



Forum agenda

**Meeting to be held on Wednesday 2 September 2009 at 3pm
Boardroom, Woburn House, 20 Tavistock Square, London WC1H 9HQ**

Agenda

1. Update on COPE activities by the Chair

2. New cases

09-15 Duplicate submission (LB)

09-16 Ethics and consent in research (ER)

09-17 Pedigree descriptions: genotyping results for family members (EV)

09-18 Editor disregards confidentiality and critical remarks (LW)

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

09-20 Alleged unauthorised use of data: possible dual publication (AB)

4. Updates

08-03 Randomisation and ethics of pilot trials (DMN)

**09-05 Suspected contact between reviewer and an author led to coauthorship
of the reviewer (PW)**

09-07 Duplicate publication or salami publication? (AM)

NEW CASES

09-15 Duplicate submission (LB)

We received a manuscript for consideration. The manuscript was assigned to one of our section editors who subsequently 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.

09-16 Ethics and consent in research (ER)

A letter was sent to the chief editor of our journal in response to a recently published article in our journal. The author had serious concerns about the ethics and consent obtained as a result of this study and the follow-up by the researchers.

The author explained that he was the physician of two of the “volunteers” who participated in this study and was concerned about informed consent procedures in the trial. Specifically, workers never provided informed consent that their tests, mandated by a company medical monitoring program, be used in any “research” study.. His concerns were in four areas.

- (1) The researchers failed to inform both the company and the injured workers that they should have been removed from further exposures when their test results showed severe impairment.
- (2) The researchers failed to report abnormal findings to the workers in a timely and appropriate manner, a failure that placed these workers’ health in jeopardy.
- (3) The researchers failed to fully inform the workers of the known risks of exposure.
- (4) The timing and location that the researchers used to obtain signatures on the informed consent forms did not permit the workers to adequately question the researchers and become informed.

One of the author’s patients who was studied was a previously (pre-employment) healthy 40-year-old woman who was found after a period of time at work to have abnormal results. However, no doctor contacted her to explain the results and written communication did not describe them as serious, and so she did not seek further medical attention. Her tests were repeated again one and two years later. The two year test indicated more severe disease. These findings were reported to her 10 months later by one of the researchers who failed to mention their significance in his cover letter to the radiologist’s report. Given the patient’s history, she should have been removed from work immediately, and the researchers should have reported this case of occupational disease to the state authorities. The following year, she sought care from a non-corporate physician and was removed from work the same day.

Another patient of the author’s had abnormal test results in 2005, which were markedly worse on repeat tests conducted in the same year. The researchers wrote to her in September of 2005 and advised her to have a CT scan and repeat testing. A year later, a member of the researcher’s group ordered a CAT scan. In November 2006, the CAT scan revealed moderately severe disease. The patient requested that these results be forwarded to her personal physician. At the time of the author’s first visit with her in late August 2008, she had never seen the results, and neither the company nor the researchers had communicated with her about her condition or continued occupational risk. The author requested that the researchers send him her complete medical records, including communications with the company and the research protocol. However, only incomplete records were sent, omitting the research protocol and including none of the communications with the company.

In October 2008, the author wrote to the IRB Director and filed a formal complaint concerning these matters informing them that one of the researchers was both a paid consultant advising on occupational health procedures while simultaneously conducting the research/monitoring program. This researcher based his published paper on a mandated monitoring program in which the “volunteer” workers had to participate as a “condition of work” in order to keep their jobs. The “research” was based on test results for which full consent had not been obtained.

The Director of the Office of Research Compliance and Regulatory Affairs responded in February of 2009, stating that although the committee's investigation determined that "no misconduct occurred" with respect to any violation of IRB policies, their findings prompted them to institute "modifications to our processes that will help us to continue to raise that bar." The author concluded that "IRB protocol modifications" were based on an acknowledgment that the researcher's study violated patient rights, even if the study did not violate IRB rules. The author believes that journal editors have a responsibility to investigate allegations like these.

