

Complaint on BMJ Statin papers

Process and timeline

August 2014: phone conversation with Virginia Barbour (VB) and Professors Collins and Baigent

October 2014: Letter from Professor Armitage and colleagues received at COPE

November 2014: Discussed at Officers' t-conference November and agreed VB would review and report back to Officers

VB investigated and prepared report

December 2014: Report discussed at Officers' t-conference

January 2015: Report sent to Professor Armitage and colleagues with copy to Dr Fiona Godlee.

VB review

Review of correspondence received at COPE

Review of BMJ enquiry – published report <http://www.bmj.com/about-bmj/independent-statin-review-panel>

Review of Papers and correspondence published in BMJ – last reviewed 1

December 2014 <http://www.bmj.com/content/349/bmj.g5688/rapid-responses>

Review of other recent related articles published in academic journals and lay press, eg Armitage, Collins and Baigent

[http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(14\)61765-7/fulltext](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(14)61765-7/fulltext)

Background

Professor Armitage and colleagues have asked us to consider the actions of the BMJ in relation to the peer review of these papers, the process and the outcome of the review commissioned by the journal. In addition we were contacted by Dr Simpson of the British Cardiovascular Society.

Specifically (from Professor Armitage and colleagues' letter)

“Consequently, given the public health implications, we are seeking advice from COPE as to whether the BMJ's handling of this matter, as described below (with embedded links to supporting materials), has been consistent with COPE's Code of Conduct and Best Practice Guidelines for Journal Editors.”

It is important to note, as I have done to Professor Collins earlier, that we are not a statutory or regulatory body but a voluntary membership organization. These are the [terms](#) under which we can consider complaints about our members. Specifically, we cannot get involved in individual editorial decisions. In addition, we do not investigate individual cases but aim to facilitate a dialogue between the parties. Finally, it is not appropriate for COPE to make a specific recommendation on the specific medical issues raised here, regardless of any public health implications.

The approach that we take therefore and the way in which we have considered this case and others, is what would have been our advice had this case been brought to a COPE forum. Specifically, we encourage an open debate (in our terms we say that “To facilitate an open dialogue, we believe that correspondence relating to concerns should be open, and we will copy all parties on correspondence from COPE (unless there are legal or other compelling reasons for confidentiality) and expect that all parties will do the same.”) and therefore we will also send this report to Dr Fiona Godlee, Editor of the BMJ.

Summary of issues

It appears that there are three issues here.

1. Was the review process pre publication appropriate for the papers?
2. Was the post publication process appropriate, including the handling by the panel and its recommendations?
3. Has the literature been corrected: is there anything further that could or should be done in this debate now?

For the first two issues, when I spoke with Professors Collins I advised him if he had not already done so and/or remained unhappy about the handling of these papers he should to contact the journal’s publisher directly. It appears that this has not happened directly but we note that Baroness Ilora Finlay, President of the British Medical Association was cced in letters to us.

Review of the above questions:

1. *Was the review process pre publication appropriate for the papers?*

Professor Armitage and colleagues lay out a number of issues that occurred during the review of the paper. These have been extensively documented and discussed, including in the report from the review panel. Consideration of this is therefore folded into the discussion below.

2. *Was the post publication process appropriate, including the handling by the panel and its recommendations?*

Was the review panel completely independent? It is worth pointing out that it is highly unusual for a journal to even consider setting up a panel to review its processes. Generally speaking journals consider these issues internally only. Notwithstanding that, the panel’s composition, its deliberations, and conclusions were apparently all made public. If there are documents or other relevant information that have not been made public as Professor Armitage and colleagues claim we would agree that they should be.

We recommend the journal review the allegations by Professor Armitage and colleagues and add any missing material.

The panel had the following terms of reference:

a) ToR1. To consider whether either or both articles should be retracted
The panel found that neither paper met the COPE criteria for retraction.

We understand that there are differences of opinion in these matters, but in the end the decision to retract papers does lie with the Editor. The Editor did seek advice from a separate review panel and this panel agreed with the Editor's decision on retraction. The panel made separate recommendations about the corrections (see ToR3)

b) ToR 2 To review and comment on the process by which the articles were published.

The panel said: "The panel has made a number of suggestions aimed at improving the editorial process and was concerned about the late inclusion of an unscrutinised reference on a short timescale. However, the panel concedes that the peer review and editorial processes must rely on goodwill to a very considerable extent and can never be completely foolproof – especially in view of the time pressures under which authors, peer reviewers and editors are working."

Our understanding from notes published in the journal that the Editor has accepted the recommendations of the panel. However, it would appear that it would be appropriate for the journal to now explain how these recommendations have been acted on. **We suggest that the journal and the publisher should work jointly to do this and make public the results of this, and specifically address the alleged breaches of the COPE Code of Conduct and what has been done to address these.**

c) ToR 3 To review and comment on how criticisms and complaints against the articles were raised, and how the journal responded.

The panel concluded "The BMJ editorial staff should implement a significant event audit in relation to the need for the correction. The aim of the audit would be to try and identify what would need to have been in place to ensure that the correction was made in a more timely fashion."

We suggest that the journal and the publisher should work jointly to do this if not already undertaken and make public the results of this.

3. *Has the literature been corrected: is there anything further that could or should be done in this debate now?*

Without having an opinion on one or other side of the debate on the use of statins and their side effects, it is clear that this is a topic on which there is a considerable range of opinion and no purpose is served by censoring either side of the debate. There has been much discussion in previous COPE forums of the

need for post publication criticisms to be aired in the journal that it was originally published in and we note that the BMJ repeatedly offered Professor Collins and colleagues the opportunity to respond, but they declined. We think that it is unfortunate that the most important issue here, ie having a full response in in the BMJ of the specific issues of concern to Professor Collins and colleagues in the Abrahamson and Malhotra papers has not yet happened and we feel this needs to be rectified as soon as possible, notwithstanding other comments published in newspapers and other journals. **We therefore strongly recommend that a response by Professor Collins and colleagues on the substantive scientific issues they dispute is submitted and published in the BMJ itself as soon as possible.**

Finally, we note that Professor Armitage and colleagues allege that in a number of instances authors of comments and other material post publication did not have competing interests fully declared. **The journal should review these comments and ensure that all competing interests are declared appropriately.**

In conclusion and in order for the debate on this important issue to be as clear as possible and hopefully to allow the discussion about these particular papers to finalized, **we urge the BMJ, its publisher and Professors Collins, Armitage and colleagues to work together to make public a follow on from this debate which addresses the various unresolved issues:**

- the outcome of the review of the peer review process that the BMJ has undertaken,
- the publishing of any further submissions to the review panel;
- a response to alleged breaches of the COPE Code of Conducts and the journal's response to these;
- the publication of a response by Prof Collins and colleagues in the BMJ itself on the substantive issues of the incidence of side effects statins.