



Forum agenda

**Meeting to be held on Monday 1 March 2010 at 3pm
The Royal College of Paediatrics and Child Health (RCPCH), 5-11 Theobalds Road,
London WC1X 8SH**

Agenda

1. Update on COPE activities by the Chair

2. New cases

- 10-01 Case of duplicate publication detected after 9 years (FJ)**
- 10-02 A case of child abuse (AN)**
- 10-03 Conflicting claims of intellectual property? (SB)**
- 10-04 Author dispute over data presented in a paper (CS)**
- 10-05 Retraction or expression of concern? (JP)**
- 10-06 Concerns over research by an author in numerous, separate publications (FI)**
- 10-07 Dispute over authorship and usage of research protocol (PK)**
- 10-08 Possible dual publication (DF)**
- 10-09 What involvement should a journal have in a dispute about an article published in the journal? (AT)**

4. Updates

- 09-06 Duplicate publication**
- 09-11 HIV homeopathy**
- 09-13 Reviewer misconduct?**
- 09-16 Ethics and consent in research**
- 09-21 Self plagiarism**
- 09-23 Scientist reads published paper by former collaborators and claims co-authorship**
- 09-24 Homeoprophylactic treatment of a zoonotic disease**

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NEW CASES

10-01 Case of duplicate publication detected after 9 years (FJ)

An original research article was published in a journal in 2000. This is a quarterly, non-indexed journal. The abstract is available on a national indexation website.

The same article with a slight change in the title was published in our journal in April 2002. Ours is a monthly journal which has been indexed in Medline since 1975.

Both articles appear the same, with the study of 190 inpatients, and both have similar wordings. The authors and the order of their names are the same. The authors were affiliated to a reputable teaching medical institution. However, with the passage of 9 years, all of the authors have dispersed and some have left the country. Their contact numbers and email addresses are not available.

As the duplicate publication occurred in our journal, we feel we should take the necessary action. According to COPE guidelines, the authors should be approached for an explanation. This is difficult as no contacts are available.

We would appreciate suggestions from the Forum as to what steps should be taken for this misconduct detected after a lapse of 9 years.

10-02 A case of child abuse (AN)

Child abuse is a common but underdiagnosed problem in our country. The abuse ranges from minor injury to severe head trauma. The true incidence of intentional head injury in children remains uncertain.

We published a case of child abuse with blunt head trauma with intracranial haemorrhage presenting as loss of consciousness simulating a diabetic ketoacidosis. We received a complaint from a reader about a photograph illustrating the case which showed details of the abuse (bruises and signs of abuse around the perineum but the upper half of the body was not visible). We believe the case report warranted that the photo be published.

However, the complainant argues that he believes it was wrong to publish the photograph at all and especially in its present explicit form. The complainant believes that publishing this photograph of the child is a violation of child's human rights. The complainant also states that before publishing the photograph, he hopes the editors had obtained appropriate consent to publish.

10-03 Conflicting claims of intellectual property? (SB)

Dr R, of University 1, has written an ‘official complain’ to Editor E alleging that a paper he was invited to review employs without permission a method that is the ‘background intellectual property’ (BIP) of University 1. He believes the paper should not be published.

Dr R asserts that he created the BIP prior to its use in several research projects at University 1, and notes that Dr A, the paper’s author, worked on these projects at University 1 under Dr R’s supervision when the method was explained to him.

Dr A’s current affiliation is University 2. Dr R asserts that: University 2 was never granted any right to use the BIP and that to do so would be an infringement; Dr A was advised of the confidentiality of the method. Dr A did not cite University 1’s BIP in his paper.

Dr R did not in fact review the paper when first submitted: several reviewers were invited and the initial ‘revise’ decision was communicated to Dr A on the basis of other reviews received. Dr R’s complaint to Editor E, which incidentally is not on University 1’s letterhead, was received when a revised version of the paper was under final review, 5 months after the initial reviewer invitation.

Editor E has sent details of the complaint to Dr A, advising him also that the review process has been suspended pending a resolution. Dr A’s response to the complaint was a direct reply to Dr R (rather than to Editor E, although a copy was sent to him), expressing surprise at the complaint and refuting the allegations, asserting instead that he was already using the methods in his paper before working at University 1 and that he had not used University 1’s methods. He also comments that despite having undertaken ‘lots of work’ at University 1, he was never included as a co-author. Editor E has asked Dr R for a response to Dr A’s views but has yet to receive one.

