

Presenter of case: Marc Edwards

COPE member involved: *International Journal of Infectious Disease*, Elsevier

Date at which case was received: 1 November 2019

Article involved

Conference abstract:

Bacterial colonization of drinking water: implications for an aging U.S. water infrastructure

Maki, G. et al.

International Journal of Infectious Diseases, Volume 79, 30 - 31

Summary of issue, as outlined by presenter

If an allegation is made of a study, regarding a possibly fabricated conclusion, for a research study in which 5 of 10 patients died, does:

- 1) the editor need to enforce production of an IRB protocol and approval
- 2) the editor need to enforce, resolution of the concern, about a potentially fabricated conclusion.

What aspects of the Core Practices do you believe that the member is contravening, and why

The relevant core practices are:

- 1) Allegations of misconduct. Specifically, suspicions of a possibly fabricated conclusion, attributing 50% mortality to use of an off-the-shelf water filter in Flint.
- 2) Ethical oversight. We would like assurance that the protocol for a research study, that resulted in the death of 5 of 10 patients, received appropriate IRB approval.

Member's response

Thank you very much for your mail of December 15th concerning the conference abstract:

February 2019 Volume 79, Supplement 1, Pages 30–31

Bacterial colonization of drinking water: implications for an aging U.S. water infrastructure

G. Maki, S. McElmurry, P. Kilgore, N. Love, H. Misikir, M. Perri, M. Zervos

I have had an extensive correspondence with Dr Marc Edwards. We have a received a letter to the editor airing the same concerns as Dr Edwards and have obtained an answer from the authors of the conference abstract, and both have been accepted without editing and will be published in the January issue of the IJID. Both attached (IJID-19-01424 and IJID-19-01527) for your easy reference.

I have discussed the points raised by Dr Edwards with my colleagues in the Intl Society of Infect Dis (the owner of the IJID) and our publisher Elsevier. We believe this is an issue between Dr Edwards and Dr Zervos and Dr Zervos home institute, and not something the IJID can or should be involved in.

Dr Zervos abstract has been peer reviewed, accepted and per Dr. Zervos, there is an approval for the study from his institutional review board. Please note that this was a conference abstract, limited to 350 words, not a manuscript.

I have several times advised Dr Edwards to talk to Dr Zervos and to his institution.

The position of the IJID is summed up in the mail to Dr Edwards of the 30th October (copied in below) and that is still our position.

Thus we believe that the IJID has been in complete compliance with the COPE guidelines and we refuse to be used in a dispute we do not understand.

E-mail of the 30th October 2019

Dear Marc Edwards

Thank you very much for your mail of the 22nd October.

I discussed your mail with our publisher, Elsevier. The authors of the abstract in the IJID you refer to promised to be in contact with you. If that does not happen I have no possibility to enforce that.

The COPE guidelines do not empower an editor to obtain the information you ask for from an author. Note that COPE is an advisory body not a regulator, and it does not rule on cases.

The IJID peer reviewed the abstract based on its apparent scientific merit and found the study of interest to a larger audience. Note that conference abstracts are most often not fully completed studies.

As I suggested previously, the IJID can offer to publish a "letter to the editor" where your concerns are expressed. Then it is up to the authors of the abstract to answer or not, but in any case your concern will be available for everyone to be seen.

If the authors does not wish to reply to your letter, we will publish a statement after your letter saying that we invited the authors to comment but we did not receive a reply.

Another option for your is to contact the authors' employer or person responsible for research governance at the authors' institution.

[Member's response to COPE's request for the journal to request further clarifications from the authors](#)

Thank you very much for your mail.

The IJID published a letter with the same questions as Mr Edwards has raised and the authors of the original abstract replied.

Both has been published without any editing from our side:

Bacterial colonization in point-of-use filters and deaths in Flint, Michigan.

Hernan F Gomez, Dominic A Borgialli, Mahesh Sharman, Anthony J Scolpino, James M Oleski, John D Bogden.

Int J Infect Dis. 2020; 91(Feb): 267.

<https://doi.org/10.1016/j.ijid.2019.11.031>

[https://www.ijidonline.com/article/S1201-9712\(19\)30471-0/fulltext](https://www.ijidonline.com/article/S1201-9712(19)30471-0/fulltext)

Author response to letter from HF Gomez, et al.

