

The COPE Report 2003

www.publicationethics.org.uk

The COPE Report 2003

Annual Report of the Committee on Publication Ethics

Edited by

Caroline White
Freelance Journalist

© BMJ Books 2004

BMJ Books is an imprint of the BMJ Publishing Group

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, and/or otherwise, without the prior written permission of the publishers.

Nothing in *The COPE Report 2003* should be interpreted as specific legal or medical advice.

The opinions and views expressed in *The Cope Report 2003* are those of the individual authors and do not necessarily represent those of COPE, the *BMJ Publishing Group*, or the *BMA*.

First published in 2004

by

BMJ Books, BMA House, Tavistock Square, London WC1H 9JR, UK.

British Library Cataloguing in Publication Data

A catalogue record for this book is available from the British Library

ISBN 0 7279 1831 1

Contents

Foreword: COPE continues to flourish	I
Michael J G Farthing	
COPE Council, Committee and Membership	2
Session 1: How do we deliver a Council for Research Integrity in the UK?	4
Introduction	4
Michael J G Farthing	
Setting the scene	5
Stephen Lock	
A view from the Academy of Medical Sciences	8
Mary Manning	
A view from Universities UK	10
Eve Jagusiewicz	
Research governance—the NHS perspective	11
Marc Taylor	
A view from the GMC	13
Jane O'Brien	
Session 2: Editorial Accountability	18
Editorial misconduct: time to act	18
Richard Smith	
Have we made progress in exposing and dealing with editorial misconduct?	20
Andrew Herxheimer, Iain Chalmers, and Doug Altman	
A survey of editors' conflicts of interest	24
Sara Schroter	
How to handle authorship disputes: a guide for new researchers	32
Tim Albert, Elizabeth Wager	
Update on cases submitted to COPE	35
Cases submitted to COPE July 2002 to September 2003	39
Guidelines on Good Publication Practice	69
Constitution of COPE	74

Foreword: COPE continues to flourish

COPE has had another good year. During 2003 the main committee considered over 30 new cases, and we continue to receive follow up on cases considered in previous years. These are detailed in the dedicated case section of this report. COPE Council has also decided to review cases that have been submitted by authors and editors, but which do not follow the standard COPE format. Some of these cases have been instrumental in developing our thoughts about editorial misconduct and the need for a code of practice for editors. Authors have written to us, alleging poor editorial practice, and “whistle blowing”; editors have also drawn our attention to possible editorial misconduct with respect to the manipulation of impact factors. Although the work of the main committee still centres around requests for help from other editors on research and publication misconduct, the Council has found it extremely helpful to consider issues beyond its standard remit. These cases are also included in this year’s report (pp. 63–8).

Two important issues were debated at the annual COPE seminar in October: “How do we deliver a Council for Research Integrity in the UK?” and “Editorial Accountability.” The first debate picked up the long running saga of the continuing reluctance in the UK to set up a national body to monitor and advise on research misconduct. Stephen Lock, immediate past editor of the *British Medical Journal* began with an overview. Stephen has campaigned for almost two decades for a UK wide approach to research misconduct along the lines of initiatives in North America and many other European countries. Contributions from other major stakeholders, including the Academy of Medical Sciences, Universities UK, NHS Research and Development, and the General Medical Council raised various issues and added several perspectives to the debate, although no individual stakeholder was prepared to take the lead on

setting up a national body. During the final discussion it was suggested that perhaps the two major employers, Universities UK and the NHS, might jointly set up a working group to plan the way forward. I am optimistic that this approach will eventually be successful.

Richard Smith led the second debate, with an exploration of the duties of an editor and how these might fall short of expectations, and amount to editorial misconduct. The contributions of Andrew Herxheimer, Iain Chalmers, and Doug Altman both challenged and inspired. Sara Schroter summarised her research on editorial conflict of interest. In essence, this indicated that many editors have a poor understanding of the concept and certainly don’t widely recognise that this might have anything to do with them. Richard Smith had produced a draft Code of Conduct for Editors, which provided an excellent focus for discussion and will be developed further through wide consultation.

In 2004 COPE will need to hold elections for its Chair and Vice Chair. The call for nominations will go out early in the New Year, with a view to holding an election under the auspices of the Electoral Reform Society. Our Treasurer, Alex Williamson, who has a five year period of office, will continue to serve until 2006.

COPE still has a great deal of work to do. There is no evidence that business is declining: editors still seem to want to consult us when they are faced with difficult cases of possible research and publication misconduct. COPE’s research and training agenda is still in its infancy, but will have increasing influence in the next year or so. And COPE will continue to support the need for the development of a Council for Research Integrity in the UK.

Michael JG Farthing
Chair, COPE
December 2003

Council

Chair: Professor M J G Farthing (Principal, St George's Hospital Medical School, London)
 Vice Chair: Dr R Smith (Editor, *BMJ*)
 Treasurer: Mrs A Williamson (Publishing Director, BMJ Journals, BMJ Publishing Group)
 Secretary: Mrs R Fetches (BMJ Journals Editorial, BMJ Publishing Group)

Professor Dame L Rees (Chairman, Editorial Board, *Clinical Endocrinology*)
 Dr S Kleinert (Executive Editor, *The Lancet*)
 Dr F McLellan (North American Senior Editor, *The Lancet*)
 Professor Sir I Kennedy (Shadow Chair, Commission for Health Audit and Inspection)
 Dr F Godlee (Head, BMJ Knowledge)

COPE Education Committee

Sabine Kleinert, UK *The Lancet* (co-chair)
 Faith McLellan, USA *The Lancet* (co-chair)
 Tim Albert, UK Trainer, medical writing
 Andrew Bottomley, Belgium European Organisation of Research and Treatment of Cancer
 Iain Chalmers, UK UK Cochrane Centre
 Susan Eastwood, USA University of California, San Francisco
 Lai-Meng Looi, Malaysia *Malaysian Journal of Pathology*
 Ana Marusic, Croatia *Croatian Medical Journal*
 Hooman Momen, Switzerland *Bulletin of the World Health Organization*
 Richard Nelson, US Surgeon/researcher
 Liz Wager, UK Freelance writer/trainer

COPE Research Committee

Fiona Godlee, UK (chair) Head of BMJ Knowledge
 Tom Wilkie, UK *Scientific Computing World* (Editor)
 Richard Lilford, UK Professor of Clinical Epidemiology, University of Birmingham
 David Moher, Canada Chalmers Research Institute, Eastern Ontario
 Mary Scheetz, USA Director, Extra-mural Research Program, Office Research Integrity
 Drummond Rennie, USA Deputy Editor (West) *JAMA*
 Mike Callahan, USA UCSF, Division of Emergency Medicine

UK Based Research Group

Martin McKee, Professor of European Public Health, London School of Hygiene and Tropical Medicine
 Peter Wilmschurst, consultant cardiologist, Royal Shrewsbury Hospital
 Matthias Egger, Professor in Epidemiology and Public Health, University of Bristol
 Chris Palmer, Deputy Director, British Council Seminars, Cambridge
 Pritpal Tamber, major medical and new journals programmer, Biomed Central, London

Membership of Cope

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

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

Session 1: How do we deliver a Council for Research Integrity in the UK? (Chair: Michael Farthing)

Introduction

Michael J G Farthing

Chair of COPE and Principal, St George's Hospital Medical School, London

The seminar programme is divided into two distinct but related sections. The first follows on from last year's seminar, when we discussed how to take forward the idea of a Council for Research Integrity. The second was inspired by comments from Professor Sir Peter Lachman, who felt that editors were doing very little to regulate their own conduct and that perhaps they should set their own house in order before taking authors/researchers to task.

But why are we once again discussing how to make real progress? History is instructive.

What does history tell us?

Despite several high profile cases of biomedical research misconduct after the Second World War, the scale of the problem had not been systematically assessed. But in 1988 Stephen Lock, who was then editor of the *BMJ*, published the results of a survey of clinical academics in the journal.¹

This indicated that there was rather more scientific misconduct than perhaps anyone had been prepared to believe, and that most of it was concealed.

In 1993 he and Frank Wells published the first edition of *Fraud and Misconduct in Biomedical Research*,² which provided an international perspective and described how the US and some European countries had begun to tackle the problem.

Importantly, in the second edition, published only three years later, the authors called for an independent investigating authority to look into allegations of research misconduct.³

This was precisely because they recognised the difficulties of conducting investigations behind closed doors without any attempt to move the process into the public domain.

In 1996 a group of editors from several major general and specialist medical journals became concerned about the number of breaches of research and publication ethics they came across during their work. The diversity of issues arising from these breaches exposed their lack of expertise in handling these cases.

The foundations of COPE

These concerns gave rise to the birth of COPE, which was founded as a self help group for editors in 1997. Richard Smith's editorial in the *BMJ* formed the basis for the first COPE seminar in 1998.

When COPE published its *Guidelines on Good Publication Practice* the following year, these highlighted just how powerless editors were to deal with alleged research misconduct.

The guidelines suggest that editors should take a stronger stance. Rather than just reject papers, they should report their concerns to employers. However, experience over the past five years has indicated that employers do not always act on referrals from editors.

1999 was the year of a consensus conference on research misconduct, chaired by Lord Robert Kilpatrick, at the Royal College of Physicians of Edinburgh. The major stakeholders at this meeting included the royal colleges regulatory and educational bodies, the Association of British Pharmaceutical Industry, and the Faculty of Pharmaceutical Medicine.⁴

Some very important conclusions were reached, chief among which was that "a national panel should be established—with public representation—to provide advice and assistance on request."

Furthermore, it was concluded that this 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.

The role of investigating cases would, however, remain the responsibility of employers.

It was left to the three colleges of physicians and the Faculty of Pharmaceutical Medicine to meet with the General Medical Council and co-opt other partners to consider the remit of such a panel.

Since then, there has been remarkably little progress. Several informal meetings, including one in February 2002, at the Royal College of Physicians, hosted by Sir George Alberti. Once again, all the major stakeholders attended, and at that point, the Academy of Medical Sciences was charged to progress the initiative.

The Academy did a substantial amount of work, but now feels that it does not have the resources to take on what is clearly a substantial responsibility.

We had very clear guidance from the consensus meeting that we have still not yet delivered. Our lack of progress is becoming embarrassing, particularly as many countries in Europe have addressed this issue.

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

2 Lock S, Wells F. *Fraud and Misconduct in Biomedical Research*. London: BMJ Books, 1993.

3 Lock S, Wells F. *Fraud and Misconduct in Biomedical Research*. Second Edition. London: BMJ Books, 1996.

4 Joint Consensus Conference on Misconduct in Biomedical Research Statement. 28–29 October 1999. Royal College of Physicians of Edinburgh.

Setting the scene

Stephen Lock

Editor of the *BMJ* 1975–91

What is the scene? It's a wasteland. After 20 years Britain has got nowhere.

The clear signs are that we are not yet going to get the national body which other countries have had for years, and which our medical grandees have continually promised us.

One of the reports that Michael Farthing did not mention is the one produced by the Royal College of Physicians in 1991, which is perhaps one of the most buried reports the College has ever produced.¹ No one has ever heard of it, and those with the responsibility for implementing its recommendations were not told about it.

We've had undertakings from the Royal College of Physicians of Edinburgh. And we've had similar words from the Academy of Medical Sciences. But nothing has been done.

Yet the mission statements of these various bodies reveal a dedication to upholding standards of good practice.

The Royal College of Physicians says that for over 450 years it has played a pivotal role in maintaining standards of medical practice in hospitals throughout England, Wales, and Northern Ireland.

The Edinburgh College speaks of promoting the highest standards of internal medicine throughout the world. The Academy of Medical Sciences states that it campaigns for better structures and support for the medical sciences. It promotes excellence in research, provides scientific advice, and encourages better communication of science.

Surely all these mission statements mean that none of the bodies involved can escape responsibility for the management of reported cases and the prevention of research misconduct?

We've tried argument, and it's failed. Why are we so far behind the rest of the civilised world? Only recently the French voted to set up a central committee. Italy has one. We stand alone.

Inaction has its roots in history

What can history tell us? We've got a tradition in this country of following the practice of *dolce fa niente*. As a nation we are the masters of preferring talk to action.

Many of the advances in every day life have taken scores, if not hundreds, of years to come about. When the Royal Society was formed in 1660 it owned slaves. Twenty years later in Philadelphia, an anti slavery movement began. But it took us another 110 years. And it wasn't until 1834 that slavery was finally abolished in this country.

The smoking chimneys of London had been an

issue since King James. But only the Great Smog in 1952 prompted the Clear Air Act.

We had four major cholera outbreaks in England in the 1800s. The Thames was known to be an open sewer, but it took the Great Stink in 1858, which stopped parliament sitting, to provide us with the sewerage we needed.

This trend continues today. Where is the Freedom of Information Act that we've been promised? What about the reform of the House of Lords? Cross Rail, the underground line that was going to link Paddington with Liverpool St, was first talked about in 1912. The first mention of any medical academy was in 1942.

The arrogance of power

Why as a nation are we so slow to follow international, proven agreed reforms? The answer is a fundamental smugness and complacency as a nation, which dates back to our imperial past.

Today politicians often say: "After all I think it's generally acknowledged that we've got the best army/transport system/ health service/ teaching profession/financial regulation in the world." These assertions are not based on proper evidence or data.

Similarly, some people still believe that misconduct doesn't occur in Britain. Or if it does, it's the domain of single handed general practitioners or just a bit of noise in the system.

Much more serious is what Senator William Fulbright called "the arrogance of power." That's to say that people whom we elect as our leaders, whether in politics or in medicine, come to believe that they can act totally independently of general opinion or logical argument.

We've never seen this so cogently as in the recent debacle in Iraq and the Hutton Inquiry. And in medicine, 20 or 30 years ago, we saw it in the debate over the need for research ethics committees.

The good and the great from the Medical Research Council, the universities, the General Medical Council, continually pontificated that it was a God given right of the profession to police itself, despite the evidence of abuses.

We see the arrogance of power in the British medical grandees' approach to research misconduct. It's easy to understand why the glitterati are so reluctant to get their hands dirty. It involves a lot of work. It's a very negative activity. It may even involve friends.

In the past 10 years I have served on two major committees of inquiry. Both took an inordinately long time, not only to read all the documents and

background information, but also to hear the evidence.

Time is hard to find for already busy people. So we've got to have encouragement from our mandarins that taking part in these kinds of activity is an essential component of professional life.

Crucially, this activity needs to be based at a permanent central body. If a registrar sees his or her boss spiking tubes, who does s/he call? We need a central repository of experience and legal expertise that is truly independent.

If we fail to put one in place, we will be condemned to perpetuate this dishonest and unethical practice, let alone remain the laughing stock of the world.

What do we need to make progress?

Firstly, we need a major scandal in the public domain, probably some deaths, and a lot of money lost, as a direct result of research misconduct. Extensive media coverage would put great pressure on the grantees to do something about it.

Secondly, we need a charismatic leader to convince his or her colleagues to take action—the equivalent of a medical Nelson Mandela. But Mandelas are short on the ground politically and medically.

Jim Petrie, president of the Edinburgh College of Physicians, was one such Mandela. As a professor of clinical pharmacology, he knew of several egregious cases of research misconduct both in academia and the industry, some of which were in the public domain.

Unfortunately, many people simply don't have any idea of what is going on. We need to gather some data, because one of the arguments opponents use is too much effort for too little return. But as a congressman pointed out in the US Congress, you don't ask how many bank raids there are in a small mid western town before you set up a police force.

If every member of COPE were to ask half a dozen colleagues, including the deans and heads of departments, of their experience, we might get somewhere. We know that half the members of the profession know of a suspected or definite case of research misconduct.

COPE might well have to change its articles of association; rather more difficult would be the need to devise a proper, rigorous structured questionnaire and the ways of administering it. But, again, COPE has a lot of expertise among its membership, including methodologists, epidemiologists, and statisticians.

We have the Commission for Health Improvement. We have the National Institute for Clinical Excellence. And we have a proposal for editors to police themselves. Why can't we police research?

I would suggest that if we want to go forward, we adopt the Danish model, confine it to medicine, have a central resource, and that we publicise it widely.

But I come back to my analysis of British national characteristics. We have to remember in this country that we are subjects, not citizens and that the veneer of democracy over Britain's political elite is very thin. Britain elects fewer people to office than any other

democratic country.

The very words franchise and ballot are borrowed from France and Italy: voters are still treated as the enemy, as an unreliable, potentially explosive force somewhere beyond the pale. You just need to substitute voters for members of COPE, trying to do something about research misconduct and pit them against the grantees and the mandarins.

1 Royal College of Physicians of London. *Fraud and Misconduct in Medical Research*. London: RCP, 1991.

Comments

Who should be included?

Richard Smith, editor BMJ: Physicists think that physics is an international business as far as research misconduct is concerned rather than focusing on individuals. Should COPE do this as well?

Stephen Lock: "In 50 years' time, perhaps. But it's better to start small, and with one discipline. And we ought to follow the example of the Danes, who despite never having had a case, were willing to consider the possibility and looked to the experience in the US, Canada, and Australia.

The following year they were prepared when an egregious case of misconduct occurred. Ten years later, they included disciplines other than biomedicine. Until there is something in place that can handle one discipline it is inadvisable to start with several."

There was some discussion about how to define biomedicine and therefore whom to include—laboratory technologists, for example, who are not disciplined by the GMC, but who have their own disciplinary bodies.

It was pointed out that the Medical Research Council covers both clinical and non-clinical scientists in their guidance for grants, and the National Institutes of Health includes medical and non-medically qualified researchers.

Who censors research?

Iain Chalmers, editor James Lind Library: "All trials given the go ahead should be registered at inception. It is quite possible that people have died because of the failure to publish disappointing results. That's an issue that is frequently overlooked."

Stephen Lock: "We used to wonder at the *BMJ* who was censoring the non-appearance of negative reports. Was it the authors? Or was it the editors? It seemed to be the authors, who felt that editors would not want these papers."

It was pointed out that pharmaceutical companies know the viability of a product relies on accurate and honest research.

Stephen Lock said this was taking far too much for granted. "We might have the best system in the world, but I don't think we have the data to prove it." He commended the industry for its good clinical practice guidelines. "In some way it has led the way. But there is still an awful lot left to do, which is why we are here today."

Peter Wilmshurst, consultant cardiologist, Royal Shrewsbury Hospital: “I have given up replicating studies in cardiology, [with less convincing results than the originals,] because when I submitted them to the original journals, they always refused to publish, even though the studies were larger than the original publication.”

Where will the leadership come from?

Michael Farthing reflected that perhaps it had been a mistake not to nominate a leader/body to take forward the recommendations at the end of the 1999 consensus meeting. The stakeholders agreed to meet, but no one was given ultimate responsibility to pull everything together, he said.

He felt the employers, should take the lead, because they inevitably ended up investigating most allegations of research misconduct.

Stephen Lock wanted to know where the impetus for all the NHS bodies, such as the National Institute of Clinical Excellence (NICE) and the Commission for Health Improvement (CHI) had come from.

John Pattison, Director, NHS R&D: “I think we have to ask ourselves: What is the body or coalition of bodies that could actually push it forward? This will not just happen by itself. The idea for CHI/CHAI had tremendous ministerial backing. That’s how most of the NHS bodies have come into being.”

He added that employers and universities are not sure if they should look to the Department for Education and Skills or the Department of Health.

It was suggested that perhaps research fraud might come under the aegis of the Department of Health’s prescription fraud sector or the business group for standards and quality headed up by the Chief Medical Officer.

A view from the Academy of Medical Sciences

Mary Manning
Executive Director

This year, the Academy is 5 years old. It may come as a surprise, but one of the Academy's very first tasks was to manage a working party looking into research fraud and misconduct.

The working party included representatives from three other national academies: the Royal Society, the Royal Academy of Engineering, and the British Academy.

The project, was inspired by the then president, Professor Sir Peter Lachman, who had a strong interest in the subject, and felt there was no time to waste in addressing the issue.

The key role of employers

The working party's preliminary deliberations were discussed at the COPE seminar last year. The group concluded that research fraud and misconduct were perceived to be problems of scientific research, and within science, a particular problem of the medical sciences.

This was not necessarily the outcome the Academy had been looking for, but that conclusion shaped the consultation process over the next 18 months. In hindsight the Academy might have been able to move matters forward much more quickly if the other academies had recognised that it was the reputation of scholarship across all disciplines that was at stake, not just medicine.

During 2001 and 2002, the Academy consulted widely with the Department of Health, the MRC, the Royal College of Physicians, the Office of Science and Technology, the Council of Heads of Medical Schools, Higher Education Funding Council of England, the Association of Medical Charities, the GMC and Universities UK.

The Academy also had exploratory talks with Professor Sir Ian Kennedy and with Guy Dehn of Public Concern at Work, who gave legal advice on data protection and the professional liability for offering services to employers.

A proposal for a scientific fraud *advisory* panel was drawn up, together with mechanisms for sharing best practice in research governance guidelines. And the offer of expert scientists to assist employers with individual cases of misconduct was mooted.

The Academy's central thesis, supported by a strong and vocal body of opinion, and reflected in the views of many of the Academy's fellows, was that while the present uncoordinated arrangements for dealing with these issues must be improved, the obligation for maintaining high standards of research and for dealing with these allegations should remain with employers.

Employers mean the universities, national research institutes and research intensive NHS trusts.

Finding common ground

COPE greeted these proposals with dismay on the grounds that they lacked legal teeth. But the Academy was not enthusiastic about the establishment of a centralised policing role.

There seemed, therefore, to be an irreconcilable difference of opinion. At an Academy meeting in 2001, the disparity of views was once again rehearsed.

On the one hand, editors claimed they regularly saw cases of research fraud; on the other, the research community felt that this was a much rarer event. These different perspectives inevitably led to different conclusions.

But the ground has shifted since then, and the research community has come to recognise the role employers must take. The Academy is no longer actively involved in the establishment of a council for research integrity, but that does not mean it feels it has no contribution to make.

The Academy will encourage research institutions to take an active role in promoting an environment in which it is difficult for research misconduct to occur. Research ethics should be an integral part of course content, for example.

We know very little about the institutional characteristics and culture that might influence research integrity. The US Institute of Medicine highlighted this as a potential area of research.

What the Academy can offer

There will always be a role for the Academy in the promotion of high research standards by teaching by example.

The Academy could assist with the training of young scientists, and currently runs a professional mentoring service for bright young clinician scientists, funded by the Department of Health. The mentors are drawn from among the Academy's professional membership.

To date, there have been 73 participants. They are keen, enthusiastic, and highly motivated, and the Academy could run workshops for them, focusing on research skills and integrity.

They will, after all, one day be the leaders in their field, and they are important role models for the next generation. And while the Academy strongly recommends that research fraud problems should be managed by employers—vice chancellors and deans—

who have a basic duty to protect the integrity of scientific and academic work, they could be assisted by the Academy and other bodies represented at this meeting, speaking up for integrity and providing independent assessors, when appropriate.

When something goes wrong and a case needs investigation: what then? Employers will need help. This could take many forms: scientific expertise, external panel members; and the sharing of good practice and experience.

Effective guidelines and practical help should be available, all of which would need to be constantly updated and revised in the light of experience, to ensure they are robust and enforceable.

Many institutions have codes of practice, but because their use is likely to be rare, they have not usually been tested by experience, and are often inadequate for the task in hand.

Many of these guidelines are unenforceable because they are not written into contracts of employment. Ultimately, we have to be realistic about how effective guidelines can ever be. Ultimately, there can be no guarantees that good policy will be used appropriately.

The Academy might be willing to nominate independent expert assessors from among their fellowship, to advise employers in the early stages of an investigation. The medical royal colleges already perform this function, which employers have found helpful.