Editor E and the journal’s publisher are both aware of the COPE flowcharts, and jointly seek the Forum’s further advice in this case:

1. Should Editor E take the lead in investigating the matter, or should this be handled by the publisher?
2. In terms of an investigation, the COPE flowcharts recommend forwarding the concerns to the author’s institution. Is this the appropriate course of action here? In a case such as this, we would be especially interested in the Forum’s view on the suggestion that the concerns be forwarded, at an appropriate level, to both institutions simultaneously.

As noted above, the review process for the paper is presently on hold.

10-04 Author dispute over data presented in a paper (CS)

A manuscript was submitted to our Journal in 2008. The six authors signed the author form for the Journal which accompanies all submitted manuscripts. The author form gives information on the role each author played in the study and states that each author has read and approved the paper for submission to the Journal.

Following peer-review the paper was accepted for publication. It was published in February 2009. In October 2009 the Journal received a letter from the corresponding author who asked for the paper to be retracted. The corresponding author stated that the first author had used data which was originally generated by a student working in the department (permission had been given to the first author to use the data) but that the data presented in the paper were different to the data published by the student in a thesis. The corresponding author further stated that the first author was being investigated by the university in which the research took place and by the Ministry of Education.

The Editor-in-Chief of the Journal and the Publisher wrote to the corresponding author and said that they would wait until the investigation by the university and Ministry of Education had concluded before deciding whether the paper should be retracted. The corresponding author responded to this letter and asked that the paper be retracted immediately and stated that the investigation would take several years.

The Editor-in-Chief and the Publisher then wrote to the first author and asked for a full and detailed explanation as to the concerns raised by the corresponding author. The first author responded and said that the dataset for the paper was extracted from a patient database which contains information on patients treated at the university. Datasets from several sources were used to update the main database and information was extracted based on the inclusion criteria outlined in the paper. The first author stated that she had identified more patients who fitted the inclusion criteria from the database than the student and this was the reason for the discrepancy in data between the thesis and the paper published in the Journal. The first author also told the Journal that the corresponding author had brought the discrepancies in the data to the attention of the Ministry of Education, the university's Academic Ethical Committee and the Faculty Appeals Committee. The first author says that these groups have accepted the reasons behind the discrepancies in the data.

The Editor-in-Chief and the Publisher also wrote to the co-authors of the paper (four co-authors, excluding the first author and the corresponding author). Three of the co-authors have responded and state that they accept the reasons behind the discrepancy in the data produced in the original project and the data used in the paper. In addition to writing to the co-authors, the Editor-in-Chief and Publisher informed the corresponding author that they were contacting the co-authors. The corresponding author responded and said that the paper should be retracted immediately and that he was considering whether to publicly announce that the paper should be retracted from the Journal.

The Journal would appreciate advice on how to proceed.

10-05 Retraction or expression of concern? (JP)

Shortly after publishing a short report, another group involved in similar work accused one of the authors (A) of the short report of fabricating and/or stealing data from their lab. The other group also stated that author A's conclusions about an image published in the short report were wrong.

We asked to see author A's original data and talked to his co-authors and the institution where his studies were reportedly carried out. We were satisfied that the data presented in the short report were real and the author's own, and there was no evidence of data fabrication or theft.

We asked for expert opinion on author A's interpretation of the image. Three experts thought that the author could not draw the conclusions he had based on the scan he presented in the publication and that reference images produced from the original data were needed to support his conclusions. We went back to author A, told him we were satisfied that there was no evidence of data fabrication or theft, but that we did think he needed to provide more data to support his claims. He did provide some additional images. However, our experts' view was that the data provided did not verify the author's claims. He had used images from published articles as reference images, and not reference images from his original data.

In the meantime, the other group submitted a correspondence article explaining how their own studies conflict with author A's claims. This was sent for review. The reviewer felt that author A's article should not have been published, but that the other group needed to provide some more experimental detail and data. At this point we approached author A telling him that we did not think the data he provided supported his claims and that he might want to consider retracting the article. Author A responded by sending us several opinions from 'experts' he had found arguing that the article should not be retracted. None of these 'experts' is an expert in the imaging technique used. He also said he would now be able to provide reference images from his original data, although we have not seen them and do not know, without checking with our experts, whether or not they would be enough.

