Forum agenda

Meeting to be held on Wednesday 2 December 2009 at 3.15pm
(following Extraordinary General Meeting at 3:00pm)
The Boardroom, Woburn House, 20 Tavistock Square, London WC1H 9HQ

Agenda

1. Update on COPE activities by the Chair

2. New cases

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4. Updates

- **08-15 How many "mistakes" are too many?**
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NEW CASES

09-21 Self-plagiarism (RO)

On initial assessment of a submitted review paper with a single author, the editor checked some of the references to the author's own work that were cited in the paper. The author mentioned in the covering letter that he had written extensively on some of the specific themes of the paper, as the references made clear, but he claimed that the paper was an original synthesis of the material.

Examination of four or five easily accessible references revealed an unacceptably high proportion of direct replication: many phrases and sentences and some complete paragraphs. The paper was rejected with an explanation that this practice of self-plagiarism is unacceptable, and that the journal would be contacting the head of research ethics at the author's institution.

The author appealed against the decision, saying that he had been open about previous publications and questioning why he is not allowed to repeat arguments and ideas, even when they were first published in little known publications with limited circulation in other fields. The journal's decision was upheld.

The journal then contacted the institution's director of research integrity. His response quoted a section from the national code for the responsible conduct of research: "It is not acceptable to repeat the reporting of identical research findings in several different publications, except in particular and clearly explained circumstances, such as review articles, anthologies, collections, or translations into another language." The institution's decision was that the author had clearly explained that the paper was a critique and that he has published before on some of the themes, drawing attention to relevant references. The conclusion was "I am of the strong opinion that the author has not committed a breach of the code for the responsible conduct of research." The issue of direct replication was not addressed in this response. Is there anything else the journal should do?

09-22 Plagiarism, double submission and possible reviewer misconduct (AC)

This is a complicated case which involves possible plagiarism, double submission and reviewermisconduct. The timeline is as follows:

- In year n, a paper P1 authored by A1 and A2 was published in the English language journal X. The paper describes a theoretical analysis of a particular phenomenon.
- In year n+6, paper P2 was published in a non-English language outlet by authors A3 *et al*, which cites P1, but carries essentially the same scientific message.
- In year n+8, A3 *et al* submitted paper P3 to conference Y without referencing P1 or P2. The main content of the paper was essentially the same as that in P1. This paper was awarded a best student paper prize at the conference and journal X, which has an arrangement with conference Y to fast track "extended" versions of best papers , invited submission of such an extended version. Journal Z, unbeknown to journal X, also invited a paper to be published in journal Z based on P3.
- In year n+8, paper P4 was published in journal Z; the paper did not cite P1 and was only a very minor extension of P2; under journal X's rules, P4 would have been rejected as not being sufficiently different from P3 since conference Y is regarded as archival in the field. The editors-in-chief of journal Z were two of the reviewers of P3.
- In November year n+8, A3 *et al* submitted paper P5 to journal X. P5 has the same theoretical content as papers P1–P4, but also has a new experimental section, which does make a new contribution. P5 does reference P1, but only incidentally and does not properly acknowledge that the theoretical content of P5 has previously appeared in P1 (or indeed in P2–P4). The editor-in-chief of journal X was not alerted to the overlap with the previous papers by the two reviewers (who were, in fact, the editors of journal Z). It is not a coincidence that the reviewers of P5 were the same as for P3 since this is part of the journal's fast tracking process. The editor-in-chief of journal X accepted the paper and it was published in year n+9.
- Around 6 years later, journal X (with two new editors-in-chief) received two independent complaints that P5 contains large sections of material plagiarised from P1, noting that although P1 is referenced, the reference is not sufficient. Journal X starts investigations. Two editorial board members and an independent reviewer confirm the facts as stated above. One of the complaints was submitted in the form of a paper for publication ; at present, this has not been sent out for review but is simply being treated as additional evidence/confirmation of plagiarism. (We have recently discovered that this paper has been posted on a web site devoted to plagiarism discussions.)

Other points:

- The co-authorship has changed over the papers P2–P5. A3 is constant (although not always first author) but the "*et al*" changes. Of particular note is that the authors of P3 are not a subset of P5, despite the fact that content-wise P3 is a subset of P5.
- P5 has become highly cited and A3, although junior at the time of submission of P2–P5, has become well known with many papers and sits on the editorial board of journals. This should of course not affect our action, but it is worth noting that our decision could have a significant impact.
- A3 has admitted in a non-English language web site that he was invited to submit a revised version of P2 to journals X and Y.

- One of the complainants has just pointed us to another publication by A3 *et al* in a foreign language journal which again appears to have a high degree of overlap, published in the same year as P3 and P4. At the time of submission of this case we have not yet contacted A3 or the referees of P5.