Advice for employers

Investigations are time consuming and painful. This does not mean they should not be undertaken, but employers and panel members need to be aware of this. In appointing panels, employers should consider:

- the status of the panel
- the process for taking evidence
- problems in identifying and declaring conflicts of interests
- the need to ensure that members are indemnified against personal liability

Panels will need to be expert, authoritative, self contained and able to command respect. Ideally they

should be able to evaluate scientific data without recourse to additional help. This will ensure that there is informed discussion at meetings, rapid interpretation of the evidence, and a speedier process, overall.

Panels will need to be aware of influential factors:

- Personality clashes
- The role and motivation of whistle blowers
- The distortion or aggravation caused by media interest
- The problem of institutional cover ups.

And they must be able to distinguish research misconduct problems from those that more properly belong to the personnel or human resources function.

Employers may wish to consider the time lag to investigation, which can severely hamper the ability of the employer or the panel to gather evidence.

New imperatives

All these issues need to be addressed, but on the basis of a clear understanding of the scale of the problem, for which there is, as yet, a high degree of uncertainty. There have long been two very different perspectives on this, but perhaps at last the gap is narrowing.

There is also a new imperative for tackling this problem. Current government policy, to encourage industry and academe to work more closely together, will rely on high standards of personal integrity and research governance.

Through the work of its industry and academe forum, the Academy is actively engaged in supporting and encouraging that partnership so that first class scientific discovery can be more swiftly translated into benefits for patients.

A high profile case of fraud or misconduct could seriously damage this process. And there is a range of conflicts of interest that needs to be explored, but in a balanced and appropriate manner.

The time is right, therefore, to demonstrate that the UK is taking steps to keep its house in order, and I hope the Academy will play its part in that process.

A view from Universities UK

Eve Jagusiewicz

Policy Advisor on Health

There are several groups at Universities UK involved in policy making. The issue of research fraud falls between the health committee and the research strategy group, which has hampered progress to date.

UUK's members comprise 121 heads of universities: membership and participation in activities are voluntary.

We also provide services to universities, including best practice, running conferences, supplying information to staff in institutions. But our main contact with universities is via vice chancellors.

Research fraud has been discussed over the past few years, but not in a very systematic way. And the discussions have tended to focus on concerns about the lack of evidence for the scale of the problem, the extent to which it needs to be handled at institutional level, the difficulties of doing this, and whose responsibility it is.

But however much we talk about the responsibilities of national and local organisations, learned societies, funding bodies, and individual employers, at the end of the day, they can only ever be responsible for promoting and nurturing a sense of integrity. The responsibility for preserving it lies with the individuals involved.

Therefore, if we are going to tackle this, we need to focus on how we can help institutions strengthen their understanding of the issues and their ability to handle them.

We need to:

- Generate better evidence of the problem to inform our own understanding
- Promote understanding of the issues
- Help managers and vice chancellors to improve guidelines in their institutions

We believe that setting up other national bodies risks taking the problem away from where it is actually located—in institutions, among supervisors, managers, and individual researchers.

We should be working with other parties represented at this seminar to generate and nurture a culture which fosters research integrity. But at the same time, we need to make sure that institutions have the right management structures and contractual arrangements, as well as access to other types of support they might need, in order to preserve research integrity.

Michael Farthing has agreed to help us, and we will be setting up a small group of vice chancellors, led by Michael, to look critically at how we deal with this. This will bring the work of the two committees together.

Comments

Employers' responsibilities

Richard Smith: "What happens when an institution agrees to retract a paper, and it is faced with the possibility that not only is that particular piece of research fraudulent, but that all the others are as well until proved otherwise? Usually, the person committing the fraud is fired and the institution washes its hands of further responsibility."

Eve Jagusiewicz: "I don't think the employer can be held responsible for resolving all the problems of the past; rather, the entire research community needs to think about how every piece of research is produced and assessed."

This approach starts to get into the realms of corporate responsibility and the associated costs that brings. Institutions have to size that up against all the other responsibilities they have, including towards other staff."

Peter Wilmshurst: "In institutions there are vested interests at work to make sure that fraud is kept quiet. Senior managers weasel their way out of any responsibility for investigating and try and stop it."

Assumptions of honesty and integrity

Peter Wilmshurst: "We assume researchers are honest, and it is very difficult to prove otherwise. On that basis, you could ask everyone to pay themselves what they are owed from a sack of money. We should start with the assumption that people are not honest."

Eve Jagusiewicz: "That is the nub of the issue, because at the moment we do assume that our staff are honest."

Michael Farthing: "We spend around £6 billion on research, which must be the largest sum of money of any major spend that is not audited systematically. The tax office assumes that we are not honest, and every year audits a sample of people's tax returns. Most financial dealings are internally and externally audited. Why aren't we doing this for research?"

Research governance—the NHS perspective

Marc Taylor

Head of NHS Research and Development Policy

When researchers crossed pigs with jelly fish to produce fluorescent coloured animals, they explained their work as contributing to xenotransplantation. But this sort of research plays to the popular notion that science is the province of boffins who are slightly mad.

Research governance, on the other hand, aims to ensure that science is carried out by people operating in supported structures that reflect the corporate responsibility of the organisations for which they work for. And there are usually several organisations involved.

In 2001 the government published a research governance framework, of which there will shortly be a second edition (*Research Governance Framework for Health and Social Care*). Research lies at the centre of several related domains of governance:



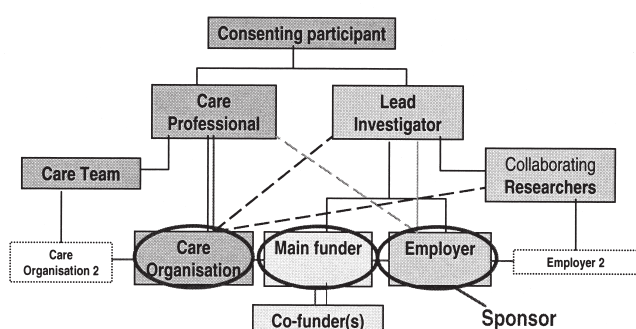
There should be systems of governance for all of these areas of activity, so that everyone knows what they are supposed to do, how they might support one another, and what might happen when the systems fail. These overlap in research governance.

In each of these areas are individuals with individual and corporate responsibilities that need to be clearly defined.

The need for a guarantor

The following schema describes the relationships between the NHS and research. On one side are the responsibilities of the NHS towards patients and on the other, the scientific chain of responsibility.

Roles in NHS research governance



Research and Development: Knowledge for Health and Social Care

This includes the implicit bargain between patients who agree to expose themselves to a certain amount of

risk when taking part in research and those who say that they will manage that risk. They need to do this in a way that is well understood and well controlled, providing a benefit proportionate to the amount of risk taken, and which comes with guarantees of how all that will be achieved.

Who should take a lead in all of this and act as a guarantor? Is it the funder, the employer, or the lead carer organisation?

Our view is that it should be the person who is most immediately involved in initiating and managing the study. It could be one of a number of bodies. But someone needs to take overall responsibility for the integrity of what can be a complicated set of relationships.

What we are aiming for is a clear understanding of who is doing what and an understanding of the way in which quality systems fit together, with the responses proportionate to risk.

This looks very complicated, and it highlights risks that some find unacceptable. Equally, some might feel that it's an attempt to stifle research with bureaucracy. This would be the case if everyone set up their own systems, which duplicated everyone else's, rather than taking the view that that this needs to be collaborative.

Putting checks and balances in place

Over the past couple of years the NHS has been working to an implementation plan, which runs to the end of April 2004, the eve of the European Union clinical trials legislation. This is the time table:

- 2001: checking systems for ethical approval and permission in NHS bodies
- 2002: establishing local implementation plans for research governance
- April 2003: setting up a network of research management primary care trusts
- April 2004: no research and development involving patients, their tissues, organs, or data may start or continue until a sponsor has confirmed acceptance of responsibility
- April 2004: research governance becomes a controls assurance standard so that it can sit within NHS risk management and is referenced into CHI and performance management at strategic health authority level.

We are trying to embed research governance into the systems the NHS has for checking corporate responsibility. Otherwise there is the risk that we might

not be able to comply with the European clinical trials legislation in May 2004.

Research fraud needs to be positioned within this system of supportive relationships.

The starting point is a quality research culture. This culture requires visible research leadership and expert management.

We need a common understanding between the NHS and the universities that the lead investigator will guarantee the outputs and that the employer has a clear code of practice, with clear lines of delegation and appropriate supervision.

Funding bodies need to check the research team's experience and expertise, while the sponsor is responsible for checking the overall integrity of the whole project, before it starts, and once it is up and running.

Publications have an important role in independent review of outputs linked to systematic reviews.

Corporate responsibilities

Fundamentally, the employer is responsible for ensuring there are systems for detecting and addressing fraud and scientific misconduct by employees. These should be analogous to those for responding to other kinds of corporate risks.

This includes systems to detect failures, such as routine and random monitoring, audit, reporting, and whistle blowing.

There are several responses to failures, including retraction of published outputs. The reasons for retracting relate to different aspects of quality control, only some of which are to do with fraud.

The NHS has created some robust processes and bodies relevant to quality control. For example, the National Patient Safety Agency is looking at adverse events and systems failures, while CHI/CHAI reviews and inspects institutions and the Medical and Healthcare

Products Regulatory Agency (MHRA) inspects quality systems for trials.

Behind these are professional regulatory bodies and the NHS counter fraud service. And there is always the possibility that if we identify evidence of criminal activity, the counter fraud services could run an investigation and prompt a criminal prosecution.

However, normally, this would be an over reaction to misconduct. We think that we should be looking for a mechanism that supports the actors in the other parts of the system. And we are very interested in proposals that support employers, particularly in organisations with little practice in handling or public exposure to, misconduct.

The EU directive, which will take effect in May 2004, only deals with trials involving medicines for human use. But it defines new legal duties for sponsors, investigators, and research ethics committees. And it makes falsifying information a criminal offence.

In summary, although we don't yet have complete systems in place, we have made significant progress. We have the processes in hand to create some robust systems. And we need to see misconduct and fraud in that context.

Cases of misconduct undoubtedly damage the trust that the public has in the NHS. But we also need to keep a sense of proportion. When things go wrong because of bad science in the nuclear industry or in veterinary science, the impact on public health is likely to be greater than when researchers falsify numbers in medical research.

Michael Farthing wondered whether the processes and structures in the NHS for dealing with employees might play in to some national repository. The General Medical Council was also extremely experienced in handling cases of research misconduct, but only covered registered medical practitioners and focused on the severe end of the spectrum. "Many of us feel there is a lot of noise out there in the system that is not being picked up by the GMC."

A view from the GMC

Jane O'Brien

Head of Standards Section, General Medical Council

The GMC was set up in 1858, and although its functions have been tinkered with, it may not be best placed to take a lead on how to deliver an entirely new organisation.

The GMC believes that the case has been made for an overarching body to deal independently with the investigation of research fraud and misconduct. The GMC has an important role, but it is partial.

The GMC was represented at the Edinburgh consensus conference and signed up to the joint statement. It has followed with interest the leaders and discussions in the pages of the *BMJ*, the *Lancet* and *Gut*.

There are plenty of international examples to draw on from Denmark, the US, and Australia, which we could use to find a model quite quickly. And we know that cases continue to emerge: the problem simply hasn't gone away.

There have been several meetings on the subject, and it is hard to escape the feeling of *déjà vu*.

We need to remind ourselves of continuing to talk rather than taking action. George Orwell put it eloquently when he described left wing academics in the 30s thus:

"Their words fall upon the facts like soft snow, blurring the outlines and covering up all the details."

Where does research fraud fit in?

Sir Donald Irvine set up an independent working group in 1998 to look at how we might construct a more uniform system for the UK to investigate research fraud. Many discussions were held, and a report was written, but there was no consensus on the best way forward.

But from the ashes, the GMC produced its own guidance on the standards of good practice expected of doctors, which was published in January 2002. But this does not focus on misconduct.

The GMC's charitable purpose is the protection, promotion and maintenance of the health and safety of the community. The scope is enormous, and clearly has to be restricted.

The Medicines Act of 1983 sets out the GMC's functions. These include giving advice on standards of professional conduct and medical ethics and the right to take action against doctors who may not be fit to practise.

It would therefore not be appropriate for the GMC to say that wider issues of research misconduct were outside its remit. We can't take the view that we are simply responsible for registered doctors.

Collaboration and partnership

The regulation of research is as complex as other aspects of health care, and one of the challenges we face is finding ways to weave together different burgeoning strands of activity. But we need to make sure that we support and help to provide an overall framework to promote good standards and ensure that research misconduct and fraud do not go undetected.

Our challenge is to work with others to ensure standards improve, complaints are dealt with promptly, and that we fulfil our unique function to deal with doctors whose conduct, health, or performance puts their registration at risk.

The GMC deals with referrals from a wide variety of sources, including employers, universities, and whistle blowers. It has been criticised for the slowness of its process and the narrowness of its approach.

These issues have been addressed over the past few years. The backlog of cases has now been eliminated, so long delays will no longer be the norm. The fitness to practice procedures are being reviewed in a bid to streamline and expedite the process. These reforms are due to be implemented by spring 2004.

The cases which come before the Professional Conduct Committee are, by their nature, the most serious kind. Since 2000, 16 cases of research misconduct have been heard. It is not always easy to define what falls into this category. These covered:

- Misappropriating research funds
- Failing to follow protocols
- Forging signatures of patients and co authors
- Falsifying data
- Failing to obtain patient consent for entry into clinical trials

The GMC is in a state of transition, with a new council of 35 since July of this year. The council would want to make sure that more regulation would lead to better regulation, that it would add value, and would want to know how it would be delivered.

We know that we can follow the models that have been introduced in other countries and we should get on with it. We should not delay until there is a catastrophe.

It's fairly obvious that there is now a familiar pattern in which a BSE, or a Shipman, or a Bristol has to occur before we do something. This does not seem a sensible or logical way of conducting our national affairs.

What can the GMC do?

Our functions are defined by law and our relationships are primarily with doctors. Our powers are to take action where a doctor may not be fit to be registered. That clearly does not encompass all areas of misconduct.

The integrity of research is nevertheless key to our purpose of protecting and promoting the health of the community, and the new council is moving towards a more expansive view of how the GMC fulfils this.

The GMC welcomes the opportunity to engage with those at this seminar to work towards progressing this initiative.

Proposal from Michael Farthing

I propose a joint working group to put together a proposal for consideration by the government.

Currently the investigation of allegations of research misconduct lies with employers, who in biomedicine are predominantly universities and the NHS. Both these parties need to be represented on the working group. But there are clearly other interested parties, such as the GMC and the Academy of Medical Sciences.

This working group will need as much advice and experience as possible and it should be able to co-opt others as it sees fit.

It should have an independent chair, and it might consider whether its remit should extend beyond biomedicine.

The proposal might refer to the consensus statement and consider that the Council for Research Integrity might:

- Advise on all aspects of the investigation of alleged cases of research misconduct and on how to prevent these from occurring
- Promote models of good practice and ensure that guidelines and procedures are consistently applied throughout the UK
- Assist, not drive, allegations of misconduct, providing external advisors to join local investigating committees. The Council might also be the place to which whistle blowers could take their concerns.
- Collect, collate, and publish information on cases: at the moment we know only about cases reaching the public domain, and it's very important that as a nation, we can begin to describe the scale of the problem

Comments

Learning from history

Iain Chalmers: reminded delegates of the importance of learning from history and the dangers of not getting the process right.

He referred to the botched investigation into alleged

research misconduct in North Staffordshire, including 16 enquiries, all of which had failed to find substantive evidence. The GMC was still investigating allegations of forged consent forms there, he said.

He contrasted the events in North Staffordshire with the case of the Kent gynaecologist Rodney Ledward, for whom a great deal of effort was made to collect evidence.

Michael Farthing: "That's an extremely important cautionary tale, and those of us who have acted as external enquirers, will know how processes across the universities differ enormously, and how they often lack robustness.

The quality of the investigations is often poor, as is the assessment of whether there is a *prima facie* case to answer. That is why we need a robust and consistent approach across the sector at that preliminary stage."

Should public funds be sought?

There was some discussion as to whether this proposed body be publicly funded. Shouldn't there first be proof of the impact of research fraud on the public? Otherwise it would have to be led and funded by a professional body.

Michael Farthing agreed. "But I would attest that there is, and that the point has been made time and time again. What we have failed to do is to convince the government and the key stakeholders."

He felt a real glimmer of hope, however. "The universities are for the first time engaging in discussions on this issue, and the NHS is tackling its own research governance. The question is the huge interface between the universities and the NHS. Many of these incidents cross the sectors. A university employee with an honorary NHS contract could be doing fraudulent research on patients."

Should we lobby politicians?

Richard Smith wanted to know if there were grounds for involving politicians, in view of the profession's singular failure to get anywhere with self regulation.

"The US Office of Research Integrity happened because of the efforts of John Dingell, a politician. As we have heard today, when a politician wakes up with an idea it happens, whereas as doctors spend 20 years talking about something and nothing happens."

Stephen Lock commented that solicitors had just lost their right to police themselves. But he warned: "We risk sophisticating this to an extraordinary extent. What about a national office managed by two experienced people that anyone can ring up for advice?"

He added: "I am extremely disappointed that the Academy is not prepared to take this on. This is one unifying part of the whole of medical sciences, and surely it should be their job."

Has the case been made?

Mary Manning said that the Academy quickly realised it would be swamped and would be unable to do

anything else. “We recognised that we did not have many of the skills needed: the legal complexities of this task must not be underestimated.

The Academy believes that data need to be collected to indicate the scale of the problem to make the case.

We are not unsympathetic to the issue, but fundamentally, we believe that the employers have to make it happen.”

John Pattison: “The case is made, but only for those people who believe the case is made, and most people you want to influence do not believe the case is made. You have to make the case from all its perspectives. The international dimension and how far behind the UK is in the league is an important case to make.

Secondly, you have to corral all the influential people in organisations to say the same thing. That tends to capture people’s interest. If there is a problem to be addressed, ministers will address it when it is clear the case has been made and a lot of people are concerned about it and want something done.

Thirdly, the last thing universities want is more obligations. Of course, they already have the responsibility [for research misconduct] whether they like it or not. It’s like health and safety and animal research, for each of which a national body monitors, helps, and polices what the local employer and employees are doing. You need to bring that in as well.

You have a lot of work to do before you get to the virtuous tipping-point where someone is prepared to do something about it.”

Michael Farthing: “The case has not been made at that level, partly because major stakeholders have been pulling in different directions and have conflicting interests. Why would a vice chancellor want to admit that he has corrupt research staff and bring that out into the public domain?”

John Pattison: “Making the case is a substantial piece of work. But once done all the colleges, regulatory bodies, educational institutions and key individuals need to support the initiative. It won’t work if one institution leads it.

The universities are in a difficult position, and it’s clear that they don’t want to take on another obligation [as in clinical trials directive]. But there’s no way of avoiding that, as there is no way of avoiding this. A scandal will seriously damage somebody, and nobody wants to be in that position.

I am not sure it is as onerous as people imagine. People look at something new and configure the worst case scenario in terms of the responsibilities, risk, and liability involved. Yet it rarely works out like that. But it’s a considerable task to convince them of that.”

Peter Wilmshurst: “The people with the greatest vested interest in concealing misconduct are the people who are being asked to set up this institution. The great and the guilty in medicine are those who have most reason to conceal it.”

Gordon Murray, Royal College of Physicians of Edinburgh: echoed the college’s frustration that so

little had been done, and endorsed the proposals.

He added: “A major theme of the consensus statement that is often forgotten is that research misconduct is much broader than research fraud. If our concern is about the contamination of the medical record, far more harm is done through incompetence than malicious fraud. There is a huge body of research undertaken by people who are not suitably trained or qualified to do it, and that should be part of the agenda for promoting good practice.”

The “dialogue of the deaf”

Ian Kennedy, shadow chair of the new Commission for Health Audit and Inspection:

“The NHS is setting up certain processes, which are important but only part of the game.

There is a ‘dialogue of the deaf’ going on, and it’s been going on for some 20 years. The pragmatist must therefore seek a way through this, with concrete proposals. What COPE is now proposing is not a million miles away from what the Academy suggested last year.

We need sufficient time, commitment, and funding to ensure that this work can be carried out. Unless we bring the two groups together, we will still be here in 10 years’ time.”

He suggested persuading a variety of groups, including the government, to put up some money in a time limited manner to investigate, collect, and publish information, and work on models of good practice, looking at international comparisons and circumstances.

Stephen Evans: “One of the late Roger Robinson’s approaches was to examine a paper and decide on its ‘sledge hammer to nut ratio.’ Recent responses had been excessive, he argued. Simplicity would be best.

“But we must look to do things that have very wide benefit across the whole scientific community, which will then have collateral effects in the area of scientific misconduct.”

Mandatory archiving of data

Doug Altman, Cancer Research UK Medical Statistics Group: “Misconduct is the tip of a large problem. We shouldn’t forget that we should see this as part of a general effort to improve the quality and relevance of research, and arguably reduce the body of it.”

But he said one of the factors hampering investigations was the lack of raw data and relevant documentation, the archiving of which should be mandatory for researchers. Employers should take on this responsibility, he said. There were also valid research reasons for the preservation of data.

“It seems to me unbelievable and completely unacceptable that people can do research using public money and yet throw away the data. We could consider a failure to keep the data as research misconduct.”

Iain Chalmers pointed out that the MRC had decided that the researchers they support should

archive their data. There was a working party convened by Peter Dukes looking into the practicalities, which were not inconsiderable, he said,

David Katz, editor, *International Journal of Experimental Pathology*: "In this kind of journal there are plenty of non-medical researchers, who may be as serious and fraudulent as clinicians. It's whether we should start small with medicine or whether we should be going bigger that is one of the difficulties."

The GMC seems to be far more concerned with consent issues than with the actual research misconduct and collection of data, and I don't see that they have taken on board in their regulations of the medical profession quite the same degree of emphasis as they place on the other."

Taking responsibility

Marc Taylor: "There's a clear view in the NHS arrangements that a different job is required in different areas of collaboration between the NHS and its partners. People need to take responsibility for their own business rather than being threatened that someone else will take charge. We need to set clear standards and be quite public about what those are, as well as creating better mechanisms of feedback to see where in the system problems arise."

It's important to decriminalise 'near misses' so as to encourage people to get out information about what might go wrong and not always have the mindset of whistle blowing. This makes it easier to own up to systems failures.

But at the same time we need to be much more vigorous about prosecuting cases that are clearly fraudulent. But that's against a background, not of assuming that everyone is a criminal, but that you have systems, which remove temptation."

Reaching the "tipping point"

John Pattison: "We think the system is good, and we haven't had the catastrophes like Bristol or Alder Hey. We haven't got that tipping point. But eventually you reach a point where people you think have had vested interests in hiding things, actually realise that's not appropriate. Otherwise why would we have CHAI and the NPSA? It's not in the NHS's vested interests to have either of these organisations."

Michael Farthing: "Some of us here think there have already been enough high profile cases to suggest that we should have responded some years ago. Editors think there are many more that have not been 'outed.'"

There is unequivocal evidence that speed cameras work, despite the fact that we all hate them. And unless we have the equivalent in other areas, including research, we won't have a major preventive intervention."

Ian Kennedy felt this argument was flawed. "While we have no doubt that cars kill people and the evidence is there in A&E departments, what we hear countless times is that people don't accept there's a problem in research. We have to confront this belief and lack of concern, and persuade people. Your proposal is a way

forward, and all I would add is a time limit."

Richard Tiner, medical director of the Association of the British Pharmaceutical Industry said that the number of incidents of serious research misconduct from member companies had definitely diminished over the past few months.

