



Forum agenda

**Meeting to be held on Tuesday 9 December 2014, 9am–10.30am (GMT)
BY WEBINAR**

1. Update on COPE activities by the Chair

2. Forum discussion topic: Publication ethics issues in the social sciences

<http://publicationethics.org/forum-discussion-topic-comments-please-1>

3. New cases

14-09 Institutional review board approval required? (TH)

14-10 Possible self-plagiarism and/or prior publication (AO)

14-11 Possible omission of information essential for conclusions in a research paper (WW)

4. Updates

13-18 Claim of plagiarism in published article

14-01 Potential fabrication of data in primary studies included in a meta-analysis accepted for publication

14-04 A case with no independent institution to investigate

14-07 Authors' contributions and involvement by medical communications company

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2. Forum discussion topic: Publication ethics issues in the social sciences

(<http://publicationethics.org/forum-discussion-topic-comments-please-1>)

Background

The history of research ethics in general and publication ethics more specifically was initially and primarily grounded in the biomedical sciences. As concern over issues of animal care, human participant protection and research integrity developed throughout the latter part of the 20th century, some members of the Social Sciences and Humanities communities raised concerns that the cultures in their particular disciplines differed and that a 'one model fits all' was inadequate to evaluate research ethics and publication ethics.

Social Sciences

Most quantitative Social Science research involves research methodology that is similar in scope and nature to that found in the natural and biomedical sciences, including hypotheses testing, statistical analysis and is nested within long recognized scientific norms of investigation. This is also true with respect to quantitative studies with human subjects and participants. In many countries, the approval of research using either animal or human participants requires the researcher to obtain prior institutional research ethics approval before undertaking this type of research. Some researchers disagree with the requirement of prior ethics approval saying that their research is low risk and needs no review. These researchers sometimes do their work under the auspices of community groups and avoid institutional ethics review.

As well, there are disciplines which object to all such requirements or find them problematic to their particular fields of study. Many of the complaints concerning the need to recognize difference come from fields including: Ethnography, Anthropology, Sociology, Criminology, and some sub-disciplines in Psychology, Education and Social Work. This list is illustrative rather than exhaustive.

Questions

- Some Social Scientists have objected to institutional research boards on the grounds that such approval is heavy-handed and inappropriate as a tool to evaluate their research. They conduct their research through community groups and avoid institutional approval. How should editors handle such studies and manuscripts?
- What should editors do when they receive manuscripts from Social Scientists who have completed the research without institutional ethics approval?
- What guidelines do editors require to assess manuscripts where authors argue that their fields should be evaluated using very different criteria than is standard in terms of research ethics and research integrity than other fields of inquiry?
- Should publishers develop policy to deal with the claim by researchers that Social Science is different from other sciences and needs to be evaluated without ethics review?
- Should university exemptions be sufficient for editors to consider publishing manuscripts which have been deemed exempt from ethics review?
- How should editors determine whether to publish research on illegal activities and illegal behaviours?

References

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Kitchin, H. (2007). *Research Ethics and the Internet*. (Fernwood Press: Nova Scotia).

Stanton, J. and Rogelberg, S. (2001). Using Internet/Intranet Web Pages to Collect Organizational Research Data. *Organizational Research Methods*, 4 (3), 200-217.

3. NEW CASES

14-09 Institutional review board approval required? (TH)

We have a query regarding institutional review board (IRB) approval for a paper in production.

The paper reports on a 2 year follow-up and cost-effectiveness evaluation for a treatment programme. A previously published paper reports on the original evaluation of the treatment programme. The authors have not obtained IRB approval for either body of research.

The initial research was described as a report of outcomes from 5 years of clinical experience with the programme, rather than as a clinical trial, and as such IRB approval was not sought. For the paper currently under consideration, the authors' original statement in the paper was that "Institutional review board approval was not required as patients were treated with approved diagnostic and therapeutic procedures according to generally accepted standards of care". We were unable to verify this as a valid reason for exemption from the requirement for IRB approval.

Having found no clear grounds for the exemption on the basis offered, we asked the author to provide a reference or further information regarding this basis for exemption. The author responded that the research was exempt under the following US federal regulation: "Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects".

Our concerns with this justification are that the data are not publicly available, and that the data include follow-up telephone interviews, which seem in conflict with the requirement that the data should be de-identified, and that indeed the follow-up interview information are new data, not existing data or records.