09-17 Pedigree descriptions: genotyping results for family members (EV)

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.

09-18 Is it a breach of confidentiality to send letters to the editor to criticised authors for comment?

(presented by Liz Wager on behalf of an author)

NB: COPE doesn't normally discuss cases from non-members but as this raised some interesting general points, we thought it would be interesting to hear Forum's views)

According to the COPE guidelines, editors should “ensure the quality of published material... publish cogent criticisms from readers... [and] ensure research articles conform to ethical guidelines”. Yet, editors enjoy an (almost) absolute power and are barely accountable. I describe here how a Letter to the Editor submitted by myself to a COPE member journal was rejected only after it was forwarded by the editor to the concerned authors purportedly to get a reply.

In that letter, I pointed out the omission of a relevant reference which I considered was deliberate. I was also concerned that the article represented duplicate publication (which was supported by evidence from Déjà Vu)

I submitted the letter to the editor in December 2008. One month later, I got a rejection letter in which the editor-in-chief expressed his reluctance to expose “not strictly scientific aspects”. I immediately appealed this decision only to get the rejection confirmed in April 2009 on the basis of the explanations offered to the editor by the concerned authors. Thus the editor seems to have violated the confidentiality of my unpublished letter in forwarding it to the authors only to ultimately reject it.

My question to COPE is, should editors treat submitted material as confidential, or is it acceptable for them to show it to the authors of the work criticised, even if they have no intention of publishing it?

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

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?

09-20 Alleged unauthorised use of data and possible dual publication (AB)

During review of a manuscript submitted to our journal, a dispute arose over some of the data used in the database that was described in the submitted paper.

The authors listed several preferred reviewers and also one non-preferred reviewer (without giving reasons). The journal's submission site states that the editors will consider the authors' preferred suggestions but are under no obligation to use any or all of them and that the editors reserve the right to approach non-preferred referees. Authors are asked to outline in their comments to the editor any particular reasons for requesting exclusion.

The paper was initially positively reviewed by two referees, one of them a preferred referee, and minor revision was requested. Neither of the initial referees responded to the invitation to review the revision (they neither declined, nor agreed, just did not respond) and as the senior author had already published with virtually all important scientists in this small field, the associate editor decided to invite the non-preferred reviewer. The non-preferred reviewer and one new reviewer agreed to review.

Shortly after accepting, the non-preferred reviewer emailed the editorial office asking whether it was journal policy to publish a reference to a database without any scientific study based on these data (the journal answered yes, citing a previously published database description) and stating "I discovered by examining this database that the senior author has used my data without permission. This applies to hundreds of measurements in country 1 and in the mountains, but also to data from country 2".

The authors state on the database website that the database contains *published* data and in the manuscript that the "measurements in the database have been collected over the last 20 years from various sites around the world (references given) and are included with permission from the collectors". The journal informed the non-preferred reviewer that, from what the authors were stating, all data seemed to be in the public domain, but advised him to put his concerns into his review or contact the authors directly, if the reviewer preferred.

By the time the reviewer received this reply he had already submitted his review and informed the journal that he also sent his full review to the senior author. The reviewer also pointed out in an email to the editorial office that the measurements published in one of the cited studies (of which the referee was the senior author) were not published in the form as they appear now in the database, and then accused the senior author of having used information which he collected as a member of the reviewer's research group a long time ago, and publishing it without the reviewer's permission. The reviewer thought that the reference to the paper was not sufficient and also stated that the conditions with the mountain data were more serious.

In the review, the referee pointed out three problems:

(1) unethical behaviour on the part of the senior author. The reviewer stated that he could not remember having given permission to use the data, but had specifically asked the senior author not to use the mountain data for anything until the reviewer had finished his analysis. He included the original email in the review.

(2) potential dual publication. The reviewer stated that because no analysis of the data was presented in the paper, a simple report on the existence of the database was not suitable for

publication in a journal and went on to point out that a first version of this database was already published (as cited on the database website, but not in the paper) as a preprint article. As a comparison of the two manuscripts did not reveal any obvious differences in content, the reviewer questioned whether this constituted dual publication.