Questions for COPE:

- It is clear that the theoretical part of P5 is effectively plagiarised as the reference to P1 is insufficient. How severe should our response be?
- There is some element of double submission (P4, P5): is this worth pursuing?
- Should we take any action against the reviewers of P5 who have arguably acted unethically, or at least less than ideally?

Other comments are welcome on this complex case.

09-23 Scientist reads published paper by former collaborators and claims co-authorship (SG)

The case concerns a paper we published, ahead of print, on the journal's website on 5 October 2009. A week later we received a letter from Dr A who claimed that the authors had a major conflict of interest and implied that she should have been listed as an author. The paper we published is based on an idea which was tested in 2002 in Country P, and in 2004 in Countries Q and R. The authors of the resultant paper, published in another journal in 2009, were author C, a PhD student of author B, and author B, with Dr A as the last author. Dr A and Dr B collaborated further in Country S in three investigations

In June 2006, November 2006 and June 2007, Dr A was invited to participate as a representative of an international centre for medical research in Country R. When in the field, Dr A examined and screened patients . Dr A used data gathered in July 2007 within the framework of a study headed by Dr B. Dr A is listed as "another scientist involved" in the report from the funder and in a grant application. This application was to be on behalf of both Dr A and Dr B, and some others, but made no mention of Dr B's study, although Dr B's study had provided the funding for gathering the data at its basis.

Dr A's grant application excluded any input by Dr B's group, contrary to what had been agreed at an earlier meeting . Dr A did not participate in the November–December 2007, June–July 2008, November–December 2008 or June–July 2009 investigations.

The paper which we accepted, by Dr B and colleagues, includes data on patients recruited in June 2007, 2008 and 2009. It makes no mention of Dr A, who would have examined and screened some of the patients in July 2007. Dr B asserts that Dr A's input was purely technical and that Dr A had no input into the conduct of the study. Dr A claims that the technique was based on her research (because she was senior author of the previous publication), which Dr B counters by saying it's a free country and anybody can use the concept once it's out there.

So we have a group of people who used to collaborate quite amicably but seem to have fallen out over some undisclosed conflict in the summer of 2007, at which point they drifted apart and pursued grants from separate donors. The patent animosity displayed by both parties precludes asking them to sort it out among themselves.

09-24 Homeoprophylactic treatment of a zoonotic disease (JP)

This research article investigated the effect of the widespread administration of a homeoprophylactic preparation against a bacterial zoonotic disease in a developing country after a period of particularly heavy rainfall. The authors claim to have given this oral preparation to all members of the population over 1 year of age, in three provinces of the country where this disease is prevalent (over 2 million people). This was done in parallel to the country's conventional vaccination and surveillance programme. The authors claim that this intervention significantly reduced the incidence of the disease in the treated provinces compared with the non-treated provinces.

We asked the authors to provide more information on how they had addressed the ethical aspects of this study and to provide supporting documentation. They stated they would include a paragraph on ethical considerations in the text, but argued that the principle aim of the study was to report the results of a healthcare intervention as a response to an emergency situation and was not classical clinical trial research. They further argued that the product used in the intervention is a registered product of common use on the public health system of the country in question and all the administration was approved and regulated by the "National Regulatory Agency" and "Competing Health Authorities". They also claimed that they had obtained ethics committee approval from four different ethics committees.

Despite repeated requests from us, the authors failed to provide documentation from the ethics committees or the National Regulatory Agency or to explain how they had obtained consent. They eventually did supply a document in Spanish purporting to be "approval from the National Regulatory Agency for the intervention that was granted after the analysis of proposals by ethic committee and meeting National Regulations from the Minister of Public Health". However, on translation by one of our Spanish speaking members of staff, it turned out to be a statement of their intention to obtain ethics approval and consent.

We contacted the CDC to enquire whether such an intervention was known to be in use in this country. We were told that they were not aware that this intervention is in use in any official capacity. We rejected the manuscript on ethical grounds explaining to the authors why we were not prepared to consider it. All authors are affiliated to a private institute. The last author is its founder.

We would welcome advice from the committee on whether and how we should take this further, given the scale of the study and the conflicting statements of the authors and the CDC.

09-25 Ethics committee waivers consent for case report, editor disagrees (JP)

The authors wish to publish a case report that aims to characterise complex chromosomal abnormalities in a rare congenital syndrome. It describes, in detail, the clinical features of two newborn infants. When asked about consent to publish, the authors said they did not obtain it because the data were reported from existing clinical diagnostic test results and therefore did not constitute a systematic investigation and that no identifiable information was included in the manuscript.

