

COPE annual seminar 2006

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INTRODUCTION

2005 had been "a bad year for fraud," began Fiona Godlee, chair of COPE, listing the culprits:

- ▶ Cloning in South Korea
- ► Safety fears over the COX II inhibitor Vioxx
- Fraudulent data published by a Norwegian researcher on NSAIDs and cancer

All these had helped bring peer review journals and medical science into disrepute, as well as garnering a great deal of media attention, she said.

1 THE UK PANEL FOR RESEARCH INTEGRITY (UKRIO)

Professor Mike Farthing said that the genesis for an independent panel had first arisen in the early 1990s, and before the formation of COPE in 1997. "It's taken a long time for something that should have been so easy to do," he said.

It then took shape at the 1999 Royal College of Physicians consensus panel in Edinburgh, which came up with the following remit:

- ▶ National panel to develop and promote models of good practice
- ▶ Assistance with the investigation of suspected misconduct
- ▶ Collection, collation, and publication of information on cases of research misconduct

But at no point was it suggested that the new body should take on the investigative role.

Part of the subsequent delay was not assigning a competent body to take it forward, said Professor Farthing, and leaving it to the Royal Colleges and the Academy of Medical Sciences to decide how to progress matters.

By 2001 not much more had happened, other than that much of the academic community were against the idea.

But in 2003 there was a breakthrough, when the establishment of a working group, distinct from the Royal Colleges and Academy and driven by major research employers, was mooted

"That was key," said Professor Farthing. "If you can't set up an investigative body with its own legal framework, you have to go back to those who are responsible for investigating and disciplining any wrongdoing."

The working party was led by the Health Committee of Universities UK, with Professor Farthing at the helm.

Panel gets backing from the CMO and educators

The Chief Medical Officer gave the concept of an independent panel his backing after being persuaded that it was an issue of patient safety, swiftly followed by the research councils, and heads of medical schools and colleges, all of whom were represented on the board.

The Panel:

- ▶ Has a strictly advisory role for employers and whistleblowers
- ▶ Promotes standards of integrity in leadership, governance and management, in the conduct of health and biomedical research primarily
- ▶ Provides practical support from trained experts who will be invited to serve on investigations in institutions and/or teach/train in institutions that don't have the resources

There was a reluctance to commit long term, because it wasn't known if the body would be useful, so it has been funded initially for three years from various sources, including the UK funding councils, Department of Health, as well as the MRC (Medical Research Council), Biochemical and Biophysical Research Communications (BBRC), ABPI (Association of the British Pharmaceutical Industry), etc, said Professor Farthing.

Its priority will be the promotion of good practice and the prevention of misconduct. And its first task would be to create one code of practice out of the multiple diverse sets of guidance already in existence.

Other tasks:

- ▶ The development of a register of advisors
- ▶ The development of a training programme for advisors and the wider community
- ▶ The publication of an annual report

The project board would be made up of a chair (non-medical/non-science), with representation from major stakeholders and non-medical/legal/scientific people.

The value of being a third party for a whistleblower should not be underestimated, said Professor Farthing.

"The experience at COPE was that if a whistleblower is able to say to a dean or head of institution that s/he has discussed it with COPE, this can be catalytic for actually pushing an investigation forward," he explained.

He then went on to praise COPE's role in the development of the Panel.

"Without the energies of individuals and the name of [COPE], it would not have happened, because there was a good deal of flailing around in other organisations," he said.

In answer to suggestions that the Panel was effectively toothless, he explained: "You have to do what you can do. It would not have been possible to get an independent body, underpinned by new legislation to give it the sort of teeth that some people felt was important."

But it would provide the beginnings for a culture change and be in line with what most other European countries were doing, he said.

Questions and comments:

Would the Panel take action on longstanding cases?

Iain Chalmers, of the James Lind Initiative, wanted to know how the Panel would help cases, such as the allegations surrounding the trial of neonates at Stoke on Trent, conducted 17 years ago. Despite numerous investigations by the hospital, the GMC, and referral to the police, the matter had still not been resolved.

Professor Farthing was not sure that the Panel would be able to do anything, but it could help in cases where there was an unwillingness to carry out full investigations or where these were unable to reach a decision, he said.

Frank Wells of MedicoLegal Investigations, said that a panel to advise on investigations was "hugely important" if these were to be effective and withstand further scrutiny.

Would the Panel prevent institutional cover-ups?

Aubrey Blumsohn from Sheffield pointed out: "Part of the problem of misconduct involves the misconduct of institutions themselves, bullying those raising the alarm or trying to prevent issues being raised in the first place." How would due process be guaranteed?

Professor Farthing said that a head of an institution's responsibility was to look dispassionately at employees, and investigate allegations of misconduct. External advice could "neutralise" a very sensitive environment where only internal people were involved, he said.

"Once a vice chancellor knows that a third party [also] knows about the problem, it begins to free up the situation and has certainly been catalytic in promoting a more open and thorough enquiry," he contended.

Would the Panel be legally watertight?

Harvey Marcovitch of COPE wanted to know how the Panel, which was not protected by an act of parliament, would tackle the difficulties of employment legislation, which made it difficult to take any action?

Professor Farthing said that was why the responsibility had to remain with the employers, working within their own contracts of employment with employees.

"All the cases I know that are going badly are precisely because we don't have an agreed robust process (legally and approved by lawyers)," he said.

"We are all still functioning as amateurs... We need to give teeth to those involved in the process. Really robust processes [such as that devised by the European Science Foundation] need to be rolled out across the country and Europe," he added.