Question(s) for the COPE Forum

- Is this research publishable in the absence of IRB approval?

14-10 Possible self-plagiarism and/or prior publication (AO)

In October 2014 it came to our attention via one of the reviewers of a manuscript submitted to our journal that an identical article (100% identical) had been previously published on the website of the author. The submitting author had not made us aware in their submission documentation that the article had been publicly available on their website at the point of submission. Two different but related issues arise from this.

Firstly, as it is the journal's policy to conduct blind peer reviews of each submission received, it is impossible to uphold this policy where submissions already exist, as does the present one, in an identical form in the public domain. Secondly, there is an issue of self-plagiarism. In academic contexts, it is not permissible to re-use identical copy for multiple submissions, and would in all likelihood be regarded as a case of academic misconduct.

We have consulted the COPE website for advice but there does not appear to be a comparable case whereby the original identical article is in the public domain but not previously published in another journal. We are also aware of the various definitions and types of plagiarism and self-plagiarism which render the details of this case a grey area (COPE Discussion Document: How should editors respond to plagiarism <http://publicationethics.org/files/Discussion%20document.pdf>), and that copyright and rights of author issues may apply.

In summary, both co-editors of the journal consider that this case constitutes self-plagiarism and possibly redundant/duplicate publication according to the COPE Case Taxonomy (<http://publicationethics.org/cope-case-taxonomy>). The two COPE case taxonomy areas we refer to in this case are:

- 'Self-plagiarism' (submitted article)—reusing one's own previous writing without being transparent about this or appropriately referencing/quoting from the original" and
- 'Prior Publication'—The publication, or attempted publication, of whole or substantial parts of the work/data/analysis that have already been published, or have been submitted elsewhere, without transparency or appropriate declaration/referencing.

We have contacted the author, forwarding the two peer reviewers' comments which both contained major revisions to the manuscript, also pointing out that we are aware of the existence of the article on the author's website.

Question(s) for the COPE Forum

We would be grateful for the Forum's advice on:

- Whether to pursue this as we would a case of self-plagiarism of a previously published journal article (ie, reject the paper) or whether it would suggest an alternative course of action(s).
- The other related issue is the publication of 'green copies'. While many journals, including our own, now encourage authors to make their own author copy available on public forums (eg, researchgate, institutional fora), such publication would normally take place *after* the publication of an article in a journal and not before. It is our concern that better policies need to be developed around *prior* publication.

14-11 Possible omission of information essential for conclusions in a research paper (WW)

In 2013, our journal published a paper describing an observational study comparing two drugs (A and B) for the management of a chronic disease over a period of 10 years. The conclusion in the paper was that mortality was higher in group A (97 deaths) compared with the other group B (52 deaths) (hazard ratio 1.76, 1.22 to 2.53; $P=0.003$). This analysis was done after adjustment for a large number of confounders, and was approved by our statistical advisor. The authors of the papers did acknowledge that this was an observational study, and did state that residual confounding might be present.

In 2014 we received a letter of concern by a researcher, employed by the company selling drug A, who felt that the authors of the 2013 paper omitted essential information that might impact on the conclusions. It appears that the routine management of this disease has changed substantially over the 10 year period, and this should have been treated as a confounder for which statistical adjustments should have been made. This change in routine management of the disease is documented in a paper published in 2014, but the researcher felt that these authors were probably aware of this much earlier and should have disclosed this information during the review process of their 2013 paper.

In our initial response in July 2014 to the letter of concern, we asked the researcher who sent us the letter of concern to send us a detailed rapid response to the 2013 paper, which we could publish. We have also asked advice of our statistical advisor who reviewed the 2013 paper, and he acknowledged that this information might impact on the statistical calculations and thus the conclusions of the paper. But with the data available to him, he is not able to make a definitive assessment of how much impact it would have. He has suggested to put these questions to the authors of the 2013 paper.

Question(s) for the COPE Forum

- The researcher who raised the concern has not made his concerns public by sending us a rapid response that we could put to the authors and publish, with their response, on our website. We will certainly put the questions to the authors of the 2013 paper, but we wonder if we should publish these concerns?
- Another problem is that, due to the complexity of the statistical calculations, we are entirely dependent on the authors to judge whether the routine management data would have seriously impacted the conclusions of the 2013 paper.

