Declarations of interests of panel members

Stephen Evans

I declare that that I have read and understood the BMJ Group policy on declarations of interest. I hereby declare the following interests, according to the policy.

I have the following interests to declare:

Personal

None (though I currently take a prescribed statin). I have given talks for pharmaceutical companies on methods for studying drug safety but I take no fees or travelling expenses or any other reimbursement.

Organisational

LSHTM has grants from many organisations including the pharmaceutical industry. I am not a recipient or a beneficiary of any of them. GSK has funded a Chair in the Department of Medical Statistics but I am not involved.

I am a member of the Pharmacovigilance Risk Assessment Committee (Drug Safety) at the European Medicines Agency as an independent European Commission appointed expert.

I have been a member of the WHO Global Advisory Committee on Vaccine Safety. For each of these I have been paid travel expenses and a daily attendance allowance.

I am or have been a member of various MRC committees including currently Chairing a Data Monitoring Committee. Where travel is necessary I am paid travelling expenses.

I was formally a statistical advisor and member of the BMJ "Hanging" committee but have not been for over 3 years. I was paid an attendance allowance at that time. I continue to act as an occasional reviewer for BMJ papers.

Unpaid positions (current)

None, other than those noted above.

Name: Stephen JW Evans, Prof of Pharmacoepidemiology, LSHTM.

Date: 24th July 2014

Addendum related to work of panel

I am an author of a paper (with Liam Smeeth - one of the referees used by the BMJ) that found most of the claims of benefits and harms of statins are not replicated in careful analysis of observational data.

Smeeth L, Douglas I, Hall AJ, Hubbard R, Evans S. Effect of statins on a wide range of health outcomes: a cohort study validated by comparison with randomized trials. *Br J Clin Pharmacol.* 2009;67:99-109.

We also published a paper that suggested (in contrast to other OS) that statins did not have an antiinflammatory effect. Lodi S, Evans SJW, Egger P, Carpenter J. (2010) Is there an anti-inflammatory effect of statins in rheumatoid arthritis? Analysis of a large routinely collected claims database. *Br J Clin Pharmac*; 69:85-94.

We found benefits in pneumonia in the 2009 paper, and published another paper on that, though I think it is unlikely that the finding is real.

Douglas I, Evans S, Smeeth L. Effect of statin treatment on short term mortality after pneumonia episode: cohort study. BMJ. 2011;342

Curt Furberg

http://www.bmj.com/about-bmj/advisory-panels/editorial-advisory-board/curt-furberg

I declare that that I have read and understood the BMJ Group policy on declarations of interest. I hereby declare the following interests, according to the policy.

 \boxtimes I have the following interests to declare:

I have served as an Expert witness in about 15-16 litigations over the past 15 years involving about 10 drug companies. In most cases I have worked in support of patients who suffered serious adverse drug effects. Many cases settled, others went to trial and some are pending. I would excuse myself from discussions of issues related to any company or any drug under active investigation.

□ I have no relevant interests to declare

Name: <u>Curt D. Furberg</u> Signature:

Curt Lungate: 12/10/12

Addendum related to work of the panel

Membership on a handful of Data Safety Monitoring Committees including the landmark 4S trial

Chairmanship of the Steering Committee of ALLHAT and the Pravastatin Pooling Project

Principal Investigator of two statin trials with a carotid artery IMT outcome

Publication of a large number of studies of statin and other lipid studies

Expert witness in a legal security case involving Vytorin. The case was settled

Member of BMJ editorial advisory board

Iona Heath

I declare that that I have read and understood the BMJ Group policy on declarations of interest. I hereby declare the following interests, according to the policy.

I have the following interests to declare:

Personal

None

Organisational

Immediate past president of the Royal College of General Practitioners.

Unpaid positions (current)

Chair of the scientific organising committee for the Preventing Overdiagnosis Conference, Oxford, September 2014.

Member of the Board of the Greensleeves Homes Trust

Name: Iona Heath

Date: 2 July 2014

Addendum related to work of the panel

Member of the BMJ primary care hanging committee from 1993 to 2001.

Wrote a 6 weekly "Op Ed" column for the BMJ from 2005 to 2013.

Chair of the BMJ Ethics Committee from 2005 to 2009.

Julia Hippisley-Cox

I declare that that I have read and understood the BMJ Group policy on declarations of interest. I hereby declare the following interests, according to the policy.