The authors were told that consent was still needed and that they should attempt to obtain it from the children's parents or next of kin. The authors said that it would not be possible to obtain consent from the parents since the mother of one child was now deceased and the other was lost to follow-up, but that they would attempt to obtain a waiver from their IRB. They provided a copy of an IRB approval letter with no specific mention of waiver of consent, but they did provide a copy of the application form which included a section where they provided a justification for not obtaining consent. The justification was that they were unable to obtain consent from the mothers and that the data they analysed was pre-existing clinical information and that no photographs or identifiable information would be published.

The authors feel that they have addressed the question of consent to publish and that their manuscript should proceed to publication. Despite the waiver from the ethics committee, one of the editors-in-chief feels that although consent would be burdensome to obtain, the study does not meet the other criteria set out by COPE to justify a waiver of consent: i.e. that the report is important to public health (or is in some other way important), and a reasonable patient would be unlikely to object to publication. Does the committee agree that an IRB waiver for consent for this study does not justify publication?

09-26 Publisher and stakeholder with misaligned conflict of interest policies (WK)

We have recently developed and begun to put into practice a policy on collection and declaration of conflicts of interest statements from any individual involved in contributing to or reviewing our pathways. This policy includes members of our editorial team, and contributor and reviewer members from our stakeholder groups. We have devised a standard form to collect these statements in a uniform way, and publish the declarations of interest from all contributors (both inhouse and external), but collect and do not make public those of peer reviewers.

Stakeholder group A, who provides clinical contributors and peer reviewers for some of our pathways, has a pre-existing declaration of interest policy for any review committee member performing work on behalf of the group which does not align with our own. Stakeholder A's review committees undertake a number of functions for the group themselves; review of our pathways is an additional role they have taken on over the past 18 months. They collect the statements on a voluntary basis annually (or as new committee members join) and it is their current policy not to share those declarations with any outside group. The stakeholder group has suggested that it would be willing to sign an annual declaration to confirm that their committee members do not have any conflicts of interest.

However, we have requested that if an allegation of conflict of interest is raised with us, we require a process to ensure that the group's committee make the individual members' names and declarations available to us. We await the stakeholder's views on this proposal, but would welcome COPE's views:

- Is it sufficient to collect a statement from the group to say that they have reviewed all of the individual statements for the committee members and determined that there is no troubling statement?
- Is it reasonable to request a change in the stakeholder's policy to ensure our access to the detail of the committee members' individual statements in case of any allegation of conflict of interest?

09-27 Sections of plagiarised text in an e-publication (GW)

An article was published online (e-pub), and a reader notified the editor about a section of the abstract that was taken from a review article published in another journal by different authors. Subsequent analysis of the e-pub manuscript found sections plagiarised from additional articles, often with citations but not quotation marks. Some sections were from manuscripts previously published by the authors in question.

At least seven articles were used to compile the entire manuscript: one for the abstract, four for the introduction, one for the results and one for the discussion. Overall the data look original but sections of the text are obviously not and have been in the literature for at least 13 years (1996). The authors have not been contacted to date.

The COPE options for plagiarism are retraction and public admission. The grey area is how to treat the situation as the science does not appear to be flawed, only how it is presented as the big picture. While the case clearly involves plagiarism (true plagiarism, self-plagiarism and unquoted use of text), there is no way to ensure the science is fairly presented while the authors are reprimanded. Accepting current e-publication status and future print publication of this manuscript as is, inadvertently declares that the publishing journal accepts partially plagiarised work; retraction limits the release of original science.

09-28 Deception in submitting manuscript for publication (EC)

A manuscript was submitted to my journal. The author, on his own accord, submitted the manuscript for review to several reviewers under the guise that this was sent by me. The author sent the following explanation:

"In some of our previous encounters, you have indicated that finding sufficient cooperative reviewers has been a problem for you. In order to provide you with some help in this area, I have invented an ad hoc entity, 'Nominated Reviewer Referral Service', under which aegis 'blind' emails were sent to an assortment of academics and journalists, advising them that they had been 'nominated' to provide a brief review and evaluation of the paper, which I attached. I did not identify myself as the author or give any kind of a 'sales pitch', nor did I try to give the impression that you had anything to do with the sending of these emails, or were even aware of them. If any of these people choose to respond, it will be directly to you, and I will never see the responses unless you at some point forward them to me."

I did hear from several people with the assumption that I had invited them to review the manuscript. I understand that I could ignore these reviews. However, I wonder what I can do with a manuscript that has been submitted under these circumstances. What is the best ethical course of action?

09-29 Falsification of certificates of deposit of new bacterial species in culture collections (RD)

The process of naming and describing novel species of bacteria is governed by the Bacteriological Code. As part of this process, authors are required to deposit the type strain of the novel species in at least two culture collections located in different countries, and they are also required to provide documentary evidence that the strains have been so deposited and that the deposited strains are viable and are available to other researchers without restrictions on their use for taxonomic research. This evidence takes the form of a "certificate" issued by the culture collection. This system has been developed to ensure that type strains are available for comparison with new strains isolated in the future, and to insure against collections going out of existence and/or changes in import/export regulations, etc. The priority of names is determined by the date of publication; in our journal, which is the journal of record for the description of novel species of prokaryotes, the date of publication reflects the date of acceptance (ie, papers are published in the strict order that they are accepted). Papers are not accepted for publication before suitable certificates have been provided for the type strains of any novel species described.

