



Forum agenda

**Meeting to be held on Tuesday 8 July 2014, 9–11am (British Summer Time)
BY WEBINAR**

1. Update on COPE activities by the Chair

2. Forum discussion topic: Fair play for “researchers”: can editors and regulators develop a common approach to the need (or lack of need) for ethical review?

<http://publicationethics.org/forum-discussion-topic-fair-play-%E2%80%9Cresearchers%E2%80%9D-can-editors-and-regulators-develop-common-approach>

3. New cases

- 14-04 A case with no independent institution to investigate (SH)**
- 14-05 Fraud or sloppiness in a submitted manuscript (CB)**
- 14-06 Possible breach of reviewer confidentiality (JM)**

4. Updates

- 13-03 Ethical concerns and the validity of documentation supplied by the authors**
- 13-05 Editor as author of a paper**
- 13-08 Unusually frequent submission of articles by a single author**
- 13-11 A case of salami slicing**
- 13-14 Ethical concerns about a study involving human subjects**
- 13-19 Identifying patient information published in a figure**
- 14-02 Coauthor fails to respond to request to confirm coauthorship**

CONTENTS

2. Forum discussion topic: Fair play for “researchers”: can editors and regulators develop a common approach to the need (or lack of need) for ethical review?	3
3. NEW CASES	5
14-04 A case with no independent institution to investigate (SH)	5
14-05 Fraud or sloppiness in a submitted manuscript (CB)	6
14-06 Possible breach of reviewer confidentiality (JM)	8
4. UPDATES	9
13-03 Ethical concerns and the validity of documentation supplied by the authors	9
13-05 Editor as author of a paper	10
13-08 Unusually frequent submission of articles by a single author	11
13-11 A case of salami slicing	14
13-14 Ethical concerns about a study involving human subjects	15
13-19 Identifying patient information published in a figure	17
14-02 Coauthor fails to respond to request to confirm coauthorship	18

2. Forum discussion topic: Fair play for “researchers”: can editors and regulators develop a common approach to the need (or lack of need) for ethical review?

(<http://publicationethics.org/forum-discussion-topic-fair-play-%E2%80%9Cresearchers%E2%80%9D-can-editors-and-regulators-develop-common-approach>)

There are a number of legitimate and valuable tools for gaining information and evidence for scientific advance and improving health care. These include research, evaluation, audit, and others. There is a real danger that UK “researchers” using tools other than “research”, duly following guidance in UK research regulation stating a lack of need for ethical review, find that journal editors will not consider their manuscript for publication because editors dispute the definition of what needs or does not need ethical review.

Many of these issues, of course, also apply to animal ethics approval.

Questions for discussion

1. What current guidance do journal editors use to determine if Research Ethics Committee review is mandatory for publication?
2. Can we develop a shared process (using current decision tools) that doesn't unfairly disadvantage “researchers” (and hinder research based care)?
3. Recognising that in inevitable grey areas, judgement is needed and will vary, can we develop a process to resolve differences between regulators and editors, that doesn't burden the researcher to start with?
4. Is this a problem beyond the UK and part of what Greg Koski has defined as the creeping “hyper-regulation” of research?

BACKGROUND

The remit of Research Ethics Committees (RECs) is the consideration of research, and the Health Research Authority (HRA) holds firmly to the view that health research should undergo independent ethical review. Audit, service evaluation and public health surveillance, usually of minimal risk, are excluded under official policy (GAfREC 2.3.12 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/213753/dh_133993.pdf). Their scrutiny lies elsewhere. While this is contended by some, it can be robustly defended and is current UK policy. Hence “researchers” need to categorise their work at an early stage to determine appropriate review. With its partners, the National Research Ethics Service (now part of HRA) collected the literature in 2009 and devised categorisation (<http://www.hra.nhs.uk/documents/2013/09/defining-research.pdf>) to help and set up a queries line to arbitrate in case of difficulty. In these it was recognised that there could be no clear, unambiguous answer. Judgement is needed and has to be given if the work is to proceed. In 2013 this guidance was further refined and a decision tool developed (<http://www.hra-decisiontools.org.uk/research/>).

By and large the distinction is clear (if it looks like a duck, then it is a duck) but difficulties in categorisation can arise and there is the risk that, in following guidance, “researchers” can then be disadvantaged if regulators, reviewers and editors either don't recognise due regulations or don't share common guidance. It is a concern that has been voiced on several occasions through our queries line. In such a case there is the possibility that REC review is deemed unnecessary within UK regulation at the beginning but later publication is jeopardised if a journal editor disagrees.

