good Research?; and What should happen next? We have reprinted the consensus statement here but it is now more than a year since the meeting and it is difficult to be certain whether any of the recommendations in this report have been taken forward. Two steps forward … and one step back?

Michael J G Farthing
Chair, COPE
September 2000

Who will lead on research and publication misconduct in the UK?

The General Medical Council continues to hold jurisdiction over medical practitioners who are alleged to have committed research misconduct. There is a steady trickle of major cases that make the headlines, but all the evidence suggests that the GMC is totally overwhelmed. The GMC has made an important contribution in the publication of its report Good Practice in Medical Research (1999), but is increasingly under the spotlight regarding its ability to deliver on the professional conduct agenda.

COPE has always strongly believed that the cases that finally reach the GMC are merely the tip of an unmeasured iceberg. The personal experience of many COPE members suggests that possible cases of publication and research misconduct are dealt with inadequately. At talks or seminars on research and publication dishonesty, asking the audience how many of them have been aware of possible research dishonesty or misconduct in their department or institution illustrates the problem. Within this admittedly selected and probably biased group, the response is generally 10–30 per cent. But when challenged with What did you do about it? the response is usually ……… nothing.

Despite new legislation few individuals feel that the current climate is conducive to “blowing the whistle.” Editors similarly feel impotent to deal with many of the cases that cross their desks, although the COPE guidelines on Good Publication Practice have gone some way to providing practical advice, which, we believe, will ultimately increase the referrals of concerns about authors and their papers to the heads of their organisations.

Nevertheless, our experience indicates that this is not a panacea. A vice chancellor or dean of a medical school may be understandably reluctant to investigate a senior colleague who, in some instances, may be a lifelong friend.

Debate continues as to who should take responsibility for investigating alleged research misconduct by non-clinical scientists. Currently it seems to be the role of the employing institution to investigate and to instigate appropriate disciplinary measures which, of course, might ultimately lead to involuntary severance. But there seems little to stop such an individual seeking re-employment in another institution, particularly if the conditions of severance are disguised, or from moving overseas. Recent events have shown how a clinician can be struck off in one country and then move to another to take up employment without any communication between regulatory agencies.

COPE members had great hopes of the Joint Consensus Conference on Misconduct in Biomedical Research held at the Royal College of Physicians of Edinburgh in October 1999. The Consensus Panel chose to use a broad definition of research misconduct: “Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standard.” Eminently sensible recommendations were made on how to promote good research, which centred around changing the culture, education, training and vigilance.

The Consensus Panel also saw fit to pronounce on “what should happen next?” Although many COPE members would have preferred a recommendation for the development of an external agency to deal with all aspects of research misconduct such as those in place in the USA and the Nordic countries, this was not to be. However, the panel did suggest that a national panel should be established to develop and promote models of good practice for local implementation, provide assistance with the investigation of alleged research misconduct, and collect, collate and publish information on the incidence of research misconduct. As yet we have seen no signs of this panel and no individual or sponsoring body has emerged.

There needs to be a real commitment to take this forward. COPE has written formally to the president of the Royal College of Physicians and the General Medical Council on the issue. A reply has been received to the effect that discussions have been held. We wait to see what action ensues.

Michael J G Farthing
Richard Smith, Editor, BMJ
Richard Horton, Editor, The Lancet
Journal membership

*Denotes publication of editorial or other article on COPE guidelines

Acta Paediatrica*
Age & Ageing
AIDS*
Alimentary Pharmacology & Therapeutics
Animal Genetics
Annals of the Rheumatic Diseases*
Annals of Tropical Paediatrics*
Archives of Disease in Childhood Biomaterials
BJU International*
Blood Coagulation & Fibrinolysis
British Dental Journal
British Journal of Biomedical Science
British Journal of Cardiology
British Journal of Dermatology*
British Journal of General Practice
British Journal of Neurosurgery
British Journal of Ophthalmology*
British Journal of Oral & Maxillofacial Surgery
British Journal of Plastic Surgery
British Journal of Sports Medicine
British Journal of Surgery*
British Medical Journal*
Child Care, Health & Development
Clinical & Laboratory Haematology
Clinical Endocrinology
Clinical Oncology*
Dentomaxillofacial Radiology*
Diabetes Metabolism Reviews
Diabetic Medicine
Dutch Journal of Medicine*
European Journal of Clinical Nutrition
European Journal of Gastroenterology & Hepatology
European Journal of Immunogenetics*
European Journal of Surgical Oncology
Experimental Eye Research
Eye
Family Practice*
Gut*
Health & Social Care in the Community*
Heart
Histopathology*
Hospital Medicine
Injury Prevention
International Journal of Dermatology
International Journal of Developmental Neuroscience
International Journal of Experimental Pathology
International Journal of Obesity
International Orthopaedics
Journal of Accident & Emergency Medicine
Journal of Clinical Pathology
Journal of Dentistry
Journal of Endocrinology
Journal of Epidemiology & Community Health
Journal of Hospital Infection
Journal of Human Hypertension
Journal of Hypertension
Journal of Medical Ethics
Journal of Medical Genetics
Journal of Medical Screening
Journal of Neurology, Neurosurgery & Psychiatry
Journal of Oral Rehabilitation
Journal of Pharmacy & Pharmacology
Journal of Physiology
Journal of the Norwegian Medical Association
Leukaemia Research
Liver: an international journal
Medical & Veterinary Entomology
Medical Education
Medical Humanities
Medical Hypotheses
Molecular Pathology
Movement Disorders
Nephrology, Dialysis & Transplantation*
Occupational & Environmental Medicine
Paediatric Anaesthesia
 Palliative Medicine
Postgraduate Medical Journal
Pre-Hospital Immediate Care
QJ Med
Quality in Health Care
Respiratory Medicine
Resuscitation
Reviews in Medical Virology*
Scottish Medical Journal
Sexually Transmitted Diseases*
The Journal of Hand Surgery*
The Lancet*
Thorax*
Tobacco Control
Tropical Medicine & International Health
Tumour Biology
Western Journal of Medicine

Addiction Biology, Chemistry & Industry, Environmental & Clinical Pharmacology, Occupational & Environmental Health have also published editorials/articles on the COPE guidelines.
The name of the Association is the Committee on Publication Ethics (COPE).

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.

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.

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.

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.

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.
Patients benefit not only from good quality care but also from good scientific research. We all expect high standards of scientific and medical research practice. The integrity, probity, skill and trustworthiness of scientific and medical researchers are essential if public confidence is to be assured. In the design and execution of biomedical and healthcare research, public participation is essential. The Joint Consensus Conference on Misconduct in Biomedical Research was convened in order to debate, address and offer guidance on key questions because "every single case [of fraud and misconduct] reduces public confidence, abuses the use of public and charitable funds, and causes insult and frustration to the vast majority of careful, honest workers".

The definition of research misconduct:

“Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standards.”

No definition can or should attempt to be exhaustive. It should allow for change. The definition should not be read as being restricted to fabrication, falsification of data and plagiarism. It is intended to cover the whole range of research misconduct.

How do we promote good research?

- By affirming a culture through example in which honesty and integrity are expected of every individual and misconduct is not tolerated.
- Through education, training and vigilance from the outset, starting with undergraduate entry and continuing through lifelong learning.
- By ensuring formal training of all supervisors of research.
- By establishing effective and efficient mechanisms for monitoring, auditing and ethics review, appropriate to the design of the study.
- By provision of expert advice, guidance and training for ethics committees.
- By respecting consent and confidentiality.
- By having a framework for and promulgating written guidance on good research practice including publication policy and dissemination of results.
- By designing procedures to ensure that funds are only allocated within a framework for good research practice and when local systems for managing allegations of research misconduct are shown to be established and effective.
- By investigating all allegations of research misconduct firmly, fairly and expeditiously.
- By developing effective and impartial local systems for employers (the universities, NHS, industry and research institutes) to manage allegations of research misconduct, including reference to disciplinary procedures or referral for criminal investigation.
- By providing access to appropriate support for whistleblowers and researchers.

What should happen next?

A national panel should be established – with public representation – to provide advice and assistance on request. The panel might:

- Develop and promote models of good practice for local implementation
- Provide assistance with the investigation of alleged research misconduct.
- Collect, collate and publish information on incidents of research misconduct

We expect that this paper will be given the fullest possible dissemination by the sponsoring bodies and that the three Royal Colleges of Physicians and the Faculty of Pharmaceutical Medicine will convene at the earliest opportunity a meeting with the General Medical Council and appropriate partners to establish and consider the remit of the national panel.

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WHAT IS RESEARCH MISCONDUCT?*

R. Smith

INTRODUCTION

At first sight it seems essential to define research misconduct. If research misconduct is accused of misconduct, found guilty, and possibly have their reputations and livelihoods destroyed, then they surely must know what is misconduct and what is not. Unfortunately, research misconduct has proved resistant to definition. Many organisations have produced definitions (see appendix), but most have led to argument. And none is an operational definition that would allow several observers to agree consistently on whether a piece of behaviour is misconduct.

A universally agreed, operational definition of research misconduct is surely unachievable, but this does not mean that definitions should not be attempted. The act of trying to define misconduct will in itself be valuable, deepening our understanding of the issue. Similarly, the debate that surrounds any definition will be useful, and the definition can then be modified. But we will not reach the Holy Grail of a universally agreed, operational definition.

AN ANALOGY BETWEEN RESEARCH MISCONDUCT AND SERIOUS PROFESSIONAL MISCONDUCT

The failure to reach such a definition is not unusual. It is similarly impossible to define, for example, 'serious professional misconduct', the offence which may lead a British doctor to be removed from the register of the General Medical Council (GMC), the body that regulates doctors in Britain. The idea of what constitutes serious professional misconduct changes over time in response to social and professional developments, and a doctor will be found guilty of professional misconduct only after a process that is strictly defined. Cases then accumulate on the record, allowing an ever clearer - but never perfectly clear - idea of what constitutes serious professional misconduct.

The GMC is over a century old and has had a long time to develop case law on serious professional misconduct. In many countries, and certainly in Britain, we are at the beginning of trying to define research misconduct. We need to continue to attempt to define research misconduct, recognising the impossibility of doing so finally, but also need to develop a taxonomy of what might constitute research misconduct. Researchers themselves should take the lead in these discussions. They may resent that they cannot be clearly informed on what is and what is not research misconduct, but they are in the same professional position as a doctor. He or she must accept that serious professional misconduct cannot be exactly and operationally defined, keep up with cases of what is judged to be serious professional misconduct, and recognise that the definition will change with time.

Continuing the analogy with the GMC (which seems appropriate because it is a professional regulatory body familiar to many who participate in the debate on biomedical research misconduct), we may need to move eventually to a taxonomy not of what should not be done but rather guidance on best practice. The GMC has recently defined what is expected of a good doctor. Students of improvement processes know that much more is achieved by improving a whole population, or system, rather than by simply cutting off those who fall below a line of acceptability. The Medical Research Council (MRC) and the International Conference on Harmonisation (ICH) have, among others, defined good research practice, and the Committee on Publication Ethics (COPE) has recently defined good publication practice.

EXISTING DEFINITIONS

The appendix gathers together seven definitions of research misconduct published between 1991 and 1998. Two are from Britain, one from the United States, and four from Scandinavian countries. The US definition is the longest, and the US has seen an intense debate around defining research misconduct. The central question is how broad to make the definition. The Nordic countries, in contrast, have played down the importance of a verdict, and others have reviewed the experience of national committees on scientific dishonesty in the Nordic countries and written:

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

The MRC definition, which has been accepted by the committee on research misconduct set up by the president of the GMC, is perhaps the most pragmatic of the definitions. It must surely be categorised as a broad definition as it includes 'deception in...reporting results of research'. Would this mean that describing yourself as an author of a piece of research when you had contributed little or nothing, or publishing similar papers in two journals without informing the editors - both very common practices - would amount to research misconduct? Table 1 shows my attempt to decide whether various behaviours might constitute research misconduct under six of the definitions. My unsurprising conclusion is that it is unclear much of the time and that these are not operational definitions, although there are some forms of behaviour - such as inventing cases or data - that are easily recognised as misconduct.

An important part of the MRC definition is making

*A background paper prepared for the joint consensus conference on misconduct in biomedical research

.Editor, British Medical Journal

*Editor, British Medical Journal

BMJ VOLUME 317 Date???
clear that ‘honest error or honest differences in the design’ are not research misconduct. Intense argument is common within science and is part of the scientific method. Researchers are understandably fearful that a legitimate but intense debate may spill over into accusations of misconduct. Similarly, making a mistake cannot be deemed to be misconduct.

**WHAT IS THE RELATION BETWEEN SERIOUS AND MINOR MISCONDUCT?**
Two important questions underlie the debate around defining research misconduct. Firstly, does research misconduct lie on a unimodal curve (Figure 1a) in which minor misconduct merges into serious misconduct, or on a bimodal curve (Figure 1b) in which minor misconduct is quite separate from serious misconduct? We do not have the data to answer this question, but many authorities behave as if minor and serious misconduct are unrelated. It is perhaps more likely, however, that the two do lie on one spectrum, particularly as this is a biological system. Something like plagiarism is also clearly a matter of degree. Researchers might steal a few words, a paragraph, or a whole study.

The second related question is whether researchers who commit minor misconduct, which we know to be common, have a tendency to progress to serious misconduct? Or are minor and serious misconduct the result of different forces? This is reminiscent of the debate of whether use of soft drugs leads to use of hard drugs. The answer is important because it adds to the case for taking minor misconduct seriously if it may progress to serious misconduct. Again, we don’t have the data to answer the question confidently, but it seems likely that minor misconduct may progress to serious misconduct and that serious misconduct is unlikely to arise without any history.

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<tr>
<td>Inventing a case</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Failing to get consent from an ethics committee</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>?</td>
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<tr>
<td>Publication of <em>post hoc</em> analyses without declaration that they were <em>post hoc</em></td>
<td>?</td>
<td>Yes</td>
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<td>Gift authorship</td>
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<td>Yes</td>
<td>?</td>
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<td>Not publishing completed research</td>
<td>No</td>
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**FIGURE 1A**
Possible relation of minor and serious research misconduct

**FIGURE 1B**
Possible relation of minor and serious research misconduct.

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*Severity of misconduct*

*Frequency*
of minor misconduct. The evidence from other areas of misconduct - for example, financial fraud - suggests that offenders may progress from the minor to the serious; and the theme of a good man turning seamlessly into a bad man is a recurrent theme in literature. Macbeth is an outstanding example.

It seems important to gather evidence to understand better the relation between minor and serious misconduct.

A TAXONOMY OF RESEARCH MISCONDUCT

Table 2 gives a preliminary taxonomy of research misconduct, arranged on a spectrum from serious to minor. I do not begin to pretend that this is a complete list nor that everybody would agree with the correct positioning on the spectrum. But the taxonomy provides a starting point for discussions on what is research misconduct. Providing a taxonomy is not an alternative to attempting to define research misconduct but rather a complementary method of answering the question ‘What is misconduct?’ No definition can ever be fully operational, and no taxonomy can ever be complete.