4. UPDATES

13-18 Claim of plagiarism in published article

Case text (anonymised)

Author A of a 2008 review article in our journal claims her article was used as the "framework" for a 2013 review article on the same subject in an open access journal by a former student of hers, author B. There was no verbatim overlap but the format (comparison of two common conditions) was indeed similar (differential diagnosis, management, pharmacotherapy, and implications for practice).

Author A sent me the articles for comparison and stated that she thought this was plagiarism and that, furthermore, her student had no experience caring for these patients so she had misrepresented herself as an authority on this topic. The student (author B) was the first author, the second author was a physician who was well published on this topic, and "writing assistance" had been provided by a professional medical writer and paid by a pharmaceutical company that manufactures drugs in this therapeutic class. I checked both papers through iThenticate and there was no verbatim overlap between the two. I had nine members of my editorial board review and compare the articles in question along with the complaints of author A. I asked for specific comparisons (quantity and quality) of overlapping material and whether or not any overlap constituted plagiarism of ideas (not words). The editorial board concluded, as did I, that this format is fairly standard for clinical articles; content overlap likely resulted from similar content in practice guidelines for these conditions; neither article is 'conceptually original'; and that updates of clinical review articles are a common practice (there was a 5 year gap between the articles). We found multiple articles in the literature on the same or related topics with similar resources, content, and format.

Meanwhile, author A contacted the open access journal stating that she was consulting a lawyer and she wanted author B's article "pulled and reviewed for integrity and rigor". Within 8 days of the complaint, I wrote to author A stating that we did not find evidence of plagiarism and that I would not contact the open access journal with a claim to protect the article copyright because I did not believe it had been violated. Author A was not pleased with my response and claims she has "confirmed" with two colleagues that there are striking similarities between the articles. I reiterated based on COPE guidelines and definitions of plagiarism, there was nothing more I could do. Meanwhile, the open access journal responded to author A's email that they have "removed" the offending article by author B from their website (in fact it is still there) and they suggested she contact the author because authors retain the copyright. I referred author A to my publishing manager, who has been apprised of this investigation since the beginning, if she wishes to pursue this further.

Questions for the COPE Forum

(1) Do I have an obligation to contact the open access journal with my findings? I am reluctant to do so given there are legal implications (lawyer contacted by author A); author B's paper has not actually been removed; and there are professional medical writers and a pharmaceutical company involved in author B's paper. I had never contacted the open access journal myself and they have not contacted me but I "feel" that I might have some responsibility to let them know that we are not making any claim.

Advice:

The editor updated the Forum that the paper by author B has now been removed from the publisher's website, with no notice of formal retraction, although it is still possible to find the paper by a search of PubMed.

The Forum suggested that the style of writing of review articles may mean that this type of issue arises. Author B may have been commissioned to write the review and asked to format it in a specific way. The Forum noted that it is possible to have plagiarism of ideas and not just words, although harder to prove, and author A may feel this is the case in this instance.

But in reality, this is an issue for the open access journal, not the editor's journal. The editor feels that the open access journal has genuinely tried to do the right thing but has just not handled the situation correctly. Should the paper in fact have been removed at all? Was there any plagiarism? By removing the paper, without issuing a retraction, the literature has not been corrected, and if the paper was not plagiarized, then what might have been a reasonable paper is no longer available. Was the editor of the open access journal pressurized into removing the paper by author A and/or its publisher because of the threat of legal action?

Is author B aware that his paper has been pulled from the journal's website? Author B and his colleagues may have legal redress against the open access journal. But it is up to the open access journal to inform author B.

Hence a suggestion was for the editor to reach out to this other editor, and perhaps discuss how this might have been handled differently. On a poll of the Forum audience, more than half agreed that the editor should reach out to the other editor, obtain their side of the story and perhaps then establish how proper correction of the literature can be done.

Follow up:

At the suggestion of the COPE Forum, the editor wrote to the managing editor of the online journal clarifying that the journal did not find any plagiarism with their published article and that the editor would not pursue any claims against the journal. The editor also noted that the article in question was missing from the home page of the journal on the publisher's website but that it remained available on the PubMed Central site for their journal. The editor asked that the journal update her if they were conducting an investigation themselves and offered information on the COPE guidelines.

