

SP13 EMAILS BETWEEN RORY COLLINS AND FIONA GODLEE

On 30 Oct 2013, at 05:34 pm, Rory Collins <rory.collins@ctsu.ox.ac.uk> wrote:

Dear Fiona

It seems that you and the BMJ have decided to take a stand against the widespread use of statins to protect people from suffering heart attacks and strokes. I can guess at some of the reasons, but I would very much welcome an opportunity to discuss this with you since I do think that there is a danger that mis-representation of the evidence in the BMJ could cause a lot of harm, which I know is not your intention.

Might it be possible for me to drop by your offices sometime soon when I am in London to discuss my concerns — as well as, of course, yours?

Best wishes,

On 30 Oct 2013, at 18:27, Fiona Godlee <fgodlee@bmj.com> wrote:

Dear Rory. Very happy to meet. Julia will be able to suggest some dates. As for the BMJ's position on statins, I don't think we have one. The article by Abrahams and co was submitted and peer reviewed and published in the usual way. I guess they might have chosen the journal because of our too much medicine campaign. If there is anything factually incorrect or misleading in it, I would urge you to send a rapid response which we would almost certainly want to publish as a letter. In fact I do hope you will do this anyway as readers will want to know what members of the CTT collaboration make of these authors' analysis. If you have any difficulties submitting a rapid response, our letters editor Sharon Davies can help and is copied in. All best wishes, Fiona

NOTE: RC VISITS FG AT BMJ OFFICES, 2 DECEMBER 2013

From: Fiona Godlee [<mailto:fgodlee@bmj.com>]
Sent: 02 December 2013 16:52
To: Rory Collins
Cc: Helen Macdonald
Subject: Re: Recent BMJ articles on statin safety and efficacy

Dear Rory, Many thanks for coming in to see me this morning.

I take very seriously the concerns you have raised about the two recent articles published in the BMJ, by Abramson and colleagues and by Aseem Molhotra. I will discuss with colleagues what the journal should do in light of these concerns. As I explained, we have already commissioned an independent review of the evidence on the benefits and harms of statins. I hope this will be ready for peer review in February and publication in March. As mentioned when we met, I invite you to write an Analysis article for the BMJ. This would present to the BMJ's readers the information you presented to me. We would want to peer review the article and we can never make absolute promises of publication until we have done this.

Information on the style and format of Analysis articles is given here

<http://www.bmj.com/about-bmj/resources-authors/article-types/analysis>

Although your article would be a response to the two articles, and to Abramson et al in particular, it would be helpful if you could use the opportunity to set your piece in the wider context of the evidence on the benefits and harms of statins.

If you would like to discuss the article further before submission, please contact Dr Helen MacDonald who edits the Analysis section. She is copied in on this email.

The other article we discussed that you might submit to the BMJ was on the use of big data and in particular the opportunities presented by the linkage of data from RCTs to routine data from hospitals and primary care. I think this would again best suit our Analysis format (1500 words, with references, figures, and tables), with a view to informing practising clinicians and researchers of the usefulness and importance of this new approach to pharmacovigilance and reliable generation of evidence. Again I can make no promises of publication at this stage.

Thank you in advance for sending me the link to the Nissan/Abramson radio interview, which I look forward to listening to.

Do let me know if I have forgotten anything from our conversation. Thank you again for coming in.

All best wishes, Fiona

Sent: 03 January 2014 12:45

To: Martin Landray

Cc: Christina

Reith; spencer@well.ox.ac.uk; c.holmes@stats.ox.ac.uk; ifarrar@oucru.org; dominic.kwiatkowski@well.ox.ac.uk; Rory

Collins; directorpa@well.ox.ac.uk; regius@medsci.ox.ac.uk; mcvean@well.ox.ac.uk; Martin Landray

Subject: BMJ.2013.017223 Manuscript Decision Analysis

03-Jan-2014

Dear Dr. Landray,

BMJ.2013.017223 entitled "Big Data: Challenges and Opportunities for Health Research"

Thank you for sending us your paper. We read it with interest but regret that we are unable to offer publication. You describe some fascinating possibilities but we thought that, at the moment, they were too far away from entering practice to engage our predominantly clinical readership.

Please appreciate that the BMJ receives more manuscripts than it can publish and that we are forced to reject many valuable and worthwhile articles. We are sorry to disappoint you.