(3) questions over the use of a particular method. The reviewer called the use of this method “scientifically unacceptable”, stating that the problems with this method have been published and concluding that it was unacceptable for the senior author to ignore these arguments (this was not mentioned by any of the other reviewers).

Checking the date of the above mentioned email and the publication date of the preprint article, the journal realised that the reviewer emailed the senior author shortly after the document was posted online. The dispute had thus been going on for over a year by the time the referee was invited to review, but the reviewer had not declared a conflict of interest.

The associate editor, having read both reviews (the second being positive), recommended rejecting the manuscript and inviting a resubmission once the authors either were able to present the permit obtained from the non-preferred reviewer or removed all unpublished data for which no data were available.

In the meantime (and before any action was taken), the senior author, prompted by the reviewer’s email to him, emailed the managing editor and the associate editor, informing them that the non-preferred reviewer used to be the senior author’s PhD supervisor. The senior author rejected as incorrect any claims over the inappropriateness of the method and the statement that the reviewer had not given permission to use what the referee claimed were his data. As the review implies several forms of unethical behaviour on the senior author’s part, he felt the need to clarify.

(1) the criticised method has been used in top tier journals such as Science, Nature and PNAS and has therefore been through rigorous quality control. Since the reviewer’s evaluation of the method did not contain any concrete arguments, the senior author assumed that the reviewer was referring to a polemic about the method by another author, published in the same journal in which the senior author countered these arguments. The method continues to be the most widely used, cited over 90 times (the associate editor points out that it was cited mainly by the senior author’s main group, but that none of the other reviewers have criticised the method). The senior author further points out that this method is not the only one used in the database.

(2) re the inappropriate use of data from country 1, the senior author assures the journal that the referee had been asked and had given permission (an email was attached), but that if the referee wanted to retract the permission, the authors would remove the data in question. Re the data from the mountains and the email sent by the reviewer, the senior author claimed that the email had been taken out of context. The senior author had indeed asked the reviewer about the possibility to perform a separate analysis on the mountain data. According to the senior author it was this request about the separate analysis that the reviewer declined and the request had not referred to making publicly available the data that had already been published in one of the references.

(3) re dual publication, the senior author stated that a beta version of the manuscript, with a completely different code and user interface and only a very reduced set of data, was posted on a preprint server, not a regular journal publication (the associate editor saw no major changes in the number of data entries and that both discuss the database in a similar way, but thought that the submitted manuscript was more detailed than the earlier (preprint) article. Figures are not identical, but basically follow the same scheme. The associate editor left it up to the editor whether he considered a full-length paper that builds upon something that has been published on a preprint server as sufficiently novel).

The senior author finally adds that because of previous similar experiences, the authors had listed the reviewer as non-preferred.

The corresponding author emailed the editorial office offering to remove from the database any data that have been collected with the reviewer's participation but emphasised that by doing so, the authors do not acknowledge any form of wrongdoing on their part, but seek to make it easier for the journal to make a decision.

After discussions between the editors, the editorial office and the publisher, the decision was to reject the manuscript but to invite resubmission. The letter pointed out (a) the disputed use of data in the database; (b) the question of dual publication; and (c) the scientific criticisms expressed by both referees. It of course included both reviews in full.

Updates

08-03 Randomisation and ethics of pilot trials (DMN)

Background

We received a paper with potentially important results. After review and revision, we accepted the paper. On further reflection, and asking more of the authors, we became concerned. It is an RCT and the only protocol available was slim but appeared authentic. There were two protocols: one for a pilot trial and, if that was positive, a second protocol aimed to randomise more people. One residual concern was that there was an imbalance in the two randomised arms. The authors' statistical advisor has explained that such an imbalance, although large, is not necessarily unexpected when using older versions of random number allocation programs.