The short report describes an invasive clinical intervention and makes claims about its efficacy. This is a controversial area of research, and our concern is about leaving something that may not be accurate in the public domain, but we also do not feel that the author has intentionally misled us or the public. We feel at this point that the best course of action is to publish the critic's correspondence article, along with the authors' response, and let the public judge for itself. However, given the clinical nature of the short report and the doubts raised about the veracity of author A's claims, we would like the committee's opinion on whether the publication of the correspondence piece and the authors' response is enough, whether we would be justified in publishing an expression of concern about author A's article or whether there are grounds to retract.

10-06 Concerns over research by an author in numerous, separate publications (FI)

The authenticity of the content of numerous publications by Author K has been questioned by ‘concerned researchers’ in an anonymous email sent to the Editor of Journal A in December 2009.

The email noted that author K had been publishing articles in numerous journals that “report remarkable findings that watching humorous films, drinking deep-sea water, exposure to road traffic, cell-phone noise and radiation, kissing, playing computer games, listening to Mozart, infant suckling, sleep deprivation and starvation all affect various [physiological] responses.” Few of K’s findings have been replicated by other authors and the ‘concerned researchers’ were clear that they believe the findings to be unusual and the research based on improbable hypotheses and mechanisms.

The data presented in each of the articles are remarkably consistent ‘and, to be frank, seem too good to be true’. Most of these articles have been published by author K as a single author, and for a lone researcher the output is prolific.

The concerned researchers, the editorial office for Journal A and colleagues from the publishing house have all attempted to find an institution that author K may be affiliated to. There are suspicions surrounding author K’s affiliations to two institutions. When the author’s name and the two institutions are typed into a search engine, a lot of references to very similar articles appear in the search results.

The ‘concerned researchers’ therefore “cannot help but question whether the data presented in these articles are genuine. If not, this appears to be a case of scientific misconduct that could have far-reaching implications [in the field] This is ongoing, with nearly 100 articles published over the last few years including some published this year (2009)”.

Journal A published a paper by author K in 2004 which, taking into account the summary above, could have easily been fabricated from the perspective of the editor of the journal. The editors and the concerned researchers wish to know more about the legitimacy of these publications and whether the articles by author K are reliable.

10-07 Dispute over authorship and usage of research protocol (PK)

In November 2009, the Editor of Journal X received a letter complaining of a serious breach of publication ethics regarding an article already published a month earlier on the Journal's website. The paper concerned had not yet been published in a full journal issue either online or in print. One of the authors of the letter, Professor X, was a named author on the published paper. His complaint was that he had never seen the article prior to publication and had not agreed to be an author.

Professor X stated that some years previously, a number of research groups around the world were invited to join a collaborative research effort. A late Dr Y made the suggestion to make the work a multicentre study and suggested Dr Z as one of the investigators. Professor X also stated that Dr Y asked him to manage all the multicentre groups and compile the work into one final paper. Professor X said that an agreement was made to use a research protocol developed by him across the whole multicentre study.

The published article has Dr Z as corresponding author in addition to a Dr W as first author. Drs W and Z are at the same research institution. Professor X claims that he tried to discuss the progress of work (using the agreed protocol) with Drs Z and W but without reply. Professor X feels that Dr Z has not followed the agreed research protocol and by not liaising with colleagues has made this publication appear as if it is his original work and taken credit for work which was not his original idea. Professor X also states that as the original research protocol was not followed, the findings in the paper are of poor credibility.

When asked about the situation, Drs Z and W stated that they thought each other had been in contact with Professor X to obtain his consent before submitting the manuscript to the Journal. They both apologised for the mis-communication and suggested that Professor X could be removed from the author list before the paper is published in a journal issue. Professor X replied saying that only a full retraction of the paper would be a satisfactory outcome for him because his reputation was damaged by the publication of work that had not followed the originally agreed research protocols that he had developed.

On gathering both sides of the story, the Publisher decided that the two parties (Professor X and Drs Z and W) should communicate with one another in order to find a resolution to the problem and agree how, or if, this paper should be published in a journal issue or whether it should be retracted outright. Dr Z has since written to Professor X saying that there was no agreed usage of the protocol or publication plan and that he was kept informed of the ongoing project. Dr Z reiterated an offer to change the list of authors including the removal of Professor X from the paper.