<table>
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<th>Serious research misconduct</th>
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<tr>
<td>- Fabrication: invention of data or cases.</td>
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<tr>
<td>- Falsification: wilful distortion of data.</td>
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<tr>
<td>- Plagiarism: copying of ideas, data, or words without attribution.</td>
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<tr>
<td>- Failing to get consent from an ethics committee for research.</td>
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<td>- Not admitting that some data are missing.</td>
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<td>- Ignoring outliers without declaring it.</td>
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<tr>
<td>- Not including data on side effects in a clinical trial.</td>
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<tr>
<td>- Conducting research in humans without informed consent or without justifying why consent was not obtained at an ethics committee.</td>
</tr>
<tr>
<td>- Publication of post hoc analyses without declaration that they were post hoc.</td>
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<tr>
<td>- Gift authorship.</td>
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<tr>
<td>- Not attributing other author.</td>
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<tr>
<td>- Redundant publication.</td>
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<tr>
<td>- Not disclosing a conflict of interest.</td>
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<tr>
<td>- Not attempting to publish completed research.</td>
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<tr>
<td>- Failure to do an adequate search of existing research before beginning new research.</td>
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<th>Minor research misconduct</th>
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Fabrication (the invention of data or cases), falsification (the wilful distortion of data), and plagiarism (the copying of ideas, data, or words without attribution) appear in everybody’s definition of research misconduct. Fabrication is perhaps the most extreme form of misconduct, and the definition is close to black and white: I cannot imagine circumstances in which the invention of data or cases could happen as part of the normal scientific process.

Falsification begins to be more difficult. It seems entirely feasible that ‘honest error’ might be confused with ‘wilful distortion’, and proving wilfullness is inevitably difficult.

Plagiarism, as I’ve argued above, clearly lies on a spectrum, although ‘attribution’ comes close to being a yes or no phenomenon. Plagiarism can occur without intent, and at other times and in other disciplines and cultures plagiarism may not be seen as a problem. Bertolt Brecht, for example, saw no problem with borrowing material from others.

As we go down the list defining misconduct becomes increasingly difficult and controversial, but I find it very useful to remember the words of John Bailar, an American statistician, that ‘disclosure is almost a panacea’ (ironically, I cannot provide a reference because I’ve never seen Bailar’s sentence written down: I heard him say it at the third international congress on peer review in Prague in 1997).

If failing to get consent from an ethics committee for research on human participants research misconduct? If the researcher got informed consent from the participants but neglected to get the permission from the ethics committee perhaps it would be more of a bureaucratic than ethical offence. Sometimes an ethics committee is not available. Then there is confusion over where audit (a routine process not needing ethics committee approval) ends and research begins. Some journals insist on ethics committee approval for audits to be published, while some overworked ethics committees refuse to consider audits, saying that they should proceed without consent.

Failing to admit that some data are missing, ignoring outliers, and failing to include data on side effects in a clinical trial are so common in published reports of trials that it might seem bizarre to suggest that they might be research misconduct. Do they amount to ‘deception in... reporting results of research’ (MRC definition)? Arguably, they do. Do they matter scientifically or medically? They do. Missing data weaken scientific conclusions. The outliers that are ignored on the assumption that they are a mistake may actually hold the key to understanding something important. Information on side effects must be important to doctors and patients when deciding whether a drug should be prescribed and which should be prescribed.

Conducting research in humans without informed consent might at first sight seem to be misconduct. But what about research on those, like the seriously injured, who are unable to give consent? What about studies on patient records, where the results are presented without individual patients being identifiable? What about research where the control group gets routine care and them knowing that they were in a trial would bias the results? The necessity of getting informed consent has given rise to intense and unresolved debate, and researchers resent the double standards for clinical practice and research. If I am a doctor treating a patient and I believe that one treatment is better than another, even though I have no hard ‘evidence’, then I can simply go ahead and treat the patient. If I decide that I want to do a trial because I am uncertain which is the best treatment, then I must get consent from an ethics committee, explain the notion of randomisation to the patient, and get informed consent from the patient both to be in a trial and to take the treatment.

The publishing of undeclared post hoc analyses is a good example of where inexperienced researchers may find themselves accused of research misconduct when they have no idea that they have done anything wrong. Imagine a researcher who conducts a trial of a drug against placebo...
in the treatment of hypertension. She finds no difference between the two patients given the drug and the placebo. She then begins to do a series of post hoc analyses, and she finds that the drug is better than placebo in women who smoke. She writes a paper saying that the drug is better than placebo in women who smoke without declaring that her result was found in a post hoc analysis. Is this research misconduct? Some would argue that it is because she is distorting the scientific record and deceiving readers: if you do enough post hoc analyses, then by definition you will find subgroups within which the treatment produces statistically significant benefit. The researcher has probably found a chance, not a ‘true’ result. But many young researchers, particularly within medicine where research training may be desultory, simply do not know that some researchers would regard the publication of undeclared post hoc analyses as misconduct. Yet again, this is an example of where disclosure does make everything acceptable.

Gift authorship (signing as an author of a paper when you have made little or no contribution), failing to attribute authorship to co-workers who do meet qualifications for authorship, redundant publication (publishing closely related papers without declaring the existence of the other), and failure to declare a conflict of interest are all examples of ‘publication misconduct’. All are common. Do they amount to research misconduct? They might under many definitions because they again involve deception in the reporting of research. Dispute over authorship was the commonest category of cases considered by the national committees on scientific dishonesty in the Nordic countries. Publishing similar studies more than once has been shown to lead to misinformation on the effectiveness of a drug; and whether or not an author has a conflict of interest has been shown to have a greater effect on the conclusion of review articles than any other factor, including the quality of the review.45

There is an entirely understandable tendency to put these common offenses into a separate category of publication rather than research misconduct, but I would argue that this is a mistake because publication is an integral part of the research process.

This leads to an even more controversial idea – that failure to publish completed research amounts to research misconduct.16 The idea that this might be misconduct is difficult to stomach because almost every researcher would then be guilty of misconduct. But failing to publish research distorts the scientific record, particularly because it is often negative results that are not published. Failure to publish might also be regarded as misconduct because publication is one of the main outputs of research, and public money and the time and goodwill of patients may have been used without any payback.

Some would also argue that failing to do an adequate search before beginning a new piece of research is misconduct. Otherwise, patients may be put at risk and public money consumed in answering a question that is already answered.

MOVING FROM DISCOURAGING MISCONDUCT TO PROMOTING GOOD CONDUCT

Something is probably wrong when we begin to propose definitions and taxonomies of misconduct that mean that most of the research community would be guilty of misconduct. But something is also surely wrong when it is ‘normal’, for example, for authors to put their names on papers for which they have done nothing.13-16 Similarly, people in the street expect politicians, judges, and the like to declare conflicts of interest, and they suspect wrongdoing when they fail to do so. But it has been ‘normal’ within research not to declare such conflicts.17

John Bailar argued at the Prague meeting that a higher standard of honesty should be expected from scientists than from the ordinary member of the public. Scientists have a duty to try and destroy their favoured theories and hypotheses. Only by repeatedly trying to falsify them can they begin to ‘believe’ them. Clinical researchers often deal with vulnerable people in highly intimate circumstances. The level of behaviour expected from scientists should be higher than that expected from the man in the street, and yet it seems in many crucial ways to be lower.

This is part of the thinking that leads to shifting the emphasis from defining misconduct to defining and describing best practice. An increasing number of such codes are appearing, and they must surely be taught and discussed in any institution that conducts research – because the code itself is much less useful than the conversation that surrounds it.

A WAY FORWARD WITH DEFINITIONS

A plan for the future could usefully include the following:

- A systematic search for material on research misconduct.
- A systematic review of what has been deemed to constitute research misconduct.
- Preparation from the review of a preliminary list of offences.
- Circulation of that list among researchers, funders of research, academic authorities and editors, asking them to define what they think constitutes misconduct and to rank the seriousness of the offences.
- Revision of the list and a second circulation among the same audience, giving them information on what had been said before but asking them the same questions.
- Publication of the review and the final list.

CONCLUSION

It is impossible to write an operational definition of research misconduct. Nevertheless, there are some flagrant acts that everybody would agree are misconduct, and we need broad definitions to begin the process of deepening understanding of what constitutes misconduct. We will also learn more as countries and institutions set up processes for investigating cases of misconduct. A taxonomy of misconduct should be created by systematically searching reports and forging international consensus. But we also need to put more energy into defining best practice.

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CLINICAL RESEARCH FRAUD AND MISCONDUCT: HOW IS IT DIAGNOSED?

F. O. Wells

INTRODUCTION
Let me start this background paper with a fairy tale. Once upon a time there was a company which used an eminent professor as one of its investigators. The company did not bother about such things as standard operating procedures (SOPs) on fraud, and anyway it trusted the professor, whose name was very valuable on published papers, because he was not just eminent, he was very eminent. The professor recruited patients fast, and was quite exemplary in keeping up to schedule when it came to deadlines. Monitors came and went and caused him no trouble nor their company any concern.

Six months later another company recruited the same professor for another trial. This company had an SOP on handling suspect circumstances in clinical trials in place, though it, too, had confidence in the professor. One day, the trial monitor for the second company came across two consent forms in a patient’s hospital notes which had quite different signatures, and she became very worried. She looked further and she looked elsewhere and she found a number of things wrong. She was quite happy to discuss this with the company medical director straight away, however, because that was what the company SOP required her to do. The medical director ordered a ‘for cause’ audit and when the audit revealed ten or so different causes for concern, indicating beyond all shadow of doubt that the professor had committed fraud, the company referred the professor to the General Medical Council (GMC).

Fairy tales have a habit of becoming true, and the professor concerned awaits a GMC hearing; the case will undoubtedly appear in the public domain shortly.

The ways in which fraud is detected depend to a considerable extent on the position of the whistle-blower. A GP partner, nurse or hospital colleague is likely to become suspicious for reasons that are different from those which apply for a clinical trial monitor, QA auditor, or company statistician, and different again for a research ethics committee or for a patient who is being exploited. This paper will therefore indicate the different roles that are played in the diagnosis of research fraud under various circumstances.

As well as these different reasons, the role of the whistle-blower is much more difficult to fulfil in some positions than in others. Thus the GP partner, hospital colleague, nurse or patient may face a considerable dilemma when deciding whether or not to report any irregularity which they may have observed in others, whereas it is part of the professional responsibility of the clinical trial monitor, QA auditor or company statistician to report exactly what they have found. Historically, for the former group, whistle-blowing brings no applause, few rewards, and little public satisfaction and the experience may be traumatic. Fortunately, here in the UK this situation is in the throes of change because as from 2 July 1999, whistle-blowing will have been made easier by the implementation of the Public Interest Disclosure Act 1998.

Research ethics committees are beginning to develop their own role in this regard, but the circumstances in which they will themselves detect fraud are likely to be infrequent. For all concerned, however, it should be axiomatic that they feel ethically and scientifically bound to report any misconduct they observe which exploits patients or potentially jeopardises scientific integrity.

The literature on the whole topic of the diagnosis of fraud and misconduct in clinical research is relatively sparse, but there are certain well-documented cases which are detailed in Scientific Deception, written by Grayson, and in Fraud and Misconduct in Medical Research, edited by Lock and Welk.

1. VISITS BY THE MEDICAL ADVISER OR THE CLINICAL TRIAL MONITOR
When a research project is about to start, the investigators who will be conducting this research have to be recruited. The details of this procedure are not the subject of this paper, but it is essential in the interests of minimising any irregularities in the conduct of the project, including fraud, that such potential investigators are assessed as to their knowledge of the principles of Good Clinical Practice (GCP), reliability, effectiveness and honesty. A visit by a medical adviser, a project manager or a clinical trial monitor may assist in this assessment of their suitability.

If there is any cause for concern at all, the medical director or equivalent senior colleague should be informed. Give-away quotes include:

- ‘I will not actually be doing this research myself, my registrar will’, in which case the registrar should also be seen and assessed.

- ‘Patients will be coming from several clinics/colleges’, in which case it is essential to know exactly which clinics are going to be used, and how patients who may be suitable for the research project are going to be referred to the main centre; or, if they are not to be so referred, by whom they will be assessed. Any associate investigators must themselves also be assessed for their suitability.

- ‘I am sure I will be able to recruit at least x patients’, in which case it is essential that the historical records for the relevant disease process in that particular centre must be scrutinised to ensure that the figure offered is realistic.

Here is an example of the value of a pre-project visit to a potential investigator, working as a consultant in a district hospital: an overseas-based company had not previously conducted any neurological research in this country, but wished to start. The medical department of the company

*A background paper prepared for the Joint Consensus Conference on Misconduct in Biomedical Research
†Medical Legal Investigations
did a literature search and chose this particular consultant who had a number of what appeared to be relevant publications to his name. When he was visited by the medical adviser in charge of the project, he confirmed that he would be conducting the clinical trial in a dedicated ‘research unit’ at a local private hospital. The medical adviser decided to visit the private hospital to see for himself, and found that the so-called dedicated unit did not in fact exist. The nursing staff at the private hospital confirmed that the consultant in question did indeed send some of his patients to the hospital as he was ‘doing research’, but went on to confirm that these beds were used for general admissions, and that a number of research projects were currently being held up because the beds were full. As a result, the company decided not to use this particular consultant for this project and learned later that the Local Research Ethics Committee (LREC) had recently turned down another project which had been submitted by this particular investigator because of the lack of suitable local facilities and because he was already conducting a number of other studies which the LREC considered did not enable him to conduct yet another clinical trial properly. Thus, incidentally, is also an example of the many different types of case currently being referred to the author and his colleague at Medicolegal Investigations, an agency specialising in the investigation of research misconduct.

Monitoring visits should be made to investigator sites throughout the course of any study. Such monitoring is an inherent component of good clinical research practice and is usually conducted by a clinical research associate (CRA). Such staff may be relatively inexperienced and clear guidance on what to check must be given. Furthermore, there should be a standard operating procedure in place for the handling of suspect data so that the CRA or project manager knows what to do if suspicions are raised. Factors that might be suspicious include:

- The recruitment of, or attendance by, patients at weekends or on bank holidays, when the surgery or clinic would be expected to be shut.
- The completion of a number of record forms all on the same date.
- The use of the same pen throughout the course of the study.
- Lack of variation in readings of, for example, blood pressure.
- Similar handwriting on consent forms and diary cards.
- Similar idiosyncracies seen on patient diary cards, completed ostensibly by different patients.
- Difficulty in obtaining access to original source documents, including pathology laboratory reports.
- Pristine source documents which might have been created for the purpose.
- ECGs which appear similar.
- Information which was missing on previous visits now being filled in.
- Alterations made retrospectively, where the alteration is over an erasure (modern erasives do not leave obvious traces as correction fluid does, but can nevertheless be detected).