A culture collection curator contacted the editor-in-chief of our journal because of concerns about three type strains that had been deposited in their collection by the same group of researchers. Investigation by editorial office staff suggested that the certificates that had been provided by the authors (which took the form of unprotected Word files) might not have been issued by the culture collection concerned. The editorial office staff then undertook an investigation of the certificates from this collection provided in conjunction with all papers submitted by this group and asked the collection to confirm: (i) the specific curator responsible for handling that strain, (ii) whether they had issued a certificate for that strain and (iii), if so, the date on which the certificate was issued. This investigation suggested that a total of six certificates provided by this group had not been issued by the collection. All six were apparently signed by the same curator (who had not in fact been responsible for handling three of the strains, hence the original suspicion).

Following the COPE guidelines for suspicions of fabricated data, as the closest match to this situation, the editor-in-chief contacted the corresponding author of these papers and asked for an explanation. It then transpired that the curator had already contacted the corresponding author to request that this group stop "misusing her signature", as she put it. The corresponding author was extremely apologetic and assured the editor-in-chief that this would not happen again. He also indicated that one of his co-authors had been responsible for obtaining certificates for these strains but that this co-author had since left his laboratory and returned to his native country. He provided a contact address for this co-author.

The editor-in-chief contacted this co-author and he admitted that he had produced the forged certificates in an attempt to expedite publication, and thereby secure priority for the names, without the knowledge of the corresponding author or his other co-authors. Again he was extremely apologetic and assured the editor-in-chief that this would not happen again.

Because bona fide evidence has therefore not been provided that these type strains have been deposited in two culture collections in different countries, the descriptions do not fulfil the

requirements of the Bacteriological Code and the editor-in-chief took the following decisions: (i) a single paper that has been published in print will be retracted and (ii) four papers that have been published ahead of print but not in print will also be retracted in print, as these papers are already listed by PubMed. A sixth paper that was still under review was withdrawn by the corresponding author at the suggestion of the editor-in-chief.

A retraction statement has been drawn up after consulting the unpublished COPE guidelines on retractions and the wording has been agreed by the corresponding author and the co-author responsible for the forged certificates. The statement indicates that a certificate was provided by the named responsible author, without the knowledge of his co-authors, that was not issued by the culture collection concerned. These retractions have not yet been published.

As yet we have not contacted any of the authors' institutions. Our preferred course of action is to contact only the institution where the responsible author is now based. The remaining authors are based in a country where scientific misconduct is a very sensitive issue and we are concerned to avoid damage to the reputations of those co-authors who were not aware of the falsification. The editor-in-chief is also considering writing an editorial to highlight this issue and to ask other collections to take steps to prevent their certificates from being similarly manipulated. We would like the advice of the committee as to the merits of this course of action.

UPDATES

08-15 How many "mistakes" are too many?

Background

We published a randomised trial by six authors. Some years later, we received a letter from a researcher who had been looking into the trial in the context of a meta-analysis. She noted "implausibilities of serious concern", including "a highly unusual balance in the distribution of baseline characteristics", 95% CIs that were non-symmetrical about the effect estimate, and use of a stratification variable the value of which could not have been known in all patients if the trial was conducted in the way reported.

We asked the corresponding author to write a letter of response, which he eventually supplied a few months later. Owing to the author's poor English and the level of statistical knowledge needed to assess the response, we sent the exchange of letters to a statistical reviewer. The reviewer said that the letter of concern was "completely correct" in everything it said and that the author's explanation for the unusual degree of balance in the covariates was "rubbish", and that the 95% CIs had either been "doctored" or "incompetently estimated".

In the meantime, an exchange of to-and-fro letters between a different researcher and the same author was published in another journal, relating to a paper reporting on a subset of the same trial data. We were alerted to this by the editor of that journal.

We sent the reviewer's remarks to the author of our trial, who then consulted two independent statisticians of his own. He soon contacted us to say that, "surprisingly and regretfully", these statisticians agreed that there were implausibilities and inconsistencies in the data, and asked for more time to investigate more fully. During this time, the author of the letter expressed concern that we had not made the possibility of these problems know to our readership, so we published her letter.

The author has now sent us a more comprehensive response, admitting that the randomisation process was not as described, the 95% CIs were all wrong (he supplied a recalculation), and the trial report had omitted some details of the protocol necessary for understanding it properly (now supplied). Our reviewer suspects that, given his free admission of all this, the author is probably incompetent rather than fraudulent, but that the extent of the incompetence could not give us confidence in any of the data. What now?

