



10 June 2015

Dr Virginia Barbour
Chair of Council
Committee on Publication Ethics

Dear Dr Barbour

Comments on the BMJ's response to COPE's investigation of potential breaches of its Code of Conduct by the BMJ

In light of your advice as Chair of the Committee on Publication Ethics (COPE), we wrote on 23 October 2014 to ask you to consider whether the BMJ's Editor had breached COPE's Code of Conduct for Journal Editors in her handling of problems with the BMJ's 22 October 2013 papers by Abramson et al and by Malhotra. As summarised below, the BMJ has not provided adequate responses to COPE with regard to the set of specific concerns that are described in our October 2014 letter (and supported by detailed background material).

Our letter raised issues of considerable public health significance. The safety of patients and the public depends on the ability to consider the value of particular treatments based on objective and impartial representations of the evidence. Instead, the BMJ has published claims about the effects of statins that they were advised in advance were incorrect (and still has not corrected them), has made statements about its processes for review that are contradicted by its own documents, and was selective about the information that it made public.

There is good evidence that people at high risk of heart attacks and strokes have stopped their statin therapy in the period after the BMJ's misrepresentations. The confusion caused by the Editor's failure to deal promptly and properly with this issue appears to have exacerbated this problem. The published results of extensive peer-reviewed research indicate that this reduction in the number of high-risk patients taking statin therapy will have resulted in many having heart attacks, strokes and vascular deaths that could have been avoided.

Given the potentially diversionary nature of the BMJ's response, we summarise below each of the specific examples of inappropriate editorial behaviour that we raised, the relevant part of the BMJ's response, and our conclusions as to breaches of COPE's Code of Conduct. The BMJ is widely read and influences patient care, so it is in the public interest that COPE does now make a clear statement about the BMJ's failure to act properly in the interests of public health.

1. Publishing incorrect side-effect claims despite being advised they were misleading

Issue raised: A peer reviewer of the paper by Abramson et al advised that "*The results presented for myopathy are misleading*", but a BMJ editor stated in an editorial meeting that "*it probably doesn't matter too much*" to publish those results even if they are wrong.

BMJ response: The BMJ justifies this course of action by claiming that the peer reviewers and the paper's authors disagreed, and by maintaining that the definition of myopathy is debatable (having taken advice on this point from the paper's authors alone). The BMJ now acknowledges that its processes should be improved.

Our comment: It is a serious concern that the BMJ still does not consider it to be necessary to 'fact-check' data relating to important public health issues before their publication. Moreover, despite the Cochrane Collaboration statin reviewers and other experts having pointed out this error in writing to the BMJ, the Editor has still not corrected it and, indeed, continues to dispute it is an error.

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

2. Publishing a misleading "correction" of other incorrect side-effect claims

Issue raised: The BMJ published papers that misrepresented a study by Zhang et al, claiming incorrectly that it showed that statins cause side-effects in 18-20% of patients. After a 6 month delay, the Editor did accept that this was an error, but then published a 'correction' that the peer reviewer had advised the Editor was "*plain wrong*" in quoting a figure of 9% for statin adverse effects.

BMJ response: The Editor states that she amended the correction to address some of the peer reviewer's comment and decided to proceed with expeditious publication, rather than to seek further peer review, because she states that the authors of the original study (i.e. Zhang et al) had agreed with her correction.

Our comment: The Editor failed to address the peer reviewer's chief concerns. Moreover, the senior author of the Zhang paper has confirmed that "*the BMJ correction as it was published*" was misleading. In matters of such public health significance (particularly when correcting errors), it is surely appropriate for journal editors to make serious efforts to ensure accuracy (e.g. by seeking additional external advice).

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

3. Publication of inaccurate editorial and media statements accompanying the published "correction"

Issue raised: The Editor stated incorrectly in her 15 May editorial that the peer reviewers had missed the misrepresentation of Zhang et al's paper in the paper by Abramson et al. However, one week beforehand, the BMJ's Analysis editor had written specifically to advise the Editor that the peer reviewers had never been given an opportunity to review the draft of the paper by Abramson et al that referred to Zhang et al's report.

BMJ response: The Editor states that she did not appreciate this point in time to amend the editorial before publication, nor when she issued an accompanying press release, and nor when she repeated this incorrect statement on the BBC Radio 4 Today programme on the following day. She asserts that the correction was posted "*as soon as it was clear that it needed to be*".

Our comment: The Editor's response does not address the point that she had also been asked to check the reviewers' comments specifically relating to the misrepresentation of Zhang et al's paper on at least 3 separate occasions in the months before her editorial was published. Nor

does it explain why she failed to take account of such specific advice from the Analysis editor. Since the Editor was contacted about the error by a reviewer on the day after publication, it is unclear why she did not feel that a correction was 'needed' until 11 days later, and why, when it was eventually published, it was not given the due prominence necessary to ensure that the medical profession and public were not misled.

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

4. Inappropriate use of Abramson to review the accompanying paper by Malhotra

Issue raised: Despite being asked repeatedly in writing during March, April and May 2014 to provide the reviewers comments for the accompanying paper by Malhotra (which repeated the misrepresentation of the Zhang et al paper), the Editor did not do so. Only when asked yet again to do so in July, did she make them available (i.e. after more than 3 months). It then became apparent that the only reviewer of Malhotra's paper was Abramson himself.