Here is an example of a visit to a suspected centre: a partner in a three-man general practice had had some difficulty in recruiting the numbers of patients he had indicated would be attainable when he undertook to do the study, and the CRA reminded him that the trial recruitment period would soon be closing. Before her next visit, he had stepped up his recruitment rate by almost double. The monitor was trained to be suspicious in such circumstances and she placed the consent forms side-by-side during her visit. At once it was apparent that the signatures appeared to be similar, but in two distinct batches: one batch was in black ballpoint and neat; the other batch was in blue ink and scruffy.

The monitor then noticed that the dates on the scruffy consent forms were all within about a notice in the waiting room - the investigator was supposed to be on holiday. Furthermore, when the monitor asked the practice manager if she could look at the appointment book, the patients had not been booked in to see any of the doctors available at the surgery on the dates they were purported to have been recruited. On further questioning, one of the practice nurses admitted that she had been asked to sign some ‘model consent forms for demonstration purposes’. The case was referred by the CRA to her line manager in accordance with the company’s standing operating procedure and appropriate action followed.

2. THE RETURNED CLINICAL TRIAL MATERIALS

The materials used in a clinical trial should all be accounted for. This includes the documents which are to be returned as well as any investigational substances. Furthermore, they should be expected to show clear signs of use; forms will be soiled, maybe with coffee stains, or be dog-eared. They will have been kept in a handbag or on the dressing table and boxes of medication will be well-thumbed. Materials taken exactly as dispensed would be very unusual, and for any group of genuine patient-subjects there will be bound to be discrepancies in expected consumption when a tablet or unit count is made. They will always make some mistakes, and it pays to be suspicious if the materials are too pristine and the numbers are too accurate. However, if there are more such materials than there should be, then again suspicions should be raised.

Here is an example of the information yielded by careful examination of returned materials: a general practitioner had taken part in a multi-centre clinical trial on a new anti-arthritis regime involving capsules supplied in calendar packs and a topical cream supplied in tubes. The returned packs were nearly all found to have started on the same day of the week, and all at the same idiosyncratic place on each blister strip. The tubes, very unusually, all appeared to have been squeezed in exactly the same way, and they all weighed much the same - indicating a remarkable consistency in the use of trial medication across a group of disparate patient-subjects. The evidence clearly suggested that all the medication had been dealt with in some way by the same person and after a forensic investigation this proved to be the case.

A device now exists which records the real time when each item (tablet, etc.) is taken. It operates by stamping on a chart kept inside the lid of the container exactly when a tablet is taken from the pack, and as this device is very readily devised, the person using the container does not necessarily know that this recording is taking place. A number of cases are known which have revealed discrepancies: for example, medication meant to be taken three times, evenly spread, throughout the day have been revealed to have been taken all at the same time. Cases have also been revealed when even the treatment for a
whole week may have been 'taken' at the same time.

The company or consultant statistician might reveal a cause for concern: in a study involving an anti-inflammatory agent the protocol required rescue analgesia to be provided, and the statistician pointed out that analgesic consumption was the same during both the placebo and the active phases of a trial. The company checked that active medication was provided where expected and the blister packaging seemed to reveal correct usage by all the patients. A 'for cause' audit revealed that the patients existed, but the consent forms all appeared to have been signed in the same handwriting. An independent agency was called in and the forgery of consent forms was confirmed by all the patients who had never taken part in the study at all. The clinical investigator had made up all the data and had disposed of some of the trial material, including the rescue analgesia, so that it looked as if the trial had been done properly.

3. THE CASE RECORD FORMS AND PATIENT DIARY CARDS

Computed record forms are now being introduced, and will be referred to later. Meanwhile, manually completed report forms, which still easily comprise the majority, should not only be checked for accuracy, but for scruffiness. If a set of clinical report forms is absolutely pristine, free from coffee stains, and without evidence of the signs of normal use, it could be 'too good to be true'. But if an audit reveals that everything that particular investigator does is meticulous, then the clinical report forms are probably quite genuine. Nevertheless, a project manager has to be suspicious of the clinical trial centre from which all the record forms are returned quickly, with everything filled in, seemingly in one pen, maybe all at the same time, with no mistakes, gaps or alterations.

The first extensively documented British case of research fraud, in 1988, was that of Dr Uzair Siddiqui, a consultant psychiatrist in the city of Durham. He was found by an astute pharmaceutical company clinical trial monitor to have invented some of the laboratory data for most of the patients purported to have taken part in the trial and to have invented one complete patient. When challenged, he blamed the irregularities on his previous registrar, though he had forgotten her name and did not know where she now worked. Forensic investigation of this case enabled the registrar to be contacted and it was clear she had played no part in generating fraudulent data. The case was a strong one to take to the GMC, where eventually the professional conduct committee found him guilty of serious professional misconduct and his name was erased from the medical register.

Statistical analysis of data sets may reveal inliers, outliers and other anomalies related to one particular centre. But it is unusual to initiate a fraud investigation based on just a statistical analysis. However, this may become more necessary to raise suspicion in the future. The most extreme example of which the author is aware is when the statistician suggested that the chance of a particular set of results from one centre being genuine when compared with the results from several other centres was as likely as winning the National Lottery jackpot on two successive occasions. Not surprisingly this led to a further forensic investigation being made; this is still under way.

4. THE FINAL REPORT

It appears to be quite rare that fraud is detected as late as this, but the statistical anecdote referred to in the last paragraph was indeed discovered at this stage.

Serenidipitously, the comparison of two very similar studies may reveal similarities unlikely to have occurred by coincidence. This has arisen when data from a suspected centre have been brought together by an independent agency recruited to investigate other suspicious circumstances. Time and again the investigation of such centres reveals multiple episodes of fraud; this type of occurrence clearly demonstrates the definition of clinical research fraud: the generation of false data with an intent to deceive.

Audit is a valuable exercise and the QA professional may discover suspected irregularities that turn out to be due to fraud. Examples include separate medical records for those patients taking part in a clinical trial, deletion of entries and replacement with new entries that are overwritten.

Increasingly frequently, and likely to happen more often in the future, data are entered into a study by means of a computer. Because there is enough evidence that records may be entered fraudulently or altered after entry to make figures appear more as the investigator feels they should look - so as to support the effectiveness of safety of the investigational product - the computer software for the clinical trial must include a programme which prevents any alterations being made. If a mistake has genuinely been made, however, this can be indicated without its being deleted and the correct data entered alongside and initialised. Computerised clinical research records are currently much more difficult to monitor and to audit, as changes can be made without trace.

5. THE ROLE OF RESEARCH ETHICS COMMITTEES

LRECs have a responsibility under the International Conference on Harmonisation (ICH) agreement on GCP to approve investigators as well as protocols. Many LRECs interview investigators on a regular basis, so that they can fulfil this role with better knowledge of the prowess, capabilities, time commitment and facilities of the investigator. Multi-centre Research Ethics Committees (MRECs) cannot fulfil this role as they cannot know whether each local investigator understands the principles of GCP, is geared up to do this particular study, is not too busy, and is interested.

Two instances are known where GP investigators have fabricated LREC approval. The investigators in question fabricated the approval by making a collage using the headed notepaper of the LREC, a fraudulently generated approval text and a forged chairman’s signature. In one instance the collage was faxed to the pharmaceutical company so that the seams could not be seen. In the other instance the fabricator went to great lengths to colour photocopy the end result so that it looked as good as an original. The fraud came to light in both cases when the pharmaceutical company medical adviser had reason to notify the investigator of a serious adverse event that had occurred at another centre. As it happens, these notifications were made when the investigators were on holiday, and so their partners were informed. In one instance the partner denied all knowledge of the practice taking part in this particular research project, and informed the company accordingly.

The company sent a copy of the ethical approval it had received to the partner who promptly queried it with the
LREC chairman, who happened to be a friend. The LREC chairman confirmed that the committee had never even considered the project, let alone approved it.

In the other case, because the investigator could not be contacted, the company informed the LREC direct - only to discover that the project had been rejected by that LREC, the "alter ego" which the company sent back to the committee being confirmed as a forgery. In both cases, as in so many instances related here, the doctors concerned were investigated further: one was referred, successfully, to the GMC for disciplinary action to be taken; the other committed suicide.

6. EDITORS
Editors and those reviewing published literature may sometimes identify articles which have appeared elsewhere (plagiarism) or which appear to have been fragmented into several component parts (salami slicing). Whereas plagiarism is clearly a fraudulent activity, salami slicing is a rather lesser misdemeanour, although it undermines the integrity of the published work, leading as it does to multiple references from the same scientific work. Much more serious, and more difficult for the editor to detect, is the wholly fabricated research that has never been done. Whistle-blowers close to the individual who has published the spurious research have to be the ones who take action, and the classic case is that of William McBride, who was one of the first to describe the thalidomide effect. The difficulties which editors have in diagnosing fraud are therefore clearly understood and the inception of the Committee on Publishing Ethics demonstrates a commitment to tackling this issue.

The story of thalidomide is well known; less well known are the attempts of William McBride, who was one of the first to describe the effects of thalidomide on the developing fetus, to discredit another drug, Debendox - known as Bendectin in the United States - along similar lines. McBride had never in fact conducted controlled trials to determine the thalidomide effect, but had at least accurately observed its toxicity. The situation was different for Debendox/Bendectin, because McBride was ostensibly responsible for conducting studies during the late 1970s on rabbits which had shown up its toxicity. It took a decade to demonstrate publicly that such studies did not exist, and another decade (1996) before McBride was publicly denounced - all of which was much too late to save what was possibly a valuable therapeutic product. Here was an example of an eminent public figure whose reputation was such that it was unthinkable that he might be telling lies. Furthermore, this case demonstrates the messianic complex occasionally seen in fraudsters who seem to believe that they have a divine right to state falsehoods as if they were proven facts, because they 'know that they are right'.

7. WHISTLE-BLOWERS
The role of the whistle-blower needs to be better understood. Where fraud is cleverly or regularly covered up by the perpetrator, then it may be revealed by the partner, research nurse or other colleague concerned that patients might be being exploited. Partners may be suspicious when patients purported in the notes to be taking part in a trial know nothing about it; or tell the partner that they have seen the other partner a lot lately but that is not in the notes; or report having had very long ECGs taken, or giving a lot of blood, maybe on successive occasions. Nurses might be required to disregard inclusion and exclusion criteria, not report ADRs, or report ADRs that have not occurred. Secretaries and others might be required, at pain of losing their job, to witness non-existent signatures. Other fraudulent activities might have arisen such as the forging of a practice cheque, or making false claims for out-of-hours visits, temporary residents and so on.

A high-profile case is that of Malcolm Pearce, an eminent obstetrician and gynaecologist, where one of the whistleblowers was a theatre technician. The consultant claimed to have performed a pioneering operation, when a subsequent enquiry found that he had not done so. He claimed to have transplanted successfully an ectopic pregnancy and achieved a successful full-term vaginal delivery. Had this really happened, it would have been the first time such an operation had been successfully performed. The subsequent history of this case is interesting on several fronts: firstly, the enquiry into the fabricated operation revealed that he had reported on a study on 191 patients with polycystic ovary disease, which was also found to be fraudulent. Secondly, both these reports were published in the British Journal of Obstetrics and Gynaecology; the article on relocation of the ectopic pregnancy was co-authored by two others, one of whom was the head of the department where the consultant worked. Furthermore, the head of the department was editor of the journal in question and President of the Royal College of Obstetricians and Gynaecologists. Obviously the head of the department could have taken no part in the non-existent operation, and his co-authorship was thus untenable. Thirdly, there could be no question of these false activities being conducted for financial gain. This case demonstrates the objective of some fraudsters, who are usually very vain, of wishing to be seen to be a pioneer.

Another example is that of Dr Geoffrey Fairhurst, a general practitioner in St Helens, Lancashire. On this occasion it was the doctor's partner who acted as whistle-blower and who alerted the authorities to activities which the GP was clearly doing his best to conceal. The partner discovered a number of consent forms which were not signed by the patients in question, and who were not aware of their involvement in a clinical trial. Furthermore, the practice nurse was required to alter the dates printed by the electrocardiograph on tracings taken for clinical trial purposes, sometimes by as much as nine months, on pain of losing her job.

The final example reveals that suspicion raised by a whistle-blower - in this case the research nurse - can be corroborated by the auditor. The nurse reported to the pharmaceutical company sponsoring a study that recruitment was not proceeding to plan and that patients who did not have the disease for which the investigational drug was under trial were being put into the study. The QA professional conducting the 'for cause' audit found that source documents for certain laboratory results were on obsolete forms - and the game was up.

CONCLUSIONS
The many ways in which research misconduct - and indeed frank fraud - is committed inevitably mean that there are no hard and fast rules on which its detection and diagnosis can be made. Vigilance in observation by those close to
the researcher is the key to identifying irregularities. Always act on a hunch, verify or exclude what might have happened - using experts if necessary - and in the best interests of scientific integrity and of patient safety, take whatever action is appropriate to stop fraud or research misconduct being perpetrated.

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FRAUD AND MISCONDUCT IN BIOMEDICAL RESEARCH: HOW SHOULD WE RESPOND?

S. Tomlinson1, G.R.D. Catto2

DEFINITION OF SCIENTIFIC MISCONDUCT IN BIOMEDICAL RESEARCH
Misconduct ‘means fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting results of research and deliberate, dangerous or negligent deviations from accepted practice in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others’. (MRC December 1997)

THE SPECTRUM OF SCIENTIFIC MISCONDUCT
The Danish Medical Research Council in 1991 set up a Commission that preferred to use the term ‘scientific dishonesty’ to cover a wide spectrum of offences rather than ‘fraud’, ‘misconduct’ or ‘scientific integrity’. ‘Scientific dishonesty’, then, includes:
1. Fabrication of data.
2. Selective and undisclosed rejection of undesired results.
3. Substitution with fictitious data.
4. Erroneous use of statistical methods in order to draw conclusions at variance with those warranted by the study data.
5. Distorted interpretations of results or distortion of conclusions.
6. Plagiarism of results or entire articles of other researchers.
7. Distorted representation of other researchers’ results.
8. Wrongful or inappropriate attribution of authorship.
9. Misleading scientific grant or job applications.
   The Danish Commission also included:
10. Duplication of publications.
11. Presentation of high profile results through the media prior to peer review.
12. Omission of earlier original observations by others.
13. Exclusion of others from legitimate authorship.
14. Salami publication.
15. Data massage.

This background paper will focus principally on deception for personal gain and use the term ‘misconduct’.