The managing editor responded thanking the editor for the clarification and explaining that the decision had been made by the publisher to remove the article in question from their website to "avoid legal complications," which had been threatened by the complaining author. He stated he did understand that removal of the article was not recommended by COPE but because the article was still listed and retrievable on the PubMed site for their journal, they thought this was a reasonable solution. He stated he would forward the editor's letter to the editor-in-chief and the publisher to see if this would change the decision; however, the situation remains the same. There has been no retraction of the article and the editor has not heard back from either the journal managing editor or the editor-in-chief.

Follow up (December 2014):

There has been no change in the status of the article in question and no further communication from the authors or the open access publisher. The article remains widely available and discoverable. The editor considers the case now closed.

14-01 Potential fabrication of data in primary studies included in a meta-analysis accepted for publication

Case text (anonymised)

Journal A has accepted a meta-analysis for publication. As is standard practice for many articles accepted in this journal, a key expert (Professor X) in the relevant field was invited to submit a commentary on the paper. Professor X expressed concerns to the journal that “we believe that some of the papers included in the review could be either fabricated or at best are heavily plagiarised”. The papers included in the meta-analysis are all primary studies published in peer-reviewed journals.

Journal A requested some evidence for the concerns raised by Professor X.

Professor X has already tried to investigate the potential research misconduct of the primary studies. He sent a comparison of five studies, three of which were included in the meta-analysis accepted by journal A. Professor X claims strong evidence of plagiarism, and questions whether the trials took place at all. He also notes that he has previously written to the authors of the trials but says that few have responded. Those that did respond, he believes, have failed to provide reassuring responses.

Example response from authors sent to Professor X include the following: “The work has been actually undertaken after proper clearance. And details of the same are available with the competent authority.” “We don't want to be get disturbed as I discussed with our main author.” “Excuse us..Bye”.

Journal A has now halted publication of the meta-analysis.

The editors of journal A are unsure how to proceed, as the potential research misconduct lies with research not submitted to the journal, but rather primary studies included as part of a meta-analysis submitted based on the “available data”.

Question(s) for the COPE Forum

- (1) How do we establish whether or not the primary studies are fabricated?
- (2) Is it journal A's responsibility to pursue this investigation or should it be the responsibility of the journals in which the primary studies are published?
- (3) How should journal A proceed with managing the meta-analysis accepted for publication?

Advice:

The Forum was told that the editor has not yet contacted the authors of the meta-analysis. The advice from the Forum was to raise the concerns with the authors initially. The editor has a responsibility to act on the information that he has, and the first thing to do is contact the authors of the meta-analysis.

The editor also needs to be sure that the evidence from the expert is sound, regarding the fact that some of the papers in the meta-analysis are fabricated or heavily plagiarised, before he draws any conclusions. The Forum suggested gathering more opinions on the meta-analysis and perhaps eliciting help from members of the editorial board. Why was the paper accepted in the first instance? Did the reviewers suspect anything untoward with the paper? The editor should go back to the reviewers and ask their opinions and also ask their advice on the response from the key expert.

The Forum cautioned against the practice of blindly re-analysing data for inclusion in a meta-analysis, without obtaining the original data, so the authors of the meta-analysis need to take some responsibility here.

Unfortunately for the authors, their paper is in limbo while there are questions over the paper. One suggestion was to ask the authors to re-do the meta-analysis using only the data that are not under suspicion.

Ultimately, it will be up to the journals in which the primary studies were published to investigate the fabricated and/or plagiarised papers, but journal A should initiate the investigation by contacting these journals. It will be the responsibility of the other journals to see that an investigation is carried out but journal A should follow the events. Of course, if the other journals refuse to investigate, there is little that the editor can do.

In summary, the Forum agreed that the editor should contact the authors and the reviewers of the meta-analysis in the first instance. If the editor has sufficient evidence that some of the papers are fabricated or heavily plagiarised, he should then contact the journals where the primary studies were published and ask them to investigate.

Follow up:

The editors need to decipher whether or not the original studies are trustworthy. The editors are unsure whether to contact the authors or the journals regarding this.

The editors will be keeping the authors of the meta-analysis accepted by the journal fully informed of where they are with the investigations.

14-04 A case with no independent institution to investigate

Case text (anonymised)

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

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

Advice:

The Forum agreed there are clearly issues with the paper and sufficient doubts for the editor to raise concerns and to contact the institution. Normally the Forum would advise that this issue was beyond the remit of the editor, and that the editor should look for an independent arbitrator, which is usually the institution. But in this situation, it is a private institution.