Advice

The Forum agreed with the editor's opinion that the author is probably incompetent rather than fraudulent and should be given the opportunity to redeem himself. It was suggested that perhaps the paper should be submitted for review again. The Forum noted that this was probably a good internal learning exercise in that the statistical errors should have been picked up when the statistical review of the data was performed by the journal. A suggestion was made for the journal to set up a "sin bin". Some journals operate a "sin bin" or "publication review committee" where once a year papers which readers or others have expressed serious doubts about post-publication are reviewed to determine whether or not it was "a mistake" to publish the paper.

However, some members of the Forum argued for stronger action and suggested contacting the author's institution. But most agreed that the paper should be retracted as the research may be unethical.

Follow-up

August 2008
We have managed to find details of whom to contact regarding informing the author's institution, and the deputy editor has written to him. We await a reply with anticipation.

May 2009
The institute has responded to say that an investigation is under way and will take another couple of months to conclude.

November 2009
Following an internal investigation by the author's institution, a number of serious problems were encountered, including: lack of ethics approval, lack of written consent, lack of treatment-allocation concealment and an inability to verify the authenticity of the data. We therefore retracted the paper on 10 October.

08-24 A breach of intellectual property rights?

Background
We recently published article A by author group X on our website ahead of print publication and subsequently received a formal complaint from author group Y alleging that the paper constitutes a breach of their intellectual property rights.

Group Y state that the described work is based on a jointly developed concept, initially resulting in a joint report (published 2004). In their view, article A therefore contains their intellectual property, which is documented by frequent email exchanges, delivery of all relevant reagents and two visits by the senior author in group X to group Y's laboratory.

Group Y further state that there has been a previous unauthorised publication of a report that also contained their unacknowledged input (intellectual input and reagents), resulting in group Y prohibiting any further publication on the same topic by group X without their authorisation (!?).

In article A, the authors state that they used commercial reagents, although group Y allege that their reagents were available to group X at this time. Group Y are seeking what they perceive to be correct acknowledgement for their contribution, and there is an ongoing legal dispute, which they are threatening to expand to include article A unless a suitable solution is found.

We approached group Y to clarify if they thought they should be acknowledged on the paper, or even included as authors, but they did not answer, as they believe that group X should be asked to clarify their position.

We approached group X for their response to these allegations. Group X maintain that their collaboration with group Y was their idea, as an obvious extension to their previous clinical publications. Group Y are chemists and had not published on any clinical topic prior to the collaboration with group X. Group X state that the collaboration came to an end in 2006 when the senior collaborator in group Y demanded that either s/he should be named as the last author or one of the junior members of group Y named as first author on any manuscript resulting from the collaboration. Group X considered this to be unreasonable and continued their studies using commercial reagents.

The editors of the journal in question believe group X's response to be appropriate and complete, and find no grounds for taking group Y's complaint any further. The editors would like to proceed with print publication of article A.

Is proceeding with publication at this stage appropriate? The editors are concerned about the threat of legal proceedings, so should they therefore be more cautious in accepting one version of events above another—do they need to request "proof" and, if so, what would this proof consist of? The Forum's advice on the next steps that they should take would be appreciated.

Advice
The Forum agreed that the paper should be considered published. It is irrelevant whether this is online or in print. Although one suggestion was to let group Y have their say, perhaps in a letter to the editor, others cautioned against this approach in the light of unresolved legal issues. If legal proceedings are threatened, the editor should withdraw from the dispute and not investigate the matter further. The response from group X could be shared with group Y only after explicit consent from group X. The advice of the Forum was to go ahead with the print publication of the paper but the editor should not get involved in correspondence between the two groups and should seek legal advice.

Follow-up
The Editor took COPE's advice and no further action resulted. The editor considers the case now closed.

09-08 Has formal ethical approval been granted that satisfies publication criteria?

Background
The issue here is whether formal ethics approval has been granted in order to satisfy publication criteria. By way of some background information, a lot of screening data are collected on many athletes in many sports, both nationally and internationally. Historically, clubs and associations have disclaimers whereby athletes sign consent for their data to be used for audit purposes on the proviso they will not be identified individually. This study appears to do exactly that, except that this is not a retrospective audit, this is an interventional study whereby these players have been subjected to a specific regimen.

In my opinion, there are several issues here.
(A) A blanket proforma that these players were asked to sign does not constitute formal ethics

approval for this interventional study.
(B) These players are under age and therefore warrant additional protection.
(C) These players are vying for selection and there is no obvious protection from them being coerced into participation

Whilst new training regimens are being introduced into clubs all the time, if the findings are intended to be disseminated through formal publication, then ethics approval should be sought beforehand. I would be very grateful for the Forum's opinion on this matter.

