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EDITORIALS

Statins and *The BMJ*

Lots of lessons, but we still need the data

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An expert panel convened by *The BMJ* has concluded that two articles published last year[1 2] and corrected in May should not be retracted.[3] The panel's report comes after a lengthy and public row over proposals to extend the use of statins to healthy people at low risk of heart disease.[4] What are the lessons from this episode for *The BMJ* and the scientific community? And what does it mean for the wider debate on statins?

The panel of seven internationally respected clinicians and researchers met seven times over two months. They acted independently of the journal, undertook a detailed statistical review of the two articles, received written evidence from all parties, and reviewed the journal's processes. They concluded that the only unequivocal error had been corrected and "were unanimous in their decision that the two papers do not meet any of the criteria for retraction."

The panel was itself under fierce public scrutiny. While those who had called for retraction questioned the panel's independence,[5] the Retraction Watch website said that the panel's report was "the most detailed justification for a journal's decision not to retract a paper that we've seen in a long time, perhaps ever."[6] This is reassuring. So too is the panel's conclusion that *The BMJ* used due diligence and acted appropriately.

However, the journal doesn't escape criticism. The panel suggested improvements to some of our processes, including additional statistical review and greater editorial scrutiny of controversial articles. It also found that we were slow in correcting the articles and has recommended "a significant event audit . . . to identify what would need to have been in place to ensure that the correction was made in a more timely fashion."

I said at the outset that we would implement all the panel's recommendations.[7] *The BMJ* has no plans to reduce its coverage of controversial issues: quite the reverse. It exists as a forum for scientific debate and will continue to challenge the status quo wherever necessary to improve health and healthcare. We recognise that doing this safely and effectively incurs extra responsibility. Additional checks and peer review of debate and opinion articles are already in place. As for a system that will ensure that necessary corrections are made promptly, we will be more proactive from now on: we will identify rapid responses that make substantive critical points about a published article, ask authors whether a correction is needed, and, where necessary, seek external expert advice.

As part of our commitment to transparency, all documents submitted to and produced by the panel are published online (thebmj.com/statins). The documentation includes the submitted versions of both articles, the peer reviewers' and editors' comments, and the revised and edited versions. Next month we will launch a long planned initiative to post such prepublication histories for all our research and analysis articles.

The panel stuck closely to its remit and resisted straying into discussion of the benefits and harms of statins. But it made three important contributions to this wider debate. Firstly, it confirmed that the debate on statins is legitimate and should not be shut down. Secondly, it asked that the debate be conducted primarily in medical journals rather than in the lay media. And thirdly, it called for the anonymised individual patient data from the clinical trials of statins to be made available for independent scrutiny.

This last is a key point. Currently only the drug companies, the trialists, and the Cholesterol Treatment Trialists (CTT) collaboration in Oxford have access to individual patient data from the statin trials. As I understand it, even CTT does not have the data on adverse events, which were specifically excluded when the collaboration was established. Nor does CTT have the right to share data with third parties. The Cochrane review group did not have access to the individual patient data. It based its analysis on the published information, including the published CTT analysis.[8]

This is not acceptable. As highlighted by the AllTrials campaign (alltrials.net), such debates will not be satisfactorily resolved in the public interest unless legitimate third parties are given access to the clinical study reports and the anonymised patient level data. At the very least this will allow greater understanding of the data's limitations. As a first next step towards this goal, I have written to the principal investigators of all the relevant clinical trials, asking them to make the data available or to explain why they will not. My letters and any replies I receive will be published at thebmj.com/statins.

For this approach to succeed, however, there needs to be a trusted group of people who can receive and analyse the data. There are at least three possible candidates: John Abramson and colleagues, who authored the main article in *The BMJ*,[1] though they will be considered by their critics to be too partisan; Rory Collins and his colleagues within the CTT, although they too may be considered by their critics to be insufficiently

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independent; and the Cochrane Collaboration, which had a key role in obtaining and analysing the industry clinical trial data in the case of oseltamivir (Tamiflu) (see thebmj.com/tamiflu). I have written to Collins to ask him whether he has now requested the data on adverse events and serious adverse events from the statins trialists and whether he will now call for these and all other data to be made publicly available. I have also written to the Cochrane statins review group to ask whether they would be willing to take on the central role in the next phase of this saga. Other candidates may also emerge.

As always, we welcome your comments on the report, on the wider debate on statins, and on these next steps towards greater transparency.

Competing interests: I convened the independent review panel and drafted its terms of reference. I am responsible for everything in *The BMJ*.

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