SP11 and SP12 POST PUBLICATION CORRESPONDENCE BETWEEN FIONA GODLEE THE BMJ AND MALHOTRA

On 21 Mar 2014, at 18:13, "Fiona Godlee" < fgodlee@bmj.com > wrote:

Dear Aseem. Good to talk just now. Lots to discuss and well done with all you are doing.

Thank you for saying you will answer the four remaining rapid responses that raise criticisms of your piece on saturated fats. As I said on the phone we will need you to do this before we take on further pieces.

We now post an editor's note in rapid responses where what we consider to be substantive criticisms remain unaddressed, saying we have asked the authors to respond and they have not done so. Sorry of this seems brutal but we show no favouritism. We have done it to and colleagues just as an example.

Sharon can send you links to the RRs in question if that will help. Please could you send your response by the end of next week (Friday 28 March).

Thanks and best wishes. Fi

On 21 Mar 2014, at 18:19, aseem <aseem_malhotra@hotmail.com> wrote:

Thanks FI, I will sort ASAP Best

Aseem

BMJ Rapid responses

Inbox x

aseem <aseem_malhotra@hotmail.com>

28 Mar

to me

Dear FI,

Just to let you know that as promised I have just submitted the response to Sharon.

A copy is attached for your interest.

Very Best

Malhotra responses

The Zhang paper reported that almost 1 in 5 (17.4%) or 18,778 out of 107,835 patients treated with a statin in a routine care setting had a "statin-related adverse event

documented." The most commonly documented side effect was myalgia or myopathy with others including musculoskeletal and connective tissue disorders, general disorders, hepatobiliary disorders, gastrointestinal disorders, memory problems and drug intolerance. 1,2

In fact the overall initial rate of discontinuation for all causes that occurred at least once for the 107,835 patients analysed in the study was far higher at 53.1% (57,292 patients) for reasons that also included the drug being "no longer necessary" or the patients not wanting to take it.

Although it is true that 92.2% that were re-challenged representing 6579 out of 11,124 patients who at least temporarily discontinued their medication were on "a statin" 12 months later, only 15.1% (996) patients were on the same statin or a higher dose which suggests the remaining majority were either on a different statin or a lower dose. There is a clearly a discrepancy between side effects reported in clinical trials and real world experience. Professor Rory Collins, co-director of the University of Oxford's Clinical Trialists Service Unit, citing a meta-analysis which he co-authored of 27 (predominantly industry funded) RCTs of statin therapy³, recently told the Guardian that "We have really good data from over 100,000 people that show that the statins are very well tolerated. There are *only one or two* well-documented (problematic) side effects. Myopathy, or muscle weakness, occurred in one in 10,000 people, he said, and there was a *small* increase in diabetes."

A double blinded randomised controlled trial published in the Archives of Internal Medicine involving 1016 low risk patients receiving simvastatin 20mg, pravastatin 40mg or placebo revealed that both drugs had a significant adverse effect on energy/fatigue exercise score with 40% of women reporting reduced energy or fatigue with exertion. ^{5,6} In reference to diabetes risk a large observational study involving 153,840 postmenopausal women between 50 and 80 years of age who were enrolled in the Womens Health Initiative study revealed statins had a 48% increased risk of developing diabetes in this group. ⁷

Although there has been evidence of benefit in reducing cardiovascular events and mortality for a heterogeneous group of patients with cardiovascular disease that includes patients with stable angina using standard dose Pravastatin 40mg or Simvastatin 20-40mg from earlier clinical trials, more recent studies have mandated maximum dose therapy for all patients post acute-coronary syndromes. The PROVE-IT study randomised 4162 patients hospitalised with acute myocardial infarction or unstable angina to receive either atorvastatin 80mg or pravastatin 40mg revealing a significant 16% reduction in death and cardiovascular events in the those on maximum dose atorvastatin within 24 months. In a systematic review of randomised trials, high dose statin therapy in the setting of acute coronary syndromes demonstrated a 22% reduction in all cause mortality as well as a 25% reduction in cardiovascular mortality. Subsequently the European Society of Cardiology recommends that all patients presenting with acute myocardial infarction with high intensity statins early after admission unless contraindicated.