Best wishes,

Christopher Martyn Associate editor

On 22 Jan 2014, at 13:44, Rory Collins <rory.collins@ctsu.ox.ac.uk> wrote:

Dear Fiona

Thanks again for the opportunity to meet in order to discuss the two BMJ articles on cholesterol and statins, and offering us the opportunity to write an Analysis article on lipid modification and statins for publication in the BMJ (subject, of course, to peer review). We are now working on this article and shall revert to you when we have it in a near-final form.

With respect to your suggestion that we also submit an article on the use of Big Data, we did do so but the terse response from your Associate Editor (see below) was rather disappointing. Given the interest that you had expressed in the topic when you wrote following our meeting (also below), I had anticipated that we might engage in a dialogue as to modifications to our draft paper that might make it more engaging to the BMJ's clinical readership (if it really isn't) rather than a somewhat formulaic rejection. Might you be willing to have another look at our draft paper (attached) and consider whether it might — with revision — be of value to BMJ readers?

Best wishes,

Rory

From: Fiona Godlee [mailto:fgodlee@bmj.com]

Sent: 26 January 2014 08:28

To: Rory Collins

Cc: Trevor Jackson; Helen Macdonald

Subject: Re: Recent BMJ articles on statin safety and efficacy

Dear Rory,

Many thanks for your message. I'm sorry the decision on your article was not more positive. I have just read the piece and, with apologies, must agree with the spirit of the brief letter you received. I fear that it does not come across as an article written for the BMJ. It is largely a rather dense list of potential opportunities for exploitation and linkage of data, without a great deal for the reader to hang on to in terms of illustrative examples of how this will benefit patients and the public - whether real or hoped for. I don't see much about the potential risks and opportunity costs. And there is no real argument through the piece that can justify the strength of your final assertion.

I have discussed it with my deputy, Trevor Jackson, who heads up News and Views, which includes the Analysis section. He, or Helen MacDonald who edits the Analysis section, will be in touch as soon as possible once they have had a chance to have a more detailed re-read of the piece. I cannot say at the moment whether they will encourage you to submit a revised version, or whether, as an alternative, we should cover this topic in a more journalistic way, including an interview with you.

As for the other piece we discussed when we met, on statins, we are very much hoping you will send us something soon. If you would like to discuss this further or are in any doubt about the format and style for such a piece, please do let us know. Here again is the invitation.

As mentioned when we met, I invite you to write an Analysis article for the BMJ. This would present to the BMJ's readers the information you presented to me. We would want to peer review the article and we can never make absolute promises of publication until we have done this.

Information on the style and format of Analysis articles is given here
<http://www.bmj.com/about-bmj/resources-authors/article-types/analysis>

Although your article would be a response to the two articles, and to Abramson et al in particular, it would be helpful if you could use the opportunity to set your piece in the wider context of the evidence on the benefits and harms of statins.

If you would like to discuss the article further before submission, please contact Dr Helen MacDonald who edits the Analysis section. She is copied in on this email.

If you were able to get it to us by mid February, that would be excellent.

All best wishes, Fiona

RE: Recent BMJ articles on statin safety and efficacy

Inbox x 30 Jan
Rory Collins <rory.collins@ctsu.ox.ac.uk>
to me, Trevor, Helen, Christina, Martin, Colin

Dear Fiona

Many thanks. Guidance on the "Big Data" Commentary would be most welcome as we too would like to make sure that the benefits to patients and the public are readily apparent, as well as to bring out both the potential opportunities and risks (as well as the obstacles).

Best wishes,

Rory

PS: We are working on the statin and LDL-cholesterol article and are aiming to get it to you soon (and, again, would welcome guidance on making sure that the messages are clear in order to help undo the harm that has been done by ill-informed, if not deliberately misleading, articles previously!).

NOTE: Guardian article appeared 24 March 2014 – Today programme discussion

From: Rory Collins <rory.collins@ctsu.ox.ac.uk>
Date: 31 March 2014 17:12:16 BST
To: Fiona Godlee <fgodlee@bmj.com>
Subject: RE: Recent BMJ articles on statin safety and efficacy

Please see attached letter below (ATTACHED)

From: Fiona Godlee [<mailto:fgodlee@bmj.com>]
Sent: 01 April 2014 15:44
To: Rory Collins
Subject: Fwd: Recent BMJ articles on statin safety and efficacy

Dear Rory,

I'm sorry this issue has become so polarised and personal. This was certainly not my intention. However, I note that this is the first time I or the journal have received a written account of your concerns despite my issuing you with several invitations to send a letter or an article for publication, including in my reply to your first email five months ago.