BMJ response: The BMJ now accepts that the use of Abramson as a reviewer was "not ideal" and that such an approach should be avoided in future. The explanation given for the delay in making the reviewer's comments available was that it was not easy for the BMJ to extract the comments from a pdf and to display the pdf and comments separately on its website.

Our comment: It is remarkable that the BMJ lacks the technical capacity to put a pdf on its website more quickly than it did. However, if that truly is the case, then the decision not to provide the reviewers' comments more rapidly in an alternative format raises concerns. In any case, it is clear that the peer review process was not unbiased.

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5. Questionable independence of the BMJ's review of published errors

Issue raised: The Editor has repeatedly described as "independent" the panel that she selected to consider retraction of the papers by Abramson et al and Malhotra, and stated that it would include people with "no dog in the fight". However, as described in detail in our submission (with supporting materials), this is clearly not correct. The Chair and members of the panel were not only not independent of the BMJ, but they were also not independent of the issue under review (i.e. the safety of statins).

BMJ response: The Editor's response characterises the issue of independence as relating only to whether the panel was independent of the BMJ, and rejects accusations of bias in the selection of panel members.

Our comment: The Editor's response appears disingenuous. All of the panel members had close links to the BMJ and its Editor and/or had published concerns about statin safety, so its decision could have been predicted by the Editor with some certainty. This represents a clear example of 'panel-stacking', which the BMJ has correctly criticised in the context of panels writing guidelines for drug treatment.

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

6. BMJ links to public statements in support of its own position

Issue raised: The “Timeline of events” on the review panel section of the BMJ’s website highlights a letter that is presented as an independent call for the BMJ and its panel not to retract the articles. However, it was not independent of the BMJ. Instead it was coordinated by a journalist (Jeanne Lenzer) listed on the BMJ website as a paid contributor and who was also a co-author of a 2013 BMJ paper about statin therapy in collaboration with Curt Furberg (i.e. one of the panel members), and with Abramson (i.e. the author of one of the papers under review by the panel) acting as a contributor.

BMJ response: The BMJ stated that it was unaware of Lenzer’s involvement with this letter, and does not consider Furberg’s association with Lenzer and Abramson on a paper about statin guidelines to be a relevant conflict of interest.

Our comment: Again, the BMJ’s response appears disingenuous. These undeclared links between Furberg, Abramson and Lenzer, and with the BMJ, represent serious conflicts of interest. It is clear that the Editor’s assertions about the independence of this review process and her panel are misleading.

The BMJ would appear to have breached COPE’s Code of Conduct in this regard.

7. Inaccurate statements about materials posted with the review panel report

Issue raised: The Editor stated “As part of our commitment to transparency, all documents submitted to and produced by the panel are published” on the BMJ website alongside the panel report. This was an incorrect statement. Instead, a detailed submission relating to misleading information about statins in a letter sent to NICE by Malhotra (who is the author of one of the papers reviewed by the panel) was deliberately excluded. Requests for this submission to be included on the website were refused by the BMJ’s Editor. In addition, other submitted material had text redacted for “legal reasons”.

BMJ response: The BMJ response states that the submission was not posted on its website because the review panel did not consider it to be relevant to its deliberations. It asserted that it was merely following legal advice when it redacted other material.

Our comment: The fact remains that the excluded material was submitted to the panel, so it should either have been posted along with the other submitted material or the BMJ should have corrected its statement (which it refused to do). The Editor’s response that the excluded submission was not relevant to the panel’s review is contradicted by the BMJ itself, which refers explicitly to the letter to NICE from Malhotra in its “Timeline of events”.

With regard to the redaction of the following statement in the submission to the panel by Professor Eugene Braunwald of Harvard Medical School:

“I am deeply disturbed by these two papers, particularly the paper by Abramson et al. I believe very strongly in the “free speech rights” in the First Amendment of the Constitution of the United States and I do not support censorship of any kind, especially in science which often advances as a result of controversy. However, it is well understood that this amendment does not give anyone the right to falsely shout “Fire” in a crowded room.”

it may be uncomfortable reading for the BMJ's Editor, but the argument that its redaction is warranted on legal grounds is untenable.

The BMJ would appear to have breached COPE's Code of Conduct in this regard.

Conclusion: We would ask COPE now to decide whether the BMJ has contravened its Code of Conduct for Journal Editors and, if so, to act appropriately to rectify the situation – particularly in light of the adverse impact on public health of the confusion about statin safety caused by the BMJ's misrepresentation of the evidence and other failures of editorial integrity at the BMJ.

The BMJ has stated that it intends to publish its response and related material before COPE has completed its assessment. This would not appear to be consistent with COPE's processes.

Instead, our understanding is that it is COPE's role to consider the original complaint, the BMJ's response and any further information before making a judgement about breaches of its Code of Conduct. Equally, it is COPE's role (not the BMJ's) to make its conclusion public along with any material that is relevant to the complaint.

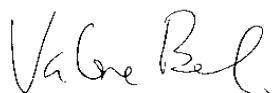
Yours sincerely



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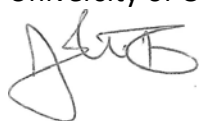
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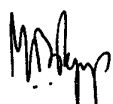
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