10-08 Possible dual publication (DF)

As editor of journal A I am handling a manuscript by an author and it is likely to be accepted, although this is not yet decided. As a reviewer for journal B, I have since been asked to review a manuscript by the same author that uses similar material and comes to a similar conclusion, but pushes the presentation of the results a little further. My gut feeling is that there is insufficient novelty for journal B. However, my problem is how do I tell journal B without compromising my role as editor of journal A?

Following advice from a COPE council member, I decided to review the manuscript for the second journal and in my comments to the authors I suggested that in order to sharpen their conclusions this study might be better embedded in a larger study. In my covering note to the editor, I wrote “Unfortunately, there may be an ethical issue to do with this manuscript. I have consulted COPE, without of course mentioning the journal, the authors or the subject of the research, but they cannot bring it to their Forum until March, which is long after the review deadline”.

The “larger study” that I mentioned is the work that is under review in the first journal. The covering note to the editor does not breach confidentiality with respect to the first journal but it does alert the editor of the second journal that there “may” be a problem and that he or she can decide to wait for a decision by the Forum.

I have since found out that Journal 2 has now rejected the manuscript, with another reviewer’s report identifying the same general scientific problems as I did in my comments to the authors. So, my cautionary covering note to the editor about a potential conflict of interest seems not to have been needed.

Does the Forum think that I handled the situation correctly or is there anything else I could have done?

10-09 What involvement should a journal have in a dispute about an article published in the journal? (AT)

Our journal published a manuscript as part of an editors' forum which, as an invited forum paper, received reviewer feedback but did not follow our usual double-blind peer review standard for regular submissions (the reviewers were aware of the author's identity but the author did not know the identity of the reviewers).

Following the publication of this article, the editor-in-chief received correspondence from a reader (hereon referred to as the "scholar"), who indicated he (used generically for simplicity without implication of the author's or scholar's gender) had contacted the original author directly and was concerned about the data used in the paper. The author also emailed the journal to advise us of his correspondence with the scholar, which had made him aware of oversights in data collection.

The original author provided a revised paper and drafted a corrigendum which was edited and published as an erratum in a subsequent issue of the journal. The scholar was given the opportunity to read the erratum prior to publication. After publication of the erratum, the scholar continued to vocalise his concern that it still misrepresented the author's data and offered readers misleading conclusions, and he remained frustrated over the original author's unwillingness to share the dataset despite his request for it.

The scholar complained to the editor-in-chief of the journal that the author ignored his many email messages and asked the editor-in-chief to pass on his concerns. After consulting with another editor of the journal and deciding that it was not the journal's place to be involved in such disputes, the editor-in-chief talked with the author by phone and asked the author to correspond with the scholar directly about this issue. The editor-in-chief also told the scholar that the journal could not be the go-between in passing messages from one to the other but would consider a written response to the published erratum so that the debate would be in the public domain. They were encouraged to talk to each other directly.

We received the response article from the concerned scholar outlining his points of contention, which was intended for publication with the understanding that the original author would be given an opportunity to reply if he chose (but the scholar would not be offered space for a further rejoinder). We provided the original author with the scholar's response article, and he prepared a reply. The scholar was then given an opportunity to read the original author's reply to point out any factual errors in need of correction, and he again felt the reply article would be misleading to readers as well as misrepresentative of his own claims. He further raised concerns about a flawed review system, not only in regards to the original article not being reviewed double-blind, but also to the editing process for his versus the original author's latest reply articles (both were edited—primarily proofreading in nature—by the editor-in-chief and another editor).

At this time, the editor-in-chief has contacted both the scholar and original author simultaneously in the hope of encouraging them to work together with shared data to produce a new paper (if, indeed, a re-analysis leads to new results). Should they not choose to pursue this, the journal intends to publish the scholar's reply and original author's response, likely

alongside a final word from the editor-in-chief. Any response or outcome along these lines is still pending.

How might editors ensure the integrity of data beyond the safeguards built into the normal manuscript review process? What role should the editor play when authors refuse to share their data? More generally, how should editors address concerns of readers who remain aggrieved by authors' responses to readers' commentary on an erratum provoked by questions raised by said readers in the first instance?