He suggested that institutions should report annually their activity in this area to create a national database, and the Panel had persuaded both the university and NHS sectors to strongly encourage their institutions to do this.

The UK Panel for Research Integrity in Health and Biomedical Sciences (UKRIO)

http://www.ukrio.org.uk/home/ 0844 7700 644

2 CHANGING THE CLIMATE OF CHEATING

Vedran Katovich of the *Croatian Medical Journal (CMJ)*, pointed out that Croatia is one of 200 countries that account for 9% of the global share of published scientific output. It has produced 4000 papers in 10 years, with 18 000 citations.

International research shows that around half of researchers publish papers because of the ego boost, career advancement, or financial reward. That's irrespective of the number of authors, he said. It was no different in Croatia.

"The analogy is, that if there's a busload of authors and an author is sitting in the back row, s/he is still going to receive some sort of accolade, just for being on the bus," said

Dr Katovich, adding that because of the requirement for a certain number of papers to attain assistant professorship, "the incentive to be less than honest is huge."

- ▶ The CMJ is a small medical journal, which started in 1992, publishing in English
- ▶ Published bimonthly, it has a circulation of 1000
- ▶ The CMJ rejects 60% of the 300 articles it receives yearly
- ▶ It has generated 0.4 to 0.9 impact factor growth in 10 years

Publication misconduct

- ▶ 28 cases over 5 years.
- ▶ Multiple problems in some cases, duplicate/redundant publication, withdrawals, plagiarism, authorship dispute, falsification/fabrication (2 cases).

"We have no idea how many we didn't catch. Some we caught because we know the authors, and we policed those ourselves," said Dr Katovich.

Over the past 5 years, 60% of submitting authors had not fulfilled authorship criteria according to the International Committee of Medical Journal Editors (ICMJE), and 94% of students the journal helps [with scientific writing], admitted to some form of cheating in the academic process.

Authors adopted a "Machiavellian attitude" to publication, believing that the end justified the means, said Dr Katovich.

The journal decided to change the "climate of cheating" by developing a pre-review policy where editors work with authors in several stages, with authors taught the art of writing science and research integrity.

Other measures included:

- ▶ Several workshops and CPD for postgraduate students
- ► Compulsory teaching of second year medical school students the tenets of scientific writing
- ► Creation of a new research integrity body

Questions and commentsDoes training make a difference?

A representative from the WHO asked if any research would be carried out on whether training makes any difference.

Dr Katovich said that there had been a noticeable change in attitude among those taking the course compared with those who had not. The journal would also be monitoring course participants.

What incentives are there to tackle misconduct?

Charlotte Haug (Norway) said that institutions in Norway were responsible for investigating suspected cases of publication misconduct. "But they don't have any incentive to go after misconduct. And that's the biggest problem. Is it a uniquely European problem, because it seems that in the US, institutions do go after suspected cases of misconduct more?" she said.

"I can say categorically that is not just a European problem," said Mabel Chew, formerly of the *Medical Journal of Australia* and now of the University of Sydney. She recounted a case in which a junior researcher had accused a senior colleague of data fabrication. The researcher alerted faculty members who did nothing. And it was only after the case came to light in the national media that the university carried out an investigation. This led nowhere, and many other researchers in the field felt obliged to defend the accused, she said.

Dr Chew added that while at the journal she would receive at least one call a week about senior supervisors wanting to be credited when they had not contributed to the study, to which the journal responded by sending out ICMJE guidelines.

How can an investigation be truly independent?

John Overbeke of the *Dutch Medical Journal* said that few institutions had independent committees to investigate suspected cases "It's all kept internal, and that has always been the problem, and it continues to be" he said.

He described an ongoing case of alleged data fabrication on a thesis. Nothing was done when it came to light, but a complaint was submitted to an independent committee similar to COPE.

The ombudsman at one of the two universities where the research was done had merely had a 30 minute talk with one of the accused, concluding that he hadn't done anything wrong. Both universities were advised to bring in an independent investigator. One (not the employer of the fraudulent researcher) did this, and concluded that the data were fabricated. The other university has not acted on the information.

What's the duty of journals to go public on misconduct?

A Portuguese journal editor said that it was very difficult to find research misconduct, which meant overly heavy reliance on the peer review process. But how much of this information should be made public, and how much should journals be used to disseminate this information, he asked?

Dr Godlee said this was a major weapon journals had at their disposal, "And we should use it as much as possible." She added: "The problem is due process, and how much you apply before going public, and the legal risks. If journal editors are not making progress by other means, it's an important way to take things forward, but it is very time consuming and potentially risky."

Publication ethics for medical students?

One delegate wanted to know if there were initiatives in the UK to make publication misconduct part of the medical curriculum.

Professor Farthing said that plagiarism was a major problem for most UK universities and began at school, where it seemed to be acceptable practice to lift chunks of work without referencing it properly.

Seema Kang of *The Lancet* commented: "Lots of [young] doctors are pretty clueless about what's involved. Many people don't understand that dual submission or rewriting another article for another journal is not acceptable. It's really important to include publication ethics in the curriculum and as part of CPD."

Mabel Chew added: "We do need to start from the bottom to instil the idea of ethics in students and young researchers. But I know as an educationalist, a lot of future practice is hugely influenced by older colleagues in the workplace, and in the cut and thrust of real life ethics goes by the board."

She said she would be happy to educate senior academics about what is and isn't acceptable, not just to be seen making life difficult for harried academics, but to show that journals have to be cost effective as well and mindful of readers' time. "People don't want to read the same thing cut up in a million slices from different journals," she said.