"It's unlikely that member companies are picking these up with their standard operating procedures which most have introduced. The reason is that the research governance framework has had a very positive effect, because there are other people in the trust who are monitoring researchers' activities. Of the cases referred to the GMC, 24 out of 26 were found guilty and there was no doubt that they were intent on serious misconduct."

Next year's statutory requirement for clinical trial site inspections will inevitably throw up dubious practice. We are in discussions with the MHRA about how these can be investigated. And that's one area where we really do need a national council, as cases not currently being picked up may be unearthed."

A body with investigatory powers will require huge amounts of resources. But there are various ways and means of fitting in with NHS systems and processes. This might be a more pragmatic and economical approach."

Scope and costs

Jane O'Brien wanted to know what level of fraud and misconduct might be expected for the UK's number of doctors and population? Were there comparable data, and if not, should that be part of evidence collected?

Michael Farthing said there were good data from Europe, but little from the UK, because universities don't report these. But he suggested that compared with Scandinavia, the numbers would be higher.

Mary Manning: "My instincts are to support a lot of the proposals. There are two possible sticking points: is this only about medicine or all scholarship? This is an issue for universities. When I raised the medical issues with them, their response was to ask what the Royal Society's position was. This means that there are some very significant and powerful voices that have not yet been heard."

The universities would not welcome attempts by the Department of Health to regulate them. Some of the NHS hasn't taken on board sufficiently its role as a research employer.

The proposals from COPE are sensible and we would be prepared to join in with them, but on the understanding that we are joining in with a consensus that other people would support.

A police force does not operate without the people's consent and it's no good acting like an invading army of military police."

Starting small and simple

Stephen Lock: "I was both impressed and depressed by John Pattison's statement about how far back we are. When I first went to the then president of the Royal

College of Physicians (Bill Hoffenburg) with my concerns, we concluded that data were needed. I undertook to write to every professor of surgery and medicine in the country. I received replies from all of them, indicating a large number of probable or definite cases of fraud, almost all of which have not been addressed.

If we are going to achieve anything, we have to keep it simple. The first thing COPE could do is to acquire some data. Let's draw on the expertise we have here to devise a good questionnaire and administer it."

Michael Farthing concluded the morning's proceedings. "There is a sound basis on which to move forward. We will see in a year's time how much we have achieved and whether we have gone any way to coming up with a firm proposal that a number of interested parties can sign up to.

I believe the evidence is there, but it is not always assembled in an easily digestible way. Stephen Lock's book provides plenty of evidence, and we should trawl through the European committees and their reports. And we may be able to get time trends from the GMC as well."

Session 2: Editorial Accountability (Chair: Richard Smith)

Editorial misconduct: time to act

Richard Smith
Editor of the *BMJ*

This morning we heard that we had, what was described as a “dialogue of the deaf.” We’ve had a dialogue of the deaf every year for the past five years. But this afternoon we are embarking on a new dialogue.

The issue of editorial accountability has not been addressed at any major meeting. I don’t think the European Association of Science editors, or the World Association of Medical Editors, or the US Council of Biology Editors have looked at this.

The reason for this is that, like everybody else, we are much more interested in other people’s accountability than we are in our own. Only one paper has ever been written on editorial accountability (1994). Cases of editorial misconduct are much more difficult to collect than cases of author misconduct.

Cases of editorial misconduct

Cyril Burt is the classic case. He founded the *British Journal of Statistical Psychology* and was its editor.

He published 63 of his own articles, and would often alter the work of others without permission, sometimes adding favourable references to his own work.

His *coup de grâce* came when he published a letter that he had written himself under a pseudonym, along with a response he also wrote himself under another pseudonym, so that he could attack a colleague.

Hans Eysenck, a pupil of Cyril Burt, followed the same pattern. He produced unbelievable and unrepeatable work, suggesting that personality was the main determinant of whether people developed cancer or vascular disease.

Much of this work was published in two journals, which he founded and edited: *Behaviour Research and Therapy* and *Personality and Individual Differences*. This raises the question of whether editors should publish original research in their own journals?

Malcolm Pearce wrote two fraudulent papers in one issue of the *British Journal of Obstetrics and Gynaecology*, of which he was assistant editor. The editor, Geoffrey Chamberlain, who co-authored one of these papers, was the journal’s editor. The paper described a re-implantation of an ectopic pregnancy, which resulted in a successful birth.

Chamberlain was also the head of department in which Pearce worked and was president of the Royal College of Obstetricians and Gynaecologists.

The college set up an enquiry to look into the matter. Malcolm Pearce was found guilty of serious professional misconduct and several of his other papers were retracted.

He wrote a randomised controlled trial on whether it

was better to induce labour or wait, which concluded that it was better to wait. Is this research reliable? We don’t know the answer.

Geoffrey Chamberlain, who had been a “guest author,” had to resign from all his posts.

The report of the inquiry made many recommendations on how journals should work. It suggested that an important step in making specialist journals more professional would be to keep minutes of editorial meetings, ensure that editors are appointed by competition after open advertisement, and disallow editors other major commitments.

George Lundberg was accused of editorial misconduct and fired for speeding up publication of a study, showing that many students did not regard oral sex as sex. He thought the study was relevant to the impeachment proceedings of President Clinton over the Monica Lewinsky case, which were going on at the time. Was this misconduct? Many will disagree.

Another case is that of Nicole Suci-Foca, editor of *Human Immunology*. She invited Antonio Arnaiz-Villena, head of the immunology department at a large public hospital in Madrid, and professor of immunology and cell biology at Madrid’s Complutense University, to guest edit a theme issue on anthropology and genetic markers.

He was given almost no guidance on what was expected of him. His keynote paper concluded that Jews and Palestinians are genetically very close and that their “rivalry is based on cultural and religious, but not genetic, differences.”

This was published just after September 11, and these and other political phrases caused uproar. Arnaiz-Villena was fired from the editorial board, the article was retracted, and subscribers were urged to physically remove the offending pages from their copies of the journal.

But did these problems arise from lapses in translation and editing, rather than political intent? And was the guest editor scape goated? The editor did not face any judgement, but should she have done?

There are three more cases, which Doug Altman, Iain Chalmers and Andrew Herxheimer will describe.

At COPE we only hear one side of the story and it isn’t possible to check all the facts. There is undoubtedly another side to each of these stories, which is why it is important to have due process if full investigation is to be carried out.

But we have had some cases of editorial misconduct:

Case 1

An assistant editor discovered that the editor in chief had

written to say he had accepted a paper after the assistant editor had rejected it. The paper was a guideline on a common medical condition and recommended a new expensive drug as the best treatment. The reviews had been mixed, but the scientific editors had decided to reject the paper.

The editor in chief had spoken at great length to the principal authors and asked for a third review. This was unfavourable, but he still went ahead and accepted it.

The association, which owned the journal, then stipulated that any editorial material published in the journal must have an elected official as an author, which clearly flouts all rules of authorship.

The chief executive of the association then announced that the journal could not publish any letters critical of the association. The editor in chief said he would protest against this, but the journal did not publish any more critical letters.

The assistant editor, who was fired, thinks that the editor and the CEO made a Faustian bargain.

Case 2

A journal published an editorial that had already been published elsewhere, without disclosing the fact, despite the editors discovering the previous publication during the peer review process. Furthermore, the editors had not sought copyright permission.

When it was later pointed out that the two articles were the same, the editors agreed that they had been at fault and published a notice of duplicate publication.

Case 3

An editor was accused of publication bias because he had invited the same trainee in radiology to write 14 commentaries over a period of five years. The most recent commentary covered the same ground as previous ones and cited mostly the publications of the trainee and the accused editor.

The editor was accused of failing to allow other authors and viewpoints to be given a voice, but the journal's ombudsman dismissed the case.

WAME case

An editor rejected a series of essays that he had already agreed to publish. The case was described on the WAME website and attracted considerable feedback, mostly of the view that the editor's behaviour was unacceptable. The editor concerned owned up: it was me.

How common is editorial misconduct?

We have no idea. We have crude data on authorial misconduct, but we are really at a very primitive stage where editors are concerned. We have only stories, and most of these are incomplete.

Why does it happen? Why wouldn't it? Another problem is we don't really know what misconduct is in an editorial context. We have vague ideas, but we don't really have a clear idea. We need to debate and define it.

And editors are peculiarly unaccountable—perhaps some of the most unaccountable people in the world, because of their traditions of editorial freedom. And there are no bodies that attempt to regulate medical and scientific editors. There is the Press Complaints Commission code, which the *BMJ* has to obey.

How should we respond?

Owners can improve their systems of accountability. After George Lundberg was fired, *JAMA* reviewed its systems, and the BMA has become much more interested in editorial accountability.

Bodies of editors like COPE and WAME should begin to introduce self regulation. I have set about coming up with a code. It includes:

- Accuracy and correcting the record
- Ethics committee approval
- Protecting confidentiality
- Pursuing misconduct
- Relationship to publishers/owners
- Economics of journals
- Conflicts of interest
- Ways to complain

But there are probably other topics it ought to cover, and some that are in there might not warrant inclusion. It's a very primitive document.

It has been sent to all the members of COPE. If we are going to live by this code, it is our intention that all the editors will sign up and agree to abide by the code.

Complaints can be made to COPE about the behaviour of editors. The chair of COPE Council would attempt conciliation, and if that were not possible, the Council would consider the case in writing, with full disclosure to the complainants and the defending editor.

If the Council found against the editor, he or she would be required to publish the full judgement, and in very serious cases, COPE could notify the publishers.

Key points:

- Editorial misconduct undoubtedly occurs
- We are beginning to collect cases that illustrate the various forms of misconduct
- We have no idea how common it is
- We can only speculate on why it happens
- No group of editors has tried to develop self regulation
- COPE is at the very start of the road

Have we made progress in exposing and dealing with editorial misconduct?

Andrew Herxheimer, emeritus fellow, UK Cochrane Centre, Iain Chalmers, editor, *James Lind Library*, and Doug Altman, Cancer Research UK Medical Statistics Group

Andrew Herxheimer reminded delegates that 10 years ago Iain Chalmers and Doug Altman had asked if there was a case for an international scientific press council. Very few cases of editorial misconduct have been published. We described three: one of persistent maltreatment of an author; one of plagiarism; and one abuse of an undisclosed vested interest.

These behaviours seem rare, but there is no effective reporting mechanism, so we really have no idea. But cases tend to be complicated.

Just who is affected?

These are the people to whom the editor has responsibilities. Authors are the most vulnerable. But associate editors are also involved and editorial board members, who are often in the dark, because they have no minutes of meetings, etc.

Journal owners are usually in control, but they are often more concerned with their image and their money. The scientific community and the public are mostly unaware, and if they are, don't know what can be done.

Other editors partly identify with the editors who misbehave and feel collegial shame that their peers are doing this kind of thing.

In July 2002 the *European Journal of Clinical Pharmacology* carried a PhD dissertation as a 68 page supplement. The dissertation included four complete published papers from various journals and one newly submitted paper.

As a member of the editorial board, I (Andrew Herxheimer) emailed the editor, requesting an explanation, which finally arrived a year later. On the journal's masthead are the editor, two managing editors, and a large editorial advisory board. What should the managing editors and the editorial board have known about this?

I copied my letter to one of the managing editors. He knew nothing about it.

When the editor replied, he said: "we missed appointing a guest editor, as ordinarily done for supplements, [so] I have editorial responsibility for this." He agreed that the permissions for reprinting the papers should have been mentioned, and he confirmed that the "submitted" papers had not been published elsewhere and now could not appear elsewhere. This paper had been accepted without regular peer review.

He thought it was obvious from the small type acknowledgements that the research as well as the supplement had been financed by a major drug company, and that there was no need to make this clearer.

I suggested that he publish an editorial note, explaining what had happened. He responded: "I am not sure. This may occur once in 20 years and I would hesitate to make a major issue of it. And it has been delayed, it would be bringing up a past event." But he agreed that it might explain journal policy on types of submission considered, including supplements.

He agreed that it was better to publish paper supplements separately rather than in a regular issue.

I sent a rejoinder that action was needed on three counts. Firstly, there should be a declaration of competing interests by authors and editors.

Secondly, there should be job descriptions for the roles of the coordinating and managing editors, and the editorial board members, who should also receive regular information on editorial policies and activities (minutes of meetings).

Thirdly, the instructions to authors should be accompanied by an explanation of the editorial process, how long it takes, who is involved, etc, for the sake of transparency.

We may not want to call this editorial misbehaviour, but these problems affect the scientific community as well as an individual group of editors, and we need ways of dealing with them openly.

The difficulties of taking editors to task

Iain Chalmers presented another example, spanning two decades.

January 1983

The *Journal of Pediatrics* published an analysis by neonatologist Jon Tyson and colleagues of the methodological quality of 86 "therapeutic studies" in the perinatal field. These had been published during 1979 in *Journal of Pediatrics*, *Pediatrics*, the *American Journal of Obstetrics and Gynecology* and *Obstetrics and Gynecology*.

Tyson and colleagues concluded that in less than 20% of the articles were the conclusions justified by the data presented and that deficiencies were very common in the papers examined. They made suggestions for improving the quality of therapeutic studies.

In an accompanying editorial in the *Journal of Pediatrics* the editor Joseph Garfunkel welcomed the paper and acknowledged a journal's responsibility for maintaining the quality of the material it publishes.

After acceptance of the paper, but before publication, Dr Garfunkel had invited the editors of the other three journals reviewed to submit responses for publication in *Journal of Pediatrics*.

March 1983

The *Journal of Pediatrics* published a highly critical response to the Tyson paper from Richard Mattingly, editor of *Obstetrics and Gynecology*, and Alfred Rimm, a biostatistician associated with the journal.

July 1983

The article by Tyson *et al* was republished in full in *Obstetrics and Gynecology*, with a statement that this was “with the approval of the authors.” The authors had not even been consulted, although the editors and publishers of *Journal of Pediatrics* had given their permission.

The letter from *Obstetrics and Gynaecology*, requesting permission, had stated: “We would like to call attention to our readers regarding the important message of this article, despite our agreement or disagreement of its statistical validity (sic).”

A defensive and complacent editorial in *Obstetrics and Gynecology* by Rimm and Mattingly began: “This is a poor study,” and contained no indication that they were aware of any “important message” that they had alluded to when seeking permission to republish it.

Summer/autumn 1984

Within a few weeks Jon Tyson and his colleagues submitted a response to the editorial, as did Iain Chalmers and Roberta Apfel, a psychiatrist in Boston. *Obstetrics and Gynecology* had had a major role in promoting diethylstilbestrol (DES) in the 1950s, and Dr Apfel felt that the complacency shown in their editorial was entirely inappropriate, given the story of DES subsequently. The editor of *Obstetrics and Gynecology* did not acknowledge any of these letters.

Having received no reply, Jon Tyson sent letters to each member of the editorial board, requesting his response be published. He was telephoned by an editorial assistant who said that he would be allowed to publish a revised version of his letter. He submitted a revised letter in November 1983.

Early 1984

Further letters were sent from Iain Chalmers and Roberta Apfel to the editor of *Obstetrics and Gynecology*.

Mattingly responded that he considered Chalmers’ letter “argumentative and non-constructive and [that it] would only enkindle the debate that will not be resolved in the editorial pages of a scientific journal.”

He rejected Apfel’s letter because of time delay, mentioning that Tyson *et al* had been invited “to prepare a rebuttal to our editorial comments so that there would be no misunderstanding of the authors’ report of this very volatil (sic) subject.”

August 1984

The response from Tyson *et al* was published 12 months after initial submission, nine months after resubmission, and six months after Apfel’s letter had been rejected because it had “arrived too late.”

The information that their article had been reprinted

without their prior knowledge had been deleted, and their letter was accompanied by a further hostile editorial by Alfred Rimm.

February 1985

Doug Altman wrote independently to *Obstetrics and Gynecology*, criticising the editorial by Rimm. No reply was received.

A further letter from him elicited a response from the deputy editor, Charles Hendricks, stating that his letter had arrived too late, and that it was necessary “to maintain some degree of balance in the editorial content of our publication.”

Autumn 1985

Doug Altman and Iain Chalmers informed Charles Hendricks that they were writing an account of the story for submission to the *BMJ*, inviting him to supply any relevant material of which they might be unaware.

Richard Mattingly responded by writing to the editor of the *BMJ*. He did not mention the letters from Chalmers and Apfel nor the obstruction and long delay in publishing the letter from Tyson *et al*. He dubbed the letter from Altman “highly inflammatory.”

Mattingly maintained that “we dutifully published both points of view,” and that “the present debate appears to center around differences of opinion between biostatisticians.”

Altman and Chalmers wrote to Hendricks and Mattingly, inviting them to supply any relevant material of which they might be unaware; assuring them that they would be invited to comment on their manuscript before submission; noting that they thought it likely that the *BMJ* would invite them to submit a response.

Hendricks resigned as deputy editor of *Obstetrics and Gynecology* in December and Mattingly died the following month.

A full account of this example of editorial misconduct has been submitted for publication without success to six journals, including *Obstetrics and Gynecology*. Some brief accounts have been published:

Shearer MH. The quality of perinatal studies: a disturbing episode. [Editorial] *Birth* 1994; 11:79-80.

Chalmers I. Editors, peers and the process of scientific review. In: Thomsen K, Ludwig H, eds. *Gynaecology and Obstetrics. Proceedings of the XIth World Congress*. Berlin: Springer, 1986;59-61.

Altman DG, Chalmers I. Authors have rights too. *BMJ* 1993;306:717.

Altman DG, Chalmers I, Herxheimer A. Is there a case for an international medical scientific press council? *JAMA* 1994; 272:166-7.

The death of Mattingly would have been an opportunity for his successor to apologise to Jon Tyson and his colleagues.

The next editor was Roy Pitkin (1986 to 2001).

June 1986

In response to a letter from Chalmers, Pitkin wrote:

"I have no further interest in involving this journal in the matter."

February 1998

In response to a conversation with Chalmers at the International Congress on Biomedical Peer Review in Prague and two subsequent letters from him, Pitkin wrote:

"After giving the matter careful consideration and consulting with my associate and assistant editors, I am not willing to issue any sort of apology."

March 2001

In response to a conversation with Chalmers at a planning meeting of the World Association of Medical Editors in Bellagio and a follow up letter, he said:

"After considering it once again, I still feel the same way. I have no interest in issuing any sort of apology or expression of regret."

8 March 2001

Iain Chalmers wrote to Roy Pitkin:

"Your letter makes clear that you have no feelings of regret about the way that Tyson and his colleagues were treated by *Obstetrics and Gynecology* by your predecessor, Dr Mattingly. I think this is inconsistent with the WAME statement on the responsibilities of editors.

How sad it is that you cannot be persuaded that there would be much to be gained and nothing to be lost by expressing regret at your dead predecessor's high handedness."

James Scott became editor in 2001.

13 March 2001

Iain Chalmers wrote to the new editor:

"I really do hope that you will feel able to do something about this. After reading the attached, I hope you will agree with me that Jon Tyson and his colleagues were treated disgracefully by Mattingly and Rimm. Jon Tyson is a modest fellow, who would never think of fighting this battle for himself. I haven't had any contact with him for years and years, but I won't feel able to let go of the matter until it has been dealt with honourably. All that is required is a short note from you, as the new editor in chief of *Obstetrics and Gynecology*, explaining that, having had this bit of history drawn to your attention, you are writing to express your regret (NB not to apologise) that Jon and his co-authors were treated in the way that they were treated. Please help to put this thing to rest so that I don't have to go to my grave, drawing people's attention to the matter!"

21 March 2001

James Scott replied:

"Since I am new to the job, I would like to take some time to review everything carefully before determining the best course of action. Because of the sensitive nature and the ongoing conflict, additional advice and legal counsel is probably also warranted at this point."

17 September 2003

In an email response to information from Chalmers about the forthcoming presentation at the COPE meeting the editor wrote:

"Thanks for bringing this to my attention. I have had a lot on my plate since I took over as Editor, but I have now again reviewed your messages and the previous correspondence. I plan to apologize to Jon Tyson and assure him that this could not happen under my Editorship."

17 October 2003

In an email to Chalmers, Jon Tyson wrote:

"I recently received a telephone call from James Scott, the current editor of *Obstetrics and Gynecology*. On behalf of the journal he offered a cordial and sincere apology to all the authors for the errors that had previously been made.

The apology was much appreciated. I hope that any long term effect of this unfortunate episode increases the emphasis on high standards for editors and investigators alike."

Doug Altman pointed out that the original version of the *JAMA* paper had been twice as long and included a lot of detail which the lawyers wanted deleted, even though two of the people being complained about were dead. He quoted from Drummond Rennie: "Outright editorial fraud is peculiarly frightening."

The case of Dr K

Doug Altman began by outlining the case of Dr K. Dr K tried to publish a letter, drawing attention to possible misconduct, which had been previously highlighted but never addressed. This related to two articles published in the same journal by the same group of authors.

The letter was accepted but subsequently rejected after he returned the proofs. He tried to get it published in the *New England Journal of Medicine*, the *Lancet*, and another specialist journal.

None of the general journals commented on alleged misconduct in their standard rejection letters. The editor of the specialist journal noted the "serious allegations," but declined to publish, saying that it was none of his business and that the matter should be resolved in the original journal. But clearly, the original journal is the problem.

Other journals see no reason to be involved, and good reasons not to be, but one option that didn't exist 10 years ago is the internet.

R Santilli wrote an "Open letter to all Editors of World Scientific Singapore" [<http://www.scientificethics.org/ws.pdf>], criticising the publisher rather than editors.

He included the following legal note:

"This report has been written as an individual U.S. Citizen under the protection of the First Amendment of the U. S. Constitution, particularly when dealing on violations of Codes of Laws perpetrated under public

financial support, as done by S. Weinberg, S. Coleman, S. Glashow of Harvard University, and their associates.”

Contacting the editorial board with a grievance is also an option. However, they vary enormously in their level of contact with the editor.

What’s happened in the past 10 years?

The *Lancet* instituted an ombudsman in 1996, and a few other journals now have one, but this is relatively rare.

WAME does have an ethics committee, which will comment on cases involving ethical issues in publication, but they don’t appear to have done much in this regard.

The CSE (Council of Science Editors) and EASE (European Association of Science Editors) do not seem to have addressed the issue at all.

COPE has: “[Editors] must consider and balance the interests of many constituents, including readers, authors, staff, owners, editorial board members, advertisers and the media.

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

But who decides what a major flaw is, and how is that defined? It’s a major flaw that COPE has not done this. And it reflects the difficulty of the issue.

Towards a taxonomy of editorial misconduct

This is a less familiar concept than research misconduct, so is often hard to understand exactly what is meant by it. We have produced a preliminary framework for what this definition might include:

Misrepresenting authors

- Publishing an article without the knowledge of the authors ... or against their wishes
- Changing the text without asking the authors

Publishing a paper known to be bad science

- For publicity or financial gain

Discriminating for or against a group of authors

- To distort the published record of precedence, for example reversing the publication of articles submitted
- Failing to remain impartial
- Failing to avoid conflict of interest
- Failing to investigate an allegation of research misconduct in a published paper
- Publishing a sponsored supplement as if it were regular peer reviewed material

Undesirable behaviour on the boundary

Using non-scientific criteria for selecting which papers to publish

- Favouring the newsworthy
- Favouring eminent authors
- Discriminating against statistically non-significant findings
- Favouring publications likely to lead to large (lucrative) reprint orders

Suppressing criticism of published papers

Questions arising from the case of Dr K (a mix of scientific and editorial misconduct)

1. What is an editor’s responsibility when the suggestion is made that a paper published in his/her journal may contain fraudulent information?
2. How should the answer be affected by the fact that the editor is a friend or colleague of the author of the published paper?
3. Is it reasonable for a journal to publish a letter that raises serious concerns about the content of a published paper, but not to seek or publish any explanation from the authors of the paper in question?