PREVENTION
Prevention of misconduct in biomedical research depends upon those involved having a clear understanding of their obligations. In a paper in the Association of Medical Schools in Europe Newsletter (AMSE) of 21 April 1998, Frank Harris, Dean of Medicine at Leicester, drew attention to a document produced by the National Academy of Sciences, the National Academy of Engineering and the Institute of Medicine entitled On being a scientist: responsible conduct in research. Professor Harris, quoting from the document, stated that acts of scientific misconduct:
strike at the very heart of the values on which science is based. Such misdemeanours erode the fundamental standards of research and scholarship and destroy the trust and confidence the public must have in scientists and scholars if there is to be a future for research. The public, whether private or corporate, are the providers of funds for research and if the scientific community demonstrably are revealed to be cheats and dishonest then the consequences for the future funding of research could be very serious indeed. In medical research especially the fabrication (making up of data or results) and falsification (changing or misreporting data or results) can have very serious consequences for the public. Once a paper on medical research is published there is usually an immediate rush to employ the new methods of diagnosis or treatment. If this data is false, patients will come to harm.

Thus, when a new researcher joins an institution (university, medical school, research institute or any part of the NHS), it must be made clear that misconduct in their research will not be tolerated. Every institution should have a manual of good research practice that outlines responsibilities of both supervisor and supervised. There should be induction courses for all researchers. Supervisors should meet their research students (or collaborators in a research project) regularly and all participants in a research project should have access to raw data and to statistical analyses. For local research projects these guidelines present few problems. Multi centre trials must be conducted in the same spirit of openness recognising that the form of close personal supervision envisaged above may not be practicable; indeed raw data may not be available until the study has been completed. There should be clear guidelines on authorship. It must be made clear to all concerned (contractually) that in the event of any investigation individuals shall co-operate in the review of allegations of misconduct and have an obligation to provide relevant evidence to the appropriate authorities.

A CODE OF PRACTICE FOR DEALING WITH ALLEGATIONS OF MISCONDUCT IN BIOMEDICAL RESEARCH
Institutions in the UK generally have little experience of dealing with allegations of research misconduct. To date, these have not been encountered equally across all research disciplines, being concentrated mainly in the biomedical sciences. Rather than waiting to respond to a specific problem, institutions should agree and publicise a code for dealing with these issues covering the spectrum of biomedical research. One such approach is outlined here.

This code of practice could be applied to a range of misconduct but was specifically drafted to deal with the most serious incidents involving deception for personal gain,
The complaint must be guaranteed anonymity and allowed to have a supporter or representative present at all interviews during the screening and formal investigation. The head of the institution must be informed of the allegations, all research material sequestered and a written statement sought from the respondent ("accused").

The screeners will then consider the evidence available. Subsequently they should pursue one of the following four courses of action:

1. They will decide that they need to seek confidential advice and they shall then be free to seek such confidential advice from experts in the relevant subject.
2. They may consider the allegation to be unfounded or malicious, they may dismiss it and inform the complainant accordingly. If the allegation is deemed to be malicious the screeners will dismiss the complaint and inform the head of the institution who may invoke disciplinary action against the complainant.
3. They may consider that there is some substance in the allegations but the matter does not warrant a formal investigation in which event they will decide what action, if any, is required to put the matter right insofar as it is possible. Under these circumstances the respondent must have a right of appeal (see below).
4. They may consider that there is sufficient substance in the allegation to initiate a formal investigation of the complaint.

STAGE 2 - THE FORMAL INVESTIGATION
The formal investigation must seek answers to the following questions:

1. What are the relevant facts?
2. Has scientific misconduct been committed?
3. If so, who is the responsible person or persons?
4. What is the seriousness of the misconduct?

The complainant and respondent must be notified in writing that a formal investigation is to be undertaken.

The Investigation Committee
The committee will consist of at least three people and at least one of the committee should be from outside the institution and a recognised expert in the field under investigation. None of the members of the committee should have conflicts of interest with the respondent or the case in question; they must have the necessary expertise to examine the evidence, interview witnesses and conduct the investigation. The respondent must be able to object in writing to any individuals appointed to the investigation committee and the head of the institution or his nominee may decide to replace the challenged person with a qualified substitute.

There must be a time limit from screening before the establishment of the committee for formal investigation
Misconduct in biomedical research

(30 days). The investigation itself should be time-limited to 90 days. The investigation will include examination by the committee of all documentation, including computer disks, materials, proposals, publications, correspondence, memoranda and notes of telephone calls. Interviews will be conducted with all individuals involved in making the allegations and other individuals regarded key aspects of the allegations. A verbatim record of these interviews must be prepared by the secretariat and approved by interviewer(s) and interviewee(s) to ensure factual accuracy; this record must be included as part of the investigation report.

The Report

The report must state how the investigation was conducted, describe how and from whom the information relevant to the investigation was obtained, state the findings and explain the basis for the findings. Agreed verbatim reports of all interviews must be included in the report normally as an appendix.

The respondent or respondents against whom the allegations have been made will be given a copy of the evidence considered by the investigation committee and a copy of the report. The respondent must be given an opportunity to comment upon the report. Written comments from the respondent must be submitted to the head of the institution (or his nominee) within 20 days of receipt of the report and shall then be attached as an addendum to the report.

The report will be distributed to the chairman and at least one member of the investigation committee to allow the respondent to challenge statements which he or she believes to be unsubstantiated. A record of the meeting shall form part of the investigation report and will be provided to the head of the institution or nominee.

The investigation committee will report its findings to the head of the institution and to the appropriate nominated person (the dean, head of research division, chief executive of an NHS trust or health authority) and the head of department or research group of the person against whom the allegations have been made.

Should the allegations be proved, the head of the institution or nominee in consultation with the appropriate person (e.g. dean, head of research division, head of the individuals department or research group) will decide what action needs to be taken. This may include informing the appropriate professional body (e.g. the GMC for medical practitioners), the grant awarding body and editors of all journals in which the respondent has published articles and the NHS regional director of R&D (if appropriate). Action may also be taken to revoke a degree or other qualification obtained wholly or partly through misconduct in research relevant to that degree or other qualification. Disciplinary action may be warranted. Even if the respondent resigns from the institution before completion of the investigation, the investigation must be completed by the institution and a report submitted to the head of that institution.

Appeal

The respondent may appeal following screening or following investigation. The appeal board would normally be appointed within 20 calendar days of the receipt of an appeal by the respondent.

There should also be a time limit for completion of the process; in the case of an appeal against the conclusions of screening this would be 30 days, in the case of conclusions of an investigation this would be 90 days from the appointment of the appeal board. The appeal board will consist of two or more individuals who were neither members of the initial screening procedure nor of the investigation committee. The head of the institution will notify the respondent of the proposed appeal board membership.

The appeal report must state how the appeal was conducted, describe how and from whom further information was obtained, state and explain the basis for the findings.

The head of the institution will then take appropriate advice and decide on the basis of the appeal report whether to endorse, amend or overturn the conclusions of the screening or the investigation. The head of the institution will notify the respondent in writing of the outcome of the appeal board and will provide a copy of the appeal report and evidence considered by the appeal board. The decision of the head of the institution shall be final.

THE LEGAL VALIDITY OF SCREENING AND INVESTIGATION PROCEDURES

The legal validity of such procedures as outlined above is unclear. A number of questions must be resolved; for example, is a respondent legally obliged to release information that may be requested at the screening or investigation meeting. Is a respondent legally obliged to release information that may be requested at the screening or investigation meeting. Is a respondent legally obliged to release information that may be requested at the screening or investigation meeting. Is a respondent legally obliged to release information that may be requested at the screening or investigation meeting.

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The COPE Report 2000

4. Regulation and procedures for handling allegations.
5. Fair procedures and appropriate protection for both the accused (respondent) and the ‘whistle-blower’ (complainant).

Thus we are left with a clear steer to have procedures in place for dealing with allegations of misconduct in biomedical research across the whole research community.

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Summary of cases submitted to COPE since its inception

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<th>Year</th>
<th>No of cases</th>
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<th>“Probably no misconduct”</th>
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<td>80</td>
<td>11</td>
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Problem (some cases presented several issues)
- Redundant publication or submission: 29
- Authorship: 18
- Falsification: 15
- No informed consent: 11
- Unethical research: 11
- No ethics committee approval: 10
- Fabrication: 8
- Editorial misconduct: 7
- Plagiarism: 4
- Undeclared conflict of interest: 3
- Breach of confidentiality: 3
- Clinical misconduct: 2
- Attacks on whistleblowers: 2
- Reviewer misconduct: 1
- Deception: 1
- Failure to publish: 1
- Ethical questions: 1

Update on cases submitted to COPE

1998 cases that remain open:
- 98/8 Redundant publication?
- 98/12 Possible redundant publication
- 98/17 Allegations of scientific fraud and unethical conduct of experiments with attempts to silence the whistleblower
- 98/30 A falling out

1998 cases that have been closed
- 98/1 Blatant example of duplicate publication?
- 98/2 Disputed authorship
- 98/3 Unethical research undertaken by a single handed GP
- 98/4 Redundant publication
- 98/5 Failing to get consent from an ethics committee
- 98/6 The critical commentary
- 98/7 Plagiarism
- 98/9 An author plagiarising the work of the reviewer
- 98/10 Unethical research
- 98/11 Grounds for retraction?
- 98/13 Uncertain treatment of four patients following previous published experiments
- 98/15 Questions of authorship, duplicate publication, and copyright
- 98/19 The double review
- 98/21 Duplicate publication and now fraud?
- 98/22 Confidentiality and conflict of interest
- 98/24 Duplication, revision, and resubmission?
- 98/25 Surprising results and a new area of research for a senior author?
- 98/27 Attempted dual publication
- 98/28 Redundant publication
- 98/29 Overseas editor dismissed from university for fraud
- 98/32 Redundant publication by an editorial board member
- 98/33 The author who wasn’t an author
- 98/34 “Inadvertent” duplicate publication

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

Case 98/14

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

A GP had submitted a letter for publication outlining research he had carried out on patients with vitiligo. He described how he had treated them simultaneously with an anti-fungal agent and an antibacterial medicine over a
prolonged period. There did not appear to be any controls, and there was a question over whether patients had
given informed consent and whether he had sought and obtained ethics committee approval.
The editor was advised to write to the GMC.

Outcome
The doctor did not have ethics committee approval. A complaint was made to the GMC, but the doctor was no
longer on the register.

Case 98/18
Triplicate publication with possibly different data in each

A paper describing an outbreak of infectious disease had been submitted to three journals. A considerable amount
of the epidemiological data had been repeated in all three papers, but there were discrepancies and inconsistencies.
The editors were advised to write to the authors, submitting copies of all three papers, and requesting an expla-
nation. It was also suggested that the respective heads of the institutions be informed.

Outcome
Two of the journals asked the chief executives of the organisations to investigate. They did, and found that things
had not been done correctly. However, they did not think that any sanctions were necessary, but they revised their
guidelines on authorship.

Case 98/16
The missing author

A doctor disputed the authorship of a paper published in a journal credited to two authors, saying that the case in
question had been admitted into her care. She also alleged that some of the clinical facts pertaining to the case
were inaccurate.
The editor was advised to ascertain the true facts or publish a retraction.

Outcome
After looking at the available evidence, it was felt that the claimant did not have a strong case for authorship.

Case 98/23
Duplicate publication

A paper was published in one journal that was subsequently found to have substantial overlap with another that
had already been published in a different journal. The editor challenged the author.
The editor was advised to obtain an independent opinion, which he duly did.

Outcome
Redundant publication was confirmed. The author was shamed in the journal.
The editor of the other journal involved followed an identical procedure and shamed the author who was a dis-
tinguished colleague. Finally the author apologised in writing to that journal but not to the one that had raised the
alarm.

Case 98/26
Partial disclosure of redundancy?

A reviewer detected a paper that was almost identical to one published by the same group three years earlier in a
different journal.
The editor was advised to seek clarification.

Outcome
The authors still maintained that the paper contained new information and an impasse was reached. The paper was
rejected and no further action was taken.
1999 cases that have been closed since the publication of last year’s report:

Case 99/2

The manipulated contributor list

A dispute developed among contributors to a published article, and a complaint was made by one of them to the Danish Committee on Scientific Dishonesty, on the grounds that the original contributor list had been altered from what had originally been agreed. The Committee upheld the complaint, but the findings were disputed.

Outcome

As a result of the dispute nothing was published.

Case 99/3

Plagiarism

A paper submitted to a journal appeared to have been plagiarised after it was discovered that it had been submitted to a different journal within the same specialty, but with different authors. The editor wrote to the deans of the medical faculties to which the authors were attached, without first writing to the authors.

Outcome

The editor received no response from the deans of the faculties of medicine to which the authors were attached, and no response from the authors.

Case 99/4

What happens when there is no local ethics committee?

A reviewer questioned whether ethics committee approval had been sought. The authors of the paper, who were Taiwanese, said that they could not seek approval, as there was no such committee at their university. The editor was advised to verify this with the authors, and to state that the paper would not be published unless there was evidence of such approval.

Outcome

Nothing more has been heard from the authors.

Case 99/9

Redundant publication and change of authors

The references of a paper submitted to a journal overlapped considerably with those of a published paper on the same subject, but by a different set of authors, bar one. There were several other areas of overlap. The authors had not sent a copy of the first paper with their submission. The editor was advised to ascertain the degree of overlap and to verify the level of disclosure by the authors.

Outcome

The case was investigated by the chief executive of whom? The overlap was evident on re-review, but the chief executive felt that there had been no deliberate intention to deceive.
Cases submitted to COPE

June 1999 to September 2000
Ethical status of authors’ actions?

A consultant in public health and a consultant clinical biochemist employed by a health authority submitted a paper. It sought to address the question of benzodiazepine abuse and resale on the black market.

The authors identified the practices with the highest prescribing rates for benzodiazepines, and asked GPs to agree to request urine samples from patients with a benzodiazepine prescription. The paper presented no clear patient selection criteria, except that cases were selected by GPs according to whether they felt confirmation of compliance would be useful. They found that only 83 of 158 patients prescribed benzodiazepines had positive urine samples, and concluded that “random urine testing is a good idea.”

The paper did not make clear whether the prescriptions requested were first or subsequent prescriptions. No mention was made of ethics committee approval or of patient consent.

When these issues were raised with the authors they responded very promptly, agreeing with the concerns. They argued that it was a mistake to have called this piece of work a study. They outlined the background of concern which led to this piece of work, and argued that rather than a study, their work represented a decision to extend the availability of urine testing for benzodiazepines to three practices that were under considerable pressure at the time. They argued that they did not see this as a research project, but as a means of coping with a difficult situation by extending to these practices good practice and facilities already available to the community drugs team. Cost considerations, they said, had prevented open general practitioner access to urine testing for drugs. This, they said was why they did not submit the proposed change for ethics committee approval.