Hence the HRA approached COPE and together it was agreed to put this discussion paper on the COPE website for discussion at the COPE Forum, to seek views and, if possible, establish a common approach which would not disadvantage “researchers” (and would expedite health care work).

3. NEW CASES

14-04 A case with no independent institution to investigate (SH)

We were contacted by a lawyer acting on behalf of the last author (author A) of two research articles published in our journals. Both articles are co-authored by one other author (author B), who was the corresponding author. Author A claims not to have been aware of the submission and also raises concerns that the timelines and dates of the before and after photos reported in the articles are incorrect. He also claims that informed consent was not received from the patient described in one of the articles for publication of their case.

On submission and publication of both articles, both authors were based at author A's own private institution. Author B has since left the institution. All authors submitting to our journals receive an automated email when a manuscript is submitted, alerting them to the submission. As far as we can tell, author A received this email in response to both submissions. However, we have had no correspondence directly from author A regarding either article.

We have contacted author B for an explanation of the concerns raised by author A, which we have been told we will receive shortly. The concerns raised by author A are serious enough to warrant an institutional investigation. However, in the absence of an independent institution that we could ask to investigate, we are seeking advice from the forum on how to proceed once we receive author B's explanation.

Question(s) for the COPE Forum

In the absence of an independent institution, how do the Forum suggest we proceed once we receive author B's explanation?

14-05 Fraud or sloppiness in a submitted manuscript (CB)

In June 2014 we received a manuscript by four authors from a well known research institution. They described a randomized trial comparing a variation in a procedure with standard care. In total, 200 patients were randomized, 100 to each arm. As measured by an interview, patients undergoing the new procedure were statistically significantly more content than those in the control arm. This manuscript was submitted 116 days after the same group of authors had sent us a first manuscript on the same topic.

The first manuscript, however, described an observational study: 50 patients had chosen the new procedure, 50 underwent conventional treatment. The patients rated the new procedure higher (statistically significantly). In their discussion, the authors mentioned as a limitation the non-randomized status of their study and called for a randomized comparison. At the time we rejected the manuscript because we were not convinced by the non-randomized design of the study. The senior author appealed our decision saying that it was very difficult and almost unethical to carry out a randomized trial. We did not change the decision but I granted the author that we would evaluate and possibly review a manuscript on a randomized study.

In the cover letter of the second manuscript, dated June 2014, the authors referred to this discussion and stated that 100 patients had been randomized to each group. [As an aside, in an online source detailing procedures carried out in the department of the authors, the procedure in question is said to have been performed more than 1200 times a year. As a consequence, it is conceivable that the authors have randomized 100 patients to each study arm during a period of 3–4 months. In his appeal to the rejection of the first manuscript, the senior author mentioned that the ethics committee had already expressed approval. And yet, common experience with randomized trials indicates that the present study would be an extremely fast trial regarding screening, consent, inclusion, examination (4 days after the procedure), and analysis.]

Here is the problem: the results are identical in manuscripts 1 and 2. In numerical form the results are only presented in tables (not in the main text and not in the abstract). In all three tables, the values are identical in both manuscripts. All three tables were submitted as one file, leaving open the possibility that the author mixed up files. The figure (a horizontal, stacked bar chart) is slightly different but the numbers indicating the results, however, are identical. This figure was submitted as a different file.

The main text of the second manuscript is identical to the first one except for minor updates in relation to the numbers of subjects and study design. All four photographs illustrating the procedure in both manuscripts are identical. The reference list is identical.

I can think of only two ways to make sense of this submission: sloppiness or fraud. Under the sloppiness assumption, the authors would have submitted a text referring to their randomised control trial and tables, referring to an earlier observational study. This is conceivable mostly because it is hard to imagine that authors believe they can get away with submitting the same data in two manuscript describing two completely different trials and separated by only 4 months. On the other hand, the tables and figures differ in layout and several details from those submitted with manuscript 1. If sloppiness is not the reason, it must be fraud, and we can only reject the paper.

I feel we should be frank with the authors about our decision to reject the paper. Confronted with this decision, however, the authors have no incentive to cooperate with us and to send us, for example, original data. Rather, they may blame the mess to an unfortunate confusion.

Question(s) for the COPE Forum

We have decided to reject the paper but how does the Forum think we should now proceed?

