SESSION 2

Chair: Professor Sir Ian Kennedy
Emeritus Professor of health law, ethics and policy, University College, London

COPE takes a role in education

Faith McLellan
North American Senior Editor, *The Lancet* and joint chair, COPE Education Committee
Sabine Kleinert
Senior Editor, *The Lancet* and joint chair, COPE Education Committee

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

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

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

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

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

Audience

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

Issues

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

How?

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

Scenario cases

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

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

CASE 2

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

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

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

Discussion

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

Sabine Kleinert asked what would have happened if the problem had arisen earlier in the review process?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CASE 3

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

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

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

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

Is the author right?

Discussion

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

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

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

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

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

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

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

These were not patients; these were people who were not consulting a doctor. They were discussing among themselves, and a medical eavesdropper collected the information for a different purpose than that which was originally intended.

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

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

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

CASE 4

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

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

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

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

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

Discussion

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

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

Is there a legal or courtesy requirement involved here?

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

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

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

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

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

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

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

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

CASE 5

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

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

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

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

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

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

Discussion

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

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

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

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

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

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

CASE 9

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

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

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

What should the editor do at this point?

Discussion

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

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

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

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

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

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

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

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

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

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

CASE 11

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

Discussion

- The key issue is public interest, but if the editor does not publish, there is nothing to stop the author from publishing it on the web.
- Try and spread the reviewers' net wider and speak to people who are likely to know what this research is about.
- Go back to the author first, saying these concerns have been raised.
- Should editors practise censorship? The line to take would be to investigate and negotiate.

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

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

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

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

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

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

CASE 13

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

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

Now what?

Discussion

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

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

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

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

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

Faith summarised the issues discussed:

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

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

Summing up

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

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

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

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

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

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

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