Marcus Zervos, Gina Maki, Nancy G Love, Shawn P McElmurry.

Int J Infect Dis. 2020; 91(Feb): 268-269.

<https://doi.org/10.1016/j.ijid.2019.11.030>

[https://www.ijidonline.com/article/S1201-9712\(19\)30470-9/fulltext](https://www.ijidonline.com/article/S1201-9712(19)30470-9/fulltext)

We think that answer your question on ethical approval.

Concerning your point "Information on when the infections took place relative to the water filter usage, and clarification about the cause of death for the patients."

We believe this is outside the task of the journal and refer to the two published letters.

Response to COPE from the International Society for Infectious Diseases

I am getting back to you on behalf of ISID's Publication Committee in response to your email to the IJID Editor Eskild Petersen dated April 19, 2020. The IJID is published on behalf of the International Society for Infectious Diseases (ISID) by our publisher, Elsevier.

The committee and I have reviewed your email and previous correspondences. It is the committee's understanding that the item in question is an abstract (not a full article) that was presented at the International Meeting on Emerging Diseases and Surveillance (IMED) in 2018. Congress abstracts are limited to 350 words and are peer-reviewed through ISID. The abstract review and selection process is overseen by the respective Congress Organizing Committee. Through an agreement with the IJID and the journal publisher Elsevier, abstracts accepted for presentation at any of the Society's international meetings are published as special supplements to the IJID without further review process through the journal. ISID's Publication Committee will therefore take over further correspondence and handling of Dr. Edward's concerns.

Specifically, the committee would like to respond to your inquiries below:

COPE Concern 1: You indicate that the journal has now published two Letters to the Editor discussing concerns about the published abstract. However, it does not appear that the journal has taken steps to address the actual concerns about the information reported in the abstract, specifically, in relation to the time at which the infections took place relative to the water filter usage, the cause of death for the

patients, and the questions around ethical oversight and approval for the study. As we indicated in earlier correspondence, it is the editor's duty to follow up on those items in relation to the published content, in order to establish whether any corrections to the record are required for the abstract. We feel that the lack of follow up on the specific concerns noted about the abstract deviates from the expectations per the COPE Core Practices.

The committee believes that adequate steps were taken to address these concerns as outlined in the author response published in the IJID (please see attached). The authors addressed the question about the study design, outcomes and limitations. Authors report the following ethical approval:

Henry Ford IRB Approval (HFHS #12383). Ethical approval was also confirmed by Dr. Margot LaPointe, Vice President of Research at Henry Ford in a correspondence between Dr. Marc Edwards and Dr. Margot LaPointe which Dr. Edwards shared previously and which is copied here: *" Like all research conducted at Henry Ford Health System, this study by Dr. Marcus Zervos was thoroughly reviewed and approved by our Institutional Review Board. The IRB determined the study was appropriately designed and was in compliance with all required federal research guidelines as well as with all Henry Ford research policies and procedures."*

[[The letter included additional text regarding a concern that Dr Edward's concern had been disclosed to the authors, COPE had clarified with Dr Edwards that this had not happened via journal channels, and indicated to the journal that this was no longer a concern]].

The committee hopes to be able to resolve Dr. Edward's concerns and is looking forward to COPE's continued guidance.

Response to COPE's request for further follow up from the Publications Committee at the International Society for Infectious Diseases

On behalf of ISID's Publication Committee, please allow me to clarify the journal's actions to date regarding your two points of remaining concern:

1. Re: "...it appears that lack of clarity remains about the time at which the infections took place relative to the water filter usage and the cause of death for the patients reported in the abstract."

The journal sought and received clarification from the authors, which was included in the published response. The journal was satisfied with the authors' response and considers that readers have been appropriately informed and can draw their own conclusions from the data. The conference abstract is now linked to the letter so readers can easily find the resulting discussion when reading the original abstract. If there is new information that readers of the journal need to be aware of, we would be happy to consider further scientific correspondence.

2. Re: "We also feel that it is important for the journal to reassure itself about the ethical oversight and approval for the study."

The journal had received reassurance regarding ethical approval and oversight from Dr Margot LaPointe, Vice President of Research at Henry Ford that the study was thoroughly reviewed and approved by the Henry Ford Institutional Review Board and that it complied with federal requirements, as well as Henry Ford policies and procedures.