Other questions

1. Is it acceptable for an editor to reject a letter, or indeed a paper, after it has been accepted for publication? If so, in what circumstances?
2. When it is clear that a journal refuses to pursue an allegation against an author, do other journals or organisations/individuals have any responsibility to investigate or give publicity to the matter?
3. What is the responsibility of other journals or organisations/ individuals to investigate or give publicity to allegations of editorial misconduct?

How might a scientific press council work?

Journals and publishers might publicly sign up to a press council scheme, or by omission, become known as not accepting it. This decision should be part of the integrity of the journal.

Their decision one way or the other could gradually influence the standing of journals; it might come to mean more than the impact factor.

A survey of editors' conflicts of interest

Sara Schroter

Coordinator, *BMJ* research

In 1993 the International Committee of Medical Journal Editors acknowledged that: "All persons involved in the peer review process, including editors, might have conflicts of interest."

Over 500 journals subscribe to the Uniform Requirements for Manuscripts to Biomedical Journals, and many now publish information about the financial conflicts of interests of authors. But little is known about editors' conflicts of interests and the mechanisms in place against them.

The study aimed to determine:

- Whether editors declare their financial conflicts of interest, and if so, where?
- How important editors feel it is to declare their financial interests
- Whether editors intend to declare these in the future
- If editors declare non-financial conflicts of interest

We posed the questions to editors, editorial boards, and other editorial advisors.

We wanted to select a representative sample of medical journals, but there is no established method for identifying a representative sample across all the categories of medicine. So we opted for one category: general and internal medicine.

Combined sampling strategy

We took a random sample of 35 of the 108 (32%) journals using the ISI Web of Knowledge Journal Database. We also deliberately selected the top five US and the top five non-US journals, based on impact factor, because these often influence editorial practices. We excluded five duplicates, leaving us with 40.

Senior editors were sent a questionnaire by fax with a cover letter signed by Richard Smith, and non-responders were contacted by telephone. Some completed over the telephone.

Results

Three journals had to be excluded, one because of insufficient contact details; two had closed. Overall, the response was 81% (30/37). And all the top 10 journals responded.

Overall, 63% (19/30) of editors felt it was either important or very important to declare the financial conflicts of interest of their editors; 43% (13/30) their editorial board; and 37% (11/30) other editorial advisors.

Only nine (30%) stated that they have a policy to deal with editors' financial interest:

The *BMJ* declares individual editors' competing interests on its website (including financial and non-financial), and one other journal published a detailed internal policy.

For the others:

- Editors have to declare if they have an interest for each paper they deal with
- Editors sign financial disclosure statements, but it's not clear if this is done only when they join the journal or if it's an annual procedure
- Editors are "not allowed to have interests"

The percentage of editors saying they do not intend to declare financial interests (this year/next year/not at all) was as follows:

- 37% (11) editors
- 53% (16) editorial board / other advisors

The reasons given for not declaring interests included:

- "unnecessary"
- "editors do not have conflicts of interest"
- "issue has never been considered"

Only eight (27%) intended to declare financial interests of editors in the next couple of years.

Similar proportions (two thirds) of editors from the top 10 journals and other journals confirmed it was important to declare editors' financial interests, but 60% of the top 10 have some sort of a policy to deal with it compared with only 15% of the others. It's not clear if this is a matter of editorial resources.

Conclusions

- Only half of those who thought it was important to declare editors' financial competing interests actually have a policy to deal with the issue.
- It's an internal, often vague process.
- And it's often not made clear exactly how some policies are put into effect and how conflicts of interest are defined.
- There are few mechanisms in place to ensure that declarations are updated.

The research was limited to one category of medicine. Is this, therefore, a true reflection of what goes on across the board?

We sampled journals which have a strong influence on editorial policies, so it is likely that we overestimated current practice across all journals. But clearly greater transparency on this issue is needed as editors should be accountable for the decisions they make about scientific research.

Comments

Has the case been made for editorial misconduct?

Richard Smith: If the case is not made for research conduct, is it made for editorial misconduct?

Sati Ariyanayagam, Multiethnic Research Council: As far as transparency and openness are concerned, the case is made, but in terms of the impact of editorial misconduct on public interest, I am not sure that it has."

Richard Smith: "Much of the focus to date has been on high profile cases of people inventing data and severe plagiarism, which are probably not that common. And the effects are not necessarily that severe. But more minor forms of misconduct—publishing more than once, not publishing at all, being unclear about authorship, not declaring competing interests, post hoc analysis (manipulating data for positive results)—these things happen often, and combined, probably have severe effects. But it may be too easy to dismiss the big cases as not having that dramatic an impact."

Iain Chalmers: "People do remain to be convinced. If editors had tackled some of these things themselves, they would be in a stronger position now."

Doug Altman: "I am not sure that there has to be evidence of clear harm to the public before this is considered to warrant action. Drug testing of sportsmen and women does not have a direct impact on the public, but we still do it."

We are talking about the whole research system, which should be based on trust and integrity. All of the things that we have mentioned chip away at trust and integrity, and all research is downgraded and devalued in the public perception. When scientific research is devalued, it's not just bad for scientists but for the public as well."

Andrew Herxheimer agreed, and added that when a conflict of interest was declared, it was rarely explained. "If someone declares sponsorship from a company, it is important to know why this constitutes a competing interest. Transparency is not just for those who know already; it has to be for those who don't know."

A code of conduct should confer a badge of trustworthiness for editors, he suggested.

Pritpal Tamber, medical editor, Biomed Central felt that it was not worth worrying about whether the case has been made. "There's a lot of poor peer review practice going on, and past the top end specialist journals, things can get murky. In areas, where there is a lot of money to be made, such as nutrition, there's a great deal of 'murky' behaviour. I think it is important, therefore, to get something established."

Richard Smith: "If people don't accept there's a problem, they won't be interested in a solution. Clearly, we've been thinking about misconduct for 20 or more years, but have paid almost no attention to editorial misconduct. That's likely to be because we don't want to face up to our own iniquities."

Don't make assumptions about the big journals

Peter Wilmshurst: warned against complacency about the probity of the big journals. He cited the case of amrinone, which had horrendous side effects. The first study detailed only six patients, with no dose response. The paper was accompanied by an editorial, which made claims that were not substantiated by the findings of the paper, but the writer was on the editorial board and a close personal friend of the lead author. The paper had five authors, two of whom were full time employees of the manufacturer, and the editorial writer was a paid consultant, nothing of which was stated in the publication.

Kurt Hellman, former editor, Clinical and Experimental Metastases, said that one of the big journals had published a new paradigm of something that had been published 30 years ago, but to which all references to the previous work had been omitted.

Stephen Evans: "The big journals have immense power and influence, so people will tolerate all kinds of misconduct, provided their research gets published in the journal. Editors of big journals have an enormous responsibility to lead the world in integrity because of that power."

Editors have to be very careful about publishing in their own journals but they should be allowed to reject a paper after acceptance, he felt, because a major statistical flaw might subsequently be found. But there needs to be a transparent process for that, with referral to an independent ombudsman.

Richard Smith: "An important point is emerging here: we don't know what editorial misconduct looks like. Quite a lot of things on Doug's list are not on the code I have drafted, which illustrates how we come at it from different angles. And it illustrates how authors have a very different view of editorial misconduct than do editors and the world at large."

Doug Altman: "People will do anything, including lie, in order to get published in the major journals. Indeed, the case could be made that the risk of scientific fraud may be higher in the major journals because the incentive is so much greater."

Iain Chalmers cited three instances of behaviour on the periphery, where changes had been made without him seeing the proofs, because of journal policy (*BMJ*). All the mistakes were now implicitly attributed to him.

Richard Smith cited John Bailar, professor of statistics at the University of Chicago and statistical adviser to the *New England Journal of Medicine*, who said: 'Disclosure is almost a panacea.'

"So I would argue that as long as we spell out that it's because we want to publish letters and obituaries quickly and don't want to get bogged down in process, you can make an informed choice about whether you want to submit under those circumstances."

Don't stifle original thinking

Brian Gennerly, President, Faculty of Pharmaceutical Medicine said that all this might

end up abolishing the department of whacky ideas, citing the use of beta blockers in cardiac failure as a case in point. This went against conventional teaching, when first described 25 years ago, as a result of which many people with congestive heart failure who stood to benefit were never given these drugs, he said.

"It's only in the past five years that we have come to recognise that this thinking was completely wrong. I suspect the reason that information never got into journals is because it went against accepted wisdom."

Iain Chalmers said that the peer review process was incredibly conservative. "There is inbuilt conservatism to ideas."

Doug Altman clarified that the intention was to prevent studies being done badly rather than to suppress hypothetical arguments.

Is inaction misconduct?

David Schrager, UCLA Center for Statistics and Medicine, *Annals of Emergency Medicine*: "Sensational research misconduct case may obscure the mass of lower level cases that may have greater impact. The amount of effort and potential legal battles are such that people tend to play ostrich. By not acting, we may be creating greater problems than the cases where the editor is guilty of gross misconduct."

Richard Smith: "COPE has changed the world for some of us in that we now feel an obligation to act, and that it's misconduct not to." Most of the problems he experienced were with unpublished papers, which led into years of fruitless correspondence, he said.

He agreed that it was harder for editors who were part time with few resources at their disposal. The few incidences on small journals created alarm, with lawyers cautioning against taking action. He wanted to know if editors should take responsibility for unpublished papers.

Doug Altman: "They have particular responsibility for correcting the record and investigating allegations for papers they have already published. Although different, they also have a responsibility for submitted papers. One is an obligation; the other is more a societal duty."

Where do editors' responsibilities end and publishers' start?

Richard Smith wanted to know where the responsibility of editors ended. If someone submitted a paper describing misconduct elsewhere, was there a duty to follow it up, except that the unwritten law of journalism, that dog doesn't eat dog, would preclude that.

Doug Altman felt that was amply illustrated by the cases presented in which authors failed to get journals to publish criticism of other journals.

Andrew Herxheimer wondered if commercial publishers would feel equally morally obliged to spend money on following up allegations of misconduct.

Richard Smith said that some of the big publishers had paid up for their journals to belong to COPE so

that there was some obligation. But **Alex Williamson, publishing director of BMJ Journals**, said that Nature Publishing Group and Reed Elsevier had not done so on the grounds that this was not an effective use of their money.

Stephen Evans said that editors were capable of putting their own house in order. "We therefore don't need to make a case to the big wide world; we need to make a case to ourselves. And that's been done."

He wondered if Biomed Central might not be able to publish "other people's dirty washing."

"We face the same issues. Editors believe in open access, but they are just not trained in these wider responsibilities," said **Pritpal Tamber**.

He felt there were many issues for small journals, about not being linked to a learned society, the quality of their peer review, their lack of accountability. "They make money for the publishers so why would the publishers want to fix what isn't broken?"

The tradition of amateurism in scientific editing

Richard Smith: "We have a whole tradition of complete amateurism. One day you are a professor of obstetrics and the next day you are an editor of a journal, with no training, no back-up, and no support. It would be totally unacceptable, if you reversed it. As an editorial community, we probably have to hold up our hands for being responsible for this as well."

Michael Farthing: "When talking about self regulation, if five editors think there is a case, there is a case, but there isn't a public interest in quite the same way. Self regulation is about spotting flaws before they become incidents."

Should editors be licensed, he wondered? Referring to the research study, which revealed that 40% of editors did not recognise competing interests, he said: "That's very serious. If they don't recognise it in themselves how will they be able to apply it to authors?"

Richard Smith pointed out the importance of the peer review congress because of its fundamental evidence of the craft of editing, yet 98% of editors did not attend the last one.

Iain Chalmers did not agree with the idea of a licence, at least until there was evidence to suggest it would work.

Doug Altman said that scientific editing was one of many things that people are supposed to know how to do without any training whatsoever. "We've recently done research into data monitoring committees: many people have no idea about what they are supposed to be doing."

Linking conduct to funding

Richard Tiner: "The concept of a European Scientific Press Council is a very sensible way forward. And there should be a website declaring publicly exactly who has signed up to it. This was suggested at the Royal College of Physicians' meeting in 2001; the funding bodies in attendance were keen on the idea

that research institutions should sign up to a National Research Council as a condition of funding."

Richard Smith said that once funders were key to making things happen. The NIH in the States and the Wellcome specify that proper mechanisms are required to deal with misconduct if money is to be allocated.

An editor of a small specialist journal said that the advent of Biomed Central made it more difficult to define who or what the editor actually is. He urged prompt action on editorial misconduct, and called for the same standards to apply to smaller journals. They were better, because they didn't operate any triage like the big journals, and dealt with everything that came in through the door, he ventured.

Redressing the balance

Hoomen Momen, editor, *Bulletin of the World Health Organization* said that research misconduct often involves patients or communities. Was there any way to redistribute justice to the community in question?

Richard Smith said that the *BMJ* tried to do this in some way, by acting on the many papers it receives from doctors who are not full time researchers, trying out their ideas on patients.

Iain Chalmers commended the *BMJ* for the value it placed on patients' interests in giving them access to its rapid response system. "It is the single most important advance in medical publishing I can think of."

Doug Altman: "Rapid responses are very important, and it's shocking that other journals have not done the same thing."

Andrew Herxheimer described how the enormous sale of COX 2 inhibitors threatens to bankrupt the pharmaceutical benefits scheme in Australia. This had arisen because publications had exaggerated the safety and efficacy of these drugs while the Licensing Authority was bound by secrecy agreements, so could not publicise the less impressive data.

Richard Smith concluded that everyone seemed to think there was a problem that needed addressing, and that there was no need to convince anyone else. He proceeded to outline the code.

Code of conduct for editors

This is very much a first draft and "work in progress," which has been produced, using the code of the Press Complaints Commission, the statement on responsibilities of editors from the World Association of Medical Editors, and my own ideas.

We will need feedback and "real cases" in order to arrive at a useful and workable code, which will continue to evolve.

I've deliberately made the statements positive rather than negative, and have aimed for a "lower common denominator" document, because it would seem to be pointless to propose a code that only a handful of editors currently meet.

I've tried to begin with an aspirational—but necessarily non-specific—statement.

Editors of medical journals are responsible for all their journals contain. They should:

- Strive to meet the needs of readers and authors
- Constantly improve the journal
- Ensure the accuracy of the material they publish
- Maintain the integrity of the scientific record
- Ensure that business needs do not compromise intellectual standards
- Always be willing to publish corrections, clarifications, retractions, and apologies when needed.

Any deviation from this code of conduct may be misconduct and could be reported to the Committee on Publication Ethics.

Accuracy and correcting the record

Editors should take all reasonable steps to ensure the accuracy of the material they publish.

Peer review processes should be described, and editors should be ready to explain any important deviation from the described processes.

Whenever it is recognised that a significant inaccuracy, misleading statement, or distorted report has been published, it must be corrected promptly and with due prominence.

An apology must be published whenever appropriate

If articles prove to be fraudulent or contain major errors that are not apparent from the text then they should be retracted—and the word retraction should be used in the title of the retraction (to ensure that it is picked up by indexing systems).

Cogent critical responses to published material should be published unless editors have convincing reasons why they cannot be. (Journals are advised to create electronic means of responding so that "lack of space" is no longer a convincing reason for not publishing a response.)

Ethics committee approval

Editors should ensure that research material they publish has been approved by an ethics committee. They should satisfy themselves that the research is ethical as they can be held responsible for publishing "unethical" research even if it has been approved by an ethics committee.

Protecting the confidentiality of human subjects

Editors must protect the confidentiality of information on patients obtained through the doctor patient relationship. As ensuring anonymity is almost impossible, this must usually be done through obtaining written consent for publication from patients.

Pursuing misconduct

Editors are often the first recipients of studies that may involve some element of misconduct. If editors

encounter misconduct on the part of authors, their staff, or other editors then they have a duty to take action.

If the misconduct is by authors or other editors then editors will need to ask their employers or some other appropriate body (perhaps a regulatory body) to investigate.

Editors have a duty to ensure that a proper investigation is conducted, and if this doesn't happen for whatever reason the editors must persist in obtaining a resolution to the problem and a correction of the record if it is needed. This is an onerous but important duty.

Relationship with publishers, owners, and the economics of journals

The relationship of editors with publishers and owners is often complex and should pay attention to the tradition of editorial independence.

Editors clearly have to accept the economic realities of their journals, but decisions on which articles to publish should be based on grounds of quality and suitability for readers rather than on immediate financial gain.

Conflict of interest

Editors should have systems for managing the conflicts of interest of themselves, their staff, authors, and reviewers.

Ways to complain

Editors should respond promptly to all complaints and should ensure that there is a way for complainants who are dissatisfied with the response to take complaints further. Ideally this mechanism should be made clear in the journal.

Living by the code

1. All editors who are members of COPE will be expected to abide by the code, tell their readers that they do so, and provide readers with access to copies of the code.
2. COPE will consider complaints from anybody about editors who are members of COPE who breach the code. Such complaints should be made in writing with supporting evidence to the chairman of COPE.
3. The editors who are complained about will be asked to respond to the complaint in writing. The chair of COPE will attempt to resolve the complaint.
4. If this is not possible, then the council of COPE will consider the case on paper. Both the editor and the complainant will see all the correspondence and have a chance to respond in writing.
5. Both the complainant and the editor will be informed of the judgment in writing.
6. If the Council of COPE finds that the editor has breached the code then the editor will be

required to publish the adjudication in full in the journal. The editor will have the opportunity to respond to the facts of the adjudication, and the council of COPE may correct the piece to be published. The complainant will see the adjudication before publication and also be given a chance to correct any factual errors.

7. In the cases of serious breaches of the code then the Council of COPE may decide to notify the owners of the journal, expel the editor from COPE, or both.

Other relevant codes:

WAME (World Association of Medical Editors)

The Responsibilities of Medical Editors, posted August 5 2003

<http://www.wame.org/wamestmt.htm#responsibilities>

The following statement was drafted at a meeting of the World Association of Medical Editors (WAME) during a meeting at the Rockefeller Foundation Study and Conference Center in Bellagio, Italy, January 22–26, 2001. It has been revised by the Editorial Policy Committee and reviewed by the Executive Committee of the WAME Board before being posted on the WAME website.

Editors should:

1. Respect their journal's constituents (readers, authors, reviewers, and the human subjects of research) by:
 - Making the journal's processes (e.g., governance, editorial staff members, number of reviewers, review times, acceptance rate) transparent;
 - Thanking reviewers for their work;
 - Protecting the confidentiality of human subjects.
2. Promote self-correction in science and participate in efforts to improve the practice of scientific investigation by:
 - Publishing corrections, retractions, and critiques of published articles;
 - Take responsibility for improving the level of scientific investigation and medical writing in the larger community of potential authors and readers.
3. Assure honesty and integrity of the content of their journal and minimize bias by:
 - Managing conflicts of interest;
 - Maintaining confidentiality of information;
 - Separating the editorial and business functions of the journal.
4. Improve the quality of their journal by:
 - Becoming familiar with the best practice in editing, peer review, research ethics, methods of investigation, and the rationale and evidence base supporting them;

- Establishing appropriate programs to monitor journals' performance;
- Soliciting external evaluations of the journal's effectiveness.

COPE Guidelines on Good Publication Practice

[http://www.publicationethics.org.uk/cope2002/pdf2002/21330_pp48_52.pdf]

8. Duties of editors

Definition

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

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

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

Actions

1. Editors' decisions to accept or reject a paper for publication should be based only on the paper's importance, originality, and clarity, and the study's relevance to the remit of the journal
2. Studies that challenge previous work published in the journal should be given an especially sympathetic hearing
3. Studies reporting negative results should not be excluded
4. All original studies should be peer reviewed before publication, taking into full account possible bias due to related or conflicting interests
5. Editors must treat all submitted papers as confidential
6. When a published paper is subsequently found to contain major flaws, editors must accept responsibility for correcting the record prominently and promptly
7. Where misconduct is suspected, the editor must write to the authors first before contacting the head of the institution concerned
8. Editors should ensure that the Instructions to Authors specify the need for authors to obtain informed consent from patients included in their research

The code is not complete, and omits several issues raised here today. But it is a framework for discussion. What do we think of it? How can we refine it? What sorts of processes do we need to go through to begin to live by it?

Silvia Bonaccorso, vice president of Merck and a member of the *BMJ*'s editorial board, has already commented. She said:

"The document lacks teeth. Even for a first draft, it lacks teeth. I see a problem with going for the lowest

common denominator. If we are going to set up a meaningful code of behaviour, it should not be guided by what editors can meet?the lowest common denominator. Editors are being held to the lowest possible standard, however the same kind of thinking is not what is required of authors, industry, and academia."

Richard sympathised, but said that drafting too rigorous a code which resulted in almost every editor being referred to COPE would be problematic.

Comments

Separating authors' and editors' complaints

Norman Noah, Editor, *Epidemiology and Infection* suggested that in the absence of a UK Council for Research Integrity, a UK association of medical editors should be formed, with a code of conduct, which was neither too all embracing nor too strict; training for editors; and a referee system with an ombudsman.

Richard Smith wasn't sure that another body in addition to COPE was needed.

Norman Noah contended that the problems of medical editors were different from those of authors, with which COPE primarily deals. COPE had more than enough to deal with, so at least an affiliated, but separate, body was needed.

Richard Smith: "COPE is an organisation of editors for editors, so we are well set up to take the next step to deal with complaints about editors. Membership provides a mechanism to require compliance with this code."

Norman Noah suggested that a subcommittee would be needed, to concentrate on the three criteria already mentioned.

Richard Smith: "We have legitimate sway over members of COPE, but have felt that we couldn't deal with editors who are not members of COPE. But we have begun to do that with authors, so if we were to establish some sort of code of conduct, we could begin to apply that to complaints made about non-members, asking for our advice."

Michael Farthing: pointed out that he was both chair of COPE council and chair of the committee, which could be regarded as incestuous. "We are not regulating editors at the moment; we are just advising them on decision making. But we can't be judge and jury. That's exactly why the GMC ran into trouble. They have now separated their strategic function from their investigatory/adjudicatory function. I think we would have to do that as well."

Complaints against editors would not be considered by the same group advising editors on misconduct, he suggested.

Richard Smith explained that this is what the ABPI had done in setting up its Code of Practice Committee. Silvia Bonaccorso had suggested that non-editors would need to be involved, if this is to have any credibility, he said.

Michael Farthing agreed, saying this was much closer to the Press Complaints Commission format, with lay representation. He felt the code was “a very good start.”

Quantifying standards

He suggested taking the Investors in People approach, which is to set the highest standards for entry at different levels (1–3). This would provide “a road along which to travel towards the highest possible standards.”

Richard Smith suggested this could be problematic, giving journals the perfect excuse to not be held accountable on the grounds that they were only on level 1.

Michael Farthing said a journal could make a public declaration as to where it was along the road to the agreed standards, and that the levels would provide targets to work towards.

He added that COPE was in the process of defining its advice to editors on specific cases in a bid to have a defensible framework should COPE ever be legally challenged.

Avoid too much detail

Iain Chalmers said that it was important to focus on what was really important. He reiterated the importance of rapid access in terms of opening up criticism. Could self criticism be included?

Stephen Evans cautioned against getting into too much detail, on the grounds that it would be too difficult to include all the possible ways in which editors misbehave.

“The fundamental thing is the way in which complaints are made to editors. For editorial misconduct, we need to have openness to comment on the editorial process, because a lot of rapid responses often criticise that.”

Richard Smith said that we should look to the differences of defining misconduct between the US, where they work to a tight operational definition, and Europe, which takes a general line to include any deviation from proper scientific standards as potential misconduct.

The European approach seemed the easiest one to start with, he suggested, with experience of referrals helping to establish more clearly what is and what isn't misconduct. “This is quite likely to change over time, which militates against producing an exhaustive list.”