Irene Hames of *The Plant Journal* felt the arguments applied to all young researchers. "If you have a good mentor, you will have good research training, but if not, you will come out not knowing what to do," she said. "It needs to start in school – the concept of not cheating all the way up through university and the research career."

Dr Godlee said that COPE's primary ability was to talk to editors. "We should be encouraging education of editors in their new roles and how they would use their positions to advocate better behaviour," but she was not sure it was COPE's role to educate junior researchers.

Workshop: What would you do if....? Case 1

You receive an email from an associate editor to whom a manuscript has been assigned incorrectly. The associate editor is a co-author on the paper, but has emailed you to say that he had not seen the paper before submission, had not worked on the paper, and in fact, doesn't know the corresponding (and first) author. The corresponding author is from a developing country, but his affiliation and email address are at a prestigious US institute.

You email the corresponding author with the associate editor's concerns and the requirements for authorship, requesting an explanation. You receive a reply from the author in which it is clear that he does not understand the requirements for authorship as the associate editor is listed as having "inspired him and provided several of his papers."

Responses

- ▶ We should assume genuine ignorance on the part of this author.
- ▶ Would further correspondence with authors be fruitful, given that guidelines have already been submitted without a suitable response?
- ▶ Reject the paper or request withdrawal.
- ▶ Should the institution be contacted to ensure that he is affiliated, as he says?
- ▶ The journal review process is flawed, because the case came to light by chance.
- ▶ It's very hard to establish strong rules, because these cases vary.
- ▶ The associate editor should write to the author and explain the inappropriateness of this attribution.
- ▶ The author deserves the benefit of the doubt, but since the paper will now have to be looked at with different authorship, the co-authors should be contacted to ensure that they know what has happened.
- ▶ Educate the author about authorship requirements: reword the letter until he does understand.
- ▶ Look to see whether these two people had co-authored papers in the past, which might shed some light on whether this was genuine or deliberate.
- ▶ A lot of this hinges on whether the journal has a tick box about authorship.
- ▶ Include a routine question when a paper is submitted about the contribution of credited individuals.

Action taken

The editor wrote to the author and his head of department. The author was very inexperienced, coming from a country where standards of publication ethics differed from those of the host country.

Case 2

You receive a manuscript from authors in another country that describes an intervention in an animal model. Both reviewers draw attention to the fact that the model used in these experiments would not be ethically acceptable in the UK.

You email the corresponding author with the reviewers' concerns. She responds promptly, stating that the work has already been presented at an international scientific meeting and that an ethical committee for experiments involving animals had approved the study. Documents in the local language of the author are provided to support the statement.

Responses

- ▶ Whether a study is ethical is up to journals and journal editors and is not dependent on where the journal is published.
- ▶ Editors should judge its merits, irrespective of ethical approval and legislation.
- ▶ The editors should write to the authors and request a translation of their ethical committee rules and permission given.
- ▶ Reference to international guidelines should be made in the instructions to authors.
- ▶ If you take the stance that it is the country of the journal that determines the ethical standard, you could find yourself in great difficulty, when it comes to embryo research, for example.

- ▶ Ethical standards vary from country to country, but if research is very important wouldn't it be reasonable to publish it with an accompanying editorial covering the ethics, and to invite comment about it?
- ▶ The other extreme is the Nazi experiments, so where do you draw the line? Non-publication is a stricture you can place on researchers.
- ▶ What if these weren't animals? What is the responsibility of a journal to the people who participated in the research? It is not right to assume that people who took part would be happy for their contributions to be hidden from view.
- ▶ There may be cases where results might be important even if they are deemed unethical.
- ► This blurs the line between unethical and poorly designed research, which doesn't get published, or at least in "visible" journals.
- ▶ Participants need to know that the research to which they are contributing is worthwhile, and we don't have any way of ensuring that at the moment.
- ▶ If people participate in scientifically valid and worthwhile research, but someone decides it doesn't meet their ethical criteria, those participants ought to be asked if the suppression of the information is what they want. This issue has not been addressed by the academic community.
- ▶ Would this be addressed by the registration of clinical trials?
- ▶ Registration does not guarantee publication.
- ▶ It could be a feedback mechanism for participants to enable them to discuss their experiences. This has not been considered.
- ▶ Publishing badly done research rewards it.

Action taken

The editors looked at whether the research was relevant to the country in which it was done and whether it answered important question(s). And they took into consideration ethics committee approval. They decided that more harm than good would be done by not publishing it.

Case 3

You receive an email from a reviewer, complaining that his review of a paper submitted to your journal has appeared on the internet. Although the review is not signed, citations to his own work make him feel that people may be able to recognise him as the review author. He asks how his review has ended up on another publisher's website when he thought it was confidential?

You rejected the paper concerned. As is normal practice, you sent a rejection email with the reviewers' comments appended. You contact the corresponding author, who explains what he has done.

The website in question is a "pre-print server" of a publisher based in northern Europe. It encourages authors whose manuscripts have been rejected to upload them with the reviewers' comments for an interactive open peer review' by readers of the site. If their manuscript is suitably revised, then the publisher will consider (for a fee), publishing it in one of their open access journals.

The author believes he has done nothing wrong as the reviewers' comments were transmitted to him by you, as the editor, and he can do what he wants with them.

- ▶ How much confidentiality can be applied to the peer review process once the reviews are given to the author?
- ▶ How could the rights of the reviewer to his intellectual property be retained?