We present this case to the COPE Forum for discussion as we had not identified a numerical imbalance that might be unacceptable. We also ask for advice: since the pilot trial showed a significant difference ($p < 0.001$), might it be considered unethical to recruit many more participants before publishing? Furthermore, should the unpublished data from the pilot trial be included in the final analysis?

Discussion and advice

The Forum argued that this was probably more of a methodological problem than an ethical issue. All agreed that the authors have a responsibility to publish the data from the pilot study or, at the very least, the editor should request that the methods and results of the pilot study are included in the final report. The Forum suggested that perhaps the editor should question the value of publishing the study. If he believes it has value then he should publish it. Other suggestions were to consider writing a commentary on the paper raising these issues.

Update (June 2008)

We presented an accepted (but not published) paper where we had concerns about randomisation imbalance and about a pilot trial that had not been presented. COPE reassured us about imbalance and suggested we ask that the pilot trial data be included. We sent a list of our concerns to the authors. The authors' responses were far from reassuring and they refused to include any information from the pilot trial. We have now rejected the paper and have instituted an investigation of our concerns about the conduct of the trial.

Update (August 2008)

We rejected this paper after the authors refused to include the pilot data in the main paper and refused to give us more information on their mode of randomisation or the way they collected side effects. We then received a letter from a libel lawyer. However, our lawyers rebutted the case. We also contacted a government body overseeing drug licensing and trial conduct in this country as the study was done at a private institute where the corresponding author is the clinical director and his wife is the administrative director. Initially someone from that institute agreed to investigate but then the head of the institute and several others were charged with corruption. We have now contacted a further different overseeing institution but have not yet had any reply.

June 2009

After discussion of this case in 2008, our worries about the paper grew. We could not get direct answers from the author. However, we did find that the data in one of their tables which showed subgroups could not be transformed back to match their table of baseline data, and that the randomisation ratio in the subgroups in that table was highly statistically unlikely to have been obtained by proper randomisation. The authors admit that their computer program had small errors, but the ratios in the table were far too high or far too low in some subgroups. Even though we had accepted the paper, we decided to reverse our decision and we rejected it.

After rejection, we asked different groups in the authors' country to start an investigation; the author is at a private institution. One person did agree but all they did was look at the paper sent here. The short report sent back did not add anything to what we already knew.

The paper, as published in another journal, does not contain the subgroup table we saw. We are concerned because we know there is a mismatch between the table we saw and the baseline table, and also because of the apparent errors in the randomisation ratio in that table. We also have other questions about this study.

Do we have a duty to take this further? Should we contact the other journal's editor?

Discussion and advice (June 2009)

The Forum concluded that the editor had done everything in his power. He had previously set up an investigation and gone as far as he could. Some suggested that the editor should contact the other journal and say that he had concerns about the paper during the peer review process but others argued that in the absence of hard evidence there is little that the other editor can do. Most agreed that the editor had exhausted all avenues available to him.

Update (August 2009)

The editor agreed with COPE's conclusion that there was nothing more to be done. The editor considers the case now closed.

09-05 Suspected contact between reviewer and an author led to coauthorship of the reviewer

A manuscript was submitted via our electronic submission system and processed in accordance with the standard procedures of the journal. This was originally a single author submission, and in the covering letter the author suggested two potential reviewers.

The Associate Editor assigned reviewers, choosing reviewer A along the suggestions of the author, and reviewer B from his own list of reviewers.

The reviews of the original version came with conclusions "Accept after major revision" (rev A) and "Accept after minor revision" (rev B). On that basis, on 12 December 2008 the Associate Editor submitted a decision "Accept after major revision", and requested the author to prepare it within 90 days.

The revised version of the paper arrived on 20 December 2008. Without sending it to any more reviewers, the Associate Editor decided to recommend acceptance of the paper in its present form. According to the Journal's procedures, the manuscript is available to the editor-in-chief EIC for a final decision.