David Schrager said that it was impossible to regulate good judgment. “If it gets too specific, you run the danger of missing the point. COPE can provide real resources for smaller journals, with something as simple as a rapid response, which not all journals are equipped to do.”

Richard Smith conceded that small journals find it difficult to launch into the process of righting a wrong, but potentially that's something that COPE could take on rather than just offering advice.

Michael Farthing disagreed on the question of detail. “If this is going to be meaningful, we do need to

include examples. People don't understand what's right and what's wrong.” The effort of providing seemingly detailed examples might clarify that.

“We rely very heavily on Cochrane reviews, which exclude many because they don't come up to standard, he added. But why don't they? Why have they been published?” He explained that in gastroenterology, the two reviews of the world literature both concluded that there wasn't a single paper which could be used to inform decisions about treatment for irritable bowel syndrome.

“What we have at the moment is the publishing cascade, where authors start at the top and then move down the hierarchy until someone publishes the paper. We could argue that we need to reduce the volume of what's published. It's certainly editorial misjudgement to publish some of these poorly controlled, underpowered, ill designed studies.”

Richard Smith pointed out that to include these studies would account for roughly 95% of the medical literature.

Stephen Evans: “Case studies are worth while, but trying to be too prescriptive is a waste of time. Instead of impact factors, there should be a factor that is a reciprocal of the proportion of papers a journal publishes which are thrown out by Cochrane.”

... But think broad

Iain Chalmers cautioned that ‘Cochrane is not a religion.’ There were plenty of other systematic reviews being done outside Cochrane. Studies can be excluded from Cochrane for several reasons—for example, the population studied in primary study not relevant to the question being addressed, he suggested. Exclusion on methodological grounds, however, would be a reasonable way to work out which sorts of papers are being published when they really shouldn't be.

Doug Altman: “Most medical research is not randomised trials, and most of these are not in the leading general medical journals. So we have to be careful to think broad.”

Andrew Herxheimer suggested that the ethics committee approving the study should be named in the paper, because “these committees operate in shadowy anonymity.” They ought to share responsibility for the studies they approve and be notified when the results are bad, he said.

Could cogent critical responses in rapid responses, if these were expanded to other *BMJ* Journals, he asked?

Richard Smith said that all the *BMJ* Journals had them, but did not use them. Of High Wire journals (400) with them, most are *BMJ* Journals. This was perhaps why the *BMJ* consciously went for the lowest threshold. “As long as it's not obscene or libellous, it gets posted; for many editors, that's a step too far.”

Andrew Herxheimer then proposed that Biomed Central might have a site, where people could post things about any journal.

Doug Altman said that the drawback to this was that rapid responses are not on Medline, so they are

not accessible to those who don't visit the *BMJ* website.

Key points

Richard Smith felt that it was time to conclude the meeting. Having established that two thirds of the delegates were members of COPE, he asked several questions.

- Who thinks we should have a code of conduct for editors? This was passed.
- How many like the idea of different levels of entry, with a progress ladder? Only two delegates supported this.
- Who thinks the code should be tougher? Only one delegate felt it should be.
- Who thinks once we have the code, we should enforce it? Majority agreed.
- Should we have separate functions for self help and enforcing code? Majority agreed.
- Should we have non-editors for credibility? Majority agreed.

Michael Farthing suggested that the code should be posted on the website to consult widely among the membership, and that others should also be consulted, given that the code has been driven by authors complaining about editors. It was decided to include WAME, CBE, and EASE.

A delegate suggested developing a grievance procedure so that everyone would know how to use the code.

Michael Farthing suggested having a committee chair and a separate chair of council, who could be a lay person, to take responsibility for complaints against editors.

Peter Wilmshurst pointed out that changing the

words 'authors' to patients and 'editors' to doctors in the code would be akin to the GMC.

Stephen Evans suggested that the chair of council should be a person who has had experience as a journals ombudsman.

Another delegate suggested that 'bad cases make bad law,' and that there was no point making it too difficult for the many small journals to live by. "It is important to keep a sense of proportion about how angelic we want editors to be."

Summing up

Michael Farthing said that he had met with Universities UK Health Committee during the afternoon. They had given him the responsibility to lead on research misconduct. He would form a group to interface with the NHS and other partners to push the initiative forward.

He said that he had reported back in some detail on what had been discussed at the seminar. This was greeted with enthusiasm. UUK recognised that consensus was needed and that it was important for everyone to go forward together. "We need to see what happens over the next few months, but I am more optimistic about the future than I have been."

He commended delegates for their hard work and felt the seminar to have been very productive. "We have a code for editors and I hope that we really will have something towards an independent body for research integrity for the UK during the next six to nine months."

He ended the day by thanking Rachel Fetches, honorary secretary to COPE, for all her hard work in organising the day, and the BMA for allowing their facilities to be used.

How to handle authorship disputes: a guide for new researchers

Tim Albert, trainer in medical writing,
Elizabeth Wager, freelance writer and trainer

One of the main tasks of COPE's education committee is to reduce unethical behaviour. This involves the rather bold step of defining when people have been behaving unethically, and then providing suggestions on how they can avoid doing so in the future. To this end we have written, and tested on a group of authors, a guide for young researchers on the area of authorship, which many people agree is one of the more confused areas. But writing a document is one thing; disseminating it is another. We would therefore welcome comments, particularly on how we can use this report to change behaviour, so that it becomes not just another discussion document, but a real catalyst for change.

In theory, authorship sounds straightforward, but in practice it often causes headaches. While preparing these guidelines, we heard about several cases. In one, a deserving junior researcher was omitted from the author list; in another a sponsoring company insisted on the inclusion of an opinion leader who had made virtually no contribution to a study. And the writer of a review article found her name replaced with that of her boss, because she was on maternity leave when the final version was submitted.

Listing the authors tells readers who did the work and should ensure that the right people get the credit, and take responsibility, for the research. Although journal editors do not always agree among themselves on what constitutes authorship, many of them subscribe to the guidance from the International Committee of Medical Journal Editors (ICMJE), also known as the Vancouver group.

The latest version, issued in 2001, states that:

"Authorship credit should be based only on:

- (1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
- (2) drafting the article or revising it critically for important intellectual content; and
- (3) final approval of the version to be published.

Conditions (1), (2), and (3) must all be met. Acquisition of funding, the collection of data, or general supervision of the research group, by themselves, do not justify authorship."

The problem, as studies have shown, is that what editors want is not what authors do.^{1,2} This is hardly surprising given the enormous pressure on individuals and institutions to "publish or perish." Thus the principles laid down by editors are often breached and by-lines often do not reflect who really did the work.¹ Many people (both editors and investigators) feel that this misrepresentation is a form of research misconduct, and that honesty in reporting science should

extend to authorship. They argue that, if scientists are dishonest about their relationship to their work, this undermines confidence in the reporting of the work itself.

We have written this document to help new researchers prevent and resolve authorship problems. In particular it provides:

- suggestions for good authorship practice that should reduce the incidence of such dilemmas,
- advice on what to do when authorship problems do arise, and
- a glossary of key concepts in authorship, with some reading lists and websites for those who wish to take this further.

How to reduce the incidence of authorship problems

People generally lie about authorship in two ways:

- by putting down names of people who took little or no part in the research (gift authorship, see below)
- by leaving out names of people who did take part (ghost authorship, see below).

Preventing a problem is often better than solving it and we recommend the following three principles.

(a) Encourage a culture of ethical authorship

One problem is that people who are being unethical about authorship are simply following local customs and practice. They need to be made aware of the views of editors, so that in time the culture will change. As a junior researcher you can make sure your departmental library has at least one book on publication ethics (see list below). You can also inquire if there is a university or departmental policy on authorship, and suggest that you start working on one if there is not.

(b) Start discussing authorship when you plan your research

Raise the subject right at the start. Start gathering views of all team members and if possible discuss authorship at a face-to-face meeting. Even before a study is finished, you should have some idea of the publications that might come out of it, such as a conference abstract, the full paper, then some supplementary papers, and who is likely to be most involved in these. Continue to discuss ideas about authorship as the project evolves, and especially if new people get involved. Keep a written record of your decisions.

(c) Decide authorship before you start each article

Many authorship difficulties arise because of misplaced expectations and poor communication. So it is important that, before you start to write up your project, you confirm in writing who will be doing what—and by when. Ideally you should do this face to face, though this may not always be possible. Keep everyone informed of any changes with a written note.

How to handle authorship disputes when they occur

The above suggestion, that every team should have a written authorship agreement before the article is written, should reduce the chances of disputes arising at a late stage, when effectively all the real work has been done. We accept, however, that many people are reluctant to be pinned down in this way, and that it will not always be possible to take such a sensible approach in real life. Disagreements about authorship can be classified into two types: those that do not contravene ICMJE guidelines (disputes) and those that do (misconduct).

(a) Disputes

These are largely questions of interpretation, such as whether someone's contribution was 'substantial' or not. In such cases you need to negotiate with the people involved. If the suggestions to include or omit names came from your supervisor, make clear that you are not disputing his or her right to make such a decision, but show dispassionately why you do not agree with the decision. Support this with evidence, such as laboratory notebooks, manuscripts, ICMJE statement, Instructions to Authors etc. If you remain unhappy with your supervisor's decision, you may consider an appeal to someone more senior, such as the departmental head or dean. But you should do this in exceptional circumstances only – and make sure your supervisor knows what you are intending to do.

(b) Misconduct

If you believe that someone is proposing to do something with the authorship list that is unethical, then you have a real problem. Should you say nothing (and therefore be complicit in the unethical behaviour), or should you blow the whistle, even though this might damage your career prospects or future funding? We recommend a third way, which is to explain the fact that the suggested author list contravenes editors' recommendations, and could be considered scientific misconduct. Again, stick to the facts and avoid being emotional. Point out that an editor could well decline to publish if he or she finds out. As soon as the meeting is finished, make a note and file it.

What you can do if authorship issues are not resolved

Authorship may be used as a bargaining tool if team members cannot agree on the presentation or interpretation of results. All authors should see the final

version of a publication before it is submitted so you can withdraw your name. This will not be an easy decision, and you must weigh up the loss of credit for the work you did with the disadvantages of being included in something with which you do not fully agree.

If your name is included on a publication against your wishes you should inform the other authors as soon as possible. If you discover this only after publication you may contact the journal and ask for a correction. Similarly, if your name is wrongly omitted, you should discuss this with the other contributors. You could contact the journal but an editor is unlikely to add your name without the agreement of the other authors. If your name is omitted by accident, and the other authors agree, then the journal may publish a correction.

Key concepts in authorship

Acknowledgements: Most journals permit (or even encourage) acknowledgement of contributions to a research project that do not merit authorship. The ICMJE guidelines state: 'All others who contributed to the work who are not authors should be named in the Acknowledgments, and what they did should be described'. All those who are listed in this way should be aware of it. Some journals (mainly in the US) will require signatures of those acknowledged.

Appeals: You may ask a journal to withdraw your name from a paper if it has been included against your wishes. However most editors are reluctant to get involved in disputes about omitted authors since they do not have enough information to judge such cases. Some journals have an ombudsman, but they deal with cases of alleged misconduct by the journal. Similarly, COPE only hears cases submitted by journal editors and is not an appeal body for cases of disputed authorship.

Contributorship: The ICMJE guidelines now recommend that authors should state their contribution to the project: 'authors should provide a description of what each contributed, and editors should publish that information'. Some journals publish this information but in most cases it is for the benefit of the editor, who wants reassurance that the criteria have been fulfilled. (See Instructions to Authors.)

Corresponding author: The person who receives the reviewers' comments, the proofs, etc. and whose contact details are printed on the article so that readers can request reprints or contact the research group. Journal editors view this as a purely administrative role, but some authors equate it with seniority. Take the views of your co-authors at an early stage, and decide in advance who will be the corresponding author. Ideally, choose somebody whose contact details are not likely to change in the near future.

First and last authors: Generally speaking, the most sought-after position is the first, which is not surprising given the convention of referring to studies by the first-

named author, e.g. 'Smith *et al.* have shown that'. The first named author is therefore generally held to have made the greatest contribution to the research. Sometimes significance is attached to being the last named author. However, views about this do seem to vary, so don't assume that everybody feels the same way about it. Authors have often given the last place to a senior team member who contributed expertise and guidance. This can be consistent with the ICMJE criteria if this person was involved in study design, the interpretation of the data, and critically reviewed the publication. However, cynics may suspect that the final author is often a guest or honorary author. (See Order of authors.)

Ghost authors: This phrase is used in two ways. It usually refers to professional writers (often paid by commercial sponsors) whose role is not acknowledged. Although such writers rarely meet ICMJE criteria, since they are not involved in the design of studies, or the collection or interpretation of data, it is important to acknowledge their contribution, since their involvement may represent a potential conflict of interest. The term can also be used to describe people who made a significant contribution to a research project (and fulfil the ICMJE criteria) but are not listed as authors. The ICMJE guidelines clearly condemn this practice and state that 'All persons designated as authors should qualify for authorship, and all those who qualify should be listed.'

Gift authors: People who are listed as authors but who did not make a significant contribution to the research and therefore do not fulfil the ICMJE criteria. These are often senior figures (e.g. heads of department) whose names are added to curry favour (or because it is expected). Another type of gift author is a colleague whose name is added on the understanding that s/he will do the same for you, regardless of your contribution to his/her research, but simply to swell your publication lists.

Group authorship: Some journals permit the use of group names (e.g. The XYZ Study Group) but many require contributors to be listed (often alphabetically) and/or the writing group to be named as well. One problem with group names is that they are often miscoded on databases such as Medline. The first person in an alphabetical list of contributors sometimes becomes the first author by default, which rather defeats the object.

Guarantor: Should we expect a radiographer to explain the statistical methods or the statistician to interpret the x-rays? To take increasing specialisation into account, the latest version of the ICMJE guidelines acknowledges that it may be unreasonable to ask individuals to take responsibility for every aspect of the research. However, the editors felt that it was important that one person should guarantee the integrity of the entire project. 'All persons designated as authors should qualify for authorship, and all those who qualify should be listed. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. One or more authors should take

responsibility for the integrity of the work as a whole, from inception to published article.'

Instructions to authors: While there is a great deal of agreement among journal editors on authorship matters, there are also some differences in detailed requirements and the ways in which by-lines are presented. You should carefully read the Instructions to Authors for your target journal.

Number of authors: There are no rules about this. In the past, databases such as Medline limited the number of authors they listed. This was shown to influence the number of authors (most groups tried to stay below the limit) and, in larger groups, probably increased jostling for position. Now, however, most databases list all authors. Rather than decide how many authors there should be, it is probably best to agree who will qualify as an author, and then simply include all those who do. However, remember that including large numbers of authors usually increases the time it takes to prepare, review and finalise a paper.

Order of authors: The ICMJE guidelines state that the order of authorship, should be 'a joint decision of the co-authors. Authors should be prepared to explain the order in which authors are listed'. They rather unhelpfully do not give guidance about the order in which authors are listed. Wherever possible, make these decisions before starting to write up the project. Some groups list authors alphabetically, sometimes with a note to explain that all authors made equal contributions to the study and the publication. If you do so, make sure it is clear to the editor.

References and further reading

- Bhopal R, Rankin J, McColl E, *et al.* The vexed question of authorship: views of researchers in a British medical faculty. *BMJ* 1997; 314:1009-12.
- Goodman NW. Survey of fulfilment of criteria for authorship in published medical research. *BMJ* 1994; 309:1482
- Dickersin K, Scherer R, Suci EST, Gil-Montero M. Problems with indexing and citation of articles with group authorship. *JAMA* 2002; 287: 2772-4.
- Epstein RJ. Six authors in search of a citation: villains or victims of the Vancouver convention? *BMJ* 1993; 306:765-7.
- Horton R. The signature of responsibility. *Lancet* 1997; 350:5-6.
- Hudson Jones A, McLellan F. *Ethical Issues in Biomedical Publication*. The Johns Hopkins University Press, Baltimore, USA, 2000.
- ICMJE criteria: www.icmje.org also *Annals of Internal Medicine* 2000; 133:229-31
- Rennie D, Flanagan A, Yank V. The contributions of authors. *JAMA* 2000; 284:89-91.
- Resnik DB. A proposal for a new system of credit allocation in science. *Science & Engineering Ethics* 1997; 3:237-43.
- Smith J. Gift authorship: a poisoned chalice? *BMJ* 1994; 309:1456-7.

Acknowledgement

We thank researchers at the Department of Pharmacoepidemiology at the University of Surrey for helpful discussion and feedback on these guidelines.

Update on cases submitted to COPE

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

Case 00/08

A paper describing a case of possible medical negligence

The authors of the paper talked to the doctor who had given the injection and to the patient who had received it. The patient was disappointed at her family doctor's performance, but decided not to take any further action.

Case 00/09

The study that may or may not already have been published

The institution conducted the inquiry: "I can only conclude that the authors have dealt according to the standards of scientific integrity, although it should have been stated that there has been some overlap with a previously published study, and that the communication between your office and the authors have been inadequate."

Case 00/15

Clinical misconduct (?), incidentally discovered

The author never responded, and the case was closed.

Case 00/22

Duplicate submission of a paper

The editor wrote to the authors pointing out that they must be explicit about what they are actually submitting.

Case 00/33

Alleged plagiarism

Outcome (after re-referral to COPE)

The editor had asked the author's institution to conduct an investigation into the issue. The editor felt that the institution's investigation had been even handed and thorough. The aggrieved party has written back and made several points:

- (i) He felt that it was inappropriate to rely on an employer to make a final recommendation.
- (ii) The COPE guidelines do not include rules for review articles.
- (iii) The COPE guidelines do not differentiate between "conscious" and "unconscious plagiarism."

The editor indicated that although the employer had made a recommendation, she alone made the final decision, which was based on her own judgement, and not that of the employers.

Many of the passages highlighted by the aggrieved author were ideas and concepts that had been published by several different authors and were not the sole provenance of that author. Although it is true that employers may have vested interests, this does not necessarily mean they are corrupt.

The notion of conscious plagiarism implies that the plagiarism is intentional; unconscious plagiarism is unintentional. It is the former that attracts sanction, and the intention must be proven. The point of requesting an internal investigation is to provide the editor with the facts so that s/he may then make a judgement, and that there are no alternative mechanisms.

The editor would write back to the aggrieved party detailing COPE's discussion, stating that from the journal's point of view, the case was closed.

2001 cases that remain open:

01/33 Redundant publication and a question of authorship

01/37 Stolen data and omission from the authorship list

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

Case 01/02

The single authored, unbelievable, randomised controlled trial.

Outcome

The university informed the editor that the lead author had resigned from his post. The author responded, explaining that it was “not practical” to respond to queries about the paper, because “all my papers are in storage and some pertaining to this study were mislaid.” The university now wishes to “close the book on this matter” unless the editor could suggest another approach.

Though the paper has never been formally rejected or withdrawn, a very similar paper has been published, raising the issue of duplicate submission of the paper.

Case 01/06

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

The journal has changed editorship and the new editor could find no evidence of further correspondence to or from the authors. The case has therefore been closed.

Case 01/12

Attempted redundant publication

The authors produced a response which satisfied the editor of Journal A that there had been no unethical behaviour. He decided, therefore, not to contact the authors' employers. The editor of Journal B agreed.

Case 01/20

Dubious surgery

The editor wrote to the regulatory body, but received no response.

Case 01/39

Referee with a conflict of interest

The editor left, and nothing further was heard.

2002 cases that remain open:

02/03 Duplicate submission to two journals and previous duplicate publication uncovered

02/05 Case of a new commercial cure for a common but incurable problem

02/08 An unethical ethical committee?

2002 cases that have been closed since the publication of last year's report

Case 02/01

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

The author wrote back to the editor, contesting that his use of the established technique in the context described was experimental and providing references for the technique. The editor referred the file to another senior editor who felt that this case was on the borderline between clinical innovation and research. Any problems with the work were unintentional and below the threshold of work requiring censure. The journal's ethics committee debated the case again and decided that no further action was required. It had been a useful interchange and it would be useful to debate with the readership where clinical innovation ends and research begins.

Case 02/02**Duplicate publication**

The commission charged with the investigation have completed their report. In the meantime Journal A published a statement, alerting its readers to the serious doubts concerning the published figure; and that the author had voluntarily offered to withdraw the figure in order to guarantee the greatest transparency in his pending legal action. The editors had concluded that that it would not be the proper response to solely retract the challenged portion of the article and called on the institute of the lead author to conduct an investigation.

Case 02/04**Plagiarism**

After discussion with the editorial team the editor decided not to contact the senior author's head of institution. The editor spoke to the senior author, who, it turned out, had participated only peripherally in the paper. This had been submitted by a very junior foreign scientist who had been a guest in the senior author's laboratory for a few months.

The senior author was mortified and very upset. He felt betrayed by the first author—however, he had taken responsibility for the validity of the manuscript by agreeing to serve as a co author. He replied ruefully that he thought he was just doing this foreign scientist a favour. The senior author informed the first author that his manuscript was plagiarised, that it was disgraceful, and that he insisted the manuscript be withdrawn from further consideration and that he wanted no further interaction with him, scientific or otherwise.

Case 02/06**Late reinterpretation and a new author**

All the issues were resolved and the piece was published with a commentary on the ethical issues involved.

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

- (1) COPE considers cases of possible research misconduct referred by editors and offers advice on what action to take. Currently the committee considers only cases referred by editors.
- (2) Cases for consideration by COPE should be sent to Mrs Rachel Fetches, Secretary, COPE, BMJ Publishing Group, Tavistock Square, London WC1H 9JR; email cope@bmjgroup.com; telephone + 44 (0)20 7383 6602; fax + 44 (0) 7383 6249.
- (3) It is for the editor to decide what action to take. There is no obligation to follow the advice of the committee.
- (4) The cases considered by the committee are published in the annual report. They include the advice given, what action (if any) was taken, and the outcome.
- (5) Editors should present their cases as briefly as possible, avoiding extraneous detail, but presenting all relevant information to enable the committee to offer good advice. Examples can be found in the COPE annual reports available on our website (www.publicationethics.org.uk)
- (6) Cases must be anonymised to avoid problems of defamation, but without losing relevant content. The identity of the editor presenting the case will not be published in the annual report.
- (7) Editors should not give the names of journals, authors, institutions, countries, or titles of papers. They should be as general as possible about essential information. For example, refer to a “common chronic disease” rather than diabetes, if this needs to be mentioned at all, and use the term “study” rather than a randomised controlled trial unless this is critical to the case.
- (8) Editors can anonymise reports by removing information, but they should not give false information. If in doubt about the presentation of a case contact the secretary, Ms Anastacia Kirk.
- (9) Editors are encouraged to attend the meeting at which their case is to be presented.
- (10) Cases will be edited before inclusion in the final report.
- (11) Editors should feedback to the committee what actions they take and the ensuing outcomes (please quote the case reference number).
- (12) Actions taken by editors following advice from COPE are taken at the editors' own risk.

Cases submitted to COPE

July 2002 to September 2003

Case 01/14

Refusal to give details of a competing interest

A journal published a paper on passive smoking in which the authors failed to declare financial support from the tobacco industry. A subsequent letter highlighted this failure, and the authors responded in a letter in which they offered some explanation, admitting funding from one source.

The editor then published an editorial in which he detailed the extensive involvement of this group with the tobacco industry. The authors sent a long letter in response, which the editor is reluctant to publish without more information on the authors' involvement with the tobacco industry. They are reluctant to comply.

The authors have also submitted another paper for consideration, which the editor has refused to consider until the other matter is resolved. The editor has offered to refer the case to the journal's ombudsman, but the authors have declined.