The primary prevention of cardiovascular disease with a Mediterranean Diet (PREDIMED) study randomly assigned participants who were at high cardiovascular risk to one of three diets: a Mediterranean diet supplemented with extra virgin olive oil (1 litre/week), a Mediterranean diet supplemented with 30g of mixed nuts per day (15g of Walnuts, 7.5g of hazelnuts and 7.5g of almonds) or a control diet (advice to reduce dietary fat). The intervention group had a significant 30% reduction in the primary endpoint of major cardiovascular events (myocardial infarction, stroke or death from cardiovascular causes). Despite the participants in the control group receiving advice to

reduce fat intake the difference in total fat were small however there were large differences in the fat subtypes reflected by the supplemental items, specifically olive oil and nuts, which were most likely responsible for most of the observed benefits of the Mediterranean diet. The fact that the control group were still advised to follow a healthy diet suggests a potentially greater benefit of a Mediterranean diet as compared to western diets. The authors conclude that the results of PREDIMED compare favourably with those of the Women's Health Initiative Dietary Modification Trial revealed no cardiovascular benefit for the "low fat" dietary approach. ¹²

Our focus on one specific nutrient or grouping all fats together has unfortunately led to an over obsession on "low fat" diets as being healthy. It is in fact the synergy of nutrient rich whole foods such as vegetables, fruits, nuts, legumes, fish and olive oil that may account for the health benefits of the Mediterranean diet by inducing positive changes in intermediate pathways of cardiometabolic risk through their impact on blood lipids, insulin sensitivity, resistance to oxidation, inflammation and vasoreactivity. 13 Most recently a meta-analysis of 72 unique studies with over 600,000 participants from 18 countries led by the Cambridge Medical Research Council concluded that current evidence does not support guidelines that restrict the consumption of saturated fats and encourage consumption of polyunsaturated fats in order to prevent heart disease. The study raised questions regarding current nutritional guidelines that focused principally on the total amount of fat from saturated or unsaturated rather than the food sources of the fatty acid subtypes. One particularly interesting finding when analysing saturated fat was one particular fatty acid (margaric acid) a dairy fat was significantly reduced the risk of cardiovascular disease. 14 These findings support those from the dietary intake of saturated fat by food source and incident cardiovascular disease analysis which concluded that a higher intake of dairy saturated fat was inversely associated with lower CVD risk. Otto, Mozaffarian et al explain this finding by stating that "dairy foods, which are a major source of saturated fat in most populations, are also sources of beneficial nutrients including Vitamin D, potassium, phosphorus, and calcium...". 15 However Professor Simon Pearce is right to point out that unlike the United States where dairy products are fortified with Vitamin D, this is not the case in the UK where the best sources come from foods such as oily fish and egg yolk. The suggestion of the UK adopting a similar Vitamin D fortification policy may hold some validity but the evidence is mounting that the health effects of the entire food and absorbing nutrients through natural means, not through supplementation, may be key to understanding associations between dietary consumption and health outcomes.

- 1. Zhang H, Plutzky J, Skentzos S, Morrison F, Mar P, Shubina M, et al. Discontinuation of statins in routine care settings. Ann Intern Med2013;158:526-
- 2. http://www.medscape.com/viewarticle/781767
- 3. Cholesterol Treatment Trialists' (CTT) Collaborators, Mihaylova B, Emberson J, Blackwell
- L, Keech A, Simes J, et al. The effects of lowering LDL cholesterol with statin therapy in people at low risk of vascular disease: meta-analysis of individual data from 27 randomised

trials. Lancet 2012;380:581-90.