14-06 Possible breach of reviewer confidentiality (JM)

Soon after rejecting a paper—after it underwent peer review but before discussion at the manuscript meeting—the author wrote to tell me that he was asked questions “about the manuscript” at a presentation at a national meeting. The author stated: “A member of the audience addressed questions to me from a copy of the manuscript, and not from the talk I gave. I had to ask him to say nothing further and that reading from the unpublished manuscript was not appropriate, particularly with the manufacturer [of the drug] present who continues to press us for the data. I then realised that this person had a copy of our manuscript because they were either a reviewer or a reviewer had given them a copy”.

Our journal has an open review policy so the author was aware of the identity of the reviewers and knew that the person who asked the question was not one of the reviewers. The authors are concerned that one of the reviewers may be a colleague or collaborator with the person who asked the question.

After receiving the author’s letter, I emailed the two reviewers to inform them of our concern about confidentiality and to ask if they shared the manuscript or its contents and, if so, how and why. Within a few hours, both reviewers replied that they kept the paper confidential and did not share it with anyone else. We take their assertions as valid and true, as we do with so many other statements by authors and reviewers.

I informed the authors about the outcome of my investigation. I also suggested that if they still think that a reviewer may have broken confidentiality, they might wish to contact the editors of the other two journals where the paper was reviewed before submission to us as well as the editor of the journal currently reviewing the manuscript.

Question(s) for the COPE Forum

Do you think that the journal handled this correctly?

4. UPDATES

13-03 Ethical concerns and the validity of documentation supplied by the authors

Case text (Anonymised)

We became concerned that not all of the co-authors were aware of a research paper submitted to our journal due to the difficulty receiving responses from the email addresses that had been supplied and their nature, given that the authors all worked in a hospital/academic institution. Despite repeated requests and attempts we remained dissatisfied with the responses and did not feel certain that all of the authors were aware of the paper. We therefore requested further documentation signed by all of the authors, but all of the signatures appeared to be signed by the same person, and hand writing analysis suggested this was highly likely. In addition, the statement from the ethics committee also had a similar signature. The letter from the 'head' of the ethics committee was on blank paper, not letterhead, and was not received as an original hard copy.

We therefore contacted the head of the ethics review committee who was different to the head on the document we had received and about which we had some concerns. The current head eventually confirmed after a second request that the doctor who had signed the previously supplied document was not on the committee. Ethics committee clearance has since been granted retrospectively after the paper was submitted.

As a result we have significant concerns about this paper, its ethical clearance and some of the documentation that has been supplied. We have advised the authors that we have suspended processing of their paper and that we would seek further advice from COPE. Our intention is to report our concerns to the hospital director and formally reject this paper.

We would appreciate guidance on any further action we should take.

Advice:

The Forum agreed with the proposed course of action of the editor. It would not be appropriate in this case to simply reject the paper. It is very clear that something serious has happened in relation to the governance of this paper, and if the editor were to simply reject it, it is quite likely that the authors will simply submit elsewhere. In these situations, COPE recommends that if an editor has a concern about a paper, even if they end up rejecting it, they must tell the authors that they will take it further and that it is highly likely that it will be referred to their institution for further investigation.

(COPE Council also discussed this case outside of the Forum). Council members agreed with the proposed course of action. This appears to be a very serious breach of ethics and the author may repeat this type of misconduct with another journal.

First you should inform all the authors of what you are going to do in a factual, non-accusatory way.

As there may be legal implications, you should also ensure that the letter to the hospital director has to be purely factual, with dates and copies of letters between the journal and the

ethics service and the authors. Claims about forged signatures need to be backed up by a report of handwriting analysis (or if you can't supply that you should not make the accusation directly). The journal should consider taking legal advice.

You may want to pursue this issue further to a higher institutional level. Hence, in addition to the hospital director, if there is another head of the academic institution or some kind of oversight office then you might consider contacting them also. If the authors are working in an academy (university) and the hospital is affiliated to that university, then there may be a research regulatory body of that university that could be informed.

Follow up:

The journal followed the advice given by COPE and sought legal advice from their publishers before writing to the hospital director raising their concerns. The editor also rejected the paper and gave the authors the reasons for doing this. The editor has had no response and so he plans to write again and also write directly to the head of the ethics committee.

Update (September 2013):

The editor has still not had a response from the hospital director despite following up the original communication and copying in the ethical review chairman. It was agreed that the next step should be to contact the research integrity office.