Further evidence revealed that the corresponding author had signed a consultancy contract with a tobacco company and has received research project funding from a cigarette manufacturers' association. The author was known to have undertaken lobbying for the industry outside his home country. The institution was aware of the author's undertakings, as previous allegations had been reported in their national press. They were embarrassed about it, but since the author had resigned from his post, the institution had not taken the matter any further.

What should be the next step?

Discussion/Advice

- The public should be made aware that the author had received sponsorship throughout his career, and had lied about it.
- An article should be written to highlight his past indiscretions and include the full history of the case. He should also be reported to the country's national research integrity council, pending the outcome of a libel case in which the author is involved.

Outcome

The editor received a subpoena to appear in court in relation to the libel case the author was pursuing against some researchers. During the hearing, evidence of even more serious allegations, including data tampering, came to light. The court found that the author's involvement in an unprecedented fraud was an accurate description.

A factual account of the court proceedings was published in the next edition of the journal along with a more detailed study, using evidence gathered during the case and exposing the tobacco company's action in establishing a secret facility to look at the health effects of passive smoking in a European country. The author in question was the link between this facility and the tobacco company, his role being to conceal the link. COPE's support had been an important consideration in the evidence presented at the court hearing.

Case 02/09

Arm twisting an editor

A paper was accepted, pending a revised version, which made use of official government information on reported health reactions in a particular age group over a 20 year period.

Two of the authors were academics and two worked for the government's health department. When the revision arrived, the names of the latter two authors were missing. One of them explained that they could not reach agreement with the first two authors on the revision, which seemed odd as they had presumably agreed the original version and the subsequent changes were minor. The lead author said that publication of the revision could lead to a major public health scare as the wording of the conclusions was very likely to mislead the media into ascribing causation to what was actually association.

The dissidents were invited to write a commentary detailing their objections. The lead author agreed, but subsequently, a high ranking official telephoned the editor, pointing out the health department's concerns. The official assured the editor that s/he had no intention of suppressing research, but asked the editor to consider the possible implications for the public interest. The official did not want the juniors to write the commentary.

The academics' head of department button holed the editor at a scientific meeting and explained that s/he was also concerned over the risks of misinterpretation but could not intervene because s/he had a conflict of interest, being a member of the government's regulatory body controlling the database used in the study.

Consequently the head of department had asked the vice chancellor, who luckily had a relevant qualification in the area, to intervene instead. The editor was informed that the senior author might have contacted a politician, requesting a parliamentary question be raised, if the data were suppressed, although this has not been confirmed. The chairman of the regulatory body then contacted the editor, also expressing support for academic freedom, but urging great caution.

The editor believed the real message was that the database concerned was an inadequate method of determining safety in the area it purported to cover, rather than the stated message, which was that certain adverse reactions had caused deaths. Concerned that the pressure exerted had tainted his judgement, the editor sought the advice of an independent reviewer, who largely agreed with him. The editor then discussed the whole issue with the authors and suggested ways to rewrite the paper, such that the data were protected, but also that the public interest was best served. Not surprisingly, the authors had been put under pressure, but agreed to consider the editor's suggestions in a further revision.

The editor wrote a commentary to accompany the article, which was directed at the media. Despite the anxieties of the authors' superiors, the paper attracted little media attention. The editor felt largely untouchable, because he is not a health service employee, but other editors who are might find similar pressure difficult to deal with.

Discussion/Advice

- If junior authors could not publish without the consent of their superiors, this raises the matter of authorship, whereby some of the authors are not acknowledged for their work, whether for credit or accountability to the readers.
- The work itself might be regarded differently because the source of the information would not be clear. In some ways this was analogous to pharmaceutical trials being withdrawn if the results were unfavourable.
- "Disappearing authors" are a frequent occurrence and the work of those who contributed significantly, for example, statisticians, is often left out.
- Ultimately, the editor can refuse to publish a piece where authorship issues arise.

Outcome

No further action taken.

Case 02/10

The author not affiliated to an institution

A contribution about training in family medicine training was published in a journal. Subsequently, a letter from the chairman of the department of family medicine at the university with which the author claimed to have been affiliated, said that the author did not work there.

The author was asked for an explanation. He replied that he had done it involuntarily and that he would be happy for an erratum to be published in the journal, making this clear.

Is the author guilty of misconduct or something else?

Discussion/Advice

- The editor needs to find out if the author had worked in the department before or whether he had never worked there.
- Had the author used the university's headed notepaper when making his submission?
- The current employer, or appropriate regulatory body if there is no employer, should be asked to investigate the use of another affiliation.
- Passing off papers under false credentials is potentially serious and could call into question the author's ability to write the paper.
- But this would only be the case if there were a deliberate intention to deceive.
- The editor needs to investigate why this happened more thoroughly and find out what the author meant by "involuntary mistake."
- Publish an erratum clearly stating the affiliation is wrong.

Case 02/11

Contacting Research Ethics Committees with concerns over studies

A paper was submitted, detailing a small overseas trial of a drug treatment of a politically controversial disease. The treatment was moderately toxic.

The paper was seen by two referees (A and B), who had considerable criticisms of the methodology used. Comments were also received from C, who was invited to review but refused, because s/he did not want his/her name known to the authors under the terms of the journal's open peer review policy.

C said that there was little justification for this trial and therefore could not imagine it having been granted research ethics committee approval. C also mentioned that the study was funded using non-peer reviewed, government funds. Another referee (D) was consulted, who again did not want his/her identity to be revealed to the authors, but reiterated C's concerns.

The paper was rejected on methodological grounds, but with an offer to see if the authors could address the criticisms. The authors revised and resubmitted the paper, which was sent to the more critical referee (B). His view was that the authors had done little to improve it.

Another referee (E) was consulted, who was also sent the comments from C and D. E was happy to take part in open peer review, and concluded that the trial had little biological justification; was poorly conducted and reported; and that it was of such poor quality that the research ethics committees who approved it must be informed.

The editors rejected the paper and wrote to the two research ethics committees who approved the study, enclosing B and E's signed reports (with their permission). The authors were informed, and wrote a letter expressing their outrage that the journal had contacted the research ethics committees.

It proved difficult to identify contact details for the research ethics committees that approved the intervention part of the study.

Should the editors do more? Should the authors be asked to provide full details of their research ethics committees now and in the future?

Discussion/Advice

- The authors should have been contacted first and asked to respond to the doubts raised before the editor went to the research ethics committees.
- Write to the authors' institution to check that the research ethics committee approval process had been correctly undertaken.
- Research ethics committee approval of potentially unethical research implicates the employer, so it would have been difficult to approach the employer first with these concerns.
- Open peer review policy needs to be explicit: it is open at all times, except in cases of suspected misconduct.
- Ask the authors to respond to doubts about the paper.

Addendum

The editors had gone back to the ethics committees and wanted to re-review the articles. Did they have a duty of confidentiality to the author?

Discussion/Advice

- Ideally, the ethics committee should contact the authors directly. If the authors refuse to send the articles then public interest in the ethics committees being able to review the work would justify a breach in editor-author confidentiality. But the editor should inform the author of any such action.
- The willingness of editors to breach editor-author confidentiality, where public interest justifies a breach, should be made explicit.
- Authors may not be aware of this fact and some rely on a lack of communication between journals to perpetrate duplicate submission and publication.
- It is usually the case that where the author is open about papers and their submission to another journal, that there are legitimate reasons to send the other papers elsewhere and sufficient differences in the papers to justify separate publication.
- In North America there was a fear of litigation arising out of such cases, but following the Tarasoff case, where it was held that the duty to warn and protect identifiable third party interests overrides a duty of confidentiality, a breach of confidentiality can be justified. In Belgium the duty of confidentiality is absolute, but there is no EU law on the issue.

Case 02/12

Babies needlessly subjected to a painful procedure for research

A paper was received, which detailed a research project conducted on newborn babies, which involved taking an invasive (and painful) sample from them.

The paper was worthy of publication from the point of view of scientific value, but two issues worried the editors. First, it was unclear whether the sick babies' samples were going to be used as part of their clinical management or whether these samples were taken simply for the trial. The referee thought that certain reported parameters indicated the latter.

Second, and more worryingly, the control group of healthy babies had a similar sample taken. The control group comprised all the babies meeting the inclusion criteria. The editors were concerned that this would not have been possible without some coercion of the parents.

The editors wrote to the authors, asking for elucidation and learned that the samples were, indeed, taken by staff when they were collecting another routine sample. The authors added: "We took the chance and asked parents for consent in taking a little more blood . . . our ethics committee would never sanction [the invasive procedure] in normal infants just for research."

The editors then asked for clarification of the precise nature of the ethics committee approval and parent consent forms, pointing out that the routine sample collection would not involve the invasive procedure performed except in limited circumstances. The authors responded by withdrawing the paper and declining to send the relevant documents. They complained that the editors had mistrusted them.

Should this be taken further? The editors think it should, on the grounds that the babies were unnecessarily subjected to a painful procedure.

Discussion/Advice

- The editors should pursue the issue further and approach the head of the authors' institution, and if necessary, involve higher authorities.
- A deadline should be imposed for a response.
- As there appeared to be a discrepancy between the authors' assertion that the sampling was undertaken as part of a routine procedure and the fact that the trial sample would have to be an additional invasive procedure, it was important to follow this up.

Outcome

The authors' institution has not replied to either of the two letters sent. The editor plans to approach a higher authority.

Case 02/13

Order of authors changing between a submitted manuscript and a published paper

A paper was submitted to an online journal with the order of authors A, B, C, D, E, F, and G. After review, the manuscript was accepted for publication, subject to the authors making some minor changes.

While making the formatting changes, the submitting author changed the order of the authors to B, A, C, D, E, F, G. This change was not noticed by the editors and the manuscript was published on the website as a preliminary PDF document while the final HTML form was being prepared.

The submitting author was notified of acceptance and the posting of a preliminary version. At this stage, author A contacted the editors to say that the author list was incorrect. As the manuscript was not in its final form, it was still technically possible to make changes to the author list at this stage.

The editor contacted authors A, B, and G (submitting author) to ask them to agree between them the correct author list and to contact the editors, via the submitting author, within one week. The editor also suggested that a possible solution might be to indicate that the authors A and B contributed equally.

Author A contacted the editor to say the author list should be A, B, C, D, E, F, G and author G contacted the editor to say that the author list should be B, A, C, D, E, F, G.

Given this disagreement, the editor decided it was not the editor's position to mediate and asked author G (submitting author) to confirm that all authors were aware of the decision to list the authors as B, A, C, D, E, F, G.

Author E contacted the editor to say that he was happy for the order to be decided by author G (submitting author). However, author G did not reply.

After receiving no reply, the editor contacted author G again, saying that unless they heard to the contrary, the article would be published with the author list B, A, C, D, E, F, and G.

After a further week, the editor had still heard nothing from author G and therefore decided to publish the article with the author order B, A, C, D, E, F, G since this was the order the submitting author had specified. The paper had been in preliminary form for over four weeks.

The journal's practice is to send an acknowledgement at submission to all authors. Papers are published on the same day as acceptance or shortly thereafter. This is the citation that PubMed picks up for indexing. The finalised html version is then posted a few days later. The journal now also emails all authors at acceptance stage.

Should the case have been handled differently?

Discussion/Advice

- It is up to the authors to sort out any disputes over author order. In cases of dispute the journal might want to sanction temporary withdrawal of the paper from the website.
- However, the order, which promoted author B, would have already been picked up for citation purposes.
- The journal could post a temporary retraction, but this would lay the process open to abuse by those maliciously objecting to the authorship order.
- A comment could be posted, outlining the authorship dispute.
- The journal could review its editorial policy and procedures concerning authorship disputes.
- Rearrangement of authorship often occurs in cases of duplicate publication or where co-authors are clearly not looking at the work.

Case 02/14

Dual publication

It was brought to the attention of Journal A that a paper published in 2002 was similar (title, summary, introduction, case, survey, results, discussion) to a paper published in Journal B. Journal A is a very technical journal that reports conference proceedings and is not peer reviewed.

Furthermore, Journal B had received a letter from the authors of another paper, published in a very prestigious journal, which had been criticised in the version of the paper published in Journal B. Journal B has a policy of not publishing letters in their journal, but the letter was sent on to the authors of the paper.

When submitting their paper to Journal A, the authors took into account some comments made in the letter forwarded by the editor of Journal B. The authors then made use of these comments in modifying the second paper without acknowledging the authors of the letter.

The editor of Journal A often felt that the article published in journal B was a full paper even though the authors disputed this. Journal B's editor said the authors had been "blacklisted."

Discussion/Advice

- Was the letter from the authors of the paper being criticised analogous to a reviewer's report? Reviewers comment on papers and authors then rewrite the paper addressing any concerns.
- The editor felt that this was not entirely analogous as the letter was not "friendly" advice and had been written with a view to publication, rebutting the article's criticism.
- The content of the letter had not been plagiarised.
- The letter authors knew that their comments had been passed on by journal B.
- The editor felt that the authors of the letter would want their concerns published.
- The authors should be asked to respond to the issues raised by the letter authors about duplicate publication and then the editors should publish a notice of retraction.
- If the article in journal B was—as the editor stated—peer reviewed, how could the authors not know about this?
- However, the publication of society abstracts can occasionally lead to inadvertent publication. Peer review can simply mean a panel reviewing the abstracts or posters for proceedings. Some societies record and print everything presented at their meetings.
- The high degree of overlap between the two papers suggested poor practice on the authors' part.
- The editor should write to the authors' employers about the issue and inform the authors of this.
- The editor should also publish a notice of duplicate publication in the journal.
- Indefinite "blacklisting" is not a considered action

Case 02/15

Possibly unethical report on the safety and efficacy of a minor operation

Two companion papers from a single author, a paediatric surgeon working in a secondary/tertiary unit, were received. He had performed the same minor operation on 420 babies and 60 children over two years. His paper purported to report safety and efficacy.

From the hanging committee's own knowledge, and after checking with a surgical board member, a paediatric surgeon might be expected to do four or five such procedures in a year in an average practice, but there were over 200 in the report.

Paediatricians regard the procedure as unnecessary. All paediatric textbooks agree. Apparently, some paediatric surgeons overseas, parent support groups, and speech therapists are quite keen on it.

There is no good evidence base on which to decide who is right.

The concerns were:

1. As there was no known indication for the treatment, should it have been part of a randomised controlled trial?
2. Ethics committee approval was not sought.
3. The stated indications for surgery were highly subjective and, in any case, mostly regarded by paediatricians as representing normal and transient physiological or behavioural events.
4. There were no statements made about mode of referral, and these surely could not have been made by local paediatricians.
5. Many infants were not anaesthetised, although the author claimed it caused no distress.

The papers were rejected, and the author was informed of the anxieties. What should be done now?

Discussion/Advice

- In the absence of an evidence base relating to the procedure's indications any trial should have a control arm and be approved by the institution's research ethics committee.
- The papers were submitted as cases series, where there had been a range of preoperative symptoms and no standardised pre or postoperative assessment reported. It was unclear whether the procedures were carried out in private or public practice. Did the papers represent a research study?
- In similar previous cases, investigators had to go back to the theatre records, patient notes, and original statistical analysis. It is sometimes difficult to draw a line between where clinical innovation ends and experimentation begins.
- The editor should seek clarification from the author, advising him that he would raise his concerns with the institution where the surgeon was based/operations being carried out, over the failure to obtain ethical committee approval for an unusual procedure.
- If patient safety is an issue there is a statutory duty on the chief executive of the hospital to ensure this.

Outcome

The editor wrote to the author's institution, informing the author about this course of action. The author had requested a copy of the letter and also the COPE minute on the case. The chief executive of the institution agreed to fully investigate the case.

The medical director convened a Trust committee/panel, which concluded that the doctor's activities did not count as research and gave the procedure a clean bill of health. The panel felt that the work submitted to the journal was a case series. The editor was not informed of the membership of the inquiry. He felt that the committee of inquiry appeared to have not taken external advice on the procedure under scrutiny.

Patients had been referred from a substantial group of non-clinicians, a normal practice in this field, but there is some disquiet in local medical circles that this procedure is being carried out in such volume.

Case 02/15 *continued*

Further advice

- The editor should try to get more information on the Trust's investigation.
- The editor should take his concerns to the doctor's and medical director's regulatory body, notifying the doctor and the Trust of his intentions. As a registered physician, the editor has a duty to report any serious concerns to the regulatory body.
- The editor is a member of the regulatory body, which imposes a higher duty to report his concerns and act on them.
- The editor's case for reporting was strengthened by the fact that he had taken the advice of COPE on the matter.

Case 02/16

Co authors' unwillingness to support retraction of a review

A review by three authors, with Dr X as the lead author, was published in Journal A.

Five months later, the editor of Journal A was informed by Professor W that a figure in the review by Dr X had originally appeared in a research paper, co-authored by Professor W in Journal B in 1990. The professor also said that Dr X had published the same or very similar figures in journals C, D (research papers), and E (review). The Journal C paper was reference 5 in the Journal A review.

Dr X denied that he had "stolen" the figure. However, after an "expert review" Journal C concluded that the figures were the same and the journal's editors retracted Dr X's paper. Dr X has since started legal proceedings against one of the editors of Journal C.

Professor W is pushing for a complete retraction of the review in Journal A. Dr X is willing to voluntarily retract the paper, but his co authors do not support this, because the figure in question makes no difference to the uncontroversial conclusions of the review. Journal A published a statement noting the retraction by Journal C, and Journal E has published a similar statement.

Journal D recruited an expert to examine Professor W's original pathological material. Journal A has collaborated with this investigation. The expert concluded that the figures published by journals A and D are the same as Professor W's original slides. Dr X has been told by journals A and D that they will request his institution to investigate the allegations made against him.

This case refers to the same disputed figure brought to COPE by another member journal in case 02/02.

Discussion/Advice

- If the figure was originally Professor W's and published in 1990, then the original journal would have copyright over the figure.
- If the review was adequate without the figure, then the journal could either withdraw the figure or acknowledge the original copyright holder.
- The original slide would have to be studied to make a correct assessment of the professor's claim.
- How could a figure belonging to one author come into the possession of another? The journal has been told that Professor W and Dr X were collaborators in the past and that the image had been entered into a database of clinical images and had allegedly been extracted from there.
- Had any copyright documents been associated with the deposit of the image on the database?
- If Dr X's co authors do not wish to retract the paper, then the journal could publish an addendum/erratum explaining the issues surrounding the figure ownership, acknowledging the original copyright holder.
- It is not the journal's duty to resolve the dispute between Professor W and Dr X.
- The editor could decide on a course of action after hearing the results of Dr X's institutional investigation.

Case 02/17

Dual submission, salami slicing, redundant publication, or all three?

Editor A wrote to editor B, indicating that one of the reviewers of a paper submitted to Journal A contained material that had been submitted at about the same time to Journal B.

Editor A requested a copy of the paper submitted to Journal B. Editor B responded, confirming that the paper in question had been submitted to Journal B (submission date two weeks earlier than the paper submitted to Journal A), but had been rejected eight weeks later after external peer review. Editor B sent a copy of the rejected paper to editor A.

Editor A examined the two papers and confirmed that there was “some degree of overlap” between the two and also felt that there was a degree of “salami slicing.”

What should the editors do now?

Discussion/Advice

- This was a case of an intelligent reviewer catching a dual submission serendipitously.
- Sending a copy of the manuscript under review to another editor might be considered a breach of confidentiality with the author, but in cases of suspected misconduct, such action was part of the peer review process and the information sent to the other editor would be on a ‘need to know’ basis.
- Public interest in preventing fraudulent publication overrides confidentiality with the author.
- Sometimes authors write up different aspects of one research study and send them to different journals, so some degree of overlap is inevitable, but as long as the authors openly declare what they have done, this is acceptable practice. They should cross reference or include a copy of the companion paper.
- Many journals have this sort of provision in their instructions to authors. These make authors think twice about attempting inappropriate dual submission.
- What would happen if an editor requests the author to provide the companion paper and the author refuses? The COPE guidelines on redundant publication state that at submission, authors should disclose details of related papers. In cases where a reviewer alerts an editor to the possibility of duplicate publication the duty to the author is to ask them to respond to the allegation and provide the other paper.
- The duty of confidentiality to the author is not absolute, and where misconduct is suspected a breach could be justified.
- The integrity of the literature is more important than maintaining author confidentiality. And dual submission is a drain on the journal’s and reviewers’ time.
- The two journal editors should write “joint letters” to the authors about the matter, pointing out why this is an important issue and requesting a response within a specified time limit.

Case 02/18

An attempt to bribe an editor

Somebody—possibly a representative of a drug company or a PR acting for the company—rang an editor on behalf of study authors to say that she would guarantee to buy 1000 reprints if the journal would continue to consider for publication a study that conflicted with a policy that the journal had just introduced. “And”, she said, “I will buy you a dinner at any restaurant you choose.”

The paper was rejected, but should further action be taken?

Discussion/Advice

- Generally drug companies have policies against PR companies approaching journals and if the drug company was identifiable then the editor could contact the company concerned to complain.
- The lead author of the study should be informed about the actions of individuals representing the product being discussed in the paper.
- The drug company might also want to know what the PR is doing on its behalf. One of the members relayed how in a similar circumstance he had complained to the drug company which had withdrawn its contract with the offending PR company.

Outcome

The editor admitted that he could not remember the name of the person involved and was unable to trace the article, but he promised to mention the incident in the journal. He fulfilled his promise.

Case 03/01

Possible plagiarism and fabrication

A group of six authors published a study in a peer reviewed journal, comparing the efficacy of the same class of two drugs (A and B) with a placebo and with each other. One year later the lead author of that study was searching in Medline for new evidence on the efficacy of drug A and found a study that had been published in another peer reviewed journal the year after his by three authors from another country.

The authors had changed the number of patients, the type of surgery, the regimen of drug A, and they had added a fourth group (drug C). However, the author of the first paper identified similarities between the two publications. After having read both papers very carefully the editor came to the following conclusions:

1. Most of the second paper uses literally identical sentences and wording as the first. This concerns all parts of the paper. The only significant “new” sentences, mainly in the discussion, are on the role of drug C.
2. The second paper cites 27 references, 17 of which are identical to the references in the first paper. Of the 10 “new” references, six are on drug C, and two on issues related to the surgery.
3. Demographic and surgical data, reported as means \pm SD, numbers, or medians (range) of drug A, drug B, and placebo groups are identical in the two papers. The only differences between the two papers concern type of surgery, and the method of postoperative analgesia (two different analgesics are used). Also, the first paper reported on the estimated drug costs; the second did not.
4. Reported postoperative VAS pain scores (median and ranges) of drug A, drug B, and placebo groups are identical in the two papers at five of five time points.
5. In the second paper demographic data and pain scores of the drug C and drug B groups are identical.
6. The reported statistical analyses are identical, including the “ranked sum test of Raatz,” a test that is very rarely if ever used in the medical literature.
7. Power analyses are identical. However, the authors of the first paper concluded that 43 patients per group were required; the authors of the second paper concluded from the same power analysis that 17 patients were needed.
8. In the second paper, the reported incidences of nausea and vomiting with drugs A, B, and placebo are sometimes identical and sometimes different from those reported in the first paper.
9. For all drug A *vs* placebo, drug B *vs* placebo, and drug A *vs* drug B comparisons, the p values for efficacy are identical in the two papers.
10. Both papers report an astonishing $p < 0.000006$ in favour of drug A compared with placebo for the difference in the incidence of vomiting. Both papers use Fisher’s exact test for analysing differences in the incidence.
11. Both papers report a $p < 0.009$ in favour of drug A compared with placebo for the difference in the incidence of nausea.
12. The second paper cites the first paper twice, once in the introduction and once in the discussion. Both citations are out of any context.