There was also no specific consent sought from patients other than the standard consent obtained under a doctor’s duty of care. They argued, however, that the testing of urine for drugs of dependency is standard practice for a community drugs team, and in general practice, in some cases.

The authors requested advice on how to present such a piece of work in an ethical manner. They also asked what were the ethics of publishing pieces of work that were never intended as research, but which turn up important information; and conversely, what were the ethical implications of not making available important information arrived at during routine work, and how one should deal with the ethics of obtaining genuine informed consent from patients for a test that is being used to assess their honesty.

The responsible editor thanked the authors for their swift reply, but pointed out that on purely scientific grounds the journal did not want to publish the study.

What is COPE’s view of the ethics of the authors’ actions? How else might the editors respond to the questions they raise? Should the journal take any further action?

Discussion/Advice

- Explain that this is a study for which ethical committee approval is needed.
- Tell authors they have misbehaved, although we can understand how it happened.
- Don’t involve GMC, but tell authors that if they want their work to be considered as research, they need to design a proper study and obtain the appropriate approval.
- The health authority funded the study: should they be informed? If the health authority’s consent were obtained, it would make a good illustrative case study to report.
- Journal to write an editorial to raise awareness of the issue.
Case 99/6

Yet another case of duplicate publication

A paper published in journal A in 1990 was published almost verbatim in journal B the following year, and yet again in journal C in 1993. None of these publications made any reference to the others. The case emerged in the process of one of the authors applying for a professorship.

The authors conceded their error when tackled on the issue. One editor agreed to publish notice of duplicate publication, but difficulties were experienced tracking down the third editor.

Discussion/Advice

- Notice of duplicate publication should be published across all three journals, preferably simultaneously.

Outcome

A notice of duplicate publication was issued.

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 to the editor. No full publication of this trial followed, despite calls for this from colleagues in the field. It took the intervention of a regional research ethics committee and a dean to persuade the investigators to write a final manuscript. This paper has still not been submitted for publication, although some of the data are available in the Cochrane library.

A few colleagues have had access to the final manuscript after agreeing to strict confidentiality. These latest data do not support the optimistic conclusion of the original letter.

Another research team has asked the journal to:

- ask the original authors to confirm their preliminary results, and if they cannot, to retract the letter
- consider retracting the letter
- consider writing about the case in another way.

Should the editors invite the research team to explain the story in a correspondence letter, and ask the original authors to reply?

Discussion/Advice

- Is it a form of misconduct not to report the final result?
- If the authors don’t discharge their responsibility, is it the duty of the editor?
- The research team should submit a letter to the editor, who should then invite the original authors to respond.

Outcome

The research team was invited to write to the journal. Their response is still awaited.
Case 99/11

The anonymous critic

A letter containing details of a case report was submitted in February 1999. The authors were from Japan. After peer review and revision, the case report was accepted and a proof was sent to the authors.

Two anonymous letters were then received, one on April 29 and another on 12 May, both from Japan. Both letters claimed that the author “has prized honour above everything else” and that he had submitted “nonsense data.” Our correspondents were “absolutely astonished” that we are publishing this letter.

Given these anonymous claims, what should be done next?

Discussion/Advice

- The immediate reaction is to dismiss them if they are anonymous but they might be serious.
- Editor advised to write to author and his head of department to ask if they have concerns, citing a similar experience that had been submitted to COPE before where the anonymous complaint was found to be justified.

Outcome

The head of department was contacted, but no reply was received.
Case 99/12

The careless surgeon

A paper was submitted in which a young surgeon described five patients who died over six months under the care of one surgeon. The author suggested that the surgeon was dangerous and that something should have been done. Nothing was done and the surgeon has since retired. The paper, a very personal one, provides an interesting insight into the difficulties that doctors have dealing with problem colleagues.

Should the editors:
- attempt to get consent from the patients’ relatives?
- worry about the fact that somebody, somewhere, is likely to be able to identify the surgeon, particularly if the article is signed rather than published anonymously?

Discussion
- This case had already been published in a journal the preceding year.
- The system has changed in the past 10 years since these issues first arose, but the committee felt that the information could be published as a source of interest on what used to happen.
- It was suggested that the article be re-published, accompanied by five people’s responses as to what would happen now.

Case 99/13

The discontented and abandoned contributor

A paper was rejected after peer review. Some time later a researcher wrote to say that he had been involved at the beginning of the study, but had withdrawn his name because he felt the study was defective. He had heard that the study had been submitted for publication, and thought it better that the editors were made aware of his doubts before publication rather than afterwards.

As the paper had already been rejected, these questions didn’t arise. But the editor asked the author of the letter, who had written in confidence, if he might copy his reply to the authors of the rejected study.

Does COPE think that the editor has done the right thing, and what more might be done?

Outcome
The author did not want the editor to forward a copy of the editor’s letter to the other authors of the rejected study. No further action was required.
Should editors get involved in authorship disputes?

A paper from Finland in a controversial area of vaccine research was peer reviewed and provisionally accepted. At the revision stage, the journal received a letter from a researcher based at an immunotherapy company in the United States, raising serious doubts over the analysis of the Finnish data. This author claimed to have been involved in the research, and proposed an alternative interpretation of the data.

This letter was forwarded to the authors, who acknowledged that the American author had highlighted some major errors which they corrected in a further revision of their paper. But they disputed his interpretation of their data. The Finnish authors acknowledged the advice given by the US author, but did not declare any financial input from him. They denied that he should have been cited as a contributor on the original paper. In due course, the paper was published.

The American correspondent continued to telephone and e-mail various members of the editorial team, seeking to have published alongside the paper a short report, carrying his opposing interpretation of the data. This request was declined, on the grounds that he was not the author of the paper and therefore had no ownership of the data.

But he insisted that the original idea for the study had been his, and that he had contributed more than £500 for secretarial support to enable the study to be carried out.

Should he have been cited as an author?

Discussion/Advice

- The American did not do the research; he generated the hypothesis that the Finns tested, using the data they had generated.
- He could be a contributor, therefore, as he meets the criteria for authorship, and his money was also accepted, suggesting collaboration.
- The American published a letter in the journal about the Finnish data, so he has been able to respond to the findings.
- It is not up to the editor to determine who is a contributor and who is an author; it is up to the Finnish employees to decide.
- It is not for COPE to dictate on this issue, although COPE inevitably gets drawn into author disputes.

Outcome

The case has prompted a formal complaint to the Finnish employers and to the relevant journal committee.
A further case of redundant publication

A paper was submitted to a UK specialist medical journal. At review, one of the reviewers alerted the editor to the fact that a very similar paper had been published in a US specialist title. It seems very likely that the reports describe the same randomised controlled trial. The only piece of new information was not an important outcome of the trial. The authors did not disclose the existence of the first paper.

The editor wrote to the authors rejecting the paper for the above reasons and informing them that he had reported the matter to COPE.

What more, if anything, should he do?

Discussion

- A randomised controlled trial is the most dangerous form of redundancy.
- The editor should write to the authors informing them of his suspicions of redundancy, cite the COPE guidelines, and give the author the chance to respond.
- The editor should seek independent advice about the degree of redundancy and report the matter to the head of the author's institution or dean, as appropriate.

Outcome

No response has been received from the authors. The matter was not reported to the head of the authors' institution.
Case 99/16

**Author dispute and dual submission**

A case report was submitted for consideration and, following favourable review, was accepted for publication by Journal A. All three authors signed the copyright release form, but about six weeks later a request not to publish the article was received by e-mail, which was attributed to a “misunderstanding and argument between two of the authors.”

The editor wrote to all three authors expressing concern, but after six weeks none of them had responded. A further letter was sent advising them that if a response was not received within 10 working days then the head of their respective institutions would be informed. This produced a response from two of the authors who accepted that there had been poor communication and admitted that the paper had been sent, presumably simultaneously, to Journal B, which had also accepted it for publication. One of the authors indicated that they would be willing to withdraw it from Journal B, as they had a preference for Journal A.

What should the editor do?

**Advice**

- The editor was advised to ask the authors to contact Journal B. The deans of the relevant institutions should be informed and the paper should be rejected.

**Outcome**

The paper was rejected. The authors apologised profusely for the misunderstanding, and in view of the fact that one of the authors moved institution, it was decided not to inform the deans.

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Case 99/17

**Submission without knowledge of the corresponding author**

A case report was received and the corresponding author was duly notified. The corresponding (and senior author) immediately faxed back, asking who had submitted the case report as he had not been consulted and had not seen the manuscript. The submission letter contained the names of all four authors; three of the signatures had been made using the same pen and probably the same hand. The signature of the senior and corresponding author was clearly “pp”.

The editor responded, pointing out the misconduct and received a prompt written response from the senior author agreeing that this was not the way to proceed. The senior author did not feel that the matter should be taken further other than through a formal letter from the editor to the author who had demeaned.

What should the editor do?

**Advice**

- The editor was advised to contact all the authors for an explanation.

**Outcome**

The editor and the senior author wrote a disciplinary letter to the offending author, but no sanctions were applied.
Case 99/18

Rights of reviewers

A clinical professor of medicine was asked to act as a reviewer for a submitted paper. The paper had not been presented publicly or in abstract form. The reviewer returned an extensive list of suggested alterations, but rated the paper highly. The other two reviewers also rated the paper highly, but suggested only minor modifications. The editor invited the authors to undertake a minor revision and subsequently accepted the revised paper without sending it back to the three reviewers. The reviewers, however, were sent a copy letter from the editor informing them that the revised manuscript had been accepted.

The editor then received a letter from the clinical professor asking if he could have a copy of the accepted revision, or the page proofs. He also declared that his own group had been stimulated to examine the same markers in their own patient group following the review of the paper, and that his group felt that they could confirm and extend the important observations made by the submitting authors.

- Do reviewers have the right to closely follow a manuscript through to the point of publication?
- What should the editor do about the fact that this reviewer appears to have altered his research activity and direction as a direct consequence of reviewing the submitted paper?

Discussion

- There was a general feeling of discomfort about this reviewer's actions but some felt that the reviewer had behaved honourably.
- Many journals routinely feedback to reviewers and there is no problem with reviewers building on this, provided the authors' permissions are obtained.
- E-print/open review solves these problems which originate in a closed system.

Outcome

Page proofs of the accepted paper were sent to the reviewer with the authors’ permissions. No action was taken against the reviewer with respect to his altered research activity.
Case 99/19

An anonymous letter in response to qualitative research

Some two months after publishing a piece of qualitative research about health behaviour in an ethnic minority group, an anonymous letter suggested that the work might be fraudulent.

The letter was in very poor English, but made two main points. Firstly, the original study did not make clear how many women were included, and secondly, the anonymous respondent could not understand who could have done the interviews. These women would have to have been interviewed by another woman for cultural reasons, and yet the only woman included as an author was British and clearly would not have been able to speak the language of the women interviewed. These two questions raised doubts in the mind of the anonymous respondent about the genuineness of the study.

These concerns were made known to the authors, who responded by saying that the paper did not specify how many women were included and that the interviews had been done by the wife of one of the authors.

The original manuscript was checked to reveal that the number of women in the study had been edited out, although this was supposed to have been included in a longer version published on the web. In fact, the longer version had never been posted.

What general lessons does the committee draw from this episode?

Discussion

- Some of these problems can be generated by too vigorous copy editing and electronic publication. Nevertheless, there are questions to be answered—namely, who did the interviews, problems with ethnic studies, and state of the raw data.
- The editor should contact the senior author and ask for clarification about who did the interviews, and their status.
- A clarification should then be published in the journal.
Case 99/20

**Dual publication may be necessary in some circumstances?**

At a recent editorial board meeting it was suggested that in some disciplines straddling several specialties, transparent simultaneous publication might be necessary.

It was suggested that this applies to sexually transmitted infections, and different readers may not have access to each other's journals. For example, in a study of human papilloma virus epidemiologists, virologists, STD physicians, immunologists and oncologists may all be looking at different aspects of the same study or patient group. It was therefore suggested that some papers, which straddle more than one field, could be simultaneously published in two journals with open reference to each other.

This question arose because the journal had recently been involved in disputes about redundant publication for some papers published from the Centers for Disease Control in Atlanta. The authors had taken the same cohort but looked at it from two entirely different angles with two entirely different readerships in mind.

What are COPE's views on this?

**Advice**

- There is no problem about simultaneous publication, assuming that the editors of both journals agree, and that full disclosure is made.

**Outcome**

The immediate issue was resolved as the original journal decided not to publish the article and the two papers were published back to back.

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Case 99/21

**Compromise of patient confidentiality?**

A paper containing three case reports of the same disease was accepted for publication. The disease reported is fairly rare. The parents of one of the cases consented to publication on condition that their daughter was referred to in the paper by her first name rather than as a case number. This particular case has been discussed in the course of a national inquiry, but it is not clear whether the other two cases were discussed. If the editor publishes this paper, the identity of the other two cases might be revealed if he respects the wishes of the parents.

What does COPE advise?

**Discussion/Advice**

- Informed consent must be sought from the relatives of the other two cases. The editor should approach the authors to this effect.
- The fact that a national inquiry is under way is not relevant.
- The authors should also inform patients that the journal has a website and that there are regular press releases, so the case might receive wide dissemination.

**Outcome**

The other two families had already given their consent. The authors contacted them again to alert them to possible press coverage. No objections were raised so the article was published with the patient's name in full, as requested by the parents.
Case 99/22

Who ensures the integrity of the editor?

An editor came across a letter from the editor-in-chief of his journal to a reviewer that asserted he had recommended the acceptance of a manuscript. He had in fact recommended the opposite, both verbally and in writing. The paper in question was a guideline on the therapeutic choices for a relatively common medical condition. The authors had claimed their conclusions and therapeutic recommendations were “evidence-based” and recommended a new, expensive medication as first-line treatment.

The reviews of the manuscript were mixed. One reviewer made only a few comments and recommended publication. The second reviewer expressed concern about an apparent bias and suspected there had been pharmaceutical company involvement in the writing of the paper. When the manuscript was reviewed at the regular meeting of scientific editors, the editor recommended rejecting the manuscript and this was written down in the manuscript “log.”

The editor-in-chief decided to request a third review, this time from a guidelines expert. In the meantime, the principal author had spoken at length with the editor-in-chief. Although the expert reviewer expressed concerns about the manuscript, the editor-in-chief chose to accept the manuscript for publication.

In accordance with journal policy, the reviewers were notified that the manuscript had been accepted, prompting the second reviewer to again express concern about bias. The editor-in-chief replied, saying that the editor had recommended publication.

Under the previous editor-in-chief, there had been a formal policy with the professional body with which the journal was associated, outlining the journal’s editorial freedom. But after he left this began to change.

A memo was sent from the association stipulating that any editorial material published in the journal from the association should have an elected official as the author, even if a researcher on staff or a scientific committee had written it. The editor questioned this policy on the basis that it was at odds with the definition of authorship by the International Committee of Medical Journal Editors (ICMJE). The editor-in-chief ignored these concerns.

