From:

Sent: 01 March 2016 09:47

To: Virginia Barbour

Cc:

Subject: Ongoing investigation by COPE into issues of editorial integrity at the BMJ

Dear Dr Barbour

We are writing to draw your attention to the recent widely-publicised statements in the UK national media by Dr Aseem Malhotra that, with respect to his claim in the BMJ that statins cause side-effects in 20% of patients (which was eventually partially withdrawn by the BMJ), the rate of side-effects with statins is even greater. The relevant extract from his interview (transcript attached) on the national BBC Radio 4 Today programme, which was in response to an article that he wrote for the Mail Online newspaper and publicised with a press release (both attached), is given below:

"That 20% figure was corrected absolutely right but actually – I will be honest with you now – it was actually probably an underestimate. In fact, actually, the side effects in terms of the side effects that interfere with the quality of life may well be higher."

Malhotra then goes on in the Radio 4 interview to raise doubts about the benefits of statins for any type of patient (for example, people at high risk of heart attacks and strokes):

"Well there has been, actually, emerging evidence from the last two weeks. Michelle de Lorgeril a cardiologist in France has actually even suggested now that the whole evidence base behind statins themselves is very questionable even for efficacy in all patients groups."

In our view, this provides yet another example of the problems caused by the BMJ's editorial failures in its review of the October 2013 papers by both Malhotra and Abramson, and its subsequent failure to deal properly with the errors in those papers by retracting them in full. These issues of editorial integrity at the BMJ have previously been drawn to the attention of COPE by a number of senior scientists and clinicians, and a decision on the outcome of COPE's investigation is currently pending.

There is now increasing evidence that such misleading claims about statin safety and efficacy are followed by reductions in the use of statins by patients at high risk of heart attacks and strokes. In particular with respect to the BMJ, a study by Professor Liam Smeeth (who, you may recall, was one of the reviewers of the Abramson paper and gave advice to the BMJ's Editor that there were serious errors in it and in her "correction" which was ignored) has estimated that the BMJ articles were followed by more than 200,000 UK patients stopping statin therapy and that this could lead to about 2000-6000 excess cardiovascular disease events over the next 10 years.

The parallels between Andrew Wakefield with MMR and Aseem Malhotra with statins are becoming increasingly close. The failure of the BMJ to deal suitably robustly with serious errors in the October 2013 BMJ papers by Abramson and Malhotra, which occurred in the first place as a result of failures in its editorial processes, has emboldened Malhotra to repeat and, as in this latest example, exaggerate further his misleading claims about side-effects, as well as raising doubts about efficacy for high-risk patients. Despite the delay, retraction of these papers now would send out a clear message to the public and doctors, as well as the media (as proved to be the case with the delayed retraction by The Lancet of Wakefield's paper).

COPE could now play an important role in helping to reduce this adverse impact on public health by stating clearly that the BMJ has failed in its duty of care to patients and the public, and requiring it to retract both papers. Not to do so in response to the issues that have been raised previously, given the increasing evidence of the adverse impact on health, would call into question the effectiveness of COPE and its decision making.

Yours sincerely

Jane Armitage, Colin Baigent and Rory Collins Nuffield Department of Population Health, University of Oxford, Oxford, UK