According to the Royal College of Physician of London (1991), this represents serious scientific misconduct as it is about piracy, plagiarism, and fraud. It is very likely that actually all the data in both papers have been made up. The authors have copied the results of the statistical analyses (and the power calculation) of the first report into their new report, without even realising that some of the analyses in the original report were flawed.

How should the editor proceed with this case?

Discussion/Advice

- This seems to be a serious case of plagiarism/fabrication, and sufficiently serious as to constitute fraud.
- The authors should be asked for an explanation within a specified time limit, and if there was no response to refer the matter to the employer/institution.
- The editor should write to the editor of the other journal, informing the authors of his intentions
- Did the second paper involve the pharmaceutical company that had manufactured “C”?
- Both papers should be shown to a statistician with experience in determining whether the data were likely to be fraudulent.

Case 03/02

An author thinks that a journal's decision not to publish is ethically incorrect

A submitted paper reported on the investigation and management of an outbreak of a disease in a work environment (Company A).

The authors acknowledged the referring physician from the workplace—who had declined on legal advice to be listed as an author—and also declared that the lead author had provided medical advice for remuneration to Company A during legal proceedings related to the outbreak discussed in the article.

When the article was submitted, the outbreak was the subject of legal proceedings between Company A, where the outbreak occurred, and the company supplying the alleged causative agent of the outbreak (Company B). The lead author had signed a confidentiality agreement with Company A in regards to his/her evidence for the legal proceedings, but not for any information already known to the public through no fault of the author.

The author had also added a handwritten addendum, stating s/he accepted the agreement “to the extent that my academic freedom to report findings of scientific and public health importance is not compromised.” On peer review the science of the paper was judged to be sound.

The journal's legal advisor had some concerns about publication; legal proceedings were active; the workplace physician though involved scientifically was not listed as an author; and the paper discussed the outbreak from the perspective of Company A.

While the article was cogent and objective about Company A, there was no information about Company B's knowledge of the outbreak. If the case resolved in favour of Company B, then the article would need to reflect this. The editor wrote to the authors, relaying the legal concerns and informed them that journal, on the basis of legal advice, could not publish while litigation was ongoing. The journal suggested that it would consider a revised version of the manuscript after the case had been resolved.

The authors submitted a revised version of the article. As part of the revisions, the authors had deleted all references to the names and locale of the companies. The legal proceedings had been concluded with an out of court settlement; the lead author had no involvement in this. The terms of the settlement are subject to a confidentiality clause and it is not known whether liability was admitted or not.

Company A does not wish the paper to be published on the grounds that this would violate the confidentiality agreement between the two parties. On the basis of legal advice from his/her institution, the author states that s/he is not bound by an agreement to which s/he was not party; that the handwritten clause in his/her agreement with Company A allows for publication of the article; and that the details of the outbreak were public as they had been presented in abstract form as well as briefly described in a local language publication.

The lead author feels that the journal's reluctance to publish on the basis of legal concerns is flawed. As originally relayed to the author, it was stated that the journal could be seen as “taking sides” in an ongoing legal dispute—a view that the author feels is “ethically unacceptable.” Company A is threatening legal action against the authors if details of the case are published, and Company B would also potentially have an action for defamation.

What should be done?

Discussion/Advice

- Editors have to be mindful of legal advice against publishing a paper and could base their decision not to publish on strong advice.
- In such a situation where legal advice against publishing was so strong, the author would have to indemnify the publisher against any legal action that might be taken.
- If an editor has been advised that publishing something was unlawful, *prima facie* that was immoral and publishing the article could potentially be held to be in contempt of court.
- In such a case then the author would also need to provide indemnity for loss of reputation.
- If the author's institution has stated that, having taken legal advice, they are happy to publish, then the work could be published on the institution's website.
- Publication would only be a possibility if both companies agreed to it.

Outcome

No further action required.

Case 03/03

A patient was given an experimental course of complementary medicine when a standard treatment was available

A case report was submitted to a journal, describing a patient with a very serious, curable infectious disease who had been given complementary medicine (plant extract) rather than the standard treatment.

A search of the literature indicated that the authors were known to support complementary therapies.

The alternative treatment was not evidence based. The case took place in a country where the standard treatment was easily available. The authors reported that the patient had given informed consent, but did not provide any detail.

No mention was made of ethics committee approval for the experimental treatment. The editors in particular questioned the acceptability of:

1. prescribing a new therapy, without evidence of its efficacy, for an infectious treatable condition;
2. prescribing experimental treatment without ethics committee approval;
3. how well the patient was informed.

A full review of the manuscript echoed these concerns. The authors were asked to confirm/explain if they had received informed consent from the patient and ethics committee approval. They were also asked to clarify the treatment plan.

In a brief email, the authors stated that they had received both consent from the patient and ethics committee approval, but after several chases, have failed to send the corresponding documents. The authors also stated that the patient was started on the standard treatment course “3 weeks later.” The manuscript was rejected.

Should the editors take further action? Does the fact that the authors advise that the patient was given standard therapy make any difference?

Discussion/Advice

- Was this a doctor's choice rather than the patient's decision? Had the patient specifically requested the alternative treatment? There was no evidence to prove either.
- This is a grave issue and the editors should definitely pursue the authors for documentation of the patient's consent and ethics committee approval.
- To have undertaken such a course of action without either of these calls the authors' medical practice and judgement into question.
- The editor should write to the authors again with a short deadline, informing them that the matter would be referred to both the authors' employers and the appropriate regulatory body.
- Even if the patient had pleaded for the alternative therapy, the fact that the disease is infectious and potential fatal means that public interest would outweigh the patient's preference.
- The editors should write to the regulatory authorities as the course of action taken had endangered both the patient and other people.
- The police might also have the jurisdiction to investigate.
- The burden of investigation does not lie with editors; it is their duty to inform the relevant authorities.

Outcome

The editors have written to all the authors explaining their editorial decision and intention to submit the case to the relevant authorities. Lawyers wrote back on behalf of the corresponding author. One author was unreachable because the email address was invalid; another expressed surprise at receiving the editors' message, explaining that he could not remember having approved any manuscript for submission. The editors are now planning to write to the authors' institutions and regulatory bodies.

Case 03/04

Attempted dual publication?

A manuscript submitted to Journal A was sent out for external review. It detailed a single case, reporting a new surgical technique. One of the external reviewers reported that the author had presented examples of several similar cases at a conference, which had not been referred to in the submitted paper. He requested further details of their results. The editor asked the authors for more information, as requested.

The revised paper was sent back to the same reviewer, who then sent the editor a recent abstract from Journal B that showed some similarities to the manuscript submitted to Journal A. The reviewer had not seen a copy of the full paper published in Journal B, so the editor obtained the paper and sent it to the reviewer, who examined the two papers and confirmed that there was significant overlap. The full paper published in Journal B contains the case submitted to Journal A as well as the rest of the cases discussed at the meeting.

How should the editors proceed now?

Discussion/Advice

- The timing of the other cases was odd—if they were available in time to get the paper reviewed and published in another journal, then they would have surely been available for submission in Journal A? The editor said that Journal A had taken some time to review the paper, but agreed that it was insufficient time for the other cases to have been documented and sent for publication.
- Not all the authors may know about the attempt at dual publication.
- The editor should write to the authors requesting an explanation within a specified time frame.
- If no response was forthcoming, the editor could refer the matter to the institution/employer. The editor could also notify Journal B of the investigation.

Case 03/05

Unauthorised use of questionnaires

A journal had two incidences in which a questionnaire was used in studies without permission of the originators of the questionnaires. Both manuscripts originated in different countries, and used different questionnaires.

1. A manuscript was submitted which addressed quality of life issues. The referees had various concerns about the data and methods, and the authors were invited to revise the manuscript. At that point the authors contacted the originator of the questionnaire they had translated and used, requesting permission to use the questionnaire and asking for assistance with the issues the referees had identified as problematic. Permission had not been sought to translate and use the questionnaire before this.

The creator of the questionnaire objected to its use in this particular study, and to it being used in a non-approved translation. Culturally specific translations are apparently available. The main concern was that an inappropriate translation could lead to potential errors in the study, as well as concerns about the propriety and legality of the study.

The editor contacted the author, highlighting the concerns of the questionnaire's originator, and the author chose to withdraw the manuscript. No other action has been taken to date.

2. A submitted manuscript reported a study based on a specific, validated questionnaire. One of the referees pointed out that the centre where the study had been conducted was not registered as an approved centre for this survey, and that neither the relevant Steering Committee nor the relevant International Data Centre had any contact with the authors. The survey's publication policy states that non-registered centres may not use the acronym.

The manuscript was rejected on the basis of poor science, and the authors recommended to contact the survey, regarding registration and for permission to use the questionnaire.

Discussion/Advice

- It may have been an innocent mistake on the part of the authors, who thought the first questionnaire was in the public domain and could be translated and used by anyone.
- The editor needs to find out more information on why the author felt compelled to withdraw the paper. It would be useful to find out whether the questionnaire was copyrighted.
- For the second case, the likely problem was the authors' ignorance of the correct mechanism for being able to use the questionnaire and the editor's course of action seems entirely appropriate.

Case 03/06

Potential duplicate publication

Three authors submitted a short paper to Journal A. It describes a questionnaire survey of 200 doctors (specialists and primary care physicians) and nurses and gives them a list of disorders, asking them which they think are diseases showing variations.

The discussion ranges over influential factors that may make people think of things as diseases, including trends towards medicalisation and the influence of the drug industry. The authors' conclusion is that health care professionals should be educated about the implications of thinking of things as "diseases."

One of the authors (X) submits a paper to Journal B. It is not a study—it's a think piece. It covers, but more extensively, the ground raised in the other paper's discussion. It does refer to the survey. The referee points out that he's seen a similar paper sent to him by journal A and advises the editors of both journals that he thinks it is broadly the same paper.

It isn't the same paper, but it does contain some of the same data and some of the same tenor of discussion, so his belief is understandable. In particular, the Journal B paper includes two of the three figures from the Journal A paper (giving data). But the reference in the Journal B paper about this data is to a different journal—to a supplement article in Journal C.

X, the author of Journal B's paper, doesn't refer to the paper in Journal A in either his covering letter or the paper. But, almost more importantly, neither does he refer to the Journal C article.

The editor of Journal A was not told about the Journal C paper. The paper submitted to Journal B is different from that submitted to journal A, but there's a fair degree of overlap and two of the figures are the same. The editor at Journal B thinks it should have been pointed out.

Journal B is awaiting a response from the editor of Journal A to see if he wants to join in writing to X asking for explanation.

Discussion/Advice

- Without looking at Journal A's "reject with offer" letter, which the editor felt was an invitation to revise, but which the author took as a rejection, it would be difficult to know whether the authors' actions were valid.
- It seems that the author didn't like the "offer" and decided to go to another journal with the paper. Generally authors do not inform journals if they decide to not resubmit when asked to revise their work—though it is courteous to do so.
- Some journals use stated rather than open ended deadlines in which authors have to resubmit a revision of their work. If authors do not resubmit (or write to request an extension) then the paper is treated as lapsed.
- Others send a letter to authors at a certain time point, indicating that the journal does not expect a revision and that the paper has lapsed.
- Others specifically request that the authors write within two weeks of receiving the revision letter as to whether or not they intend to submit a revision of the paper.
- This is a useful learning point for journals to consider when offering a revision.

Outcome

No further action required.

Case 03/08

Is it duplicate publication when the first study is referenced in the second paper?

A paper entitled: “X and Y versus X alone for condition A in children” was submitted to Journal A and published in 2001. Journal A has since been alerted to a paper published in Journal B in 1999, entitled: “Comparison of combination of X and Y with X alone in the treatment of condition A,” written by two of the four authors in conjunction with another author not listed on paper A.

Most of the abstract, methods, and discussion of the two papers are identical. The main difference is that paper B has four more patients in the study group and in Journal A all patients are referred as being 16 years old.

In Journal B, the authors mention that the treatment dose was lowered for children but do not identify how many of the study group were 16 years old. The figures in the two articles have identical axes but the curve is slightly different. Tabular data show the two papers’ subject groups have different age ranges, but the breakdown of boys to girls is very similar as is the breakdown of the subtypes of the condition being treated.

All of the references in paper B are used in paper A, but the authors have added six extra references, one of which is the reference to paper B. The reference to paper B is made in the discussion section of paper A where the authors say: “Recently we reported that a combination of X and Y is a highly effective therapy for the treatment of condition A.”

What should the editor do?

Discussion/Advice

- It was surprising that the editor and/or reviewer(s) didn’t pick up on the fact that the reference was in the paper. But the onus is on the author to send in any papers that may have potential overlap with a submitted paper.
- This case was an example of poor behaviour on the authors’ part.
- The second paper sounded like the same study, or perhaps a subset of the same study. It was not clear whether the author had made any form of declaration as to the earlier study other than the reference and brief mention of the first study in passing.
- Some journals now search and pull authors’ references as a matter of course. This is primarily to find suitable reviewers, but often highlights duplicate papers.
- This is easier with an online submission system where a paper’s references are automatically hyperlinked to the Medline reference.
- The difference of four patients suggests an element of deception.
- If he has not already done so, the editor needs to ask the authors to give their side of the story.
- The editor should check the initial submission letter to see if the author did make any kind of declaration about the other paper.
- The editor should also pursue this matter with the authors’ employers and request an investigation.
- It is important to notify the author that the editor is planning on this course of action.
- The editor should contact the head of the authors’ institution(s), as a department head would be too closely involved.
- Ultimately, the editor may have to withdraw the paper as its publication would skew data on the treatment being investigated.

Case 03/09

Potential duplicate publication

Following publication of a report, a country's national health ministry set up a pilot study on two sites to examine the feasibility and acceptability of screening for infection X. The pilot study was co-ordinated by a national agency. It was agreed from the outset that the agency would lead on analysing data, co-ordinating any publications, and that the major publication output would involve both sites and the agency. The meeting at which this was agreed was not minuted.

The pilot study data were submitted, with joint site/national agency co-authors (with the agency as lead author), to Journal A in April 2002.

Drafts and the final submitted version were approved by both sites and by the national agency. The data were submitted in the form of two papers (1 and 2). The first was on the methodology and acceptability of the study, and the second on the prevalence and evaluation of positive cases.

Just as the papers were submitted to Journal A, site 1 told the national agency that they had submitted their own data to Journal B in March 2002 (paper 3). Journal A rejected the two joint site/national agency papers and they were submitted to Journal B in mid June 2002.

In late June 2002 the editor of Journal B spoke with the lead author of the joint site/national agency papers (1 and 2), and following this, asked the authors of paper 3 to withdraw their paper: they did this in early July 2002. The editor specifically mentioned the cross site issue and the fact that paper 3 seemed to contain similar data to one of the joint site/national agency papers.

The two joint site/national agency papers were accepted by Journal B in October 2002 and published in February 2003. The site 1 authors then submitted paper 3 (virtually unchanged) to Journal C, where it was accepted October 2002 and published in January 2003.

In February 2003 the editor of Journal B was contacted by a reader because of concerns about apparent overlap between one of the two papers in Journal B and paper 3 in Journal C. The editor felt the suggestion—that there was duplicate publication—was correct. The editor asked for three independent opinions (in confidence) from colleagues in the specialty. One of these was Journal B's ombudsman. All three felt there was significant overlap between paper 2 in Journal B and paper 3 in Journal C. They also pointed out that neither of the papers in Journal B nor paper 3 in Journal C cited each other. The three papers had published literally days apart. The lead author is an overlapping author but the papers' authorships are mostly driven by the site that the data come from.

The editor of Journal B contacted the editor of Journal C as well as the corresponding authors of both the Journal B and C papers. It was difficult to contact the editor of journal C who was handing over to a new editor imminently, and he initially disagreed with the view that there was duplicate publication. Apparently, the authors of the site 1 paper told the editor of Journal C that they had withdrawn their paper from Journal B and were submitting a "different" paper to Journal C. A copy of the version withdrawn from Journal B was sent to the editor of Journal C: the withdrawn and published papers are virtually identical.

The corresponding author of the joint site/national agency papers published in Journal B was contacted and provided a full and detailed account of events, backed up by copies of emails. He was unable to explain why—when all authors knew of the plan for the joint submission to Journals A then B, and had from an early stage seen drafts—paper 3 had been submitted to Journal B (ahead of the joint site/national agency paper) or to Journal C (when the joint site/national agency papers were under review with Journal B).

The corresponding author of paper 3 published in Journal C was contacted. This author did not reply, but a response was received from two other authors on behalf of all the authors at site 1. This stated:

1. The authors felt that the emphasis and message in the two papers were different and there was not "significant duplication."
2. They mentioned at the time their paper was submitted to Journal C they did not know the citation for the papers in Journal B.
3. They added that the editor of Journal C knew that there were other papers due to be published in Journal B.
4. They stated that "the publication of two different papers in two different journals with different readerships on "x" screening must surely be beneficial if the basic messages reach more readers."
5. Finally, they stated that "We are more than aware of the ethical considerations, as several of our members have sat on LREC and national agency ethics committees."

The editors are concerned that the duplicate publication will skew data on the screening of x condition and that there is now a situation of dual quoting of data. What should the editor of Journal B do next?

Case 03/09 continued**Discussion/Advice**

- The editors have an obligation to pursue this issue further, by writing to the authors' employers, informing the authors of their intention.
- The editors should request a detailed notice of all action taken to investigate the matter.
- Journal C's editor should publish a simultaneous notice of duplicate publication.
- The editors should contact the new editor and also the publisher of Journal C.
- Given that Journal C published just a few days before Journal B, who should be responsible for retraction? COPE felt that a notice of duplication would be sufficient as this would be picked up by Medline.
- The editors should publish a notice of duplicate publication in their own journal and write an editorial aimed at educating authors on the issues such as authorship, duplicate publication, correct citation, and salami publication.

Case 03/10

Potential redundant publication

A group of authors from the same specialty unit published a study in Journal A on all prehospital X procedures. They then sent another paper on X procedure in a subgroup of patients to Journal B. Paper B references paper A, but does not make it apparent that there is any overlap in these studies. On questioning by editor B, they stated that no patients in paper B were included in the previous study.

Paper A studied all prehospital X procedures between February 1998 and February 2001 and states that all patients requiring X procedure were included. Paper B includes a subgroup of patients requiring X procedure between March 1998 and March 2002 and states that all patients were included.

The two papers have similar methodology, use the same equipment and analysis; large sections of the text are identical; half of the references are the same; and the patients come from the same geographical area.

The two papers cover overlapping periods and are undertaken by the same organisation. Both state all patients are included; no mention is made of any exceptions. However, the authors state that no patients were included in both studies. Therefore either patients from the subgroup in the period March 1998 to February 2001 were included in both studies, or the subgroup were somehow allocated to only one study. Any such allocation is not described in the text.

The authors clearly state that there is no overlap of patients between the two studies but the editors feel that the article should not be published. Is this course of action correct? Should this be explored further to determine if the patient groups are completely different. Should a request to see the original database be made?

Discussion/Advice

- There appeared to be some evidence of misbehaviour on the authors' part.
- The editors need to go back to the authors and explicitly challenge them on their assertion that there were two non-overlapping patient sets.
- In some situations it was permissible to publish studies of subgroups, but there had to be full disclosure of that fact and very good reasons for doing so.
- If the editors request the raw data, the journal rather than the institution should analyse them first.
- It is preferable to request the raw data in electronic format. Investigating raw data can incur substantial costs and it is the institution's responsibility to investigate its own staff.
- But the editors should make it clear that if there are still unhappy with the explanation they will contact the authors' institution to request it also reviews the researchers' raw data.
- How can the editors pursue this course of action if they do not wish to publish the paper? If the editors told the authors of their intention not to publish, their position would be weakened and the authors might not bother to reply.
- Editors are privileged whistleblowers as they are harder to attack than a colleague expressing concerns over someone else's work. Also, authors believe that editors are powerful and so it is still possible to get a reply from authors even if the paper is no longer in consideration.
- Ultimately, editors have the ability to publish an account of any misconduct in their journals.
- Editors should make it clear to authors when they did not wish to publish a paper.
- Editors should also make it clear to authors that there are concerns about a paper and that they would still pursue the issue even after rejection.

Case 03/11

Extensive plagiarism

An article published in Journal A in 2003 contains extensive, almost verbatim, unattributed quotations from an article published in Journal B in 2001. The editor asked a member of the editorial team to compare the two articles line by line, and there appears to be a high degree of overlap without any reference to the original article in Journal B. The authors of the article and the editor of Journal A were asked for an explanation. It's hard to see that there is any explanation apart from plagiarism. The authors of paper A claim that there is only 5% overlap between the two articles.

Discussion/Advice

- Journal A should retract the plagiarised article.
- The employers of the authors of paper A should be alerted that this plagiarism had occurred. Extensive plagiarism breached Journal B's copyright over the work.

Case 03/12

“Research” without ethics committee approval

Eighteen patients with a variety of symptoms and 10 controls had various measurements taken after being given an oral glucose load. Participants also had routine blood sampling and were put on a defined diet for three days.

The authors did not consider it necessary to obtain ethics committee approval, but all participating subjects signed a consent form recording their agreement to take part and to have the results published. The authors seem to be private practitioners.

The journal does not want to publish the research as it's scientifically meaningless. In a similar case the editor had referred to the national regulatory body, the body had acknowledged that the research study under investigation was useless but that it was not a competent body to make a pronouncement about that. The editors also think that ethics committee approval should have been gained. The authors disagree. What should the editors do now?

Discussion/Advice

- Was there a national body that the authors would be registered with? Where would such private practitioners go to get ethics committee approval for such a study?
- In private health care research the lines of accountability are often unclear and this may have been an inadvertent omission on the authors' part.
- Some groups did fall between organisations set up to approve research and it is difficult for them to know who to approach for ethics approval. The main problem for small private researchers is the incoherence of the structures.
- This problem becomes even more pronounced when authors are from other countries where the research ethics committee system is less comprehensive. Occasionally editors receive papers from countries with no research ethics review system.
- Editors should only publish research that would meet the standards of a research ethics committee in a developed country.
- In some countries though there is nominally a system in place, in reality the mechanism is purely administrative not ethical. Editors needed to be aware of this and should not assume that the ethics committee approval process had been carried out to the same level as in developed countries.
- As these particular authors are responsible to a national regulatory body, the editor should report his concerns to that body after informing the authors of his intention to do so.
- If the researchers are working in a private hospital, such hospitals do have research governance frameworks.

Case 03/13

Attempted plagiarism of a published report

A review paper covering the prevention of a certain type of infection was submitted to Journal A. One of the reviewers identified that the paper was based word for word on a report that had published guidelines on the same area. The authors of both pieces are different. The only significant differences between the submission and the original paper were in the introduction and conclusion.

The editor of Journal A contacted the corresponding author by letter, email, and subsequently mobile phone. During the telephone conversation, the corresponding author acknowledged that there was some overlap, but the telephone call ended abruptly at that point. The editor has been unable to contact the joint authors who work at the same institution. The editor subsequently contacted the lead technical writer/editor of the report who considered this scientific misconduct and is to present the case to her editorial board.

Should the editor inform the director of the institution from which the paper emanated? Should s/he inform other people who have published papers with these authors? Should s/he publish details of this episode in the journal and identify the sources?

Discussion/Advice

- This is a serious case which warrants persistence.
- The editor should go ahead and contact the head of the authors' institution but needed to notify the author of that.
- The editor should wait to hear back from the institution before contemplating further action.
- If the institution's response were inadequate, publishing details of the episode in the journal may be appropriate.
- The editor may wish to coordinate any published response with the editorial team of the original report.

Case 03/14

Sloppiness or deception?

A case control study that links miscarriage to a particular event was published in Journal A. The paper says that most women were pregnant when interviewed. Whether or not they had miscarried when interviewed matters because of "recall bias." In fact, most of the women who miscarried had already miscarried and so were not pregnant. The statement that most of the women were pregnant is "true" because all of the controls produced live births and were pregnant. The statement is thus misleading.