Following discussion with the officers of COPE, the summary of advice is as follows:

1. Double blind review is not always possible. For example, in small fields, most people can easily know the author of a piece of work. Also, there is no evidence that double-blind review is better than single-blind or non-blind reviews.
2. The editor cannot possibly double check the accuracy of the data in every paper and thus it is a good policy for the editor to allow readers a forum to voice their concerns about the published work.
3. The editor has the right to decide what gets published in the journal in light of the mission of the journal, its style, and the space constraints.
4. There is a point where a critique/concern becomes an opinion. The editor has the right to decide when the disputants have had the chance to voice their views and when it has reached the point for the readers to judge the merit of the grievance or responses from the published comments.
5. I have given the reader the courtesy and opportunity to voice his/her view.

Does the Forum agree with the officers' advice and is there anything more I should do?

UPDATES

09-06 Duplicate publication

Background

We are fortunate to have very knowledgeable reviewers who are immersed in their specialty and in the literature. A reviewer informed us that s(he) was working on a review of a manuscript and thought that there had to be more qualitative studies on this subject. S(he) began to look and found three articles not cited by the author and then a fourth.

The fourth study was published in another journal but was written from the exact angle, reporting the same data and in the same way as the article submitted to us. While some of the wording had been changed and the introductory material moved around a bit, it was essentially the same study. The quotes describing each category had also been changed, but little else. Surprisingly, one of the major differences is that the published article contained a much richer explanation of the methods, a sample description and study limitations than the version submitted to us. We do not understand what the author was thinking, submitting essentially the same paper, albeit one of lesser quality.

I ask that COPE provide me with recommendations as to the follow-up course with the author.

Advice

The Forum was unclear about whether the same authors were involved—was this a case of plagiarism or duplicate publication? The Forum also noted that any action depends on the journal guidelines. Does the journal document in its guidelines how much overlap is allowed? If the authors are the same, the advice was to follow the steps in the COPE flowchart “Suspected redundant publication in a submitted manuscript”. The flowchart advises that you check the degree of overlap. If it is substantial, contact the authors and request an explanation. If an unsatisfactory response is received, reject the paper and contact the authors explaining your position and the expected future behaviour. The editor might also like to consider contacting the author’s institution and informing them of the author’s misconduct.

Sometimes the author makes a genuine mistake or the instructions to authors are not clear enough (does your journal say that submitted work should be original and not submitted elsewhere?) or the author is very junior. In such cases writing to the author explaining the situation and outlining the expected behaviour is sufficient.

Follow-up

May 2009

We rejected the article and the author said he learned an important lesson. The editorial board met and it was unanimous that the situation should be reported to the author’s university academic integrity committee for review.

February 2010

The case is now closed. The author self reported within his university and did a faculty workshop about the issue. He submitted some information to the editor that we will incorporate into our editorial on duplicate publication.

09-11 HIV homeopathy

Background

The authors carried out a study. A homeopathic treatment was given to people with HIV/AIDs. The outcome was quality of life, as measured by a questionnaire after 1 month and 18 months of treatment. Participants were selected for inclusion if they had a HIV seropositive status at the time of study and were not taking any other kind of HIV/AIDs treatment.

The participants were stratified into severely ill (including those who could not walk and were cachectic) and not severely ill. The authors said that they had obtained ethics approval for this study from their own institution in their country of origin and that the Ministry of Health in the country where the trial was conducted had “authorised” the study.

We asked the authors whether the participants had been offered antiretroviral treatment at any time and if not why not? The authors confirmed that the study protocol did not include antiretroviral therapy because “There is no obligation of the ARVs use and conventional medicine is expensive. Many patients...were afraid of white people and of the side effects”.

We asked what the participants were told when they gave consent. The participants were given details of the homeopathic treatment but no mention was made of the existence of antiretroviral treatment. We asked to see copies of the protocol submitted to their ethics committee and the actual approval. The document, which was translated by a member of our staff, did not mention antiretroviral treatment. We asked to see documentation of “authorisation” from the Ministry of Health of the country in which the trial was conducted. There was no written documentation. It was verbal.

We asked why they sought approval from their native country and not the country where the study was carried out. The authors told us that once they had approval from their country, the authorities in the country where the trial was conducted did not require local approval.

We asked how the study was funded and what the authors’ relationship was with the funding body. They provided the names of two funding bodies but no documentation (funding came from funding for a Master’s degree of one of the authors). They did not clarify whether they had any relationship with the funding bodies.