Examination of the revised manuscript led to a disturbing discovery. This version was headed by two authors, and the name of the second author was the same as the name of reviewer A.

The whole reviewing procedure was immediately halted. The editor-in-chief together with the Managing Editor sent an email to the original author with a request to confirm in writing the authorship of the revised version (this was done also because in the covering letter and in the revised version there were different sets of names). The author confirmed that the revised version was co-authored by two authors: he and reviewer A.

The conclusion of the editors was that indeed there was serious misconduct, most probably on the side of the reviewer. We can only speculate if there is misconduct on the side of the author or of both people together.

The author was asked by email to explain how the second author, reviewer A, had been included as a co-author of this contribution? The reply was that: "Reviewer A helped me improve the manuscript in grammatical and logical feature, and provided some new references. Furthermore, we share some detailed skills in the experimental methods, so I added him as a co-author in the revision paper."

This situation led the editor-in-chief to assign the paper to reviewer C to determine if the manuscript is indeed worth publishing. The final recommendation of that review was that the manuscript should be rejected.

The editor-in-chief is asking for COPE recommendation as to the further processing of this manuscript:

- The editor-in-chief is convinced that the paper should be rejected. However, should it be rejected on pure scientific or also ethics grounds?
- Should the authorities from the author's institution be informed?
- It seems that more obvious guilt is on the side of the reviewer A. Permanent removal from the journal's database seems to be an obvious decision. However, from other sources we also know that he is a member of editorial boards of other journals. Should we try to contact editors and inform them about the whole situation?
- This reviewer was also keen to become a member of our Editorial Board. This would of course be impossible in the present circumstances. However, should we try to inform the authorities of his institution about his serious misconduct?

Advice

The Forum wondered whether the editor has asked the reviewer for an explanation of his behaviour. Has he given his side of the story? The Forum noted that it is possible that the criteria for authorship might be satisfied by the reviewer. If the reviewer made a substantial contribution to the revised paper, he could legitimately become an author. So there may be a legitimate reason for the reviewer being an author and the editor needs to contact the reviewer

and clarify this. If the editor is satisfied that the reviewer is an author, the paper should be re-reviewed and sent out to a new reviewer. It may then be rejected on scientific grounds. The Forum did not think reporting the case to the institution was a good idea at the present time.

Follow-up

Following presentation of this case at COPE, we followed the advice of the Forum and contacted the reviewer with a kind request to explain his side of the story. At the same time, the manuscript was evaluated by an independent reviewer and the recommendation was to reject this submission.

When the explanation was received from the reviewer, it differed from that of the authors and thus we decided to reject the manuscript and not to undertake any further action against either of the persons involved.

The reviewer is still providing services to our journal and no further signs of misconduct have been observed. However, we have decided that we will not propose the reviewer to become one of the associate editors for the journal.

09-07 Duplicate publication or salami publication? (AM)

An author submitted an article to my journal. The editorial board discovered that the author had already published his article in another journal. The editorial board communicated with the author and he defended himself stating that they were two different articles with different titles. However, the editorial board could find no significant difference between the two papers.

There are two issues related to this article.

(1) The author did not notify us, prior to his submission to another journal.

(2) Almost all of the text is the same, indicating duplicate publication. Can this be taken as salami publication? How should we handle this issue?

Discussion and advice

The advice of the Forum was for the editor to assess the degree of overlap between the two papers. If the editor judges it to be major overlap, he should reject the paper. If it is minor overlap, the editor should contact the authors for an explanation. It was suggested that the editor could consult the “sample letters” on the COPE website which deal with “Overlap of figures or text with a manuscript submitted or published elsewhere”. There is also an issue of copyright, as the same figure appears in both papers. Hence the editor’s journal could be in breach of copyright if it published this paper. It is clear that the authors have not been transparent in their submission of the paper and some advised that the editor could report their behaviour to their institution. Ultimately, it is up to the editor to decide if the paper is sufficiently novel to warrant publication. How much extra value is there in the second paper?

Update

The editor rejected the paper.