Responses

- ▶ Sending on third party comments could open a journal up to accusations of malicious falsehood.
- ▶ Were the comments confidential to the author, editor, or reviewer?
- ▶ Should reviewers be asked to sign away their copyright? Should their permission be sought for passing on reviews?
- ► Should comments go back to the author on the understanding that they are not for release into the public domain?

- ▶ Journals often send on comments via the net. There should be a warning to the reviewer of the potential for dissemination, and reviewers should be reminded that they are accountable for the content of their review.
- ▶ Some editors edit out the more contentious parts. The reviewer signs away their copyright and their rights to some sort of ad hoc edited version unknowingly. Is that justifiable?
- ▶ In general, there should be better guidance for reviewers.
- ▶ This is really an argument against anonymised peer review. If it were open, this problem would not arise.
- ▶ What about journals who pay their reviewers? Is the review then their property?
- ▶ Commissioning a reviewer to write the report, providing you give adequate guidance about what happens, gives you a degree of ownership and the liberty to share it with an author.
- ▶ Journal editors need to be explicit about what will happen to the reviews.
- ▶ The web publisher should ask the reviewer's permission to publish their report. Clarify to the authors, that just as the reviewer will treat the paper in confidence, so should the comments going back to them be for private use only.
- ▶ Reviewers should feel confident to stand by their comments.
- ▶ Some fields are so narrow, it is quite clear who the reviewers are. It's good practice for the author to inform the journal and/or the editor that they intend to publish the reviews.
- ▶ There may be a conflict of interest, where people feel compelled to compliment an article for fear it will prejudice their professional career. It's useful for authors to know who the reviewer is sometimes.
- ▶ Each journal has to decide its own policy and the minimum/maximum amount of guidelines. Everyone has to know what the contract is when they submit or review for a journal.
- ▶ Some journals advertise for papers with reviews from named journals. As an author, if you have two damning reviews and two good ones, which ones are you going to send? That is selective peer review without any authority. Edited manuscripts could contaminate the scientific literature.

Action taken

The publisher wrote to all its editors, asking them not to forward material to other publishers.

This prompted further discussion:

What's the difference if papers are passed from editor to editor within the organisation, one delegate asked?

Dr Godlee pointed out that if the *BMJ* rejects an article, and the author has given permission at the outset, it may be referred to one of the *BMJ* Journals for their consideration. Peer review reports are passed on with it...but not necessarily with the peer reviewer's permission.

Open peer review would not prevent this sort of problem, nor would allowing reviewers to sign the report, contended another delegate.

But one editor suggested that editors should be mindful of the fact that the medium has changed, and if more information was put in the public domain, "how do we help readers sift through it? We select for the reader in a print journal."

"We have huge double standards as editors. We give author reviewers' comments, but tell them not to disseminate it. But if I had received a paper from another journal, I would ask for the reviewer's comments," said another

"A way to open up discussion is to make it clear to the reviewer that the review is confidential while handling, but after it has been passed to the author, they can do as they want. It's an editor's responsibility to ensure that authors and reviewers are clear about their responsibilities," said one delegate.

"We have an editorial team who read and review every article submitted, and the actual decision is made by at least two and possibly the whole team. We work with authors all the way through the writing process. For those that are rejected, a summary of the main points is written, and sent out quickly," said one editor.

"Editorial review is dangerous. It's prone to bias of particular editors and there is no recourse for authors. If you don't understand the methods used, you either take it on trust that the authors have got it right, or you seek external advice. Speed does not always mean sound publication," contended another

Asking authors to transfer reviews from previous journals can be difficult, because you don't know who they are or why they have been chosen. The journal could have chosen the wrong reviewer as well, pointed out one delegate.

If the reviewer's permission is obtained for an author to use a review elsewhere, you lose control over it, another cautioned.

3 THE ETHICS OF ANIMAL RESEARCH

Professor David Katz, Editor of the *Journal of Experimental Pathology* and Professor of Immunopathology UCL, London, set out his key themes.

- ▶ What's happening at the moment?
- ▶ What's the impact on publications?
- ▶ Is there any detailed monitoring of input into animal research?

Research is regulated by the Home Office under the Animal Scientific Procedures Act of 1986 in Britain, which licenses premises, personnel, and projects, he said. The holders report procedures annually (anything done to animals for experimental/scientific purpose that may cause pain, suffering, distress or lasting harm), but they are not subject to peer review and there is no good access to them.

Number crunching

- ▶ About 4000 animal research projects are in train in the UK
- ▶ 227 licensed premises.
- ▶ About one in four licence holders say no procedures have been performed, but this doesn't mean that no animals have been killed.
- ▶ About 5% are reused in experiments
- ► <1% done on dogs, cats, horses, and primates
- ▶ Increase in genetically modified animals, mostly mice.
- ▶ 85% of experiments are done on rodents
- ▶ 10% of experiments are done on fish and birds.
- ▶ 30% used in fundamental basic research and 25% in applied animal research

The Home Office adopted certain criteria for the governance of animal research, and the creation of a body to fund research projects that either substitute animals, reduce the numbers used, or refine procedures to limit suffering, Professor Katz continued.

Monitoring

What about monitoring of output? Is it the subject of research ethics approval? What about animal derived materials, which are used in a considerable amount of biomedical research?

"At this level, we are dealing with the interface between basic science and industry, clinical studies and industry, and innovative science based on animal studies and phase 1 trials," said Professor Katz.

