

CASE SUMMARIES FOR DISCUSSION

CASE 1: Interview-based study on assisted reproduction

Possible salami publication detected after acceptance of paper) (not published)

Issues that arose:

In this study of commercial ARTs, it was found after peer review, revision and acceptance, that self-plagiarism could be a problem. Paragraphs from the text had already appeared in another published article by the same author. When asked for a clarification, the author stated that there had been two studies at two clinics where ARTs were practised.

When asked why two studies on the same subject by the same author had been approved by the same review board, the author stated that s/he had studied two separate clinics of which only the findings from interviews at one clinic had been reported in the submission to *IJME*. A submission based on interviews at the other clinic had been accepted for publication in another journal. It was also claimed that the approach and methodology were different in both, but the author was unable to show how they were different.

On further investigation, it was found that the author's previously published article reported on both clinics, and the one submitted to *IJME* did not offer any new insights. It seemed this could amount to salami publication with data collected from the same study being split into segments. When we sought more clarifications from the author, s/he preferred to withdraw the submission. What emerged was that guidelines regarding salami publication within social science research are not very clear. A second issue was that institutions do not have clear rules regarding ethics review for social science research. So, a submission could not have been rejected on those grounds alone.

Some deception was also involved as several facts emerged only after constant questioning:

- Ethics approval had not actually been granted by an institutional ethics committee but by participants at an external workshop;
- It was not made clear whether informed consent was sought and if privacy and confidentiality were ensured.

We learned that we needed to introduce some safeguards and began asking authors to (a) provide references to any other article published from the same study/data; and (b) provide details of how ethical conduct of the study was ensured if the institute did not have an ethics committee.

Case 2: Plagiarism found post acceptance

Issues raised:

In this case, a paper on data exclusivity was reviewed by two experienced reviewers, revised and accepted; and found, during copy editing, to have extensive lifting of entire paragraphs from published works, without acknowledgement. These had been inserted during revision from references suggested by the reviewers! When asked for an explanation, the author, an assistant professor, claimed inexperience in writing. This was felt to be unconvincing, especially with the author being a teacher.

Action: Rejected.

We realised that:

- (i) We did not have a policy of checking all submissions for plagiarism. Peer reviewers cannot be expected to do this;
- (ii) Authors in certain positions and professions cannot claim ignorance of rules regarding plagiarism;
- (iii) We needed clarity on action to be taken regarding:

(a) whether revised text (after finding explanation and changes satisfactory) should ever be published by us;

(b) Whether the institution be informed - as a rule, or in particular cases. If the latter, in what sort of cases?

Case 3: Retraction due to publication under fake identity and affiliation

On October 30, 2017, a paper on "Increase in Cervix Cancer Incidence Among Women Below 50 Years-Of-Age in Sweden. Does HPV vaccination play a role?" by Lars Andersson, claiming affiliation to the Karolinska Institutet, Sweden was submitted. As we have published extensively on HPV vaccine, we were interested in the issue. The manuscript editor felt that: *"The article makes a limited point – Swedish data for certain years showed an increase in ca cx in a particular age group of women given the HPV vaccine. One possible explanation for this increase is that in women already infected by HPV at the time of vaccination, the vaccine might trigger/hasten the development of ca cx. The author made this argument based on the data, a comment in an FDA clinical review of Gardasil, and biological plausibility. The author called for more studies on this subject, as it is an important question when deciding on whether the vaccine's benefits outweigh the risks..... The HPV vaccine is being introduced widely around the world, including in India, and for older women as well as for younger women. A comment on this would be important."*

The paper was reviewed by two experts, one an international external reviewer and a statistics reviewer. Several issues were raised by the reviewers and the paper was duly revised. Further queries were raised by the manuscript editor regarding: the period when the immunisation

programme covered a substantial number of women in Sweden, and asking for more references. These were complied with and the submission was approved for publication on March 20, 2018, and published online on March 30, 2018.

Within a few days of online publication, we received a mail from the Karolinska Institutet PRO stating that no such person as the author worked or had ever worked in the relevant department of the Institute, and demanding that the affiliation should be corrected forthwith. The Editor contacted the author and got an admission that s/he had in fact been working at the institute earlier, that s/he had written under a pseudonym, but was qualified in the relevant field, and had feared pressure from powerful lobbies had publication been under the actual name. The name and affiliation right away, with an explanation that it was a pseudonym, but a decision was made not to retract the paper, which could be of value.

Meanwhile, we continued investigating the author's background and found s/he had published at least three short letters/comments in established international journals, under the same name and affiliation, which had never been discovered before.

The decision not to retract the paper was criticised by editors and ethicists on the social media on grounds of:

- a) going beyond our discipline of ethics,
- b) being 'anti-vaxxers'
- c) the qualifications of our reviewers and manuscript editor;
- c) and our decision not to retract on grounds of the author's deception while dropping the affiliation as showing toleration of malpractice.

Extensive discussions took place with the entire Editorial team and Board. The Board suggested setting up a group to come up with a decision. The publisher was also informed. The publisher asked for the name of the author which it was felt would be breaking the promise made by the editor to the author.

Finally, it was decided to retract the article.

Since this case, we have begun routinely requiring institutional email ids of authors, and publishing controversial papers along with commentaries, as safeguards against such deception.

Case 4: Prospective approval for previously completed study

The initial submission, based on a study carried out in 2007 on medical graduates' choice of career destination, was received by *IJME* in February 2018. The study population was obtained from an institution's electronic database of batches of medical graduates from 1966 to 1995. A questionnaire on present area of work and reasons for choice of area was sent by email and post to the potential participants.

The paper had no mention of ethics committee approval. We requested details of ethics committee approval and informed consent, and the authors responded saying that in 2007, when the study had been done, IRB submission for studies among peers was not a requirement, and that the institutional requirement was only a permission letter from the Vice Principal. We then asked for a certificate from their IRB to that effect. The authors initially said their IRB team had

asked them to submit the same study proposal for a retrospective review; and later said the IRB had refused to provide a retrospective review and asked for submission for a prospective review in May 2018.

Retrospective ethical reviews and approval of studies are not acceptable, and a prospective IRB approval is obtained before a study is conducted. However, we gave them the benefit of the doubt about possibly wanting to re-do the study after the prospective approval, and waited for them to get back with an IRB decision.

More than a year later, in April 2019, we received copies of IRB approvals and a copy of an informed consent document from the authors. The IRB approval letter was dated March, 2019 from a meeting held in January, 2019. The IRB approval stated “We approve the project to be conducted as presented”. This implies that the IRB has approved the study prospectively, to be conducted in the future.

Since they had represented a prospective review and approval of a study proposal as the approval for a past study done in 2007, we considered it inappropriate research conduct. We therefore, declined the study for publication in IJME in May, 2019, and emphasised that all research on human participants must be submitted to an Ethics Committee, which should then decide on whether to exempt the study from review (less than minimal risk studies), go through an expedited review (not more than minimal risk studies) or through a full board ethical review. Ethical approval obtained after the conduct of the study does not serve the purpose of protection of the potential research participants and is, therefore, not appropriate.