Update (February 2014):

The editor has now had a response from the ethics committee, recognising the nature of their concern. The ethics committee is going to inform the university rector.

Update (June 2014):

Following correspondence with the National Research Council, the editor was informed that the president of the ethics committee had contacted the rector of the university, and he was subsequently informed that all efforts aimed at clearing up the facts had been supported and appropriate measures had been taken. Although the journal asked for clarification of what measures were actually taken, they were advised that information on the specific measures applied could not be provided.

13-05 Editor as author of a paper

Case text (Anonymised)

A subject editor, who oversaw a manuscript, was invited by the authors to become a co-author after the first review round. After inviting the subject editor to become an author (and adding his name to the author list), the revised version of the paper was submitted to the journal. The authors expected that a different subject editor would handle the paper in the next review round.

However, when the revised version was submitted, no one (including the subject editor himself) noticed the addition of the subject editor's name to the revised paper, and the subject editor took "automatic" care of the revised manuscript when it was assigned to him by the editor-in-chief, who also had not noticed the addition of the subject editor's name to the paper.

The second revision was directly accepted by the editor-in-chief. During proof corrections, no one noticed that the subject editor was listed as an author and also as the communicating

editor (it is standard practice on the journal to name the subject editor on the published paper—ie, "Communicated by ...").

Thus the article was published online before the authors became aware of the problem and contacted the editor. The editor-in-chief believes the subject editor was acting in good faith, but is very concerned about the situation and the breakdown of the journal process. The manuscript managed to slip through two rounds of the journal's editorial process.

The authors are also very concerned about this awkward situation, which looks like preferential treatment, and have asked the journal what can be done to avoid this impression.

Question

What can the journal do?

Advice:

The Forum agreed this was a failure of journal processes and the editor in chief must take responsibility for this. The change was not detected but there should be processes in place when any change in the authorship of a paper is noted. Authors should be required to clearly state when any changes in authorship are made after the initial submission, and the journal needs to ensure it tightens its processes to detect this. So the journal should reinforce the processes it has in place and make any necessary changes.

The editor confirmed that a conflict of interest statement was signed by the corresponding author on behalf of all of the authors. The Forum suggested that, in future, the journal may like to consider asking each author to sign an individual conflict of interest form. If this had been done in this case, for example, the addition of another author would have been spotted.

The advice from the Forum was to publish an erratum, with the editor in chief as the "Communicated by" editor, and also explaining clearly what happened in this case. The journal may also have to publish a correction to its conflict of interest statement on the paper.

The Forum also advised that the journal should have a written process in place for what to do when an editor becomes an author and wants to publish in his journal.

Follow up:

The journal added a note to the paper from the editor in chief, stating that due to an unfortunate technical mistake when handling the article, one of the authors was also a subject editor at the same time. The editor in chief also stated that he guaranteed that the scientific standards and honesty had not been violated in any way.

13-08 Unusually frequent submission of articles by a single author

Case text (Anonymised)

A sixth year medical student, with expected year of graduation of 2013 (Mr X), submitted 29 original articles and 17 letters to the editor in the period February 2012 to October 2012 to our journal. This amounted to an average of five submissions per month. Mr X is an author and corresponding author in every article. Of these, he is the first author of eight original research articles and 12 letters. In the remaining one he is a co-author. The articles are on very diverse subjects.

This set us thinking that, apart from his clinical work and studies, how he had time to conduct research, analyse the results and write the articles.

The journal first wrote to Mr X for the necessary justification. He responded promptly, "I am one of the best researchers of my country and have multiple publications in every field of medicine and have won multiple prizes". He provided a list of 72 publications to his credit. He also provided the name and email of the chief of the research committee of the university.

We wrote to the concerned parties asking them to endorse the submissions as being ethical and valid for the purpose of publication. The chief replied that Mr X was a member of the student research committee with some research background in medicine which led to multiple awards and publications. He confirmed the research background in a vague manner and there were no more comments or endorsements of the submitted articles.

We then wrote to the vice chancellor of the university asking for verification and endorsement of the articles according to the ICMJE guidelines. The director of research affairs was also approached, who asked for details of all the articles submitted. These were duly sent.

In the meantime, Mr X contacted us stating that his e-mail had been hacked and someone else had sent letters and articles with his name. This was incorrect, as all mails had the same e-mail address. We also sent an email to the Publication Commission in our country on 6 March 2013. There has been no response.

We face a dilemma. The articles are lying unprocessed. It is a mystery as to why the higher authorities are not taking any action or replying to our emails.