Advice
The Forum was concerned that the volunteers involved were under age and so coercion may have been a problem. The Forum were unanimous in their view that ethics approval and informed consent should have been sought specifically for the study and that the study should not be published without these. The authors may also have contravened the Declaration of Helsinki, which covers all human trials. The Forum agreed that blanket consent is not sufficient and that the specific treatment needs to be detailed and consent obtained from individual subjects. The ICJME guidelines state that procedures followed should be approved by an ethics committee and be in line with the Helsinki Declaration. There is also a European directive on obtaining ethics approval and informed consent. A suggestion was for the editor to write an editorial in their journal highlighting this problem in general.

Follow-up
The editor wrote to the authors conveying the decision of COPE and they responded that they did after all have approval. The editor requested to see this approval and it was dated after the study had been completed. The editor then wrote to the authors explaining in no uncertain terms that retrospective approval was not acceptable and that he was extremely concerned that throughout the submission process they had failed to demonstrate any insight into research governance. The editor suggested lessons to be drawn for the future and rejected the paper.

09-09 Authors bearing gifts …

Background
The editor of an international journal is bothered: he has received a gift that looks expensive, though it might not be.

The sender is an author of a paper submitted to the journal; he has just received a "major revisions necessary" decision. In previous emails, the author has suggested hosting the editor in "his native beautiful city", an invitation the editor has acknowledged, saying he had already visited the city, and it was indeed beautiful! The author identified himself as a student in further emails, thanking the editor in flattering tones for the reviews.

The editor needs of course to acknowledge the gift (no letter was included), or perhaps to return it, but feels very uncomfortable with the situation. The possibilities for this gift range from an innocent gesture of a proud citizen, to one expecting something in return.

The publisher's code of ethics and business conduct does cover this subject, but its provisions apply to the publisher's employees, officers and directors, and not to its editors.

The editor therefore asks his publisher, and through him, COPE, for comments, advice and guidance.

Advice
There was general agreement from the Forum that the author should return the gift with a polite note. Although there are no general rules on the acceptance of gifts, some believe that the apparent value of the gift should be considered and whether or not it would be deeply offensive to return it. Often there are cultural issues and the editor should avoid causing offence. However, in this instance, all agreed that it would be wrong to accept any gift while a paper is still in the process of being reviewed. One option would be for the editor to say that his company has a policy that he would have to declare a conflict of interest at the bottom of the paper if he accepted the gift so he thinks it is better to return it.

Follow-up
The editor concurred with the Forum's recommendation, and felt that while returning the gift after an unavoidable delay might lead to offence, the guidance would be invaluable for any future occurrences.

09-10 Concern about reporting of a trial and also its DSMB

Background
We received a paper reporting a trial. There has only been one previous trial of this intervention in this condition that we know of (which was also done by these investigators). There were substantial issues with the reporting of that trial but the end result, as reported by them, favoured the intervention.

The trial we received, presumably approved after that result had come out, had the complication that most patients also received another treatment, and on an intention to treat (ITT) analysis of all patients, those given the intervention did no better and there was increased mortality in the intervention arm. The only positive outcome was from a per-protocol subgroup analysis of patients who did not have the other treatment (which they say is the only group comparable to the previous trial, and hence shows that the first trial was correct).

Although the trial was investigator led, it seemed to us that the authors were trying very hard to make something positive out of this actually rather worrying result. We sent the paper for review, including to a statistician; the reviewers raised a number of issues about the interpretation (eg, the overemphasis on subgroup analysis) and the analysis and reporting.

We felt that this was an important trial that needed to be reported, mainly because of the excess mortality in the intervention arm, but we had the rather odd situation that the authors wanted to emphasise the positive, and the need for further trials of this intervention, whereas the

reviewers and editors saw the paper as delivering a negative message and feel actually that the paper will be the death knell for this treatment.

We therefore rejected the paper but offered to see a revised version if it was written more in line with our concerns.

The authors revised and the paper was re-reviewed. The paper was felt to be more balanced, but not yet completely satisfactory (ie, there was still too much emphasis on the positive result in one subgroup and not enough on the mortality).

A further issue then arose in that a reviewer spotted (on re-review) that three of the authors were noted as being on the DSMB for this trial. In their author contributions all are listed as having been involved in "analysing the data" and one, X, as "supervising the statistical analysis"

We asked the authors about these points and they replied:
"(1) We are fully aware that it is unusual for members of the DSMB to be listed as authors, as independence is obviously important for such boards. In our case, the DSMB's independence was not affected for the following reasons:

(a) Members of the DSMB worked for the entire study period (ie, between 2003 and 2008) completely independent and without any promises or expectation that they would be credited later by a coauthorship.