We felt that all participants should have received standard care with antiretroviral therapy, that ethics approval should have been sought from a local ethics committee and that the participants should have been informed about antiretroviral therapy when consent was sought. We were also concerned that this protocol apparently was approved by an ethics committee. We rejected the manuscript and wrote to the authors’ institution expressing our concerns and requesting they investigate further and keep us updated on their progress.

Is there further action we should take?

Advice

The Forum questioned whether in fact there was a local ethics committee, which may be a reason why the authors obtained approval in their own country. However, the Forum was unanimous in their view that the authors had behaved unethically. All agreed that the editor had done all he could and there is little more action that he can take, although some advised contacting the ethics committee or the licensing body of the authors. If there is no response from the institution, the editor could consider contacting the ministry of health in that country (he should copy in the authors in this communication if he does).

Follow-up

We contacted the authors' institution, ethics committee and the Ministry of Health but have not received a response from any of them.

09-13 Reviewer misconduct?

Background

We have received threats of legal action from the authors of a manuscript rejected by our journal, henceforth referred to as journal A. These "aggrieved" authors claim that their manuscript was unfairly reviewed by a close competitor, who then used some of their findings in a paper subsequently published in journal B, without either attribution or citation.

The "accused" scientist had indeed reviewed the paper for journal A, and the date on which he/she had first been sent the paper preceded that of his/her own submission to journal B. The steps of our investigation were as follows:

The aggrieved author was asked to provide additional details on which aspect of his work he/she suspected of being unethically used, and he/she identified a particular paragraph in journal B's paper, which named two genes which our authors claimed to have identified for the first time in the particular bacterial genus studied in both papers.

Meanwhile, the "accused" scientist was asked to respond to the accusation. His response identified the paragraph in question as being a small area of overlap between the two papers, however, he categorically denied that the content of this paragraph drew in any way on the information presented in the manuscript which he had reviewed for journal A. The accused backed up this denial by sending us a copy of an earlier version of the paper, which had been submitted to and rejected by a previous journal (journal C) months before he had first reviewed the complainant's paper in journal A.

We confirmed this by contacting the editors of journal C who, after obtaining permission, provided us with an independent copy of the manuscript that had been submitted to his journal. On examination we found that the paragraph in question had remained unchanged, and that the description of the two genes was indeed present before any submission to journal A took place.

We agreed with the accused that this data analysis was a very minor part of the paper published in journal B.

Questions for COPE

- At this point, we feel that our investigation has exonerated the accused reviewer of one

allegation (unethically using information obtained during the peer review process in his/her own publication). Does COPE agree?

- If the manuscript submitted to journal C (providing independent confirmation of the accused's defence) had not been available, how would such a case be investigated?
- The other allegation (of the reviewer causing the authors' manuscript to be unfairly rejected) remains unresolved. The reviewer denies misconduct, but there is at least the appearance of misconduct on the basis of conflict of interest. However, we do not think that any further investigation can resolve this issue. Does COPE agree?
- The aggrieved authors have asked for a correction to acknowledge their work (which was published in yet another journal one month before journal B published its article). While the reviewer did not "steal" any data or ideas, he may have unfairly "squashed" the authors' publication. However, the data analysis in question is a very minor point in the article published in journal B, and the authors' work may simply be independent corroboration. At this time we do not feel a correction is warranted because we have no evidence of wrongdoing. Does COPE agree?
- Are there other options that might be used in place of a correction?

Advice

The Forum agreed that the accused reviewer had been exonerated. The advice from the Forum was that the editor should obtain permission from the reviewer to contact the authors, tell them that their allegations were unfounded and explain the situation to them. The authors should be informed that the reviewer has given his permission for this disclosure as the editor is not obliged to reveal the names of reviewers if the journal operates a closed peer review system. The editor might also suggest that the authors may like to consider an apology to the reviewer. However, some Forum members voiced concerns that the reviewer did have a conflict of issue and that he should have declared this initially.

Follow-up

The reviewer was notified (as were the editors of the other journals) that he had been exonerated, with thanks for his patience and for his cooperation throughout the investigation. The author was also contacted and told that the reviewer had been exonerated. The authors did not formally apologise to the reviewer.

09-16 Ethics and consent in research

Background

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.