As it happens I am pleased to say that the issue you have raised in relation to the paper by John Abramson has been raised by another reader, Amrit Takhar, in a rapid response posted on 26 October (see <http://www.bmj.com/content/347/bmj.f6123/rr/668850>), to which Abramson and colleagues replied on 12 November (<http://www.bmj.com/content/347/bmj.f6123/rr/671660>). The two responses are reproduced below. Aseem Molhotra has also responded to comments on his article, including about his reporting of the Zhang et al results (see <http://www.bmj.com/content/347/bmj.f6340/rr/692280>).

For the moment I am satisfied with these replies and do not believe retraction of the articles would be remotely justified. There may be a case for further clarification over and above that provided by the authors in their replies. I would be happy to share your letter with them and ask them to provide additional comment on [bmj.com](http://www.bmj.com). Please let me know if I have your permission to do this. But better by far would be for you to send a letter for publication to which I could ask them to respond.

You are welcome of course to contact the Committee on Publication Ethics about this matter. I am afraid that peer review comments for journal articles are confidential.

With best wishes, Fiona

Rapid responses from Amrit Takhar and authors' reply

RAPID RESPONSES BELOW

Re: Should people at low risk of cardiovascular disease take a statin?

26 October 2013

This analysis by Abramson and colleagues is a useful counterbalance to the Cochrane review on use of statins in primary prevention and useful to me as practising GP discussing the pros and cons of statins on a almost daily basis.

However I do think that the final point in key messages box that "The side effects of statins...occur in about 20% of people treated with statins" is not conclusively backed up by the detailed evidence and references presented.

The authors quote Zhang's retrospective cohort study finding that 18% of statin treated patients had discontinued therapy (at least temporarily) because of statin related adverse events. However the results of the study also showed that 35% of those who discontinued due to statin adverse effects were rechallenged and the majority of these (92%) were still taking statins 12 months. This would imply the true figure for statin related adverse events is much lower than the 20% quoted in the key message.

While I would not wish to minimise the possible adverse effects , I do feel the key messages should not overstate the case against either as this same message may be seen by someone at high risk of CVD or in secondary prevention and discourage them from taking a valuable drug in preventing further events.

Reference:

Zhang H, Plutzky J, Skentzos S, Morrison F, Mar P, Shubina M, et al. Discontinuation of statins in routine care settings: a cohort study. *Ann Intern Med* 2013;158:526-34

Competing interests: None declared

Authors' reply to Dr Takhar 12 November 2013

We thank Amrit Takhar for his thoughtful question regarding the final bullet point in the box titled "What low risk patients need to know." The bullet states: "The side effects of statins...occur in about 20% of people treated with statins." Dr. Takhar questions the validity of this statement because 35% of those who discontinued statin therapy due to adverse event were rechallenged with 92% of these patients continuing statin therapy 12 months later. We agree with this statement, but disagree with the opinion that we have "overstated the case against" statins.

First, as stated in the article by Zhang et al "The rate of reported statin-related events to statins was nearly 18%" in this retrospective cohort study. Second, the incidence of statin-related adverse events reported in the study is far more likely to be a floor rather than a ceiling. As noted in our article, spontaneous reporting of side effects is likely to underestimate the true incidence compared to rates determined prospectively by structured interview. Also, Zhang et al note, the incidence of side effects may have been under-reported because only the first reported statin-related event for each patient was included their analysis.

From a clinician's perspective, the most important response to Dr. Takhar's concern is that the incidence of statin-related side effects reported by Zhang et al was, in fact, "approximately one fifth." For low risk patients who do not derive an overall benefit from statin therapy, the finding that many of the patients who experienced statin-related side effects could tolerate statin therapy on rechallenge does not negate the fact they experienced a drug-related side effect while taking a drug that provides them with no net health benefit.

John Abramson
Harriet Rosenberg
Nicholas Jewell
James M Wright

Competing interests: JDA and NJ serve as experts for plaintiffs' attorneys in litigation involving the drug industry (including a statin). JDA has received payment for lectures from several universities, medical schools, and non-profit organisations. He was formerly executive director of health management for Wells Fargo Health Solutions.

On 14 April 2014 16:33, Rory Collins <rory.collins@ctsu.ox.ac.uk<<mailto:rory.collins@ctsu.ox.ac.uk>>> wrote:

Please see attached letter (ATTACHED)

> From: Fiona Godlee [<mailto:fgodlee@bmj.com>]

> Sent: 23 April 2014 19:13

> To: Rory Collins

> Subject: Re: Recent BMJ articles on statin safety and efficacy

> Dear Rory. Thank you for your further letter. My apologies for being slower than usual to reply - I am just back from holiday.