Question

What would the COPE Forum suggest we do?

Advice:

The Forum suggested that it may be useful in this case to help rather than punish the author. As an initial approach, the Forum asked if there was any pastoral care available to the student, or whether the medical school has anyone who could talk to the student in a confidential manner. This may be more of a problem with the student, rather than research integrity concerns. The institution has a responsibility to its students and they need to ensure that students are sufficiently supported. So the editor should consider contacting someone in this role at the author's university.

However, that still leaves the dilemma of the unprocessed articles and what to do with them. The Forum advised that the editor needs to be certain that the articles are all from the author and that he takes responsibility for them. If there is any doubt, then the articles should not be processed. However, if the articles are genuine and have scientific merit, then they should be processed in the normal way, as there are no grounds for rejection.

The Forum also suggested contacting any co-authors on the papers for an explanation and to confirm that the papers have all been written by the author. The editor should make it clear to the author that the papers are on hold while the issue is satisfactorily resolved.

Another suggestion was for the editor to consider contacting some higher authority or regulatory body, or ministry of research, and asking them to investigate the case.

Follow up:

As suggested by the Forum members, we did some investigations ourselves as the higher authorities, including the Vice Chancellor of the University to which the author belonged, were unresponsive.

As a sample, an Internet search was made for three of the articles. One was found to be copied in full from a similar article in another online journal.

A search was made for the correct names and email addresses of the coauthors, as those stated in the articles submitted to us were wrong. We spoke to two coauthors by telephone—one knew nothing about the concerned author or about his name being included as a coauthor. He also knew nothing about the article. Another senior coauthor spoke in favour of the author. He said, “Mr X is a very intelligent and knowledgeable researcher and writes very well”. He could not justify how Mr X could write on such diverse topics.

We received only one email reply from a senior professor. He wrote : “I was really shocked to see the paper published without my knowledge. I do not know Mr X (author). I have never met him. He has never worked with me. He has stolen my published data. I am going to forward this message to the ethics department and make a complaint on the concerned person at the university”.

We have had no comment or reply to our queries from the officials of the university. From the Internet searches made by us, we can conclude that Mr X, the medical student (author) is:

- Not only good at writing in English but is also excellent in fabricating and stealing data.
- He has the support of one or two senior faculty members of his university.
- He has been committing these unethical acts for quite a few years as there are a number of articles with his name.
- The articles submitted to our journal had fake email addresses and names, even with incorrect spellings, making contact difficult.
- The signatures of all authors were forged.

Questions for the COPE Forum

- (1) Should we just close all the files and bury the case?
- (2) If not, what steps should be taken?

Advice on follow up:

One view from the Forum was that, as suggested before, the editor should contact a higher authority, regulatory body, or ministry of research, and ask them to investigate the case, given the institution’s unwillingness or inability to engage with the editor on this issue.

However, others argued that it is the responsibility of the institution to deal with this student. Institutions not responding to editors’ requests is a common problem, and the advice was to contact the institution every 3 months, requesting a reply and including copies of the information on the case. The editor should say that he/she does not consider the matter closed and request that the institution investigate the case. If the institution does agree to an

investigation, the editor should publish the findings of the investigation in the journal, using the text from the institution's report.

The Forum advised the editor not to accept any more papers from this author. The editor should write to all of the authors of the submitted manuscripts to say that no further papers will be considered from this student.

Regarding the published papers, the editor should consider contacting the editors of the other journals that published papers by this author.

Update (December 2013):

The Secretary National Ethics Committee updated the editor that the university was conducting an investigation. The Committee have confirmed that more misconducts had been detected against this author and the concerned authorities were still looking into the case. The Committee suggested that the journal should take an independent decision on the unprocessed articles in the journal's office. The journal plans to make a final decision on the pending articles very soon.

Update (February 2014):

The Secretary National Ethics Committee told the editor that more misconduct cases had been detected against this author and the concerned authorities were still looking into the case. He suggested that the journal should take an independent decision on the unprocessed articles. We will make a final decision on the pending articles shortly.

Update (June 2014):

The decision of the editorial board of our journal was to close all 27 pending files on the grounds of fraud. The decision was also taken to debar the author. The Secretary National Research Ethics Committee of the author's university was informed.

