

Nuffield Department of Population Health
Richard Doll Building
Old Road Campus
Headington
Oxford OX3 7LF

15 April 2016

Dear Professors Armitage, Baigent and Collins

We are writing in response to the concerns raised to the attention of COPE regarding the publications in the BMJ by Abramson and Malhotra. The concerns and the journal's response have been reviewed by three of the COPE Trustees. Trustees with a potential conflict of interest were not included in the decision-making process.

We would like to first of all reiterate COPE's remit and the scope of our review of this case (<http://publicationethics.org/contact-us#complaints>). COPE is a membership organization and not a regulatory authority; COPE membership by journals and publishers is voluntary.

COPE's goals are the education of our members and the promotion of a better understanding of publication ethics overall. We provide a number of resources to our members, one of these is the COPE Code of Conduct which also includes best practices as an aspirational guide on steps journals can take to enhance their workflows. COPE guidelines are just that and not mandates, failure to implement all of the goals outlined under the best practice guidelines does not in itself imply deviation from ethical publishing practices.

COPE does not complete regular audits of member journals to verify compliance with the Code of Conduct, however we do consider complaints against members and follow up on those as necessary. We encourage self-audit at journal level and have developed a self-audit tool which we make available to our members. This is intended to assist them in identifying aspects of their practices that may require improvement and to promote transparency in their processes.

In situations where concerns are identified about a journal's process, either through an internal audit or a complaint, the key consideration is to ensure the journal is able to address the original issue in a reasonable manner and implement any necessary procedural changes to prevent the situation arising again. The fact that an error or a procedural gap is identified does not demand sanctions, and as noted above COPE does not have regulatory powers.

Upon review of the information available, we understand that the BMJ completed a self-audit of their processes related to the peer review of the articles and the handling of the concerns raised upon publication. The journal took steps to correct the articles and implemented procedural changes to address issues identified through their internal audit.

We believe that the journal took extraordinary steps to follow up on the concerns raised by convening an independent panel, whose findings they have since reported publicly at <http://www.bmj.com/about-bmj/independent-statins-review-panel>.

We recognize that different journals will have different processes in place and differing resources available to follow up on concerns raised to their attention, and thus that some level of flexibility is necessary on how journals develop and implement practices to address ethical challenges they face. In light of this, the main principle for addressing such challenges is to be as transparent as possible; we consider that the BMJ acted as per this principle by posting information on their internal audit publicly.

COPE also has a Code of Conduct for publishers which indicates that publishers should foster editorial independence. The documentation supplied by the publisher supports that they acted in line with this expectation.

In consideration of the above and upon review of the information available, we believe that the BMJ acted appropriately by completing an internal investigation and audit to a high standard, and promoted transparency by making information on the process publicly available.

While we appreciate that our response will not fully satisfy your original request, we believe that the journal acted with due diligence and in line with the expectations under the COPE Code of Conduct. We appreciate that differences in opinion may remain that COPE is unable to resolve in the context of this review. It is clear there are differing opinions on the science, however, those differences are best resolved by open dialogue in the scientific literature.

Thank you for raising this matter to the attention of COPE and we apologize for the time it has taken to conclude this case.

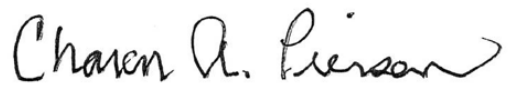
With best wishes,



Chris Graf, co-Vice-chair



Geri Pearson, co-Vice-chair



Charon Pierson, COPE Secretary