Journal A was alerted to the problem by an editor from Journal B, which had accepted, but not published, a paper from the same authors with the same design. Their reviewers had identified the problem, and the authors were asked to change their wording.

The editorial team of Journal A felt that the authors should have alerted them to the problem when it was flagged up by Journal B, as it may well affect the validity of the results.

Should the authors have made the same change in the Journal A study? Might they be actively misleading readers? Should any action be taken?

Discussion/Advice

- The authors should have come back to the editorial team about the problem.
- Such a change warranted at least an erratum in the journal and the editor should go back to the authors and ask for an explanation.
- The editor felt that the authors should publicly apologise for their actions but felt that these probably did not constitute a serious enough breach to retract the paper.
- The editor should copy his letter to the head of the institution in order to raise awareness in the institution.

Case 01/03C

Manipulation of a journal's impact factor

An editor had been recently sacked from her/his job as an assistant editor with a medical research journal. The editor stated that “s/he believed that the reason for his/her dismissal was in large part motivated by disagreements with the editor in chief over several editorial policies at the journal.”

During the review process it was common practice for the editorial staff to ask authors to add references to the journal in their submitted articles. The editorial staff sometimes asked the authors to find “pertinent” references themselves and sometimes suggested references that should be added. The editor was told by the editor in chief to imply, but not overtly state to authors, that the acceptance of their submissions depended on these additions.

Although some refused, many of the section editors of the journal—under pressure from the editor in chief—would determine possible references to be added and then state that one or more of the anonymous referees had insisted on these additions during the peer review process.

The sacked editor had archived examples of this and other policies that consistently manipulated the impact factor at the journal during her/his employment. Several previous employees have also stated their willingness to testify on this matter.

Discussion

- If COPE were to take this issue further, then the potential editorial misconduct issue needs to be dealt with separately from the employment issue, which is not COPE's concern.
- In principle, it is wrong to artificially inflate a journal's impact factor and it is corrupt, or corrupting, to do so.
- Impact factors are a subject of ongoing debate among journal editors, who often seek to reduce their denominator for the ISI measurement or engage in deliberate publication policies aimed at increasing their impact factor.
- At what point does “playing the game” become a “wicked” practice? Authors are also under pressure to publish and so would be susceptible to suggestions to include references to secure publication. Such practices inhibit the dissemination of ideas.
- European researchers are fascinated by impact factors; in the US these are primarily only of interest to journal editors. This is because research assessments in the UK are based on the impact factors of journals publishing the research. However, even US researchers will rank a journal's importance by its impact factor.
- The impact factor system is biased towards North American journals as it is an American database based on American journals.
- Why do editors inflate their journal's impact factor? Primarily because they want the better submissions: and the higher the impact factor, the better the submissions. There is a direct incentive to researchers as funding follows publication in a higher impact factor journal, illustrating that it is a corrupting driver in the pressure to publish.

Advice

- COPE should anathematise such behaviour, and include this issue in its guidelines. COPE should therefore write back to the editor to draw the evidence out so that this issue could be debated.
- Council wondered whether it would be possible to carry out an anonymous survey among journal editors about this issue (and others) that could be used to gain evidence for debate about editorial misconduct issues. It is very difficult to define at what point editors transgress into “wicked” practices.

Case 02/03C

Accepted papers become rejected papers

An author complained that his/her paper had been accepted for publication in Journal XX. This journal was then discontinued and all papers submitted to it were forwarded to Journal X. The editor of Journal X then wrote to the authors stating that their paper was unacceptable for publication in that journal.

Discussion/Advice

- When there is a change of editor, a new editor generally honours a previous editor's decisions for about six months.
- This is not a case of misconduct if there is no obligation on the second journal to publish the first journal's papers, although it is annoying for the authors.
- It would be worthwhile contacting the new editors to determine if the transfer of accepted articles was covered in the contract. Writing to the editors would also help develop policy for COPE, and ensure that both sides of the story are available for debate.
- Was there a mechanism for transfer and did the authors' paper receive due process? Clarification of the protocol for transfer of articles from the wound up journal should be requested. The second journal could have a different focus from the original journal.

Outcome

The editor of the second journal informed the Chairman that the only connection between the two journals was that the publishers of each journal had been taken over by the same new publisher. When the first journal folded, the publisher asked the editor of the second journal to look at the accepted manuscripts; unfortunately, none of the accompanying paperwork was available.

The editor of the second journal was not sure what amendments had been made to the articles since submission and decided to start from the beginning with the manuscripts. The editor noted that there were many case reports among the accepted papers. The publisher confirmed that the choice of articles was purely a matter for the editorial board. The editor felt considerable sympathy for the disappointed authors, some of whom had experienced long delays since submission. The editor personally edited many of the articles to make them acceptable for the second journal, but rejected a small number, mainly case reports. The editor noted that the publishers had informed the authors about the closure of the first journal and had given them the opportunity to resubmit to the second journal or withdraw and try elsewhere.

Case 03/03C

Rejecting a paper after favourable reviews

An author submitted a paper for publication. It was reviewed favourably, according to the author, by two reviewers who suggested minor modifications. The author then received a reject letter from the editor:

“... The manuscript has been read by two experienced investigators in this field and by the Editors. Based upon their comments and recommendations, I regret to inform you that we will not be able to accept your paper for publication. The comments from the reviewers are attached. Dr Z, I am sorry that we could not make a more favourable decision regarding your paper. However, the high priority required for publication in Journal Y leaves no choice . . .”

The author that although s/he felt this was a little unusual, s/he did not query it because the editor's decision is final. But s/he was subsequently contacted by one of the referees, who was unhappy about the decision, particularly as he had also seen the second referee's positive report. The referee contacted the journal but had not received a reply.

The author then wrote to the editor:

“... I accept the absolute responsibility for you as editor, to accept or reject any article based on suitability for Journal Y.

My perception is that the offence you have caused is that you ignored the referees' recommendations and despite favourable reports decided to reject the article. As you will be aware, referees are essential to enable you to assess the quality of papers submitted. All of us who do this receive no payment. We recognise that this activity is part of the corporate responsibility for academics to ensure high quality support is provided for editors, such as yourself. I am sure that you have refereed many papers but I suspect that you have forgotten the amount of time and effort that goes into preparing referees' reports to a high standard. It appears to me that you went ahead with the referees' reports even though the paper was not suitable for Journal Y. Consequently, despite favourable reports, you rejected it on grounds of [priority]. As a referee and speaking for all referees, I find this approach unacceptable. If you felt it was unsuitable for publication you should not have sought referees reports . . .

I accept the decision of the editor to accept or reject articles on the grounds of priority. I do not accept your abuse of the referees' generosity of spirit.”

Discussion

- It happens often enough that the editor simply does not read the paper thoroughly enough when it is originally submitted. It often happens that the handling editor reads it and thinks it is good enough to review, but then when it reaches a hanging committee other editors might be much more critical.
- A reviewer is an advisor and does not make judgements about whether an article should or should not be published but whether it is or is not publishable.
- It is good practice to give feedback to (1) authors about why a paper was rejected, and (2) reviewers about the editorial decision. It is sometimes difficult to be precise about whether a journal is “interested” in a paper before review.

Advice

- The Chairman should write to the referee detailing the Council's discussion.

Case 03/04C

The indefinite ban imposed on authors for repeatedly contesting editorial decisions

Authors were advised that they had been banned from a journal for a considerable period, and as far as they were aware, the ban still applied. The authors sent a letter to test the ban (see below). The letter was never formally acknowledged, accepted, or rejected, despite numerous attempts to get such acknowledgement, acceptance, or rejection. It summarises what led up to the ban and the authors and members of the national academic body of the country concerned felt that such matters should be made public to alert readers of the journal that such actions occur.

The letter reads:

“I received a registered letter from the editor of Journal A informing me that it was his decision, in consultation with the Editorial Committee that ‘... Journal A will no longer consider articles, editorials or other manuscripts from ... my colleague and myself ... for publication in this journal.’ The reason advanced for the ban was our ‘... repetitive contestation of editorial decisions regarding the publication of submissions ...’ Our trespass would seem to be one common to many ethical scientists, few of whom have not contested certain editorial decisions regarding their submissions. Since then:

1. Although the ban has been lifted, at no time have any reasonable scientific reason/s been advanced for the ban, despite our repeated requests.
2. At no time has the editor of Journal A made any effort to apologise for placing this unjustified and/or unjustifiable ban.
3. Despite repeated requests to meet with representatives of Journal A to discuss the ban, no effort has been made to accommodate a meeting.
4. The lifting of the ban only occurred after one of us had complained to the national medical association.

We believe that this matter can only finally be resolved by an unambiguous apology from the editor of Journal A. Until then, the negative consequences to the professional reputations of those originally banned continue. Indeed, until such an apology is forthcoming, we believe that this continues to impugn the scientific and professional credentials of all ethical scientists from this country.

Readers should know that this matter was brought to the attention of the national academic body of country X between 1996 and 1999 under various presidencies, as well as a fellow of the national body, regarded as a leading medical ethicist. None of these individuals, or their respective councils, were prepared to openly condemn or resist such bans. This was despite the intercession of a local committee of the society, to obtain a ruling in principle, against such attacks on scientific freedom of expression.”

Discussion

- The editor had been frustrated by the authors’ repeatedly contesting rejections and had banned future submissions. This ban had subsequently been rescinded on paper, but perhaps not in reality.
- The question here is whether it is unreasonable for a scientific journal to ban authors because they repeatedly contested editorial judgements?
- It is serious to ban authors from publication in a scientific journal as this could affect their careers if they were restricted in where they could publish material. Questioning editorial judgement does not warrant a ban on further submissions.
- Scientific journals must consider all work submitted and must not arbitrarily refuse to consider certain authors’ work.
- In some contexts an ability to ban people with impunity could be abused so that an editor could “ban” rivals and hinder careers.
- Normally anyone subject to a ban should be afforded recourse to another person or body to mediate, and any ban should be backed up with reasons that would stand up to scrutiny.

Case 03/04C continued

- COPE guidelines state that in cases of serious misconduct, editors can refuse to accept future submissions for a stated period. Authors in this situation could go to the publishers/owners of the journal.
- Cases like this are often not resolved. Even when authors repeatedly question editorial judgements, a controlled and considered response is still required.

Advice

- COPE should write to the editor of journal A to request his/her side of the story, and the reasons for the ban. The authors should be informed of COPE's discussion.

Case 03/05C**A question of authorship**

A research assistant alleged that the co-authorship s/he had had with his/her previous employer had cost him/her his/her job, visa, and total loss of rights to authorship. The research assistant gave details of anonymised correspondence between him/her and his/her supervisors.

In a letter to the research assistant's direct supervisor, summarising a meeting about authorship, s/he expressed dissatisfaction about the authorship of two abstracts submitted to a scientific meeting. The research assistant felt that s/he should have been the second author on abstract 1 and an author on abstract 2. The research assistant stated that to his/her knowledge, the authorship on abstracts generally became the authorship on the final publication.

The research assistant based his/her claim on the fact that for abstract 1 s/he had generated all the data for the project over the previous two years and had driven the project forward. The particular project had been in the laboratory for 12 years and the research assistant had brought it to completion, with guidance primarily from another senior researcher in the laboratory, and to a lesser extent, help from his/her supervisor. The research assistant had to press for details of how the project would move forward and expressed that s/he had at times upset his/her supervisors by being "pushy."

The research assistant stated that s/he had taken the job in the laboratory on the understanding and assurance given by the senior researcher that s/he would be allowed to work on various research projects and would be given due credit on the resulting publications. The research assistant pointed out that s/he has qualifications that allow him/her to contribute substantially to a research project and to be credited as an author. S/he noted that in previous positions heads of departments had not had reservations about putting names of technicians, summer and rotation students, or any other person who contributed to the project on the publications, and s/he provided an example of a previous employer's authorship policy.

The research assistant acknowledged that the senior researcher had written all the relevant protocols, taught the research assistant the necessary techniques to carry out the project, and had answered any questions, for which the research assistant was indebted. The senior researcher had emphasised that the project belonged to the research assistant and his/her supervisor. He was an author on abstract 1. Once the project completed the research assistant had to chase the supervisor about how to proceed with collecting data for writing a paper. The research assistant noted that the senior researcher had commended the research assistant on his/her good results on the project and gave the impression that s/he would be an author on the final publication.

In regards to abstract 2, the research assistant based his/her claim for authorship on the fact that s/he had been doing all laboratory work and data collection. Additionally, the research assistant stated that s/he was going to be involved in analysing these subjects in the future and deserved appropriate credit on the resulting publication.

The research assistant stated that the supervisor's response to these arguments was that s/he would not be the second author on the first paper because s/he didn't have a doctorate, and should do so if s/he wanted his/her name on the publications. The supervisor also said that the research assistant had been working as a technician and many laboratories don't put technicians' names on the publications; the supervisor and the

Case 03/05C *continued*

senior researcher had been directing the research assistant's work and would be the first and second authors on the paper while the research assistant had been given credit as third author on abstract 1; and that the supervisor had managed this project for a decade and had put a great deal of thought into it.

The research assistant felt that "my work and tireless initiatives to make progress in this project do not count because I am just a technician." The supervisor compared the research assistant's efforts with another technician's work without whom no experiment would be possible but who is not credited with authorship on papers. The supervisor stated that s/he had looked at the various results generated by the research assistant but that similar results had been made in the senior researcher's laboratory some time ago and that the abstract was written from previous experience.

The research assistant was "extremely shocked, disheartened," by this and wrote to his/her supervisor:

"I cannot describe my agony when I saw that I was not the second author on abstract 1. I never expected to get so little credit for my work after slogging for two years." S/he felt that professors should give credit to the person who did all the work, and those who do not are selfish, unjust, unethical and unprofessional. "I have worked in very good labs until now that don't justify authorship on the papers based on job title, academic degrees and give credit to the people based on the merit of their scientific contributions to the project. This is the basic etiquette in scientific community."

The research assistant then received a disciplinary letter from the head of the group, accusing him/her of characterising the supervisor as "selfish, unjust, unethical and unprofessional". The head stated said that authorship is not a right and that the research assistant would be removed from the final paper. The research assistant alleged that s/he was pressurised to leave and his/her employment was finally terminated in January 2003 as a result of false allegations. The university's human resources department overturned the termination and gave the research assistant an opportunity to look for another job in the same university.

The paper is still not published. The research assistant stated that s/he would like to file an official complaint with the university regarding the misconduct of the senior researcher and supervisor. The research assistant was worried that because the senior researcher is very influential in the university, the research assistant's complaint would be "brushed off" and that s/he would face further retaliation.

Discussion

- The experience described by the research assistant is, sadly, still common in academic life. Harvard University has set up an academic dispute unit to deal with such disagreements.
- In a similar earlier case the Council had advised a PhD student to write to the Dean of the university and mention that they had taken advice from COPE, which had a good outcome.
- When considering such cases it is worth bearing in mind that the complainant might be lying, although this did not appear to be an issue in this instance.
- Based on the facts set out in the research assistant's letter to his/her supervisors it appeared that his/her claim for authorship was justifiable. All too often claims for authorship are still based on power and influence and not necessarily contributions.
- This is why the *BMJ* now uses the concept of contributorship. Under the Vancouver criteria statisticians used to be excluded from authorship.
- Generally generating 100% of the data usually qualifies a person for authorship. If other authors leave out any person significantly involved in data generation any of them could be held responsible should subsequent problems arise.

Advice

- The research assistant should exhaust the proper processes at his/her institution first before COPE becomes directly involved in the case.
- The research assistant should first write to the designated dispute officer, copying in the president of the university. S/he should mention that advice from COPE had been taken and render a more succinct and shorter version of events.

Committee on Publication Ethics (COPE)

GUIDELINES ON GOOD PUBLICATION PRACTICE

Why the guidelines were developed

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

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

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

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

How the guidelines were developed

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

What they aim to do

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

1 Study design and ethical approval

Definition

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

Action

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

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

2 Data analysis

Definition

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

Action

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

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

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

3 Authorship

Definition

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

Action

- (1) The award of authorship should balance intellectual contributions to the conception, design, analysis and writing of the study against the collection of data and other routine work. If there is no task that can reasonably be attributed to a particular individual, then that individual should not be credited with authorship.
- (2) To avoid disputes over attribution of academic credit, it is helpful to decide early on in the planning of a research project who will be credited as authors, as contributors, and who will be acknowledged.
- (3) If professional writers employed by pharmaceutical companies, medical agencies, or other parties have written the paper, then their names should be included, and any conflicts of interest declared.
- (4) All authors must take public responsibility for the content of their paper. The multidisciplinary nature of much research can make this difficult, but this can be resolved by the disclosure of individual contributions.
- (5) Careful reading of the target journal's "Advice to Authors" is advised, in the light of current uncertainties.
- (6) Authors should be vigilant about allowing their name to be used on a piece of work to add credibility to the content.

4 Conflicts of interest

Definition

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

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

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

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

Action

- (1) Such interests, where relevant, must be declared to editors by researchers, authors, and reviewers.
- (2) Editors should also disclose relevant conflicts of interest to their readers. If in doubt, disclose.
- (3) Editors should also consider disclosing to readers their own conflicts of interest and those of their teams, editorial boards, managers, and owners.
- (4) Sometimes conflicts of interest may be so extreme that publication will not be possible or people (for example, reviewers or editors) may have to be excluded from decisions on publication.

5 Peer review

Definition

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

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

Action

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

6 Redundant publication

Definition

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

Action

- (1) Published studies do not need to be repeated unless further confirmation is required.
- (2) Previous publication of an abstract during the proceedings of meetings does not preclude subsequent submission for publication, but full disclosure should be made at the time of submission.
- (3) Re-publication of a paper in another language is acceptable, provided that there is full and prominent disclosure of its original source at the time of submission.
- (4) At the time of submission, authors should disclose details of related papers, even if in a different language, and similar papers in press.

7 Plagiarism**Definition**

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

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

Action

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

8 Duties of editors**Definition**

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

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

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

Actions

- (1) Editors' decisions to accept or reject a paper for publication should be based only on the paper's importance, originality, and clarity, and the study's relevance to the remit of the journal.
- (2) Studies that challenge previous work published in the journal should be given an especially sympathetic hearing.
- (3) Studies reporting negative results should not be excluded.

- (4) All original studies should be peer reviewed before publication, taking into full account possible bias due to related or conflicting interests.
- (5) Editors must treat all submitted papers as confidential.
- (6) When a published paper is subsequently found to contain major flaws, editors must accept responsibility for correcting the record prominently and promptly.
- (7) Where misconduct is suspected, the editor must write to the authors first before contacting the head of the institution concerned.
- (8) Editors should ensure that the Instructions to Authors specify the need for authors to obtain informed consent from patients included in their research.

9 Media relations**Definition**

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

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

Action

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

10 Advertising**Definition**

Many scientific journals and meetings derive significant income from advertising.

Reprints may also be lucrative.

Action

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

Dealing with misconduct

1 Principles

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

2 Investigating misconduct

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

3 Serious misconduct

- (1) Editors must take all allegations and suspicions of misconduct seriously, but they must recognise that they do not usually have either the legal legitimacy or the means to conduct investigations into serious cases.
- (2) The editor must decide when to alert the employers of the accused author(s).
- (3) Some evidence is required, but if employers have a process for investigating accusations—as they are increasingly required to do—then editors do not need to assemble a complete case. Indeed, it may be ethically unsound for editors to do so, because such action usually means consulting experts, so spreading abroad serious questions about the author(s).
- (4) If editors are presented with convincing evidence—perhaps by reviewers—of serious misconduct,

they should immediately pass this on to the employers, notifying the author(s) that they are doing so.

- (5) If accusations of serious misconduct are not accompanied by convincing evidence, then editors should confidentially seek expert advice.
- (6) If the experts raise serious questions about the research, then editors should notify the employers.
- (7) If the experts find no evidence of misconduct, the editorial processes should proceed in the normal way.
- (8) If presented with convincing evidence of serious misconduct, where there is no employer to whom this can be referred, and the author(s) are registered doctors, cases can be referred to the General Medical Council.
- (9) If, however, there is no organisation with the legitimacy and the means to conduct an investigation, then the editor may decide that the case is sufficiently important to warrant publishing something in the journal. Legal advice will then be essential.
- (10) If editors are convinced that an employer has not conducted an adequate investigation of a serious accusation, they may feel that publication of a notice in the journal is warranted. Legal advice will be essential.
- (11) Authors should be given the opportunity to respond to accusations of serious misconduct

4 Less serious misconduct

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

5 Sanctions

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

- (1) A letter of explanation (and education) to the authors, where there appears to be a genuine misunderstanding of principles.
- (2) A letter of reprimand and warning as to future conduct.
- (3) A formal letter to the relevant head of institution or funding body.

- (4) Publication of a notice of redundant publication or plagiarism.
- (5) An editorial giving full details of the misconduct.
- (6) Refusal to accept future submissions from the individual, unit, or institution responsible for the misconduct, for a stated period.
- (7) Formal withdrawal or retraction of the paper from the scientific literature, informing other editors and the indexing authorities.
- (8) Reporting the case to the General Medical Council, or other such authority or organisation which can investigate and act with due process.

Appendix

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

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

ABPI fact sheets and guidance notes:

Clinical trials and compensation guidelines, January 1991.

Guidelines for phase IV clinical trials, September 1993.

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

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

Good clinical trial practice, November 1995.

Patient information and consents for clinical trials, May 1997.

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

Good clinical research practice, July 1998.

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

General Medical Council. Good medical practice guidelines series:

Consent, February 1999.

Confidentiality, October 1995.

Transplantation of organs from live donors, November 1992.

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

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

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

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

Medical Research Council. *Responsibility in the use of animals in medical research*. London: MRC, 1993.

Medical Research Council. *Responsibility in the use of personal medical information for research. Principles and guidelines to practice*. London: MRC, 1985.

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

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

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

Office of Research Integrity, US Department of Health and Human Services. *Managing Allegations of Scientific Misconduct: a Guidance Document for Editors*. <http://oridhs.gov/html/publications/guidelines.asp>

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

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

Acknowledgement

The following are gratefully acknowledged for their contribution to the drafting of these guidelines:

Philip Fulford (Coordinator)

Professor Michael Doherty

Ms Jane Smith

Dr Richard Smith

Dr Fiona Godlee

Dr Peter Wilmshurst

Dr Richard Horton

Professor Michael Farthing

Other members of COPE

Delegates to the Meeting on April 27 1999

Other corresponding editors

Constitution of the Committee on Publication Ethics

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

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

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

3 Membership

3.1 Membership shall consist of the following:

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

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

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

4 Subscription

4.1 Every member shall be liable to pay a subscription in accordance with the initial rates set forth in Schedule 1 and thereafter as determined at the Annual General Meeting.

4.2 It is the intention that corporate members' subscriptions shall be based on a scale of charges determined by the number and frequency of publication of journals they publish.

4.3 Any member falling into arrears of subscriptions for more than two months shall be excluded from the committee.

5 Officers

5.1 The officers of COPE shall be:

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

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

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

6 Council

6.1 The Council shall comprise:

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

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

6.3 The Council shall be responsible for:

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

6.3.2 The general and financial management of COPE.

6.3.3 All matters in the general interests of COPE.

6.3.4 The appointment of independent auditors.

6.3.5 The appointment of a secretary.

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

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

7 Annual General Meeting

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

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

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

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

7.1.4 Fix the annual subscription rates.

7.1.5 Consider any other business as determined by the Council.

8 Notice of Business at Annual General Meeting

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

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

9 Special General Meeting

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

10 Notice of Meetings

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

11 Quorum

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

12 Alteration of Constitution

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