I have the following interests to declare:

Personal

Relationship with the BMJ

I was a member of BMJ primary care hanging committee and subsequently am editorial adviser for the BMJ 1999-2013. Honoraria paid were around £200 per editorial session attended (approx. 6 per year)

The majority of my research has been published as research papers in the BMJ over the last 15 years with 30+ original research papers.

Organisational

Professor clinical epidemiology university of Nottingham & sessional NHS GP. Have undertaken unfunded research and published various research papers into risks and benefits of statins. I have not undertaken work for or received any funding or reimbursement from the pharmaceutical industry for over 20 years. Other academic divisions within Nottingham University may be in receipt of funding from the pharmaceutical industry but I am not involved in any of them. The Chancellor of Nottingham University is also CEO of GSK but this does not affect my freedom to publish, research programme or funding.

Director of QResearch – not for profit research database run as a collaboration between university of Nottingham and EMIS. Has been used for studies of adverse drug associations

Medical director ClinRisk Ltd – medical software company which undertakes research and develops risk prediction tools (supplied as free open source software and paid for close source software). This includes a risk prediction tool to cover many clinical outcomes including cardiovascular risk (www.qrisk.org) and to quantify risks and benefits of statins www.qintervention.org

Unpaid positions (current)

The positions I hold below are listed for transparency though as far as I know, none of these are involved with either of the two papers under consideration.

Member EMIS National User Group – charity representing clinicians using EMIS systems. Member of Primary Health Care Specialist Group Member Confidentiality Advisory Committee, Health Research Authority Fellow RCGP Fellow RCP

Name: Julia Hippisley-Cox

Date: 24.05.2014

Addendum related to work of the panel

I have published a number of articles on statins in the BMJ over a long period– several papers are referenced in the Abramson paper.

My first publication in the BMJ was letter in 1995 entitled "lowering patient cholesterol. Extrapolating trial of simvastatin gives room for doubt"¹ which highlighted issues about translating evidence from trials into real world populations, lack of mortality benefit for women in the 4S study; high levels of exclusions from RCTs and need for more evidence.

In 2003, we published a study in the BMJ entitled "cross sectional survey of effectiveness of lipid lowering drugs in reducing serum cholesterol concentration"² which concluded "the percentage reductions agreed with those from the RCTs indicating likely benefits in unselected patients in primary care. As the initial serum cholesterol concentrations were higher than those in the RCTs which could mean "that the absolute reduction in cardiovascular risk in primary care is greater than thought".

In 2005, the BMJ published our paper on "effects of combinations of drugs on all-cause mortality in patients with ischaemic heart disease"³

In 2006 we published a study on effect of statins on mortality of patients with ischaemic heart disease⁴ which concluded that "the benefits of statins found in RCTs extend to unselected community patients with ischaemic heart disease. Since patients in a community setting are likely to be at higher risk from those in trials the potential benefits from stains are likely to be greater than expected" ⁴

We have published several observational studies on associations between statins and cancer risk which were largely reassuring⁵⁶. We reported an observational study suggesting current and recent exposure to statins is associated decreased risk of pneumonia⁷.

In 2010 we published an observational study in the BMJ to quantify unintended effects of statins which is referenced in the Abramson paper⁸. We also published a paper in Heart on the derivation and validation of a new risk prediction algorithm designed to individualise risks and benefits of

statins⁹ which is associated with a publically available risk calculator <u>www.qintervention.org</u> which is in use across the NHS in England on a daily basis. This quantifies absolute 5 year risk of liver dysfunction, acute kidney failure, cataract, myopathy and CVD in patients with and without statins. I am lead author on a series of BMJ paper about the QRISK2 cardiovascular risk prediction algorithm¹⁰⁻¹⁴ which is now the preferred algorithm in England for CVD risk assessment and recommended by NICE. One of the QRISK2 papers was references by Abramson and which is recommended by NICE.

We have published other papers in use of statins in patients with and without mental health problems¹⁵ as well as gender and age inequalities in uptake of statins¹⁶

1. Hippisley-Cox J. Lowering patients' cholesterol. Extrapolating results of trial of simvastatin gives room for doubt. BMJ 1995;**311**(7006):690-91.

2. Hippisley-Cox J, Cater R, Pringle M, et al. A cross-sectional survey of the effectiveness of lipid lowering drugs in lowering serum cholesterol in 17 general practices:how well do they work? BMJ 2003;**326**:689-94.