(b) My personal decision to include three of the four DSMB members in the list of authors was made a significant time after the final database lock. This decision was long after completion of the clinical study and its analysis. It credited three members of the board who made some significant advisory contributions to the present manuscript. Only for this reason they were included as coauthors, and it was quite unexpected for them. This decision from December 2008 has in no way influenced their independence and objectivity at the time when the study was running.

(2) As to the contribution of X (one of the members of the DSMB), we have to admit a simple language problem. In our use of the word "supervision", the word meant that he took a final comprehensive look at our data analysis before the paper was submitted for publication. Importantly, he never supervised (like an academic supervisor) data analysis at any time point before database lock and processing of the data by the clinical research organization. We will change the terminology accordingly."

We subsequently found that X was also an author on the previous trial.

Finally, the authors did not declare initially any competing interest but after we enquired specifically, they declared that the corresponding author "holds a patent on the use of t[he intervention] for treatment of [the condition]".

Our concerns overall therefore were that this paper not only reports the outcomes in a way that is not appropriate, but also the composition of the DSMB and the presence of some DSMB members as authors means that the trial may not have had adequate independent oversight.

We felt we had two possible options with regard to publication:

(1) We reject the paper because it was inappropriately conducted and not appropriately reported.

(2) We publish the trial after further revision to ensure it is reported appropriately and publish alongside it an editorial that lays out our concerns with the conduct of the trial, but notwithstanding those, our reasons why we think it should be published.

We also discussed whether we needed to raise the issue of the DSMB with the authors' institution.

We discussed the paper with our internal ethics board and they unanimously agreed we should reject the paper (mainly because of the concerns over the DSMB) and inform the authors' institution. We have as yet heard nothing from the institution.

We are bringing this to COPE as this paper raised a number of serious issues we had not come across before. We would appreciate the Forum's opinion on whether we handled this correctly.

Advice
Some of the members of the Forum suggested that perhaps the journal should have a formal policy that DSMBs should be independent and not involved in the study in any way. The Forum questioned whether these authors fulfil the criteria for authorship, as outlined in the ICJME guidelines. One opinion was that perhaps the paper should not have been rejected until the outcome of the investigation was known. However, most agreed that rejecting the paper was the correct decision and the editor might consider contacting the ethics committee who approved the study if no response is received from the authors' institution.

Follow-up
The editor reported the case to the author's institution but no response has been obtained. The editor is pursuing the case.

09-15 Duplicate submission

Background
We received a manuscript for consideration. The manuscript was assigned to one of our section editors who sent it for review. Subsequently, the editor-in-chief received an invitation from another journal to review the same paper. The editor-in-chief recognised the paper straightaway, declined the invitation to review and alerted the editor-in-chief of the second journal of the duplicate submission.

We subsequently emailed the authors of the paper asking for an explanation, especially considering they had confirmed at the time of submission that their manuscript was not under consideration in any other journal. The authors withdrew their paper from the second journal and responded to us by saying that they were very sorry for their "low-level error" in submission and apologised for the occurrence of duplicate submission. The corresponding author claimed that he had entrusted one of the authors to submit it to our journal. Then the corresponding author was away with no telephone access and on his return he found that the paper had been submitted to two journals. He went on to say that his colleagues have access to his e-mail account and so they used his email account to submit to the different journals but he had no knowledge of this. The corresponding author also stated that because the original idea was to submit the paper to our journal, he had revoked the submission from the second journal and apologised to the editor. He hoped that we would still consider his submission. He agreed to standardise the management of submissions and correspondence between his colleagues so that this would not happen in the future.

We are unsure as to how to proceed. If we go ahead with the review of the manuscript, this sends a message to the authors that there are no consequences for their misconduct (whether or not it was an honest mistake). Therefore, we would like to have COPE's advice on the best course of action. We have put review of the paper on hold.

Advice
There was conflicting advice from the Forum. Some suggested rejecting the paper, while others thought it was more appropriate to write a firm letter to the authors explaining that their behaviour was unacceptable. If the author is very junior then sometimes this behaviour is excusable based on inexperience. However, this was not the case in this instance. Some questioned whether the instructions to authors in the editor's journal make it clear that papers should only be submitted to one journal. Most agreed that a firm letter to the authors and a letter to journal B would be sufficient. The letter to the authors should state that this behaviour is not acceptable and will not be tolerated in the future. It was also suggested copying the letter to the dean of the author's institution so that the institution could put in place guidelines on submission of papers so that this does not occur again.