- 4. http://www.theguardian.com/society/2014/mar/21/-sp-doctors-fears-over-statins-may-cost-lives-says-top-medical-researcher
- 5. http://www.medscape.com/viewarticle/765472
- 6. Golomb BA, Evans MA, Dimsdale JE, White HL. Effects of Statins on Energy and Fatigue With Exertion: Results From a Randomized Controlled Trial. *Arch Intern Med.* 2012;172(15):1180-1182. doi:10.1001/archinternmed.2012.2171.
- 7. Culver AL, Ockene IS, Balasubramanian R, Olenzki BC, Sepavich DM, Wactawski-Wende
- J, et al. Statin use and risk of diabetes mellitus in postmenopausal women in the Women's Health Initiative. *Arch Intern Med* 2012;172:144-52.
- 8. http://www.nejm.org/doi/full/10.1056/NEJMoa040583#t=citedby
- 9. http://www.ncbi.nlm.nih.gov/pubmed/17503884
- 10. http://www.escardio.org/guidelines-surveys/esc-guidelines/Guidelines/Documents/Essential_Messages_AMI_STEMI.pdf
- $\underline{11}$. Estruch R, Ros E, Salas-Salvadó J, Covas MI, Corella D, Arós F, et al. Primary prevention of cardiovascular disease with a Mediterranean diet. N $Engl\ J\ Med$ 2013;368:1279-90
- 12. Howard BV, Van Horn L, Hsia J, et al. Low-fat dietary pattern and risk of cardiovascular disease: the Women's Health Initiative Randomized Controlled Dietary Modification Trial. JAMA 2006;295:655-66.
- 13. Jacobs DR Jr, Gross MD, Tapsell LC. Food synergy: an operational concept for understanding nutrition. Am J Clin Nutr 2009;89:1543S-1548S
- 14. Rajiv Chowdhury, Samantha Warnakula, Setor Kunutsor, Francesca Crowe, Heather A. Ward, Laura Johnson, Oscar H. Franco, Adam S. Butterworth, Nita G. Forouhi, Simon G. Thompson, Kay-Tee Khaw, Dariush Mozaffarian, John Danesh, Emanuele Di Angelantonio; Association of Dietary, Circulating, and Supplement Fatty Acids With Coronary RiskA Systematic Review and Meta-analysis. Annals of Internal Medicine. 2014 Mar;160(6):398-406.
- 15. De Oliveira Otto MC, Mozaffarian D, Kromhout D, Bertoni AG, Sibley CT, Jacobs DR Jr, et al. Dietary intake of saturated fat by food source and incident cardiovascular disease: the Multi-Ethnic Study of Atherosclerosis. Am J Clin Nutr2012;96:397-404

Correction to your article

Fiona Godlee <fgodlee@bmj.com>

23 Apr

to aseem, Trevor, Karl

Dear Aseem. In response to a complaint from Rory Collins I propose to publish a correction to your article on saturated fats. It is similar to a correction we will be publishing to the article by Abramson et al. The wording of the correction is below. We will publish this on Friday and welcome any comment from you before then. All best wishes.

Fi

Correction to article by Aseem Malhotra

In referring to an observational study of patients taking statins, an article by Aseem Molhotra [ref] said that 20% of participants had side effects resulting in discontinuation of the drug. This overstated the study's findings. The study, by Zhang et al, in fact reported that 17.4% of patients had statin related adverse events. The authors concluded that "as many as 87%" of these patients discontinued the drug as a result.[ref Zhang et al]

On 23 Apr 2014, at 09:02 am, aseem aseem malhotra@hotmail.com> wrote:

> Dear FI,

> Thanks for letting me know. Makes sense.

> I do believe I have responded in greater detail already.