Shortly thereafter, the association’s CEO announced that no letters should be published in the association’s journal that criticised association policy. The editor-in-chief initially stated to the journal staff that he disagreed with this and requested that any such letters be directed to him. He assured staff that if he thought these letters merited publication, he would discuss them with the CEO. Since then, no letter criticising association policy has been published.

When a scientific editor submits an article to his own journal, the policy was that another scientific editor would handle the manuscript; likewise, the fate of the manuscript would be made known to the author/editor in a confidential manner.

The editor had co-authored a manuscript with another researcher and had submitted it to the journal for consideration. Several months later, in a meeting of copy editors and publication staff to discuss the placement of accepted manuscripts, the editor-in-chief announced that the reviewers had recommended rejection. He had not informed the editor beforehand. In actual fact, none of the original reviewers had recommended rejecting the paper.

Manuscripts that had not been accepted were not usually discussed at these meetings and such behaviour contravened the ICMJE recommendations. The editor-in-chief said he would request another opinion before he made the final decision.

When the co-author of the paper wrote, asking when the final decision would be taken, the editor-in-chief accused the editor of breaching confidentiality but wrote to the co-author assuring him that the manuscript would be treated fairly and promptly.

The editor did not send out the manuscript for another opinion for almost two weeks. When he did, he identified in the covering letter that “he would elect to reject the manuscript” but sought the reviewer’s opinion. However, two days earlier, he had sent a letter to one of the original reviewers asking him to write a “single or several papers” on the exact same topic. About two weeks later, the editor-in-chief rejected our manuscript, apologising for the delay, and noting “we had some difficulty finding a person to give an editorial opinion of the review.”

In a further instance, the editor was asked to review a manuscript for the journal that purported to be an evidence-based guideline. The other reviewers included the previous editor of the journal and an outside reviewer. The editor identified several concerns and included suggestions on how the manuscript could be strengthened; the previous editor gave very similar feedback. The third reviewer had only a few superficial comments, such as a title change.
Case 99/22 (cont)

However, the editor-in-chief requested an additional review from an expert in evidence-based medicine, but accepted the manuscript with minor revisions, including the title change, before receiving these comments. Later, the additional review came in, seriously questioning the evidence base of the manuscript, but it was never sent to the author. The manuscript was published with minor revisions.

The editor was sacked. The staff were told only that confidentiality precluded giving an explanation; unofficially it was intimated that he had simply been too difficult to get along with.

The journal is still publishing, and the relationship between the Association and the Journal is increasingly intimate. There appears to have been a Faustian bargain made between the CEO of the Association and the editor-in-chief of the Journal whereby, in exchange for compromising editorial freedom in sensitive areas for the Association, he could publish what he wanted without feeling constrained by the usual editorial standards.

- If feedback from peer review is ignored, who will know? Most journal editors work in relative isolation and there is virtually no quality control.
- Who polices the relationship between a science-based association and its journal, a relationship that has its own particular set of challenges, involving both scientific and political elements.
- What can be done to stop/prevent corruption within the editorial office of a scientific publication, an issue that has virtually escaped discussion and consideration within the scientific community?
- What will it take to create the political will to ensure the integrity of scientific editors?
- There is often no way to formally investigate and address alleged abuses of editorial power, especially if these abuses are in the interests of the publisher or parent organisation.

Discussion

- The editor has acted as a whistleblower and has been fired as a result.
- This raises several questions about the integrity of scientific publications.
- COPE is not in the business of disciplining editors and authors, but perhaps it could devise a code of behaviour, which editors could sign up to, and be formally disciplined by COPE if they breach it.
- COPE feels that this case is worth publishing in a major journal and on web sites to encourage discussion.
Case 99/23

Publication bias arising from an editor’s activities

The committee’s attention has been drawn to alleged publication bias in Journal X. It is alleged that an editor on X had invited a young trainee in radiology to author some 14 commentaries over the past 5 years. His most recent commentary draws attention to one important study from France but otherwise covers the same territory as his previous commentaries without mention of relevant contrary viewpoints. Five of the 12 articles cited are by the commentator and/or the editor in question.

Why has commentary on a particular field been monopolised over five years by a graduate student with little breadth of experience in the subject? Why have respected authorities been overlooked? Why has a particular viewpoint been allowed to dominate Journal X when contrary and broader views exist? Most importantly, has favouritism for a particular commentator and/or viewpoint been allowed to influence other articles in this field of research submitted to Journal X?

How should the editor in chief respond to these allegations?

Discussion
- This is a complaint about an editor and is not in COPE’s remit. It is the responsibility of the editor in chief to respond, and if necessary, to take the matter up with the journal’s ombudsman.
- As COPE was contacted, the chairman will write to the accuser, say the matter was discussed, and that the editor in chief will refer the matter to the ombudsman as necessary.

Outcome
The complaint was deemed unfounded by the ombudsman.
Case 99/24

Invasive intervention without consent

A study was submitted on the safety and feasibility of treating patients with acute stroke with an invasive procedure that would cause them considerable discomfort. The editor did not want to publish the study because it had negative results, did not include a power calculation, and was almost certainly too small to detect a clinically useful difference.

The study had obtained local ethics committee approval, but the editor was worried about the level of consent. The authors were therefore contacted and they responded:

“Besides the approval from the local ethics committee, all patients or their relatives had to give spoken as well as written informed consent before inclusion in the treatment group. The majority of the patients were awake, and therefore able to understand the information both orally as well as in writing. All the signed informed consents “in the local language” are kept for further documentation if needed. None of the patients included withdrew their consent during or after the study period. As you may know already, a national body controls the ethical aspects of clinical trials in this country very rigidly. This study could never have been performed without informed consent from the patients or their relatives.”

Should the editors accept this statement or is further action required?

Advice

- Whatever the ethics committee said is almost irrelevant because the study design was poor and the sample too small to give meaningful results.
- The editor should write to the institution and report that the ethics committee was not functioning correctly, stipulate that the study design was poor, and request the consent forms.
Case 99/25

The results that were too good to believe

A study made it a long way through the peer review process before one of the statistical advisors said that the results seemed “too good to be true.” The authors were asked to send in the original data, which the statistician analysed. He remained very concerned about the data. The authors were notified and the journal asked the university to investigate.

Has the editor done the right thing?

Advice
- COPE agreed that the editor had acted correctly and observed that this was a common problem.

Case 99/26

The declared and the undeclared competing interests

An editorial was published on a particular subject in which the author’s competing interests were declared. He had given evidence on behalf of patients making a claim against a manufacturer. Three people then separately pointed out that we had already published a commentary on the same subject in which there had been no declaration of competing interest for the author. The three people all said that this author did have competing interests.

A review of the documentation revealed a statement of competing interest from the author in his role as reviewer of the paper on which he subsequently produced a commentary. In his statement he said that he received funds from the pharmaceutical industry for speaking, researching, and advising—and for employing staff. He then, however, ticked the box to say he had no competing interest. He had not been asked to sign a separate statement of competing interest for the commentary, and so nothing appeared.

He has now been asked to make a declaration of competing interest, which he has done.

What lessons can the committee draw from this case, and should anything more be done?

Advice
- It is important that editorial staff are more vigilant in scrutinising competing interest forms.
- In this case enough has been done.

Outcome

The competing interests of the authors were published on the journal’s website.
Case 99/27

Misconduct on a massive scale?

Almost five years ago two outsiders approached an editor suggesting that a large series of papers from a particular researcher, including some published in high profile journals, might be fraudulent. Those contacting the editor thought it possible that the patients described in the studies had never existed at all.

Round about the same time a few papers from this author were circulating in the journal’s peer review system. The editor asked an outside consultant epidemiologist and a statistical adviser to review both published papers and the papers in our system. The epidemiologist rapidly produced a report suggesting that many of the studies may have been fraudulent. The statistician began his work and, and after a while the author was asked to produce his original data. These data took a very long time to arrive, and they eventually arrived in a large box and written in pencil. These data were entered in the computer, but this proved a very time consuming and expensive process. The statistician, who had many other things to consider, got bogged down.

Eventually a few months later the statistician produced a report on a particular paper, arguing very strongly that the data were probably fraudulent.

The author resides abroad and seems to be the head of the institution in which he works. Because there was no formally appointed head of institution the editor wrote to him asking for a response and said that if none was provided, he would write to the national body.

If this body cannot produce a response, then the editor will consider publishing a piece explaining the doubts about the 30 or so studies, most of which have appeared in prestigious journals on both sides of the Atlantic.

The editor feels that he has been desperately slow, but is this what he should now be doing?

Advice

- There has to be an investigation and it needs to be by a national body as the author is head of the institution.

Outcome

The author replied that it’s “ex-colonials complaining about the downtrodden.” A national body has been asked to investigate.
Case 99/28

**Author dispute concerning ownership of data**

A paper submitted to Journal X was reviewed and rejected with the recommendation that it be submitted to a more clinical journal. The paper was duly submitted to Journal Y. The authorship was A, B, C, D and E, with E being the corresponding author linking together two research groups in different cities, but in the same country.

Journal Y sent the paper to reviewers and, after discussion, their decision was to open negotiations. Then, author C, the senior author from the collaborating institution wrote to the editor of Journal Y saying that E had used his data without permission. He now wants the paper withdrawn from Y. These data would then be combined with other data to be submitted to Journal Z.

The editor of Y contacted E, who was stunned—C had not told him about his letter. E claimed the data were his and did not belong to C at all. C was the principal investigator on a government grant covering one particular study. The paper with Y was a sub-study, not included in the government grant. Thus C, according to E, had no jurisdiction over these data.

Author C is getting increasingly angry.

**Advice**

- The editor thinks it’s good work and has already gone back to E and told him to resolve the dispute with C—they are at different institutions.
- The funding agency has jurisdiction over the main study only; the substudy was funded by E’s institution.
- The editor of Y should stay out of this and put the heads of the two institutions together to resolve the matter. C signed off for Journal X, but not for Journal Y.

**Outcome**

The matter is still ongoing.
Case 00/01

A surgical series that is scientifically meaningless, has no ethics committee approval, and does not mention informed consent

A study from a foreign author was submitted in which he describes a series of patients whom he has operated on to treat their migraine. The operation is something that he has devised himself and consists of suturing a superficial temporal artery. The surgeon has operated on over 1200 patients. There is no clear definition of how the diagnosis was made and no control group. There is no mention of ethics committee approval and no mention of informed consent.

The editor has written to the surgeon saying that he plans to ask the author’s employer or the local regulatory body to investigate his methods. Has he done the right thing?

Discussion/Advice

- There is insufficient evidence for a scientific procedure and it is clearly an example of poor practice.
- Although editors are not inquisitors, there was sufficient anxiety to report this to the author's institution.

Outcome

The editor wrote to the local regulatory board and the author’s employer, but the institution did not feel that there was a problem.
The COPE Report 2000

Case 00/02

The overlapping papers with conflicting data

Three papers concerning one hospital problem had been submitted to three different journals. Before publication the three editors of the journals became aware of the three different papers and the substantial overlap between them.

The three editors communicated with each other and realised that they had four concerns:

1. There was very considerable overlap among the three papers. There didn’t seem to be any justification for publishing three papers rather than one or two.

2. The authors of the papers had not disclosed the existence of the other papers to any of the editors.

3. The three papers all had different sets of authors, and it seemed most unlikely that all authors met the definition of authorship devised by the International Committee of Medical Journal Editors. It also subsequently emerged that at least one author was unaware that he had been listed as an author on one of these papers.

4. There were inconsistencies among the papers. One particular patient was described in all three papers, and there were inconsistencies in the nationality of the patient, the readmission date, the results of a particular test, and the final diagnosis.

The three editors took a very long time to decide what action to take, and in the end differed in their responses. One editor decided simply to notify the authors that she would not publish the paper and that she was concerned about the circumstances of the paper. The two other editors decided to ask for an investigation.

One editor wrote to the chief executive of the institution where the authors had worked some ten months ago, but no explanation of what happened had been received.

What should the editor do now?

Discussion/Advice

- The chief executive has now responded and agreed there were problems with redundant publication and as a result they will be revising their policies. Reasonable answers had been given that explained the discrepancies raised.
- A letter should be published in all of the journals regarding the redundant publication.
- A common agreement between all of the editors should be obtained, noting that it could be a protracted procedure.

Outcome

The matter was investigated by the chief executive, who agreed that the overlap was evident on re-review. But he believed there was no deliberate intention to deceive.
Case 00/03

Editorial compliance with duplicate publication

An editorial that was very close to a paper that had already been published in another journal was submitted for publication. The authors did not make clear that the editorial was essentially the same as the one already published, but this was discovered during the peer review process. Nevertheless, the journal went ahead and published the editorial without disclosing that it was very similar to the one that had already been published. Copyright was not obtained from the author. The failure was brought to light some time after the editorial had been published, and the editors concluded that both they and the authors were at fault. The journal intends to publish a notice of duplicate publication.

Has it done the right thing? Should the editors do more?

Discussion/Advice

- A much broader audience has been reached with the publication of the editorial.
- Publication in two languages is not a duplication issue, provided the authors are transparent and disclose any previous publications on submission.
- The onus is on the authors to disclose previous publications as their promise of honesty.
- Most readers don’t expect editorials to be completely new, but word for word repetition of previous published articles would not be allowed. This would clearly be an improper use of power, but it is not unethical to reproduce material over and over.

Outcome

Notice of the previous publication, and an apology, have been published in the journal, although the authors were much aggrieved, being under the impression that duplication wasn’t an issue for editorials.
Case 00/04

The single author, randomised controlled trial

After a randomised controlled trial from a single author had been published, a letter was received in which the correspondent suggested that the original trial might be fraudulent.

Firstly, the writer claimed that it was highly unlikely that just one author could perform a prospective, randomised, double blind, placebo controlled trial, especially in a small district hospital. The correspondent was also worried that there was no mention of other standard treatments. Advice was sought from a statistician and a gastroenterologist, both of whom raised serious doubts about the paper.

The editor asked the chief executive of the hospital to investigate. Initially, the medical director of the hospital wrote to say that it would be impossible for them to investigate unless the journal was willing to pay for the investigation. The editor replied, saying that he thought this absurd, on the grounds that if someone makes a serious complaint to the police, they don’t expect to be asked to pay for an investigation. The medical director eventually agreed with this and arranged for an experienced and independent researcher to examine the case.

It emerged that the author had already been suspended for clinical reasons and that a university professor had been asked to look at the research when it was first published. An experienced statistician, he found no serious problems. Nor did the independent researcher find any serious problems.

No further action has therefore been taken, but are there any conclusions to be drawn?

Discussion/Advice

- An attempt should be made to find who else had worked on the paper. A sole author rarely does all of the work, but yet has complete intellectual ownership of the data, although it is not impossible to be a single author.