13-11 A case of salami slicing

Case text (Anonymised)

A reviewer of our journal noticed similarity between a published paper (P1) and a manuscript under review (P2). At the same time, a member of the editorial team noticed similarity between another accepted manuscript for publication (P3) and both paper P1 and manuscript P2. All three papers were submitted by the same authors based on the same trial, reporting three different endpoints measuring the same effect. The earlier paper P1 reported the results on the most accepted and validated efficacy measures. The latter manuscripts reiterated the findings of the published paper but did not cite the same.

The editor-in-chief decided to hold P2 and P3 and follow the COPE guidelines. The editorial team asked clarifications from the authors, who in reply stated their ignorance about publication practices and argued that the two other efficacy measures will substantiate the results of P1. The results of the papers were contradictory to current practices and hence the editorial team decided to be lenient with the authors. The editors suggested combining the two manuscripts under review (P2 and P3) into one short communication and asked the authors for appropriate modifications (eg, reporting ancillary data).

The authors modified the manuscript but quoted a guideline for analysis, which had not used before, was not present when the authors completed their study and was not related to the topic. This raised questions about the overall integrity and reliability of the authors. The editorial team decided to hold the manuscript and refer to the COPE Forum for consultation.

Questions for the COPE Forum

- (1) What should be the stand of the editorial board, especially if authors want to withdraw the paper?
- (2) Should the editors share the review information with editors of other related journals?
- (3) Should we disclose the names of the authors to other journal editors in the sector?
- (4) Should we have an alert list of such authors?

Advice:

The Forum agreed that even if the authors wish to withdraw the paper, and they have every right to do so, this does not mean that the issue is gone away or is resolved. If the editor has concerns, he/she retains the right to follow-up with the author and/or the institution. The editor can still contact the author's institution and ask them to investigate. COPE always advises that even if a paper is rejected or withdrawn, the editor has a duty to follow-up any issues relating to suspected misconduct. The editor may like to explain this to the authors.

It may be necessary to share the information with related journals, but the editor may need to assess the scale of the problem first by doing a search for other articles by the same authors and determining what other journals are involved.

Regarding an alert list, COPE always advises against blacklisting authors or sharing alert lists with other editors because of the risk of litigation and the danger of harming other innocent associated authors.

Follow-up:

The editor asked the authors for clarification, but did not get a reply even after several reminders. The editor also contacted the author's institution and asked them to investigate the case but received no reply. The article was rejected on the grounds of compromised publication ethics.

The case was discussed by the editorial team members. The journal has improved the editorial review methods of the journal to filter out possible cases of plagiarism and salami slicing. The editor discussed the case (without revealing any of the author's details) with editors of related journals who said that they also experienced similar cases and expressed the need for efforts to create awareness to avoid publication misconduct. The editor acknowledges the guidance from the COPE website in strengthening the journal's editorial processes.

13-14 Ethical concerns about a study involving human subjects

Case text (Anonymised)

A manuscript was submitted to our journal describing a study of a new drug. The manuscript had only one author who gave their affiliation as a company that we can find no record of online. It describes a study in which they appear to have developed a new drug, carried out a toxicology study in mice and then, because no adverse effects were seen, tested it on one

patient and five healthy volunteers. There appear to have been no stages in between. There is no statement of informed consent in the manuscript. There is a statement that says the study was reviewed by the institution's human subjects committee but we cannot find a record of the institution.

We had ethical concerns about the study so we asked the authors for more information, specifically: the details of the ethics committee that approved the study; whether they had informed consent from the patient and healthy volunteers; whether the trial had been registered before it commenced; how the patient and controls were recruited; what information the patient and controls were given before they agreed to participate; where the study took place; what safety/monitoring was in place in case of any adverse effects; what approval was obtained (eg, from the country's drug regulatory body) before this drug was injected into a human for the first time; and what other research had already been carried out on this new drug? The author responded to our email asking to withdraw the manuscript but did not answer any of our questions. We responded that we had serious ethical concerns and therefore would not be withdrawing the manuscript at this time. We informed the author that we would be investigating the potential ethical issues and asked again for answers to our questions. We have heard nothing from the author since.

The author is based in a country that does not appear to have a national medical board and is not affiliated to an academic institution or hospital. The affiliation given is the company that we can find no record of. The author's email address is not an institutional or company email address. We have contacted the professional society for the medical specialty of the author but they have informed us that the author is not a member and therefore they cannot investigate. We have also searched for the author on the registry of the regional medical board for the region in which the author is based, and they are not registered with them either. We do not want to reject the manuscript until an appropriate body has agreed to investigate but we are struggling as to how else to report this.