> http://www.bmj.com/content/347/bmj.f6340/rr/692280

> Very Best

> Aseem

Re: Correction to your article

Fiona Godlee <fgodlee@bmj.com>

23 Apr

to aseem, Trevor, Karl

Thanks Aseem. I think it is a small point and that readers will see it as such. But I would prefer that we address Rory's complaint head on and get on with the more important issue of calling for access to the data, rather than allowing this to become a distraction. Looking forward to seeing your revised open letter. Best wishes. Fi

Re: Correction to your article

Fiona Godlee <fgodlee@bmj.com>

23 Apr

to aseem, Trevor, Karl

Dear Aseem, I have looked again at the Zhang paper and realise that I got it wrong - it's a rather confusing account of a study! Below is the proposed text of the correction. I have sent this to Rory Collins, as well as a draft correction for John Abramson et al's paper, and will finalise the text once I have heard back from you all. Best wishes, Fi

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

On 28 April 2014 08:37, Fiona Godlee <fgodlee@bmj.com> wrote:

Dear Emma, Could you send me the press releases for the John Abramson et al paper on statins, and the Aseem Malhotra column on saturated fats. Many thanks indeed. Fi

Re: Statins and fats

Inbox x

Emma Dickinson

28 Apr

to me

Fi

We didn't press release Abramson - think it slipped through the net while I was away on holiday. Here's Malhotra's release below.

Emma

Time to bust the myth of saturated fat's role in heart disease, says cardiologist

Observations: Saturated fat is not the major issue

Advice to cut down on saturated fat has increased our risk

It is time to bust the myth of the role of saturated fat in heart disease, argues a cardiologist on bmj.comtoday.

Aseem Malhotra, interventional cardiology specialist registrar at Croydon University Hospital in London, says scientific evidence shows that advice to reduce saturated fat intake "has paradoxically increased our cardiovascular risks."

And he says the government's obsession with levels of total cholesterol "has led to the over-medication of millions of people with statins and has diverted our attention from the more egregious risk factor of atherogenic dyslipidaemia" (an unfavourable ratio of blood fats).

Saturated fat has been demonised since the 1970s when a landmark study concluded that there was a correlation between incidence of coronary heart disease and total cholesterol, which then correlated with the percentage of calories provided by saturated fat, explains Malhotra. "But correlation is not causation," he says. Nevertheless, we were advised to "reduce fat intake to 30% of total energy and a fall in saturated fat intake to 10%."

He points out that recent studies "have not supported any significant association between saturated fat intake and risk of CVD." Instead, saturated fat has been found to be protective.

One of the earliest obesity experiments, published in the Lancet in 1956, compared groups consuming diets of 90% fat versus 90% protein versus 90% carbohydrate and revealed that the greatest weight loss was in the fat consuming group.

And more recently, a JAMA study revealed that a "low fat" diet showed the greatest decrease in energy expenditure, an unhealthy lipid pattern, and increased insulin resistance (a precursor to diabetes) compared with a low carbohydrate and low glycaemic index (GI) diet.

Malhotra also points to the United States, where percentage calorie consumption from fat has declined from 40% to 30% in the past 30 years (although absolute fat consumption has remained the same), yet obesity has rocketed. One reason, he says, is that the food industry "compensated by replacing saturated fat with added sugar."

And despite the fact that in the UK, 8 million people take statins regularly, he asks why has there been no demonstrable effect on heart disease trends during this period?

Adopting a Mediterranean diet after a heart attack is almost three times as powerful in reducing mortality as taking a statin, writes Malhotra. "Doctors need to embrace prevention as well as treatment."

"The greatest improvements in morbidity and mortality have been due not to personal responsibility but rather to public health," he concludes. "It is time to bust the myth of the role of saturated in heart disease and wind back the harms of dietary advice that has contributed to obesity."

Commenting on the article, Professor David Haslam, Chair of Britain's National Obesity Forum said: "It's extremely naive of the public and the medical profession to imagine that a calorie of bread, a calorie of meat and a calorie of alcohol are all dealt in the same way by the amazingly complex systems of the body. The assumption has been made that increased fat in the bloodstream is caused by increased saturated fat in the diet, whereas modern scientific evidence is proving that refined carbohydrates and sugar in particular are actually the culprits."