Outcome

This is a good example of why lists of contributors should be published, but this will not be pursued further in this case.
Case 00/05

Duplicate publication based on government data

A group of researchers from departments of psychology and public health submitted a paper based on a survey that had been commissioned by the NHS Executive. The paper was received at Journal A on 14 May 1998 and a decision to offer publication of a revised version was made on 25 June 1998.

Over a year elapsed between this offer and the resubmission of a revised version of the paper due to illness and a change of job, on the part of the corresponding author. The revised version finally arrived in July 1999 and was accepted on 28 July.

In September, the corresponding author contacted the editor to say that a longer version of the paper was due to appear shortly in Journal B. The author was anxious that this should not appear before the paper in Journal A had been published. However, neither of the editors had been informed of the submission to another journal.

The editor wrote back to the author requesting a copy of the letter sent to the editor of Journal B. The letter made no mention of the previous submission to Journal A. The copied letter of submission to Journal B was not dated, but an accompanying letter from the author said that it had been sent in the week of 25 July. Both authors wrote independently to express their concern that they might have “inadvertently” acted with impropriety.

In the end, the corresponding author wrote to say that on reflection, they had decided to withdraw the short paper from Journal A.

The editor of Journal A gained the impression that the authors had acted, although incorrectly, “in good faith.” Nevertheless, an undisclosed duplicate submission had clearly been made.

Discussion/Advice

- This is a case for the record. No further action need be taken.
Case 00/06

Paper submitted by a PR company without the knowledge of the authors

A paper was submitted for which there were seven contributors, but no corresponding author. The only identification of who had sent the paper was an accompanying e-mail from a public relations company. When contacted by the editorial office, the PR company confirmed that the paper was to be considered for possible publication. The named contributors were then contacted and asked whether they had given permission for their name to be attached to the paper, asked who was the corresponding author, and also if they wished to declare any conflict of interest.

This produced a very interesting flurry. One author said the paper had been produced as a result of a seminar to which he and the other contributing authors had been invited. He himself believed that he was simply giving advice to the drug company concerned, for which he had received a fee. He believed that a misunderstanding had led to the PR company to send the paper for review, but that he had no knowledge that they had done so, and suggested that the paper be shredded.

Another author telephoned to say he could remember very little about it and certainly hadn’t seen the final document. A third author telephoned in some distress, anxious that he might be accused of some form of misconduct and had never thought that his involvement would lead to a paper being submitted to a journal.

The most interesting letter of all was from the first named author who had subsequently written an editorial for the journal that was fairly critical of the drug concerned. The PR company who was acting for the drug company, she said, had submitted the paper on her behalf without her knowledge. Guidelines about the drug had also been published, with which she was not happy, but she had eventually signed an agreement to let her name be used in connection with these. The company told her that she was the only person among all those attending the seminar who had refused to do so, and as such, was creating unnecessary difficulties.

The same company had previously published another article to which they had put her name, but which she had not written. This author feels very abused, particularly as she wrote to the PR company requesting that they did not use her name again.

The intriguing finale to the story is that a Royal College had been negotiating with the PR company to represent it. On hearing of this incident, the College decided to make other arrangements.

Discussion/Advice

- A case for the record, and one that could be used when reviewing the COPE guidelines.
**Case 00/07**

**The unacceptable use of a placebo**

This was a small randomised controlled trial of a medication for an active inflammatory condition. The trial was unnecessary, as several large trials and a recent non-systematic review had shown that the medication was beneficial for flare-ups of the condition.

In this case, all patients were taken off non-steroidal anti-inflammatory drugs (NSAIDs) and then they were randomly allocated to receive the medication or an inert placebo. The randomisation was inadequate (“patients were consecutively enrolled in two groups”). The paper gave no details of ethical approval or informed consent.

As patients had to stop taking NSAIDs, which were controlling their pain and other symptoms, is it ethical that half received an inert placebo?

**Discussion/Advice**

- Ethics committee approval should be requested, but how far could this be challenged if the authors had it, in which case the local ethics committee in question should be queried.
- It was correct to trial an established treatment against a new treatment, and not just a placebo. But it would be wrong to test a drug against other drugs that had been found to be ineffective.
- The editor should go back to the authors and ask whether they had informed consent, to reply to the concerns about poor practice demonstrated, and show evidence of ethics committee approval.
- If no reply is received then the editor should go directly to the head of the institution. Which point was the most serious? Firstly, that the trial shouldn’t have been done at all; secondly, that the patients had been taken off the effective treatment; or thirdly, that there had been insufficient randomisation?
- COPE has no agenda to say whether a trial should or shouldn’t have been done and that insufficient randomisation would probably not constitute the need to report to the author’s institution either.

**Outcome**

The editor wrote to the author and received a satisfactory reply. The authors had obtained patient consent. Few if any patients had to be taken off painkillers for the study, because they had inactive or burnt-out disease.
Case 00/08

A paper describing a case of possible medical negligence

A paper was submitted, describing a doctor who had given an injection of a drug (actually a herbal/homeopathic remedy) to a patient who had already experienced recurrent swelling when given previous injections of the drug. The patient suffered a severe anaphylactic reaction, but survived.

The reviewer suggests that it was negligent to give such an injection. It seems at least plausible that this was negligence, and the question for the journal is whether any action should be taken.

COPE has made it clear that editors have a duty to act on information about research misconduct. Do editors also have an obligation to act when papers describe clinical misconduct?

Discussion/Advice

- This raises the issue of just where the editor’s responsibilities end—at what level should misconduct be investigated. Do editors have a broader obligation?
- The editor should draw it to the attention of the local regulatory body, as there is a responsibility to the public, and this could only be played out if the matter was presented to a such a body.

Case 00/09

The study that may or may not already have been published

A study purported to have been stimulated by a systematic review that had already been published in the journal. The new study included 15 patients who had been treated in one arm of a study and 15 who had been treated in another arm. The peer reviewers noticed that the original systematic review included 31 patients from the same authors.

The editor contacted the authors asking them to make clear whether this was a new study or a presentation of existing data. Despite asking twice, the authors never gave a clear answer. The head of the institution was therefore informed and asked to provide one instead, and to consider whether this was an example of research misconduct.

Has the editor done the right thing?

Discussion/Advice

- The authors should make it clear if it was a duplicate article, and thus far had failed to do so.
- Can a meta-analysis be published before the data have been reviewed.
- Why should only part of these data be published, particularly when they have already been published in a systematic review?

Outcome

The editors are still awaiting a reply from the head of the institution.
Case 00/10

The hazardous drug used in an unlicensed way

The author (a clinician) sent in a case series, involving two patients. Both patients presented with severe pain, which was resistant to strong analgesics. The author then gave them a drug with potentially very serious side-effects, including a small risk of disability or death. This drug is only licensed for a small number of indications. Neither of these two patients met the clinical criteria for its use, yet the author gave it to them in a quasi-experimental way.

It is unclear whether the doctor told them that the drug was being used in this way. There is no mention of informed consent or ethics committee approval. In the UK, when using this drug for its licensed indications, it is a standard procedure to warn patients about the serious side effects and ask for their consent before giving it.

Does COPE feel that this constitutes clinical and/or research misconduct?

Discussion/Advice

■ Where there has been no hypothesis, but yet the treatment has worked, what should then transpire?
■ The authors were not suggesting that this was research, and it is not possible to assess how hazardous the treatment was from the information given.
■ The treatment should have been carried out with patient consent, and the editors must be satisfied that this has indeed been obtained.
■ This prerequisite should be met before submission and should be made clear to all authors intending to submit manuscripts.
■ Ethics committee approval was not required in this case, but patient consent was necessary.

Outcome

The author was contacted. The reply merely says “Thank you for the letter.” The editor will write again.
The COPE Report 2000

Case 00/11

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

A randomised controlled trial raised three aspects of concern:

1. The participants’ physical characteristics at entry to the study were listed in a table. For the two groups—intervention and control—one physical characteristic was given as a mean ± the standard deviations (SDs). However, the SDs for both groups were much smaller than they should have been.

2. The inclusion criteria were unusual. These excluded half of the eligible population.

3. The intervention was more successful than the control in managing the condition. The language of the paper adopted the style of an advertisement. The company manufacturing the intervention had assisted financially in the study.

An independent statistical reviewer did not believe that the over-stringent selection criteria could have explained the low SDs.

Does COPE feel that these concerns might indicate research misconduct?

Discussion/Advice

- Was this a simple mistake between standard error and standard deviation?
- Further meta studies should be requested.
- Further clarification from the authors should be obtained along with a request for the original data.

Case 00/12

Undeclared conflict of interest

A paper on a controversial topic from three authors was published. All three authors completed forms to say that they did not have competing interests. This was stated at the end of the paper.

A reader subsequently contacted the journal to say that she had clear evidence that one of the authors did have competing interests. He had, she said, been involved in legal cases and received substantial payments for his work. The article related to these legal cases.

The author intends to write to the complainant and ask her permission to send her letter to the author. If he accepts that he did have a competing interest, then the journal will publish a statement saying so.

Does COPE agree with this? Should anything more be done?

Discussion/Advice

- The public has the right to know if there were conflicting interests and that if there was any doubt, it is better to disclose.
- Just because the material is in the public domain does not exonerate an author from declaring such interests.
Case 00/13

Authorship dispute

An article was published with three authors' names. Not all of the authors' signatures had been included on the original submission letter. A complaint was lodged by Y, who said that X had submitted the paper without either his or Z's consent or knowledge, and that there were several specific errors and omissions.

Y then submitted a statement for publication in the journal dissociating himself from the published article. The statement was copied with Y’s approval to the corresponding author, X, to give him the opportunity to respond.

X responded and arranged for two colleagues, A and B, to submit statements about the research work in question. Y (the complainant) also submitted further information about the research work. This correspondence spawned a series of allegations, denials, explanations and counter-allegations.

Although the journal feels it should publish Y's dissociation from the article in the journal, would it be wise to publish this without anything from X? Additionally, if the editors are sure that X submitted the article without the approval of his supposed co-authors, should action be taken against him, such as barring him from publishing in the journal for a period of time?

Discussion/Advice

- The corresponding author should have the right to reply.
- There had been a clear breach of publication ethics as not all the authors signed the original agreement on submission.
- It probably is not enough to publish a statement and the matter should be referred to the head of the institution for an investigation, after which the journal should publish the consequences.
- A representative from the other institution—that of author X’s—should also have the right of reply, and the editor would also need to comment on the issue.
- Institutions can hide behind confidentiality agreements and there is evidence that internal enquiries are not always useful.
- The heads of the institutions of all the authors should be informed and the journal should not make any public statement until the responses had been received.

Outcome

A letter of dissociation from the author was published by the journal. The heads of the institutions were not contacted.
Case 00/14

The missing ethics committee and lack of written consent

A study that helps with the microbiological diagnosis of a clinical condition had been peer reviewed and accepted for publication when it was discovered that the study had no formal ethics committee approval and that the patients had given verbal rather than written consent.

The journal contacted the authors, who responded by saying that the chairman of the ethics committee in their area did know of the study, and that asking people to give written consent might have reduced the numbers in the study and caused unnecessary distress.

A letter was sent to the chairman of the ethics committee for his opinion, but the journal was not happy with the response received. The instinct would be not to publish the paper.

What does COPE think?

Discussion/Advice

- The authors had short-circuited ethics committee approval; there were reduced numbers in the study; and any unnecessary distress to patients does give cause for concern. But written patient consent must be obtained.
- More information is required before this can be discussed further.
- This is a case that gives COPE an opportunity to act on its guidelines, and make it clear that authors should observe proper procedures.

Case 00/15

Clinical misconduct(?), incidentally discovered

An author submitted a speculative article offering a new explanation for the aetiology of premenstrual syndrome, and a new suggestion for its treatment. The paper was wholly based on a priori reasoning, rather than evidence. It was rejected.

The authors appealed, citing as evidence in favour of publishing their paper that they had had successful results treating two patients with the proposed medication—corticosteroids. The dose used was not stated.

The editor wrote back to the authors confirming that the journal still did not wish to publish the paper, but requesting reassurance that the two patients treated had given their full, informed consent. Should the matter be taken any further?

Discussion/Advice

- Where does practice end and research start?
- This was a hypothesis only, and part of practice, so obviating the need for ethics committee approval, but the investigator should be taken to task.
- No consent had been gained from the patients and a proper trial should have been undertaken.
- The editor should write to the author stating that this was not good practice.
- Do not involve the GMC.
Case 00/16

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

The possibility of dual publication of two papers with almost identical titles and an identical list of authors emerged in the course of appointing a short-listing panel for an NHS award. The potential duplication was spotted in the publications list of an applicant for the award, who was not the first author on either paper. The editor of Journal A, in which one of the papers was in press, was a member of the awards short-listing panel.

Subsequent discussion and exchange of the manuscripts between both journals revealed that the research group in question had submitted a full paper in mid-1999 to Journal B, which had requested a re-submission as a short report. The group then clearly sent the same full paper, accompanied by an identical covering letter, to Journal A, without any indication that a shortened version had already been accepted for publication in Journal B.

The editors conferred and also took advice from COPE. A short letter inviting comments from the senior author of the papers was sent by the editor of Journal A and elicited a telephone response from the senior author. He apologised, but presumably because he was unaware that the editor had seen all the manuscripts, asserted that in fact these were quite different papers.

When he was informed that it was clear that the paper submitted to Journal B was identical to the original paper submitted to Journal A he offered to withdraw the short report in press at Journal A. The editor of Journal B told him that it was the inclination of both editors to withdraw both papers. The senior author offered to fax Journal A’s proofs so that they could be compared with the original sent to Journal B.

Under the circumstances, and following further discussion, the editors agreed they should pull both papers from publication and wrote to the senior author to inform him of this decision.

Discussion/Advice

- Both the editors should write to the head of the institution. The authors had not only lied, but had been deceitful—a double offence.
Case 00/18

Research involving unethical animal experimentation

A manuscript was submitted which described an intervention that partially corrected the results in stress injury in an animal model. Two reviewers drew attention to the fact that the stress model used in these experiments would not be ethically acceptable in the UK.

The editor raised this with the senior author, who responded promptly stating that the work had already been presented at an international scientific meeting and that an ethical committee for experiments involving animals had approved the study. Documentation was subsequently provided supporting the statement.

What should the editor do now?

Discussion/Advice

- Different countries have different standards but there should be a universality of procedures and editors should not encourage lower standards allowed elsewhere.
- The editor should obtain written evidence that ethical approval had been obtained locally and to determine whether this technique would be acceptable in the UK.
- The case raises the ethical issue of variable ethical guidelines for animal research in different countries.

Outcome

Written evidence (in the local language) of ethical approval was provided, and this was confirmed to be correct by expert translation.