Follow-up
The editor continued with the review of the paper and sent the authors a firm letter (copying in the editor-in-chief of journal B and the head of the authors' institution) stating that their behaviour was unacceptable and will not be accepted in future. In the meantime, the manuscript has been reviewed, and the editor recommended it be revised. The authors have now submitted a revised version which is still under review

09-17 Pedigree descriptions: genotyping results for family members

Background
We received a paper which describes genotyping results from a large number of individuals (>50) from five unrelated families, in which family members had various blood and liver conditions. On submission we noted that the paper included specific details regarding the

clinical histories of individuals in each family. Some individuals were described in substantial detail, others only briefly. For example, information about probands included age at presentation, sex, ethnicity, clinical history, occupation, clinical complications (some quite specific), clinic attended (for some individuals), history of alcohol consumption, ages of relatives, clinical details for relatives, age at death etc.

Genotyping results were given for specific individuals. Some individuals are described as still alive, some deceased. We felt that the paper fell under the journal's privacy policy and that we would need to know before going further that all living individuals described have seen a copy of the paper and consented to publication. The journal has a consent form for this purpose but we do not ask to see the patient's signatures (instead just requiring the authors to obtain consent, file the form in patient records and update the paper to state that consent to publication has been obtained).

The authors responded that when initially obtaining consent to the research project, patients consented that "[t]he results from studies on the research samples may be published, but individual patients will not be identified in the publications". They claim that details included are not identifying, and that it would be impractical now to trace all living relatives. They asked whether our consent form has been approved by an IRB, and say that before using it they will need to have it reviewed by their IRB.

We are unsure how to proceed but feel that when consenting to the research project the individuals may not have realised they would have been described to this level of detail, and that we should respect their privacy. One option might be to ensure the authors seek consent to publication from all probands, but then remove extraneous detail regarding the relatives. However, it is possible that the IRB may have useful input regarding the publication of individuals' details from this study.

Advice

The editor was asked if the personal information was essential to the study. If it were deleted, would the paper still have value? The editor confirmed that the information was crucial to the study and could not be deleted. All agreed that the editor needs to weigh up the need to publish against any harm that might be caused by publication. Most believed that the harm involved was probably quite severe and so outweighs the need to publish. One test that can be applied is to consider whether an investigative journalist would be able to identify the patients from the study (in this case, most Forum members felt that they could, therefore the risk of identification is high). The Forum did not believe it was that impractical for the authors to obtain consent and so they thought it was reasonable to ask the authors again to obtain consent. Did the authors make it clear to the patients how much detail and history would be published? Also, some noted that with pedigree studies, it can be very easy to identify patients. As with all such cases, the editor needs to make a judgement concerning the harm that might be caused to the patients in publishing and the benefits of publishing. Most believed that the risk of identification was high and that the editor should not publish without consent. The advice was to go back to the authors and ask them to obtain consent. COPE was asked about whether it could produce a generic consent form for all journals (to avoid problems of having to use multiple forms if a manuscript is reject by one journal and submitted to another). COPE Council agreed to consider this suggestion.

Follow-up
The editor informed the authors that the case had been taken to COPE, and the agreement of those who attended was that patients and family members would need to give consent to publication of the case(s) having read the paper. The authors went away for many weeks, and then responded to say they had traced the patients and obtained consent to publication. They updated their paper to state this in the revised text, and also updated the text to minimise some details of family members, and to state that details were minimised to maintain anonymity but that further clinical details could be made available to other researchers on request.

09-19 Provenance of a correction: undisclosed court case involvement

Background
The first author of a paper published in 2004 has submitted a "letter to the editor" (LTTE) offering some corrections, and reaffirming some conclusions. The letter has not been published. A pharma company (whose drug is linked by the paper to a negative side effect) has followed this up claiming that between authoring the original article and the letter, the author has become a paid expert witness in a trial relating to the drug in question (the LTTE was shown to the drug company's counsel during the trial). The LTTE does not mention this. The drug company also claims that the letter's corrections are based on its work and cross examination in court (again not stated in the LTTE). It also claims the author does not disclose or correct all the errors and downplays others. The company says its claims are backed up by the original study's source data, currently embargoed by the author's institution under a court confidentiality order.

Conflict of interest seems open-and-shut. However, a further question seems to be: can/should anything be done before the drug company is able to supply the original source data to the editors? And what if the source data remain embargoed?

Advice
The Forum thought that this was a major conflict of interest and found it difficult to believe that it was an oversight. All agreed that there is little that the editor can do while the court case is ongoing. It was suggested that the editor could consult the flowchart "What to do if a reviewer suspects undisclosed conflict of interest (CoI) in a submitted manuscript". The editor should point out the seriousness of the CoI to the author. The editor cannot proceed with publication. It was suggested that the editor should make sure that he is not giving in to commercial pressure by not publishing the paper – there were concerns that the author was deliberately trying to influence the court case by publishing the additional data. The harm of not publishing was considered to be minimal. The consensus was that the editor should not publish the letter. It was suggested that the editor should inform the author that he will not publish the letter but if the author has new data, he should submit this in a new paper.

Follow-up
The paper was returned to the authors and will not be published.