The monitoring of output and animal rights activists precipitated the establishment of the Nuffield Council of Bioethics Committee, which looked at animal research. Their report suggested that certain kinds of information should be known about licensees, including the:

- predicted benefits of animal research
- probability of achieving these
- ▶ number and species used
- ▶ likely outcome
- grounds for rejecting alternatives,
- ▶ source of funding and steps taken to replace/reduce/refine

The report concluded that duplication was unacceptable, but replication was not. "But it can be hard to determine which is which," said Professor Katz. The report also said that academic competitiveness and commercial confidentiality had to be taken into account. But no comment was made about an obligation to publish the actual outcomes.

Impact on journals

The *Journal of Experimental Pathology* looked at the processes in journals. Were the ethics reports from licensees or institutional review committees? In Brazil they appear to have a licensing system and an institutional approval system. China and the EU don't say. In Britain, the granting of institutional approval varied.

There is no universally accepted practice. Sometimes there's a failure to:

- ► report anything
- ► investigate thoroughly
- ► report accurately
- ► report negative studies

Professor Katz cited Lewis Wolpert, who said the nearer you get to the human, the more fraud and deceit you find in research.

"We have an ambivalent attitude to animal research. But ethical standards need to be considered in the same way that they are for human research," he said

Changes in public opinion

Professor David Morton, Centre for Biomedical Ethics at the University of Birmingham, referred to a survey of people's attitudes to animal research, which had been going on since the war. This showed that support had fallen.

The question posed by the survey is: should scientists be allowed to do animal research that causes pain/injury to dogs and chimpanzees, if it produces new information about human health problems?

Strong support for this dropped from 63% to 44% in 2001. But if applied to mice, 68% agreed. Yet worldwide trends in the treatment of animals show that this is becoming more, rather than less humane, cruel practices are being banned, and a duty of care towards animals is being promoted, he said.

Animal research causes public concern. But editors can meet that concern by providing information to scientists to prevent future harms to animals and humans. "There is now a body of research showing that people who readily inflict injury on animals are damaged by so doing," said Professor Morton.

"Editors are standard setters because the life blood of scientists is publications," he added. The country most opposed to the use of dogs and chimpanzees is France, despite their use of *foie gras*. At the other end of the spectrum lie Greece and Portugal. But an international journal will receive submissions from all over the world.

Can UK editors rely on the Home Office and the local ethics committee? Are editors legally obliged to ensure all work is done under the EU directive? Can editors reject work carried out under international law, and what about outside the EU?

He suggested that editors/reviewers/researchers should pose certain questions before undertaking/accepting research.

Questions editors/reviewers/researchers should ask:

- ▶ Where do you get your funds from?
- ▶ What are the potential benefits?
- ▶ Are they clearly spelled out in the paper?
- ▶ Do animals have to be used?
- ▶ Has their use been justified strongly enough?
- ▶ Many of the ways in which animals are kept are not published, so that it can be duplicated in other laboratories: but should there be a specific animal section addressing that?

- ▶ Will the study design achieve scientific objectives and reduce an animal's suffering, so that the information can be passed on to other scientists, encouraging them to look at these aspects as well?
- ▶ Have all the animals used been accounted for?
- ▶ Are the statistics robust, to avoid too few or too many animals being used?
- ▶ Should the use of an independent statistician be routine rather than relying on one type of statistic to analyse data?

A papers review carried out by the *Australian Journal of Biological Sciences* found that 29% were statistically acceptable and 26% drew the wrong conclusions. The statistical design of experiments is extremely important right from the outset, said Professor Morton.

Animal wellbeing and husbandry

Animals live in their cage for 100% of the time but are only part of an experiment for 5% of their lives. More damage is done by keeping them in barren environments than by using them in research, claimed Professor Morton.

It's important to acclimatise animals to their cage before experiments are done. There's a 60-fold difference in LD50 between animals that have got to know their cage first and those just plonked in a cage, presumably because of stress levels, he said.

There are plenty of data to indicate that the wrong result will come out of studies without due care and attention to husbandry and the way in which the experiment is conducted, he added. And he had this advice for researchers:

- ▶ Check the husbandry conditions, health status of the animals, and the analgesia used.
- ▶ Could the work be replicated in another laboratory? So often it can't.
- ► Are there sufficient details of adverse effects to prevent other people making the same mistakes?

All this information could be posted on a website if it can't be put in the journal itself, he said.

- ► The Home Office weigh harms against the benefit. But would an editor ever reject a paper on this basis or would s/he always accept because it's good science?
- ▶ Are certain procedures inherently unethical—neuromuscular blocking agent, without any anaesthetic, for example?
- ▶ Or does the importance of the results take precedence? There has been a rise in the use of transgenic mice from 8000 to nearly a million, and this will continue.

The selection and training of referees to make informed decisions on animal research papers was also important, he said, but an issue that tended to be neglected.

Referees

- ► How are these selected?
- ▶ Is this done on the basis of the science, or the way in which the research was done, or the detail of reporting?
- ▶ Do they have the right knowledge, skills, and attitudes?
- ▶ Do they care? Should they?
- ▶ Would it be helpful to publish a list of reasons why a paper was rejected?
- ▶ What about more information about publication ethics on the COPE website?

Editors should encourage progressive and reliable science, with the least inhumane treatment of animals in research, he concluded.

Questions and comments

A UK editor on an international journal wanted to know if he was right to reject a research paper with very good credentials, carried out in accordance with local regulations, but not with UK regulations?

There are international laws, but these are very general, but there is general agreement on certain issues like neuromuscular blocking agents and major surgery on animals, replied Professor Morton. "The ICH and WHO stipulate that full consent is needed from

adults, but there is no equivalent from animals so we have to apply the same standards as we would for adults unable to consent."