Professor Robert Lustig, Paediatric Endocrinologist, University of San Francisco added: "Food should confer wellness, not illness. And real food does just that, including saturated fat. But when saturated fat got mixed up with the high sugar added to processed food in the second half of the 20th century, it got a bad name. Which is worse, the saturated fat or the added sugar? The American Heart Association has weighed in - the sugar many times over. Plus added sugar causes all of the diseases associated with metabolic syndrome. Instead of lowering serum cholesterol with statins, which is dubious at best, how about serving up some real food?"

Finally, Timothy Noakes, Professor of Exercise and Sports science, University of Cape Town, South Africasaid: "Focusing on an elevated blood cholesterol concentration as the exclusive cause of coronary heart disease is unquestionably the worst medical error of our time. After reviewing all the scientific evidence I draw just one conclusion - Never prescribe a statin drug for a loved one."

Contact:

Aseem Malhotra, Interventional Cardiology Specialist Registrar, Croydon University Hospital, London, UK

Tel: +44 (0)7786 075 842

Email: aseem malhotra@hotmail.com

Re: Statins and fats

Fiona Godlee <fgodlee@bmj.com>

28 Apr

Press release: BMJ authors withdraw statements about adverse effects of statins

Inbox x

Emma Dickinson

14 May (6 days ago)

to john_abramson, aseem, me

Dear John / Aseem

Below is the press release that will be issued shortly - based on Fiona's editorial in this week's journal (there's a link to the full editorial at the end).

It's embargoed until just after midnight UK time tonight - when the full editorial / corrections will be published on bmj.com

Fiona is happy to take calls from journalists today / tomorrow, but you may also want to prepare for calls

If possible, could you both send me a contact number that I can give to journalists wishing to speak to you.

Many thanks Emma

BMJ Press Release Embargo 00:01 hours (UK time) Thursday 15 May 2014

BMJ authors withdraw statements about adverse effects of statins

Decision whether to retract articles will be made by an independent panel

Editorial: Adverse effects of statins

Authors of two articles published in The BMJ last year are withdrawing statements about the adverse effects of statins.

An editorial by Editor-in-Chief, Dr Fiona Godlee aims to alert readers, the media, and the public to the withdrawal of these statements "so that patients who could benefit from statins are not wrongly deterred from starting or continuing treatment because of exaggerated concerns over side effects."

Dr Godlee has also asked an independent expert panel to decide whether the articles should be retracted.

In October last year, The BMJ published an article by John Abramson and colleagues that questioned the evidence behind new proposals to extend the routine use of statins to people at low risk of cardiovascular disease.

The authors re-analysed data from the Cholesterol Treatment Trialists' (CTT) Collaboration and suggested that side effects of statins occur in 18-20% of people. This figure was repeated in another article published in the same week in The BMJ by Aseem Malhotra.

The BMJ was alerted to the error by Rory Collins, professor of medicine and epidemiology at Oxford University and head of the CTT Collaboration whose data were re-analysed by Abramson and colleagues.

This error was due to a misreading of data from one observational study, and was not picked up by the peer reviewers or editors, explains Dr Godlee. "The BMJ and the authors of both these articles have now been made aware that this figure is incorrect, and corrections have been published withdrawing these statements."

She explains that writing, peer reviewing, and editing are human processes subject to error, "which is why we must be, and are, ready to correct things when they are found to be wrong."

Professor Collins has requested retraction of both articles, but Dr Godlee questions whether the error is sufficient for retraction, "given that the incorrect statements were in each case secondary to the article's primary focus."

Guidelines of the International Committee on Publication Ethics state that journals should consider retracting a publication if there is clear evidence that the findings are unreliable, either as a result of misconduct or honest error.

Dr Godlee has decided to pass this decision to an independent panel, chaired by Iona Heath, former chairwoman of the Royal College of General Practitioners and of The BMJ's ethics committee.