The ISID Publication Committee hopes that these responses address Dr. Edwards remaining concerns.

COPE's review

A member of the Facilitation & Integrity subcommittee reviewed the case. Upon review of the information provided by the presenter the case was deemed to fall within the scope of the Facilitation & Integrity process.

COPE approached the *International Journal of Infectious Disease* for comments on Dr Edwards' concerns about the conference abstract. The editor indicated that they had received a letter to the editor airing similar concerns and the journal would be publishing this and a response by the abstract authors. The journal offered Dr Edwards the possibility of submitting a letter to the editor for publication, and noted that any concerns about ethical oversight for the study should be pursued with the authors' institution.

COPE followed up with the presenter for comments on the journal's response, and for clarification on the concerns about the study conclusions and the IRB process for the study. Dr Edwards noted that he remained concerned that there was insufficient information on the deaths reported in the abstract to establish if they related to the water filter measurements reported in the abstract, and noted he would like to see the ethical approval documentation for the study.

COPE followed up with the journal to indicate that it seemed important for the journal to request from the authors information on when the infections took place relative to the water filter usage, clarification about the cause of death for the patients and the documentation for the study's ethical approval.

The journal replied indicating that they had published the two letters to the editor previously mentioned and that those covered the matter about ethical approval. The journal also indicated that they viewed it beyond their remit to ask for further clarifications on study design.

COPE followed up with the journal to note concerns that the lack of steps from the journal to address concerns about the contents of the study/abstract did not align to expectations per the COPE Core Practices. COPE noted that it is the editor's duty to follow up on concerns about published content, and thus we viewed the additional clarifications outlined (time at which the infections took place relative to the water filter usage, cause of death for the patients, ethical approval for the study) as coming within the editor's remit.

COPE received a response from the Publication Committee of the International Society for Infectious Diseases (ISID), the publisher of the journal. The ISID indicated that they felt adequate steps had been

taken to address the remaining concerns by the publication of the authors' response to the letter to the editor published in the journal.

The Facilitation & Integrity subcommittee discussed the letter from the ISID. COPE indicated that the expectation per COPE Core Practices would be for the journal to pursue information from the authors on the remaining questions about the time of the infections relative to the water filter usage, the cause of death for the patients, and the ethical approval documentation. COPE requested that the journal take those steps and report back to COPE.

The ISID responded with a letter reiterating that they considered the earlier follow up with the authors in the context of the published letters to the editors addressed the items related to the study, and they considered that earlier interactions with the institutional IRB had addressed the question related to the ethical approval for the study.

Upon review of the latest response from the ISID, the Facilitation and Integrity subcommittee referred the case to the COPE Trustee Board for input and to determine whether further action was needed per [COPE's sanctions framework](#). The case was reviewed by three Trustee Board members, who determined that the case did not merit a formal sanction, but advised providing feedback to the journal on the importance of alerting readers about concerns relating to the validity of published conclusions, and the journal's policy and expectations around data availability.

The ISID submitted a response to COPE's feedback, which was discussed by the full Facilitation & Integrity subcommittee. At this point, the subcommittee determined that it had exhausted facilitation steps in this matter.

Conclusions

Upon consideration of the concerns and the member's response, the Facilitation & Integrity subcommittee considers that the journal followed steps to handle the concerns raised about the published abstract to a reasonable degree within the expectations of the COPE Core Practices.

The journal followed up on the presenter's concerns via a process that involved consideration of a letter to the editor with a critique of the study, and contact with the authors to request a response to the critique; the follow up also involved contacts with the institution regarding ethical approval for the study. Upon review of the information available, the editor considered that the public letter to the editor and the authors' response to this adequately made issues related to the study design and the strength of the conclusions available to readers.

COPE's review is focused on an assessment of the process that the journal and publisher followed to evaluate the concerns raised. The ultimate decision on whether any concerns that arise after publication require a correction to the record lies with the editor. This falls within the remit of editorial decision making, which is beyond the scope of our review.

In this case, and while the Facilitation & Integrity subcommittee would have liked to see further follow up from the journal, we consider that the journal took sufficient steps to follow up on the concerns raised about the publication to inform their determination on whether a correction to the record was necessary. At the same time, we recommend that the *International Journal of Infectious Diseases* completes the COPE journal [audit](#) to evaluate whether there are any areas of the journal's policies, processes or practice that require attention.

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