Animals should not be left to die, because they were dehydrated and unfed.

If we can predict death we should kill them humanely rather than leaving them to die. "COPE could set out some common ethics standards for the treatment of animals," he added.

In certain countries tumours are allowed to grow to a size that removes an animal's ability to walk. A large number of birds will be killed in pursuit of treatment for the bird flu epidemic, he said.

Professor Katz referred to the issue of publication bias and research into research methodology of animal work, which has been going on since the 1980s. It has led to the CONSORT statement, which is now widely accepted for reporting controlled trials. Systematic reviews of animal studies commissioned by the NHS R&D programme are beginning to show the variable quality of animal studies.

The licensing system in the UK is now coupled to local ethics committee concerns looking at the broader issues of whether the research should be carried out in the first place, he said.

In other countries it's all down to local ethics committees, so decisions depend on their composition. In Australia these include a member of the equivalent of the Royal Society for the Prevention of Cruelty to Animals (RSPCA).

CONSORT emerged from general medical journals, and there is no reason why this could not be done for animal research if editors of major journals, publishing animal research, got together. Certain techniques and types of activities could be banned and avoidable suffering prevented, he said.

Because of the current climate, a lot of animal research studies get buried and people tend to keep quiet about it.

4 DEBATE: MASSAGING PAPERS TO IMPROVE THE IMPACT FACTOR

Against: Pritpal S Tamber

The typical scenario is the provisional acceptance of an article but the editor writes to the author asking for five references to include his/her journal.

A series of responses from WAME listserve editors indicated that the impact factor was:

- ▶ inadequate
- ▶ not watertight
- ▶ biased towards English language
- ▶ only covered a quarter of peer reviewed journals
- ▶ those journals with news articles and non-citable articles fared better

An assessment of *Nature's* impact factor showed that 90% of cited articles referred to 25% of content.

Citation can mean influence: "If a lot of people are citing you, you are influential, but have you really influenced clinical practice?" he asked.

The impact factor helps:

- ▶ libraries choose journals
- ▶ funding agencies decide who to shortlist
- ▶ authors decide where to submit
- ▶ influence academic appointments and promotion
- editors assess how good their journal is.

The Council of Science Editors and WAME say that editors are supposed to protect the integrity of the author's work and the integrity of the scientific record, acting as gatekeepers.

"Editors are supposed to be meeting the needs of authors and readers, so if we are massaging are we doing our job? A good impact factor does not mean the journal serves its readers well. And perhaps it makes you accept an article because it's a sexy topic, which will get you cited, rather than because it's a useful article."

"Readers have to trust editors. Trust is the hardest thing to build, but also the easiest thing to lose. And if we mess around with people's citations, then do we really deserve the trust of readers and authors?"

"The whole process is flawed. It's a battlefield out there, with authorship disputes and undisclosed conflicts of interest, etc. But if editors behave badly, they will get the same in return. What goes around comes around," he suggested.

"Be careful with your authors, and don't blindly trust your reviewers. They delay because they are working in the same field, or are too critical because they are in the same field, or not critical enough, because the author is a mate," he warned.

"We should try and find a way to play fair," he concluded.

For: Tim Albert

- ▶ Why do some people feel impelled to make up their data?
- ▶ Why are so many members of the public suspicious of science?
- ▶ Why does it take so long between discovery and implementation?
- ▶ Why do one in five authors claim to be authors when they are not?
- ▶ Why do two thirds of references contain citation or quotation errors in some journals?
- ▶ Will litigation mean the end of peer review?
- ▶ Why do we seem to be going through an epidemic of journal editor sackings?
- ▶ Should we be worried that some editors are contacting authors, asking them to quote articles in their journals?

"The only really important question is the last one," said Mr Albert. "And it's on that question that the future integrity of medical publishing actually rests. If you manipulate, are you are a bad editor?"

What do we actually mean by massaging? When it comes to impact factors, perhaps a bit of massaging here and there is the best thing we can do, he suggested.

Most people understand the term massaging as the act of asking an author to quote from the journal in question, but it wasn't that simple, he ventured.

- ▶ What about asking someone to write an article? Does that count?
- ▶ What about taking someone out to dinner and asking them to write an article? What about changing the labels around and the contents, so that the denominator changes and the impact factor goes up. That's done by very reputable journals.
- ▶ What about turning short reports into letters?
- ▶ What about choosing one paper over another, because it's likely to be cited?
- ▶ What about using a press officer? If an article is cited in the press, the citations go up, but only rich journals can hire press officers.

Two or three references in a submitted paper relating to the target journal makes that editor happy, but it also makes sense to refer to some of the previous "conversation" in that journal, he said.

"Why is it OK for a non-editor to advise an author to insert a few references to the journal, but not for that journal's editor? It's not an ethical problem we are dealing with here but a problem of etiquette," he contended.

What's wrong with the impact factor, and why should we worry about boosting it? Firstly, it suggests quality. But the responses from WAME indicate that the impact factor should be used, like medicine, with care, and with the full knowledge of its side effects, he continued.

"As long as it's adopted by research assessment exercises all over the world, we are creating a huge problem. It's not enough to publish, you have to publish in certain journals. This wastes huge amounts of time and money when first timers submit to the

big hitters. But throughout medicine is the quaint idea that if you send an orange to someone who wants a banana, somehow they won't notice."