> The authors of the two articles have defended their overall conclusions in relation to the rates of statin related adverse events. However I agree that their representations of the Zhang et al paper were not entirely accurate, and I propose to publish corrections to both papers, the text of which is below. Please could you let me have any comments by close of play on Friday 25 April.

> I note your request for Abramson et al's declarations of conflicts of interest. These are provided at the end of their article. If you would like to ask for further detail, could you please send a rapid response on bmj.com<<http://bmj.com>> and we will ask the authors to provide additional information. You have also asked again for sight of the peer reviewers' comments. We will ask the two reviewers for permission to post these as a data supplement to the article.

> Should you wish to make any further comment on either of these papers, or indeed on anything else the BMJ publishes in future, please could you do so in the form of rapid response on bmj.com<<http://bmj.com>>. This will ensure that readers are immediately aware of any issues you wish to raise and will allow us to ask authors to provide a timely response.

> There is clearly continuing uncertainty and controversy over the balance of benefits and harms of statins, especially in low risk people. There is a growing view that this will be best answered by open scrutiny of the clinical study reports from the industry trials. You may have seen Ben Goldacre's recent rapid response on bmj.com<<http://bmj.com>> calling for this in relation to the side effects of statins.

> <http://www.bmj.com/content/348/bmj.g2151/rr/695338>.

> As I have said before, we would welcome an article from you on any aspect of this debate.

> Best wishes, Fiona

>

> Proposed correction to article by Abramson et al

> In referring to an observational study of patients taking statins, an
> article by Abramson et al said that 18% of patients discontinued
> therapy at least temporarily because of statin related adverse
> events.[ref] This was incorrect. The study reported that 17.4% of
> patients had a statin related event documented, of whom 59.2%
> discontinued the statin at least temporarily. The authors of the study
> concluded that "as many as 87%" of these discontinuations could have
> been due to statin related events.[ref Zhang et al]
> Proposed correction to article by Aseem Malhotra
> In referring to an observational study of patients taking statins, an
> article by Aseem Malhotra said that 20% of participants had side
> effects resulting in discontinuation of the drug.[ref] This was
> incorrect. The study reported that 17.4% of patients had a statin
> related event documented, of whom 59.2% discontinued the statin at
> least temporarily. The authors of the study concluded that "as many as
> 87%" of these discontinuations could have been due to statin related
> events.[ref Zhang et al]

> Fiona Godlee

> Editor in Chief

> [http://resources.bmj.com/repository/images/BMJ_Logo_email_signature.p

> ng] BMJ, BMA House, Tavistock Square, London, WC1H 9JR

> T: 020 7383 6002

On 25 Apr 2014, at 13:16, Cathy Harwood <secretary@ctsu.ox.ac.uk<<mailto:secretary@ctsu.ox.ac.uk>>>>
wrote:

Please see attached letter (ATTACHED)

FW: Recent BMJ articles on statin safety and efficacy

Inbox x

Cathy Harwood

25 Apr

to me

For the avoidance of doubt, the letter is not for publication

On 25 Apr 2014, at 04:01 pm, Fiona Godlee <fgodlee@bmj.com<<mailto:fgodlee@bmj.com>>> wrote:

> Dear Rory, Please send a letter for publication setting out your concerns, as previously and repeatedly requested. I will ask the authors to respond. I will also respond. We will then fashion a correction. I will write an editorial that will highlight the correction and we will press release it.

> Letters to the editor are the tried and tested approach to dealing openly with post-publication concerns, on which the BMJ has an excellent record. Your reluctance to summarise your concerns in a letter to the editor has done little to move things forward. I see that I made the request that you send a rapid response (which is the entry point for all letters to the editor at the BMJ) in my first email to you on October 30. Please now act on this request.

> If you tell me that you don't want to write a letter for publication, I will write a rapid response myself summarising what I understand to be your concerns, to which I will ask the authors to respond. We will fashion a correction. I will write an editorial highlighting the correction and we will press release it.