Questions for the COPE Forum

- (1) Does the Forum agree that we should continue to try and find someone to investigate this before we reject?
- (2) Does the Forum have any suggestions on how we can report this?

Advice:

The Forum agreed that the editor had made a tremendous effort in trying to resolve this case. The Forum reiterated that in instances where a paper is rejected or withdrawn, there is still a responsibility to pursue any suspicions of misconduct. In this case, where the author wishes to withdraw the paper, it was agreed that the editor had probably done as much as he could. In some countries, this type of behaviour might be considered criminal, and a last resort might be to inform the legal authorities in that country.

The Forum advised that there is always the possibility that the paper is a hoax, but the editor has to assume, until otherwise proven, that the author has submitted the paper in good faith and should investigate this as far as possible. This is a particularly difficult case as it is a single author paper. If there had been more than one author on the paper, the journal could have applied the revised criteria of the International Committee of Medical Journal Editors (ICMJE). The fourth criterion states that all authors are accountable for all aspects of the work and are responsible for ensuring that questions related to the accuracy or integrity of

any part of the work are appropriately investigated and resolved. However, this is not applicable in this case as there is only one author.

The only other suggestion was for the editor to write an editorial on this topic, emphasizing that this type of behaviour is unacceptable.

A Forum member suggested this paper may be of interest
http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2245850

Follow up:

After the case was discussed at the forum, the journal made one further attempt to report the unethical research. This was successful and the case is now being investigated by the relevant governmental department in the country where the research was carried out. The editor also discovered that while he had been trying to resolve this case, the article had been published in another journal. He informed the editor of that journal of the duplicate submission and his concerns.

Follow up (June 2014):

After the relevant governmental department agreed to investigate, the manuscript was rejected by the journal. The journal did not receive a response from the editor of the other journal in which the article had been published.

13-19 Identifying patient information published in a figure

Case text (Anonymised)

A reader emailed a society, which forwarded the message to the journal office, noting that he can read the name of a patient in a figure in a published letter to the editor. The letter was published online 3 months earlier and had just appeared in print; it was the print version the reader saw. The reader asked if the patient's name could be removed.

The journal's author instructions already stated that no identifying patient information should be included. At all stages following submission (journal office review of initial submission, publisher production of processed manuscript, copyeditor review, and author review of proof), the patient's name was not noticed.

Within 2 days of the reader's email, the publisher had replaced the figure with a version that did not include the patient's name. It was agreed that an erratum would not be issued so as not to draw attention to the matter.

Both the journal office and publisher have since instituted new procedures in reviewing figures to detect any patient information. Additionally, new text has been added to the author instructions: "Patient's identity must be removed in all figures (ie, x-rays, MRIs, charts, photographs, etc). Informed written consent is required from any potentially identifiable patient or legal representative, and should be presented in either the methods section or the acknowledgements".

The publisher and its legal counsel also created a patient consent form (the rural clinic in another country where the patient was treated did not have one) and we able to contact the

author who asked her patient to sign the form, post-publication. The patient agreed and signed the form, and the matter is now closed.

Questions for the COPE Forum

(1) Were we right in deciding not to issue an erratum? Is there any other text that you would recommend adding to the author instructions?

Advice:

The Forum agreed that the editor should not issue an erratum. Correcting the literature is very important, but patient confidentiality is overriding in this case. No useful purpose would be served by issuing an erratum, particularly as written patient consent has now been obtained, and in fact it would draw attention to the name of the patient. A poll of the Forum audience indicated that only a few people would issue a correction—the majority would not. But some argued that in the interests of transparency, perhaps there should be some acknowledgement that a change was made, even if the change is not specifically mentioned.

The Forum discussed having a universal consent form, which has been discussed by COPE in the past. Hence if a patient consented to publication for one journal, if the article was then rejected and submitted to another journal, another consent form would not have to be completed. From a poll of the Forum, there was some support for a universal consent form. About a third of the audience currently use a specific consent form for publication that requires the authors to have gained written consent from the patient before any identifying material can be published.

The Forum suggested an editorial note on the importance of preserving patient confidentiality might be useful, as a reminder to authors. The editor might also like to check that their instructions to authors are clear and up to date on this issue.