Full details of the panel and processes will be published shortly, and all submissions to the panel will be placed in the public domain on bmj.com. Dr Godlee has also committed to implementing the panel's recommendations in full.

Meanwhile, she says, "The BMJ will continue to debate the important questions raised in both these articles: whether the use of statins should be extended to a vastly wider population of people at low risk of cardiovascular disease; and the role of saturated fat in heart disease.

Contact:

Fiona Godlee, Editor-in-Chief, BMJ, London, UK

Tel (via Emma Dickinson, BMJ Press Office): +44 (0)20 7383 6529

Email: edickinson@bmj.com

RE: Press release: BMJ authors withdraw statements about adverse effects of statins

Inbox x

Abramson, John David

14 May (6 days ago)

to Emma, aseem, me

Dear Emma and Fiona,

I believe the following sentence from the press release is not quite correct:

"The authors re-analysed data from the Cholesterol Treatment Trialists' (CTT) Collaboration and suggested that side effects of statins occur in 18-20% of people."

Our re-analysis of the CTT data showed that there is no mortality benefit associated with treatment of people whose risk of ASCVD is < 20% over the next 10 years. This has not been challenged. Our error was in the citing of data from a completely separate uncontrolled observational study as showing that statin side effects occur in 18-20% of patients. This is the statement we withdraw.

Is it possible to have both of these points clarified in the press release?

Much thanks, John

Re: Press release: BMJ authors withdraw statements about adverse effects of statins

Fiona Godlee <fgodlee@bmj.com>

14 May (6 days ago)

to John, Emma, aseem

Thanks John. Emma could you make the change. Many thanks. Fiona

Re: Press release: BMJ authors withdraw statements about adverse effects of statins

Inbox x

Emma Dickinson

14 May (6 days ago)

to John, aseem, me

Thanks John. Revised version below (changes in red - OK)?

BMJ Press Release Embargo 00:01 hours (UK time) Thursday 15 May 2014

BMJ authors withdraw statements about adverse effects of statins

Decision whether to retract articles will be made by an independent panel

Editorial: Adverse effects of statins

Authors of two articles published in The BMJ last year are withdrawing statements about the adverse effects of statins.

An editorial by Editor-in-Chief, Dr Fiona Godlee aims to alert readers, the media, and the public to the withdrawal of these statements "so that patients who could benefit from statins are not wrongly deterred from starting or continuing treatment because of exaggerated concerns over side effects."

Dr Godlee has also asked an independent expert panel to decide whether the articles should be retracted.

In October last year, The BMJ published an article by John Abramson and colleagues that questioned the evidence behind new proposals to extend the routine use of statins to people at low risk of cardiovascular disease.

The authors re-analysed data from the Cholesterol Treatment Trialists' (CTT) Collaboration. This showed no mortality benefit associated with treatment of people with a less than 20% risk of developing cardiovascular disease over the next 10 years. This has not been challenged.

However, they also cited data from a separate uncontrolled observational study showing that statin side effects occur in 18-20% of patients. This was repeated in another article published in the same week in The BMJ by Aseem Malhotra – and is the statement the authors have now withdrawn.

The BMJ was alerted to the error by Rory Collins, professor of medicine and epidemiology at Oxford University and head of the CTT Collaboration whose data were re-analysed by Abramson and colleagues.

This error was due to a misreading of data from one observational study, and was not picked up by the peer reviewers or editors, explains Dr Godlee. "The BMJ and the authors of both these articles have now been made aware that this figure is incorrect, and corrections have been published withdrawing these statements."

She explains that writing, peer reviewing, and editing are human processes subject to error, "which is why we must be, and are, ready to correct things when they are found to be wrong."

Professor Collins has requested retraction of both articles, but Dr Godlee questions whether the error is sufficient for retraction, "given that the incorrect statements were in each case secondary to the article's primary focus."

Guidelines of the International Committee on Publication Ethics state that journals should consider retracting a publication if there is clear evidence that the findings are unreliable, either as a result of misconduct or honest error.