> Best wishes, Fiona

> Sent from my iPad

> From: Fiona Godlee [fgodlee@bmj.com]

> Sent: 25 April 2014 17:40

> To: Cathy Harwood

> Cc: Rory Collins

> Subject: Re: Recent BMJ articles on statin safety and efficacy

> Dear Rory. I realise that I didn't give a deadline, which would have

> been helpful. Could you send a rapid response/letter for publication,

> or a message that you will not be sending a letter for publication, by
> this time next week (close of play Thursday May 1). Many thanks and
> best wishes. Fiona
> Sent from my iPhone

On 29 Apr 2014, at 06:21 am, Cathy Harwood <secretary@ctsu.ox.ac.uk> wrote:

> Dear Fiona
> Please see attached letter. (ATTACHED)
> Best wishes
> Rory
> -----Original Message-----
> From: Cathy Harwood
> Sent: 26 April 2014 14:13
> To: Rory Collins Personal
> Subject: FW: Recent BMJ articles on statin safety and efficacy

From: Fiona Godlee [<mailto:fgodlee@bmj.com>]

Sent: 01 May 2014 16:32

To: Rory Collins

Subject: Re: Recent BMJ articles on statin safety and efficacy

Dear Rory. Many thanks for your letter. Please don't apologise. I believe we share the same aim and I think we would both agree that the process so far has been less than ideal. For my part in any misunderstanding, let me in turn apologise. My first error was to assume that you would put something in writing before or soon after we met, and my second was not to have made sufficiently clear to you that I would not be able to act on your concerns without having them clearly set out, preferably in a format for publication. After that it has been a case of trying to unpick what exactly can and cannot be said on the basis of the Zhang et al paper, which although straight forward to you does not seem so straight forward to others.

However, I think we are getting closer to resolving matters. You have now explained why you don't wish to send a letter for publication and, for the moment at least, I am happy to continue on this basis. I will at some stage explain to readers in general terms what has transpired.

I have asked the authors to withdraw their statement that side effects occur in 18-20% of patients taking statins and to reframe their comments on the evidence relating to the adverse effects of statins in people at low risk of CVD. I hope to have a draft correction along these lines to share with you and others early next week - I have given them a deadline of first thing on Monday.

I am prepared for the fact that there will be dispute over some issues

- for example, what is meant in the Zhang paper by "statin related event". Your interpretation is not shared by others so I propose to invite Jorge Plutsky and H Zhang to peer review the correction, as well as asking the two BMJ reviewers and one or two of the people you have suggested.

I hope in this way we will be able to reach agreement on the wording of a correction from the authors. If not, I have a second level of process in mind, which would involve convening a small panel with an independent chair, in view of your concern that I am not entirely unbiased in this matter, and inviting submissions from you and the authors from which the panel would draft a correction. But I hope it will not come to that. If there is any prospect of further delay in reaching a resolution I will put a note against the paper alerting readers to the issues in discussion.

You have been kind enough to offer me advice. Might I offer you some in return. Firstly, your public stance seems to be that statins cause almost no side effects. This seems to me to be an extreme position that is at variance with many clinicians' and patients' experience, and which does not help to advance a reasonable debate, especially given what I understand to be the paucity of good evidence and long term follow up in people at low risk of CVD. Is there no room for doubt in your mind on this? Secondly, there will be calls, in the BMJ and elsewhere, for access to the CSRs from the statin trials. I will support these calls but will do my best to do so in a way that makes clear that I have no view on the outcome of any third party review of the CSRs. I believe you would be acting most in the spirit of science and would do yourself great credit if you were to yourself support these calls rather than standing in their way.

I would welcome any thoughts on this and will anyway be back in touch next week.

Best wishes. Fiona

PS: The two peer reviewers have agreed to the posting of their signed reviews on bmj.com and I will arrange for that. And once we have agreement on the wording of a correction for the Abramson paper we will publish a correction to the Malhotra article. As an opinion piece this was read before publication by Abramson I think. I will check what record we have of this.

Sent from my iPhone

NOTE: 8 MAY - RORY COLLINS VISITS FIONA GODLEE

From: Fiona Godlee [mailto:fgodlee@bmj.com]
Sent: 12 May 2014 16:29
To: Rory Collins
Subject: Correction to Abramson et al

Dear Rory, Many thanks for coming in to see me last week. I am now able to share with you the correction we will publish against the Abramson et al article. It has been peer reviewed. I have also sent it to Zhang et al to check that they are happy with the interpretation of their data, which they are.

We will also correct the Malhotra article, and we will add links to these corrections from my editor's choice articles and the observations article in which Abramson et al replied to Huffman et al.

I am writing an editorial to highlight these corrections, which we will publish this week and will press release.