At a conservative estimate, four to six hours are needed to make a paper aimed at one journal suitable for another. This time could be more usefully directed to patient care, he said

Preserving the status quo is what the impact factor is good at. It's hard to remove it, so if you are a journal at the top, you get all the best papers, and if you are at the bottom you don't.

A small journal, like the *Italian Journal of Gastroenterology*, probably has an impact factor that is 20 times less then the *New England Journal of Medicine*. But for an article on pasta poisoning in lower Tuscany, the Italian journal is going to be the right one. "Why should people have to submit to five international journals before finally deciding that?" he asked.

The impact factor distorts the whole process. Editors stop editing on the basis of what their readers want, and instead, start making decisions based on the likelihood of boosting their impact factors.

It's no longer about communication, but about getting up the league tables. But a good editor will get things buzzing with the journal, and the impact factors will follow, he said.

"But some editors will be less interested in editing, and more interested in manipulation and sending their impact factor rocketing. They are less worried about behaving badly and more worried about a bad league table. Massaging is not clearly defined, and it's not prohibited. But it's doing us good, because it shows us how flawed the impact factor is in the first place," he said.

"A league table relying on a self defined audience of several thousand alpha males is doomed. COPE should stop being prissy and state clearly that there is nothing wrong with an editor wanting a couple of references to previous articles in his/her journal," he said.

If we do that, the playing field will level out and the problem will go away, and we can start looking at the really serious problems facing medical journals, he concluded.

Comments

- ▶ It's totally unethical to massage the content of papers, and why would authors trust an editor who does that? But what is wrong with promoting content that is in your journal? A lot of us are commercial concerns and we need to make a profit.
- ▶ It's unethical to massage content, but it's also unethical to make authors jump through hoops. But when do you start saying I prefer an envelope full of £10 notes if you are going to submit to my journal? That's the line you are going down.
- ▶ Changing the culture of academia, and journal editors is hard. The impact factor is all, and it's considered alright to play the game. As long as that continues we will never have a better measure of quality for journals.
- ▶ It's worth thinking about why we want people to cite work in the first place. We want them to do it because we want them to compare their work to prior literature which is relevant, to previous methods and similar research that has been done. So the purpose is to reflect their work in the context of the existing scientific literature. Sometimes reviewers can point out work that has been missed, and reviewers are chosen because of their expertise, so it is relevant for a reviewer to request inclusion of their own work. The editor can decide on the validity of that request.
- ▶ What is not acceptable is for a reviewer to say that everything is fine except for the omission of his/her own research. We recognise that that is abuse; equally, authors can do the same and only refer to their own previous work, ignoring that of others. They may claim that they came up with the technique or cite their own previous review article to back up a range of research rather than citing the original research. We recognise that as abuse, so why, then, do we allow editors to request previous work in their own journal that is not of relevance? Surely that is abuse as well, especially if acceptance of the paper is contingent on those additions?
- ▶ We should argue strongly and publicly that this process is severely flawed, and suggest alternatives. And we should make this argument to grant awarding bodies and universities, because they are the ones who are forcing us to play this silly game with the impact factor.

- ▶ There are around 40 English language journals covering infectious disease. Last summer the journal that led the field, with an impact factor of 10, was *Lancet Infectious Diseases*, which is a review journal. There is nothing original in there.
- ▶ Publishing a review of an article published at the same time as an editorial, saying that an article was not that good, is a combination that can raise the impact factor spuriously.
- ▶ What one does with the journal in terms of structuring it is a matter for the editor, not the publisher. But manipulating an article to make it something it isn't, purely for the purpose other than the intention for which the article is written is fundamentally wrong. And I would like COPE to state on its website that a request from an editor to an author to include references to the journal purely to boost the impact factor is unacceptable.
- ▶ The impact factor is a flat metric a simple calculation on the number of citations and the number of articles, with no way of differently weighting self citations or from the other highly cited journals. It's straightforward, because it's clear how it works, but this also makes it vulnerable to manipulation. It's interesting to compare it with what Google does to generate page ranks, because Google does incorporate weighting. Other types of journal metrics will emerge, which will take account of differential weighting.
- ▶ Will this discussion no longer be relevant soon, because the authors will all know the right tricks and simply add in citations to the journals without the editor having to ask?
- ▶ This notion of the integrity of a paper is a series of compromises, with people being told what to put in and take out. If an editor asks someone to consider including a reference termed unacceptable behaviour but if a reviewer asks for it, it's called peer review.

Massaging the impact factor is wrong: the motion was defeated.

5 CITATION TRACKING AND INDEXING SERVICES

Matthew Cockerell, publisher of Biomed Central, said that a citation tracking service could be used to search the bibliographic information to find items on a particular topic, but unlike PubMed, it could also be used as a filter for articles on a given topic, by finding only those that have been highly cited.

A citation service that connects all the articles together on the web allows you to follow them forwards and backwards in time so you can see how particular research has generated other material and how the various areas of research interconnect.

The impact factor crops up as a short cut to wading through long lists of publications to decide what's worth looking at. A qualitative measure indicating how good a journal is, helps tackle that difficulty. But this information only becomes available a year or two after publication, so article citation doesn't tell you quickly enough what is likely to be good research.

Strength and weaknesses of the impact factor

- ▶ Well understood and established
- ▶ Includes tens of thousands of journals
- ▶ Article based metrics and journal based metrics

But:

- ▶ Web of Science is hugely important, but hugely expensive and largely unavailable to individuals.
- ▶ Coverage is huge, relative to the entire scale of cited literature, but it is incomplete.
- ▶ A lot of material is excluded for economic reasons, the restrictions are arbitrary, and lots of important research is not captured by ISI.