The editor wrote to the UK Home Office for clarification of the status of this model in the UK who advised that a particular procedure such as that discussed in the paper would not be absolutely excluded, but the editor was reminded that at all times the minimum stress should always be applied to answer the research question raised.

The editor, associate editors, and the reviewer considered that the stress was excessive in this instance and the paper was rejected.

The corresponding author challenged the decision, stating that the same technique had been recently published in a journal in a third country (not the author’s or the UK).

Case 00/19

The dubious scientist

A scientist wrote to a medical journal asking if it was interested in receiving an editorial from him. The editorial would criticise current HIV vaccine research. The scientist is the senior partner of a technology company, and he printed his company's website in his communication to the journal. The home page of the website advertises a patented toxin, and the site claims that this toxin can “destroy free HIV virus” and that it “eliminates the need” for conventional anti-retroviral drug treatment. No evidence is cited for its clinical effectiveness.

The journal naturally declined to publish his editorial, but does COPE think that this case has broader implications?

Discussion/Advice

- Inform the Medicines Control Agency, as it is illegal to make therapeutic claims like this.
Case 00/20

Duplicate publication based on conference proceedings

A paper was submitted to Journal A and concern was raised by a reviewer that a substantial part of the paper had been previously published in two other journals. This point was taken up with the authors, who denied any lack of originality and maintained that their manuscript contained previously unpublished data. They did admit that part of the work had been presented as an invited lecture at an international conference and that three articles had subsequently been published, but had acknowledged this in their original submission letter. They had also included a copy of one of the published articles for information. The authors had also suggested that a member of the editorial board could act as the editor for their paper because he had been present at the conference and was aware of their presentation.

On inspection of one of the previously published articles in Journal B, it was found that it had been peer-reviewed, and that substantial parts had subsequently been reproduced in the paper submitted to Journal A: around 60 per cent of the introduction had been re-used. A forward by the editor of Journal B indicated that the papers had all been peer reviewed and based on a presentation at a conference. It was therefore not just another publication of conference “proceedings” and the copyright was owned by Journal B.

The editor of Journal A has no intention of publishing the article, but would like advice on what to do next.

Discussion/Advice

- The authors did disclose the other articles so they were partly in the right, and obviously not trying to be deceitful.
- It is also difficult to define as a percentage what constitutes duplication of previously published material, in which case it is difficult to take this any further.
Retrospective correction: how far back do we go?

In 1990 a case report was published in which it was alleged that the use of a particular endotracheal tube had led to tracheal damage, requiring the child to have a tracheostomy and a tracheal reconstruction. This paper was from a specialist surgical unit, and a letter was subsequently received from the paediatricians who had cared for the baby at the referring hospital before and after the transfer to the surgical unit.

They pointed out that the baby had never needed a tracheostomy, and that in fact the child had had dysmorphic features with an abnormal upper airway, which may have accounted for the problems that occurred subsequently. This letter was shown to the authors of the case report, who replied; both letters were published in the journal.

The reply was an extraordinary brush-off, which said that misuse of this particular tube could lead to tracheal stenosis, and that whether the child was dysmorphic or whether he did not eventually require a tracheostomy was irrelevant, adding “we believe that the child was fortunate not to need tracheostomy.”

This issue was resurrected because over nine years after the original publication one of the authors of the critical letter offered the journal a filler article, using this story as a lesson about the possible unreliability of conclusions from single case reports. The writer of the filler article did not give a reference to the paper or the journal, but since he seemed to be suggesting misleading and inaccurate publication, he was asked for the reference and it turned out that the journal was responsible.

It is clear that the case report published was grossly inaccurate and misleading, and it is very surprising that the journal allowed the authors of it to get away with such an offhand reply. At the very least the journal would now have made the authors of the original paper publish a correction, with an apology from them, or that perhaps more probably the journal would have made them withdraw the paper, saying that the report was inaccurate and the conclusions could not be relied on.

Is it worth doing anything about this now? The main conclusion is that the journal’s standards about what is acceptable in publications and in errors in publications have markedly changed over the past nine years. But should the journal now acknowledge errors made long ago, and if so how long ago?

Discussion/Advice

- There are three main issues: the continuing possibility of harm, pollution of the scientific literature, and results that had been obtained through scientific fraud.
- There should be no time limit on retractions, but editors cannot be expected to retract all obsolete work.
- An editorial on “lessons in retraction” could be written, airing concerns that had come to light recently, to which the authors could be invited to respond, and asking the question “how far back do we go?”
Case 00/22

**Duplicate submission of a paper**

A paper concerning the prevention of coronary disease in primary care was received. This examined the practical consequences of following some recent national recommendations and suggested that the recommendations were unrealistic.

A few weeks later another paper from the same authors was submitted, which the editor who first read it thought was probably an inadvertent duplicate submission of the same paper. On comparing the two papers, however, they were not identical. They had different titles, and although the second one contained a very substantial amount of the same material as the first one, it added on a suggested solution to the problem. Neither the covering letter to the second paper nor the paper itself made any reference to the earlier submission.

The authors were asked to explain why they had submitted the material in this way. They replied that they had conceived the papers as a series—they envisaged further ones to follow. They had not referred to the first paper in the second one as it had not yet been accepted for publication, and they thought it was unnecessary to make any mention of the first paper in the covering letter to the second one as they assumed that we would realise that they were related. They acknowledged that the degree of overlap between the two papers was unacceptable.

The journal decided that there had been no deliberate intention to mislead and that the apology from the authors should be accepted. Nevertheless, the way the authors had handled these submissions seemed very odd, and can pose problems for a general medical journal with a substantial number of submissions.

Papers may go in the first instance to be read by anyone of a number of editors, so there is a strong possibility that related papers like this will go to different editors and will get a long way down the line of assessment before someone realises that there is major overlap between them. It happened in this case that both papers went to the same editor, but usually this would not happen.

Does COPE have any views on how this sort of situation should be prevented and what action should be taken when it does arise? The journal’s advice to authors is clear about the importance of advising if there are previous related papers that have been published or submitted.

**Advice**

- Write to the authors pointing out that they must be explicit about what they are actually submitting.
Case 00/23

Scientifically meaningless research without consent

A private practitioner submitted a paper in which he had treated a series of patients without ethics committee approval. Many people would regard the treatment used as scientifically dubious. Furthermore, some of the patients had been treated with increasing doses of a new treatment that randomised controlled trials have shown to work. In effect, therefore, the study was a dosage study of the new treatment. The practitioner admitted that he did not have ethics committee approval, and our judgement is that the study is effectively scientifically meaningless. It would be impossible to conclude anything with confidence.

The men in the trial no doubt gave consent for the treatment, although there must be doubts about how informed their consent was. It’s not clear, however, whether they knew that they were part of a study. One of the complexities of this case is that if this practitioner had simply gone ahead and treated these patients then there would probably be no question of misconduct. But because he has chosen to write up the series as a scientific paper, the question of misconduct arises.

We have referred the case to the GMC. Have we done the right thing?

Discussion/Advice

- The GMC had responded, saying that it had no role in this case and did no intend taking any action for serious professional misconduct.
- Shouldn’t the Preliminary Proceedings Committee investigate this in any case?
- Was this a study or simply normal practice during a surgical procedure?
- It had been written up, so it was evident that the author was trying to get it on the scientific record.
- Does a change in normal practice have to be reported in a medical journal before a change in procedure can occur?
- GMC should be contacted again for clarification.

Outcome

The GMC responded by saying they would investigate if research were suspected of causing harm, if consent had not been obtained, or serious fraud or deception had been alleged. The standard required by journals as to what they published was not, however, a matter for them.
**Case 00/24**

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

The paper was sent to two reviewers and published after modification. Between acceptance and publication, some modelling that had been included in the original paper was removed.

Some time after publication one of the people who had reviewed the study submitted a letter for publication that included this model. The original authors were rather surprised by this and they sent us a letter pointing out that their original paper had included this material.

The question arises as to whether the reviewers had done anything improper. The authors of the paper knew who had reviewed their paper, and were rather surprised that one of them should have submitted this model. Nevertheless, the reviewer did not recommend removing the material, and he would not have known that the material had been removed until the paper was published. The authors have therefore taken the view that no further action should be taken, and we have complied with their wishes.

Have we done the right thing?

**Discussion/Advice**

- The authors wanted to know if the model had been removed on the recommendation of the referee who had then gone on to use the model himself.
- It was thought that the reviewer had breached his duty to the editor, and should be asked (in a neutral sense) to clarify this.
- This case highlights the imbalance between reviewers and authors. If a senior author had refereed a junior author’s paper, s/he might be less likely to disagree or raise an objection in situations such as this.
Case 00/25

A paper which discloses confidential material

In March 2000 author A submitted a research letter to journal X, on behalf of a national screening programme. He also submitted a commissioned editorial to journal Y, relating to the same subject.

At the same time, author A sent copies of both articles to B, a recognised authority on the subject. He made it clear that they were confidential and in press and asked for some information on a test used by B which he could include in the editorial. He also suggested to B that he might wish to respond to the research letter if it were accepted.

B did not reply, however, but at the end of March he submitted a paper to journal Z. This paper compared the screening programme run by B, with the suggested screening programme detailed in the unpublished research letter by author A, and concluded that the former was greatly superior.

The editor of journal Z in all innocence sent B’s paper to author A for review.

Author A wasn’t too impressed by the paper. He was much less impressed by B taking an opportunity to write a paper specifically involving confidential material that he, A, had shown him. He was also concerned about B knowing he was the reviewer as he had only recently persuaded B to join him in a joint grant proposal and he did not want it prejudiced by bad feeling between the two of them.

Perhaps it is not necessary to add that the arguments are all to do with which particular screening programme might be accepted by the NHS. Not only prestige but also possibly income from a patented testing tool may be involved.

Should the editor accept A’s view that B’s paper is poor, or should he send it to another reviewer? Does it matter, since the ethical issue means that B’s paper would be unacceptable even if a new reviewer liked it? How should the editor deal with B, in pointing out the ethical issue, bearing in mind the delicacy of the situation?

Discussion/Advice

- B’s paper should be ruled out unless a satisfactory explanation was received.
- There was a problem of timing, particularly as there was a patent pending.
- Paper B had been submitted as a commentary but was written up more as a paper. A commentary would have been acceptable if paper A had been published.
- It was suggested the editor ascertain what had happened to paper A, and if published, he should find out exactly when, because this will determine the timelines.
Case 00/27

Possibly unethical plastic surgery

A paper was submitted in which a plastic surgeon described what we thought was a very strange and unconventional operation. We asked the opinion of another plastic surgeon, who described the procedure as “very dangerous.” He said that there was no consistent evidence that this operation could possibly work.

The operation had been conducted in a private clinic, and we are sufficiently concerned that we are thinking of contacting the GMC. Are we doing the right thing?

Discussion/Advice

- The GMC should not be informed.
- The author did send in several papers from the US where this procedure is being carried out, but there had been no randomised trials.
- Patients might not have been given the whole story—only told, for example, that it was successful in California.
- The editor would like to publish the whole case and ask for readers’ responses.
- The editor should write to the Special Advisory Committee on Plastic and Reconstructive Surgery at the Royal College of Plastic Surgeons to get advice on this procedure.

Outcome

A statement of declaration of competing interest was subsequently published which mentioned that this had been omitted because of naivety.
Case 00/28

Plagiarism or redundant publication?

A manuscript was submitted with a covering letter clearly stating the originality and unpublished nature of the work. The authors stated that the results had already been orally presented at a meeting the previous year. Before sending the manuscript for review the editors discovered that the manuscript contained 60% of the Materials and Methods text and 90% of the Results section of a previously published paper. Even the data were identical. Moreover, the authors’ citation to the first article suggested that it was different from the current work (the corresponding author and the first author were the same in both manuscripts). The editors were not convinced that there was a deliberate attempt to mislead, but nevertheless they rejected the manuscript with a stern warning to both the first author and the corresponding author. As yet no reply has been received from any of the authors.

Discussion/Advice

- There had been some deception and a case of redundant publication, not plagiarism.
- The authors failed to declare an overlap, and citation is not enough.
- The authors should be given a chance to reply.
- A reminder should be sent (giving a time limited response), with reference made to the COPE guidelines otherwise the matter will be referred to the authors’ institution.

Outcome

The authors emailed a detailed and apologetic reply. While the editors were convinced that there had been no deliberate attempt to mislead, the manuscript was rejected because a large part of the work had already been published.
Case 00/29

Authorship dispute

Two manuscripts were received by Journal X, from author A. Both were accepted and sent to the publisher. On receipt of the galley proofs, the corresponding author removed the name of the last author from both manuscripts. Shortly before the page proofs arrived, the journal editors received a request that author A be allowed to remove author B from the authors’ list and instead make a suitable acknowledgement.

The editors asked if author A had sought agreement from author B concerning this change, and added that it was not journal policy to make these changes. The reply from author A included a long and detailed account of what was clearly a personal dispute that had developed between these two authors subsequent to submission of the manuscripts. The editors, however, decided to reinstate author B according to the original author listing, and notified the publisher.

Some weeks later the publisher received a communication from author B indicating the possibility that his name may have been removed from three manuscripts that he was previously involved in preparing and submitting. It seemed that author B was in fact the senior author, while author A was a researcher in his laboratory. The publisher could only account for the first two and therefore contacted the editors for clarification. On further investigation, it was discovered that the third manuscript had been rejected by the editors of Journal X, but was later tracked to Journal Y (who also used the same publisher). It was also noted that author B had already been removed. The publisher alerted the editors of Journal Y to the problem and the manuscript was rejected.

The editors considered contacting the host institution, but discovered that the institute itself was racked with scandal and staff disputes. The editors finally decided to reject all future submissions from both authors A and B.

Discussion/Advice

- The authors had behaved improperly, but a decision had been reached by the editor without appropriate evidence.
- The funders of the research should be contacted.
- Further investigation was required, and even though the institutions had their own troubles, they should be informed, with a copy sent to a higher authority, such as the equivalent of the GMC.

Outcome

As a result of the COPE discussions the editors reversed their decision. Manuscripts will be accepted for evaluation from either author. The journal is also re-evaluating its policy guidelines. The editors decided that in this particular instance it would be inappropriate to contact the host institution.
Case 00/30

Duplicate publication: how much is too much?

A paper (hypothesis) was submitted and sent out for peer review. One of the reviewers pointed out that large parts of the paper had been published, almost word for word, in a previous publication not cited by the authors.

We rejected the paper voicing concern about the previous publication of largely similar material.

The authors have appealed against our decision to reject the paper and said that they did not agree with our assessment of duplicate publication, arguing that the repetitions are mostly quotations from the literature and in words they amount to around 10 per cent of the paper.

We rejected the paper again. Should we have done/do more?

Discussion/Advice

- The authors had failed to declare any overlap, and this could possibly be a case of plagiarism.
- Two independent reviewers should decide on the degree of overlap.
- The editor should inform the reviewers of the background of the case.