Advice

All agreed that this was a very serious matter and possibly of criminal concern and were surprised that the complainant had not taken any more action or taken the matter up with the medical authorities or the police. If medical staff are aware of abnormal test results and they do not tell their patients, the staff should be reported to the GMC in the UK or to a similar authority in the country where the research took place. The editor should contact the authors and ask for a detailed copy of the ethics approval. The editor should explain that he has had a complaint about the paper but he should not divulge the name of the whistleblower. The editor should also ask for copies of the consent forms.

It was suggested that the editor might want to consult the flowchart on “What to do if you suspect an ethical problem with a submitted manuscript”. All agreed that this case has wider implications than ethics or patient consent and that the whistleblower should pursue other avenues. There is little that the editor can do other than to contact the authors and request an explanation. All agreed that the journal cannot offer due process to investigate the concerns itself but must leave this to the institution involved or the committee that gave ethical approval for the research.

Follow-up

Following the advice from COPE, the chief editors wrote to the authors of the paper to mention that we had received a complaint regarding the ethics of the paper. The chief editors asked for proof of approval of the study from the authors’ university and also the patient consent forms. These were both received from the authors and the chief editors were happy with the documents provided and have therefore taken no further action.

09-21 Self plagiarism

Background

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?

Advice

Some members of the Forum expressed sympathy for the author. However, the article was submitted as original work (not solicited by the journal) and the author failed to mention the other papers in his covering letter. Some Forum members commented that it may be legitimate to present the same material for different audiences and both articles may therefore have a place. All agreed however that this was a question of transparency. Authors should declare if they have published previous papers, as well as citing them in the text. There may be a question of breach of copyright and the editor might want to remind the author of copyright law. Otherwise, the Forum agreed that the editor has done all he can but he should ensure that his instructions to authors are very clear regarding this matter.

Follow-up

We wrote to the head of research governance at the author’s institution saying that the case was taken to the COPE Forum and the Forum disagreed with the author’s opinion that self plagiarism is acceptable in the context of a review paper. We wrote that we believe it is not sufficient that “an author who submits ... work similar to work already published, must disclose this at the time of submission”. The important issue is not disclosure, but that publication of such work would be redundant. The previously published material remains in the public domain and is generally subject to copyright. Discussion of the work is, of course, acceptable, but not replication of whole sentences or paragraphs. No further action is contemplated, but we strongly suggested that they reconsider their policy in relation to this issue. We have not received a reply but we hope they may at least be reconsidering their policy.

09-23 Scientist reads published paper by former collaborators and claims co-authorship Background

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.

Advice

All agreed that this is fundamentally an author dispute. The advice from the Forum was to ask both parties to set out clearly their complaints. The Forum was unanimous in its opinion that the journal cannot get involved in an author dispute, and the editor cannot act as adjudicator. The advice was to contact the authors’ institution or funder. The authors should be informed of the editor’s intention. The editor should ask the institution to investigate the case. If the institution does not respond, the editor has a duty to alert readers to the situation and so he should publish an expression of concern or notice of disputed authorship. Other advice was to ensure that the journal’s instructions to authors make clear the criteria for authorship and contributorship. Another suggestion was to ensure that in the future, all correspondence is sent to all of the authors and not just the corresponding author.

Follow-up

We followed COPE’s advice and wrote to the rector of the university, copying the authors, asking him to resolve the authorship conflict, and mentioning that unless they managed to do this quickly we would have to take unspecified measures to inform our readers. They did. The author who had started the whole complaint by claiming that her idea had been hogged was removed from the acknowledgement section in a revised online version and of course in print. This permitted her not to be associated with the research. Rather surprising outcome but it kept everyone happy and we did not have to retract the paper, with all the unpleasant ensuing consequences.

09-24 Homeoprophylactic treatment of a zoonotic disease

Background

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.

Advice

The Forum was told that this study was funded privately. The Forum questioned whether it was in fact a study? From the description, it seemed to be a report of a public health intervention. If that is indeed the case, then consent is not needed. The advice from the Forum was to seek confirmation that these interventions actually took place (since the numbers involved are so large and because of the discrepancy with the information from the CDC). Did the government introduce it? The Ministry of Health could be contacted. If the editor discovers that the whole event was fraudulent, then he should bring the case back to COPE.

Follow-up

We attempted to contact the Ministry of Health without success. We have contacted the director of the PAHO and are awaiting a response.