ISI uses 1960s technology to cover the entire research base, and new publishers like Biomed Central have a job ensuring their work is captured.

Saying that a journal has a high impact factor and therefore every article is important conceals the fact that 80% of the factor comes from 20% of the articles. A few highly cited articles make an enormous difference.

Alternatives

- ▶ **SCOPUS** (www.scopus.com) is a paid for service from Elsevier, which has a similar degree of coverage to Web of Science. But it doesn't generate a journal metric analogous to the impact factor.
- ▶ **Google Scholar** is entirely generated by computer (robot harvesting) which means it is free.
- ▶ **Citebase** (www.citebase.org) is a shoestring operation, with similar functionality to Web of Science. But it only works with the data readily available to it, so it's based on open access content, primarily from the physics archive.
- ▶ **CrossRef** (www.crossref.org) assigns DOIs, and takes reference data from publishers. It provides a forward linking service, which allows you to find out what articles cite a particular article in the future.

Because citation linking comes for free, once you put the structured data from the articles in XML form in a database, it's easy to put the links in place.

Any modern journal system, whether it brings together articles from multiple publishers, like Biomed Central or HighWire, or specific publisher sites, like Science Direct, will have the navigational links to get you to the forward citation. But it's all based on the silo of that publisher's content. If it's big, the more useful it is, but it can never be as good as a truly comprehensive service.

For example, the Public Library of Science (PLoS) bases its citation links on CrossRef, but limited to what is covered by CrossRef. An article from Biomed Central is cited by 168 different articles according to ISI, 45 on PubMed Central and 212 on Google Scholar (only limited to what it has access to).

ISI still dominates the world in terms of evaluating research, but this dominance will be challenged in the future.

Citation tracking is not by itself the complete answer to finding the best research. Citation metrics are too crude, and individual level article citations take too long to emerge.

Article access is a simple method, but it does also include access by the author, access by mistake, or for the wrong reasons. If an article is highly accessed, for the type of journal and for the age of article it is, it can be flagged up as being in the top 10% and given a permanent logo. Authors can then put this on their research article CV.

Different kinds of metrics

It will be increasingly important to have more subjective metrics. That's already done by peer review to some extent, but whether a paper is accepted by one journal is not the end of the story for that piece of research, because it is likely to end up elsewhere. How do you take account of that?

Biomed Central has set up The Faculty of 1000 Medicine, originally in biology, but this has now been extended to medicine. A panel of specialists in the field highlight and evaluate research that they think is particularly important, wherever this is published. The research is then flagged up with a badge, showing why it's important, and given a rating, with descriptive comments signed by the individual specialist. This is all done within weeks of publication of the research.

The ratings go from exceptional, must read, to recommended, and the score of the frequency of these judgments can also be used. Contributors are also asked to classify the article as either an interesting hypothesis, a technical advance, or a refutation of previous research. All this information helps people to filter the article.

This has been driven by technology. CiteULike (www.citeulike.org) is a service, whose primary function is to allow you to follow interesting references to websites. It can be used as a personal bibliographic store to which notes can be added as to why it is being

followed. The bibliographic items are shared, and you can check what everyone else has been accessing and how they tag (describe) them.

Questions and answers

Q: How are the articles policed? Is conflict of interest declared? What about highlighting bad articles in high impact journals?

R: There's a hierarchical process to hiring the experts to ensure they have suitable expertise, and the whole editorial team behind The Faculty all vet contributions, so everything is filtered.

In terms of responsibility for highlighting poor articles, at one level it's deciding what's important. The Faculty of 1000 Medicine is trying to deal with information overload, so highlighting bad articles won't help with that, but there are some areas worth drawing attention to it. You can flag an article as controversial and you can add a cautionary dissent, and the authors are invited to have some comeback and defend themselves.

Q: How do you ensure that the contributors do actually cover the wealth of information out there?

R: The Faculty is somewhat subjective and based on contacts within the fields, including knowledge of research not yet published. But the diversity compensates for subjectivity.

Comprehensive coverage is desirable. The Faculty member chooses 10 articles representative of a particular topic, and anything that comes out that's relevant to those 10 will generate an automatic alert to that Faculty member.

The "hidden jewels" section lists articles that have been highly rated even though they are not in the usual suspect 20 journals.

Q: What's the effect on the number of times a paper is accessed once it has been given a highly accessed flag, and does that itself influence access?

R: That hasn't been looked at but it's related to whether an article appears on the most viewed list, which can have a self perpetuating effect. But this is less of an issue with highly accessed papers.

Q: Citeulike says you can share your library. Is this limited to open access material, and if not, are there copyright issues?

R: Citeulike, like Endnote, only preserves bibliographic data. But in the long term, there's potential for these tools to manage your own copy of the article, so it will make a difference if it's open access or not.

6 IDEAS FOR COPE IN THE FUTURE

- ▶ Survey UK medical colleges plus science faculties in other countries to find out the extent of training in publication and research ethics for undergraduates and postgraduates. Until we know that baseline, how can we improve on it?
- ▶ Invest in research in automated methods to track fraud in articles, including image manipulation, data fabrication (digit preference), and spotting plagiarism, so removing reliance on hard-worked authors and editors.
- ▶ Develop the COPE website as an educational tool, including an interactive educational tool on publication ethics.
- ▶ Find out what advice senior people are giving to medical students...and everyone
- ▶ Give some money to the UKRIO.
- ▶ Give annual prize money to the preferred charity of an important whistleblower.