Dr Godlee has decided to pass this decision to an independent panel, chaired by Iona Heath, former chairwoman of the Royal College of General Practitioners and of The BMJ's ethics committee.

Full details of the panel and processes will be published shortly, and all submissions to the panel will be placed in the public domain on bmj.com. Dr Godlee has also committed to implementing the panel's recommendations in full.

Meanwhile, she says, "The BMJ will continue to debate the important questions raised in both these articles: whether the use of statins should be extended to a vastly wider population of people at low risk of cardiovascular disease; and the role of saturated fat in heart disease.

Contact:

Fiona Godlee, Editor-in-Chief, BMJ, London, UK

Tel (via Emma Dickinson, BMJ Press Office): +44 (0)20 7383 6529

Email: edickinson@bmj.com

Embargoed link to full editorial: http://press.psprings.co.uk/bmj/may/statins.pdf
Public link once embargo lifts: http://www.bmj.com/cgi/doi/10.1136/bmj.g3306

Emma Dickinson

RE: Press release: BMJ authors withdraw statements about adverse effects of statins

Inbox x

Abramson, John David

14 May (6 days ago)

to Emma, aseem, me

Emma,

Yes, changes in red are accurate. Thanks to you and Fiona for the quick response. The best way for journalists to contact me is at this email address and on my cell phone 978-314-5409. Sincerely,

John

Re: Press release: BMJ authors withdraw statements about adverse effects of statins

Inbox x

Emma Dickinson

14 May (6 days ago)

to John, aseem, me

Wonderful, thanks for your help. Will get this out now. Emma

Emma Dickinson

ress release: statin panel terms of reference

Inbox x

Emma Dickinson

12:27 (23 hours ago)

to Rory, John, aseem, iona.heath22, me

Dear All

Please find below a press release that will be issued shortly, announcing the statin panel and terms of reference.

This information has just been posted online at: http://www.bmj.com/about-bmj/independent-statins-review-panel

Best wishes Emma

For immediate release: Monday 19 May 2014

The BMJ establishes an independent panel to review statin articles

Draft terms of reference and membership of panel now on bmj.com

An independent panel has now been established to review two articles published in The BMJ by John Abramson and colleagues and Aseem Malhotra. Last week, the authors withdrew a statement in their articles about the side effects of statins after it was found to be incorrect.

The draft terms of reference and membership of the panel are now available on bmj.com.

The panel will be chaired by **Iona Heath,** former chair of the Royal College of General Practitioners and of The BMJ's ethics committee, and will have six other members:

Stephen Evans, professor of pharamcoepidemiology at the London School of Hygeine and Tropical Medicine

Curt Furberg, professor emeritus of public health sciences at Wake Forest University School of Medicine, North Carolina

Julia Hippisley-Cox, professor of epidemiology and general practice at the University of Nottingham

Harlan Krumholz, Harold H. Hines Jr. professor of medicine (cardiology) and professor of investigative medicine and of public health (health policy) at Yale School of Medicine

Cynthia Mulrow, senior deputy editor at Annals of Internal Medicine and adjunct professor of medicine atTexas University of Health Science Center

Paul Wilks, vice president of innovation, Patients Like Me

The panel's remit will be to consider whether either or both articles should be retracted and to review and comment on the process by which the articles were published. The panel will also review and comment on how criticisms and complaints against the articles were raised, and how the journal responded.

The panel will then make recommendations to The BMJ's editor in chief in a report that will be published onbmj.com.

To ensure full accountability and transparency, all submissions to the panel and all documents used by the panel will be placed in the public domain on bmj.com, either at the time of submission or as part of the panel's final report.

Panel members and all those submitting information to the panel will also make full declarations of their interests, which will also be published on bmj.com.

Read full details here:

http://www.bmj.com/about-bmj/independent-statins-review-panel

To comment on the draft please jsmith@bmj.com by Friday 23 May 2014.

Emma Dickinson