The Forum asked the editor if the institution had any associated regulatory or professional body which oversees it who could be approached? There is guidance on the COPE website in the form of a flowchart on what to do if you have ethical concerns about a published paper and there is no institution. The advice is to go to a higher regulatory body or, if not, to a medical regulatory body. In the UK, the medical regulatory body would be the General Medical Council (GMC). The GMC note that publication ethics is within their remit, so it is possible to raise this issue with a similar body if the authors are medical professionals, especially if there is no higher authority.

Although it is not the job of the editor to carry out investigations or police the research, the editor does have a responsibility to the readers of the journal, and so he should consider publishing an expression of concern.

The editor may have been able to avoid this situation if the journal had dealt with the ethical issues on submission. While the editor told the Forum that journal policy is to send email confirmation to all of the authors on submission of a paper, they do not ask for confirmation of authorship. This may have helped in this situation. The recently published fourth criteria of the International Committee of Medical Journal Editors (ICMJE <http://www.icmje.org/>) states that if you are an author of a paper, you have a requirement to help investigate any issues with the paper. Hence author A cannot recuse himself from any association with this paper.

Follow up:

Despite extensive efforts, the journal was unable to obtain an investigation from a higher regulatory body. As the editor was therefore unable to verify the concerns raised, expressions of concern were published for both articles. The case is now closed.

14-07 Authors' contributions and involvement by medical communications company

Case text (anonymised)

The editorial office was contacted by someone who indicated that s/he has been working with a medical communications company on several manuscripts and has become concerned about the minimal extent of the authors' contributions to manuscripts handled by the company. The work requested by the company goes beyond language editing, and involves developing parts of manuscripts into narrative on the basis of an outline, and also the addition of references. Based on responses from authors, our contact was also concerned about authors' level of understanding of the work and study design being reported in the manuscript. Our contact has been asked to respond to reviewers' comments on behalf of authors.

We asked for details of the manuscripts this person worked on; one is currently under consideration by the journal. On submission, the authors declared language editing assistance by this company, but not developmental editing. The cover letter included several inaccuracies about the work reported in the manuscript. After being queried about these errors, the authors acknowledged that they followed a template for the cover letter provided by the company and that it was their first time writing a paper of this type.

Our contact has been willing to work with us on the basis that we will maintain anonymity. We feel that there are sufficient concerns about the contributions to the manuscript that we should confront the authors about this point—however, this will reveal that we have had interactions with the person involved in the editing.

Question(s) for the COPE Forum

1. Should we proceed to contact the authors regarding the contributions to the manuscript?
2. What is our duty towards the person who raised the concerns to our attention?
3. Are there any steps that we can take to identify this type of situation in the future?

Advice:

The Forum suggested there were two separate issues here—dealing with the author and dealing with the medical writer. Is the medical writer a member of any professional organization, such as the American Medical Writers Association (AMWA), the European equivalent (EMWA) or the International Society for Medical Publication Professionals (ISMPP). If so, these organizations usually have a code of conduct that should be followed, so this is an area that the editor could look into.

The Forum suggested that the editor needs more clarification from the author. As there is some discrepancy in the author knowledge of the paper, this could be a way in for the editor to approach the author for more information while preserving the anonymity of the whistleblower. The editor needs to obtain evidence without disclosing the whistleblower.

One suggestion put forward was for the editor to check the properties of the original paper and see who authored it. This can sometimes reveal any discrepancies, although the Forum advised that in-depth investigations are beyond the remit of the editor.

As this is a clear case of ghost writing, the Forum suggested that the editor has an obligation beyond rejecting the manuscript, and that the editor should report the case to the institution and ask them to investigate.

On a show of hands, the Forum were unanimous in COPE discussing the role of the medical writer further, perhaps as a topic for a Forum discussion in the future. We need more clarity on the role of the medical writer in relation to authorship, and their relation to the author.

Follow up:

The journal followed-up with the authors and stated that the editors had reasons to believe that there had been substantial input into the editing and preparation of the manuscript beyond that declared in the authors' contributions. The editor requested comments on this and a copy of the original rough document the authors had submitted to the medical communications company. The authors indicated that they only requested input from the company after completing the rough draft, but they submitted a file that did not list as author any of the authors on the manuscript—in fact, the name listed as author on the file was that of the freelancer.

The editors decided to reject the manuscript, indicating to the authors that concerns remained as to whether the work was designed and written by the authors to an acceptable extent. The journal plans to raise the case to the attention of the authors' institution.