Follow-up

The editorial team updated their instructions to authors. CC

14-02 Coauthor fails to respond to request to confirm coauthorship

Case text (Anonymised)

Prior to publication, our journal requires coauthors to respond to an email to confirm their authorship status and the author list. A coauthor did not respond to these emails, and when we contacted the corresponding author for help, s/he told us that his/her attempts to reach the coauthor have failed, and that s/he believed the coauthor was attempting to hold the paper hostage.

According to the corresponding author, the coauthor was fired from their institution (which is in a different country than the journal) for ethical lapses, and was now extremely upset and was suing the institution. The corresponding author believed that the coauthor was deliberately ignoring the confirmation requests in order to punish the corresponding author.

Although in general we believe that authors have to resolve their own authorship disputes (involving the institution if need be), we felt this case was different because it did not appear to be a case of disputing who should/should not be an author, or a situation in which a coauthor objected to some aspect of the paper. Instead, if the corresponding author is to be

believed, it is simply a disruptive manoeuvre that twists the journal's ethics safeguards (intended to prevent ghost/honorary authorship) into a weapon.

We decided that it was reasonable for the journal to expect a coauthor to perform the straightforward task of confirming coauthorship, and that if that individual did not do so (for reasons of malice or not), they would forfeit coauthorship. We sent an email to the recalcitrant coauthor (we did not have a postal address because the institution had requested this individual be deported), copying in the other authors, detailing the many attempts to reach him/her, and explaining that if we did not hear back from him/her within 6 weeks from the date of acceptance we would proceed with publication without his/her name listed as an author.

Normally of course our policies require that someone who does not meet the standard of authorship is named in the acknowledgements. However, because we also require anyone named in the acknowledgements to give their permission for this, we decided that if this person did not respond, we would ask the authors to acknowledge the person's involvement by referring to their job title—for example, “The authors acknowledge the assistance of a medical student in the early phases of this study”. (The phrasing is a little awkward but we felt it was important to include it. If it later came to light that there was evidence of misconduct in the study, we felt it needed to be clear from the outset that there was someone else involved in the work.)

Fortunately, in this case, the first author was eventually able to convince the non-responding author to confirm coauthorship, so we did not have to carry through our threat. However, we want to be prepared in case a similar situation arises again, and so we are considering updating our information for authors to include a policy of forfeiting coauthorship after a 6 week period has elapsed without response.

Question(s) for the COPE Forum

1. What is COPE's view of our proposed policy of requiring coauthors to respond or forfeit their coauthorship status?
2. If it is not appropriate, should we have refused to proceed with publication until the authors resolved the issue?
3. If the authors' institution had stepped in and ruled on how the dispute should be resolved, should we have accepted their ruling, despite their being a party to a lawsuit?
4. If the forfeiture process is considered appropriate, may we still retain our policy that an author who dies may be named as a coauthor if the corresponding author attests that to the best of his/her knowledge, the deceased individual met the definition of authorship up to the point of death, and all the authors agree?
5. What about an incapacitated author (we have a manuscript working its way to acceptance where a coauthor is in a coma)?

Advice:

The general feeling from the Forum was that the journal does not have the right to deny authorship. Hence the Forum would not agree with the policy of forfeiting coauthorship status imposed by a journal. Exercising the right to remove an author is not within a journal's jurisdiction. However, others argued that if it is journal policy that coauthors must confirm

their status as an author, then technically they are not an author until they have confirmed their contribution.

The case of deceased or incapacitated authors is more straightforward and the Forum would suggest a statement from the corresponding author attesting that to the best of his/her knowledge, the deceased/incapacitated individual met the definition of authorship, and all the other authors agree. In such cases, authorship is given and so the individual remains as an author.

Although it is necessary to prevent ghost/honorary authorship, the Forum suggested that if a coauthor refuses to confirm coauthorship and there is a possibility that he is attempting to hold the paper hostage, then the editor should consider contacting the institution and asking them to mediate or investigate the situation. If the institution does not or is unwilling to respond, the editor might still consider publishing a statement from the corresponding author detailing the contribution of the coauthor. Another suggestion was to explain the contribution of the coauthor in the acknowledgement section.

This situation could be avoided if at the time of submission all authors are contacted and asked to confirm their status as an author. On polling the Forum delegates, about half said they require confirmation of coauthorship either at submission or at a later stage.

Follow-up:

The Editor-in-Chief agreed to drop the proposal to have non-responsive coauthors forfeit authorship. A statement will be included in the acknowledgements, along the lines that author X was not available to confirm coauthorship, but the corresponding author Y affirms that author X contributed to the paper and vouches for author X's coauthorship status. CC