On the decision about whether we should retract the Abramson et al article, I plan to pass this to an independent panel. Iona Heath, former chair of our ethics committee, has agreed to chair the panel, which will comprise Harlan Krumholz (agreed), Julia Hippisley-Cox (agreed), ■■■■■■(awaiting reply), Paul Wicks (agreed), and ■■■■■■ (awaiting reply).

I hope they will be able to move quickly to reach a decision. Iona will be writing to you shortly to ask for your submission to the panel. All submissions will be placed in the public domain on bmj.com.

Best wishes, Fiona

RE: Correction to Abramson et al

Inbox x

Rory Collins

12 May (7 days ago)

At 17.27

to me

Dear Fiona

I shall be sending you my notes shortly on the reasons for withdrawing the Abramson et al and Malhotra articles (and why a correction does not suffice for such serious misrepresentation of the scientific evidence). With regard to your email and the draft correction:

1. In addition to the observational epidemiologists (i.e. Krumholz and Hippisley-Cox), it would be prudent to include someone on the panel with expertise in doing randomised controlled trials. One suggestion would be ■■■■■■, who is a neurologist and trialist not involved as an investigator in any of the statin trials or meta-analyses (although he has been on the Independent Data Monitoring Committees of some of these trials, including our own, which makes him well placed to comment on the safety data). Alternatively, you might consider a clinical trial methodologist, such as ■■■■■■ or ■■■■■■.

2. With regard to the draft correction by Abramson et al, the final paragraph of the online version should be removed as it was not the specific issue that was being raised about misrepresentation of the evidence by them.

Thanks for meeting at short notice last week, particularly on what must have been a busy day for you with the BMJ awards that evening: delighted to see that Iain Chalmers was honoured for his contributions.

Best wishes,

Rory

From: Fiona Godlee [mailto:fgodlee@bmj.com]

Sent: 12 May 2014 22:45

To: Rory Collins

Subject: Re: Correction to Abramson et al

Thanks Rory. Yes I am seeking a methodologist and a CVD expert - ideally in one person. ■■■■■■ has said he is too close to the issues and has declined. I have other people in mind and hope to have the panel finalised by end of this week. Best wishes, Fiona

Sent from my iPad

RE: Correction to Abramson et al

Inbox x

Rory Collins

14 May (5 days ago)

to me

Dear Fiona

One clinical trialist and methodologist who you might consider is ■■■■■■, who is ■■■■■■. She was originally ■■■■ but then led trials ■■■■ ■ has not worked in the lipid area but has huge experience in trials and in trial regulatory issues. (I've interacted with ■, but have not worked with ■ for more than 20 years ■■■■ so she would be appropriately independent.)

Best wishes,

Rory

NOTE: 15 MAY 2014 – BMJ PRESS RELEASE AND TODAY PROGRAMME DISCUSSION

From: Rory Collins <rory.collins@ctsu.ox.ac.uk>

Date: 15 May 2014 11:20:40 BST

To: Fiona Godlee <fgodlee@bmj.com>

Subject: RE: Papers for the panel considering the retraction of papers misrepresenting the evidence on statin side-effects

Dear Fiona

Thank you again for agreeing to meet in order to discuss the way forward. As you requested, I have drafted a note for the panel which is being formed to consider retraction of the papers by Abramson et al and by Malhotra, and it is attached to this email along with some other relevant materials for their consideration (i.e. my four previous letters on the subject and your emailed responses, along with my updated conflict of interest details). I think that you'll find, when you have a time to consider this issue more

carefully, that the errors are more severe and repeated than you currently have allowed in your public statements.

I would welcome an opportunity to comment on the draft of terms of reference (TOR) for the panel. In particular, the TOR should be clear that the specific reason for considering the retraction of these papers is the repeated misrepresentation of the magnitude of the rate of side effects caused by statins based on the cited paper by Zhang et al. It has nothing to do with the issue of whether or not statins should be given to people at lower risk or about making data from clinical trials available (both of which are important, but separate, matters), so these issues should not be allowed to distract the discussion from this reason for retraction.

In addition to considering the retraction of these papers, the TOR should perhaps also include the consideration of whether, in light of the repeated nature of this misrepresentation (which could be construed to be deliberate misconduct), the BMJ should indicate that it will not publish any further materials from any of these authors in the future.

I note in your email to me and in the Editorial that you intend that the panel be independent. It is not clear whether Iona Heath's previous involvement with the BMJ as chair of its Ethics Committee raises any issue about independence, but it has been drawn to my attention that her previous publications on the adverse effects of statins in the elderly (for example, see attached) are relevant.

Best wishes,

Rory