3. Hippisley-Cox J, Coupland C. Effect of combinations of drugs on all cause mortality in patients with ischaemic heart disease: nested case control analysis. BMJ 2005;**330**:1059-63.

4. Hippisley-Cox J, Coupland C. Effect of statins on the mortality of patients with ischaemic heart disease: population based cohort study with nested case–control analysis. Heart 2006;**92**:752-58.

5. Vinogradova Y, Coupland C, Hippisley-Cox J. Exposure to statins and risk of common cancers: a series of nested case-control studies. BMC Cancer 2011;**11**:409.

6. Vinogradova Y, Hippisley-Cox J, Coupland C, et al. Risk of colorectal cancer in patients prescribed statins, nonsteroidal anti-inflammatory drugs, and cyclooxygenase-2 inhibitors: nested case-control study. Gastroenterology 2007;**133**:393-402.

7. Vinogradova Y, Coupland C, Hippisley-Cox J. Risk of pneumonia in patients taking statins: population-based nested case-control study. Br J Gen Pract 2011;**61**(592):e742-8.

8. Hippisley-Cox J, Coupland C. Unintended effects of statins in men and women in England and Wales: population based cohort study using the QResearch database. BMJ 2010;**340**:c2197.

9. Hippisley-Cox J, Coupland C. Individualising the risks of statins in men and women in England and Wales: population-based cohort study. Heart 2010;**96**(12):939-47.

10. Hippisley-Cox J, Coupland C, Vinogradova Y, et al. Derivation and validation of QRISK, a new cardiovascular disease risk score for the United Kingdom: prospective open cohort study. BMJ 2007;**335**(7611):136.

11. Hippisley-Cox J, Coupland C, Robson J, et al. Derivation, validation, and evaluation of a new QRISK model to estimate lifetime risk of cardiovascular disease: cohort study using QResearch database. BMJ 2010;**341**:c6624. 12. Hippisley-Cox J, Coupland C, Vinogradova Y, et al. Predicting cardiovascular risk in England and Wales:

prospective derivation and validation of QRISK2. BMJ 2008:bmj.39609.449676.25.

13. Hippisley-Cox J, Coupland C, Vinogradova Y, et al. Derivation and validation of QRISK, a new cardiovascular disease risk score for the United Kingdom: prospective open cohort study. BMJ 2007:bmj.39261.471806.55. 14. Hippisley-Cox J, Coupland C, Vinogradova Y, et al. Performance of the QRISK cardiovascular risk prediction algorithm in an independent UK sample of patients from general practice: a validation study. Heart 2008;**94**:34-39.

15. Hippisley-Cox J, Parker C, Coupland C, et al. Use of statins in coronary heart disease patients with and without mental health problems. London: Disability Rights Commission 2006.

16. Hippisley-Cox J, Pringle M, Crown N, et al. Sex inequalities in ischaemic heart disease in general practice: cross sectional survey. BMJ 2001;**322**(7290):832.

Harlan Krumholz

http://www.bmj.com/about-bmj/advisory-panels/editorial-advisory-board/harlan-krumholz I declare that that I have read and understood the BMJ Group policy on declarations of interest. I hereby declare the following interests, according to the policy.

✓ I have the following interests to declare:

Board membership: ImageCor, LLC (start-up to evaluate the technical quality and interpretation of coronary angiograms for quality improvement) - Board of Directors and equity American Board of Internal Medicine American College of Cardiology Patient-Centered Outcomes Research Institute

Consultancy: UnitedHealthcare, Inc. - Chair, Cardiac Scientific Advisory Board Institute for Healthcare Improvement - Chair, Cardiac Scientific Advisory Board VHA, Inc. – Scientific Advisor Board Premier, Inc. – Scientific Advisory Board Chinese National Center for Cardiovascular Disease - Scientific Advisory Board

Grants/Contracts (institutional): National Bank of Egypt - Research grant to improve healthcare in Egypt with a focus on cardiovascular disease (ended 2010) Medtronic, Inc. – PI of research grant/Independent assessment of INFUSE data NIH grants FDA grant CMS contracts

Payments for lectures: Premier, Inc. – Educational lectures VHA, Inc. – Educational lectures Centrix Technologies Pvt Ltd. - Educational lectures Academic Institutions – Educational lectures Chinese National Center for Cardiovascular Disease - Educational lectures

Editorships: Circulation Cardiovascular Quality and Outcomes Journal Watch: Cardiology CardioExchange

Name: Harlan M. KrumholzSignature:	Harla	m. Mum	nx
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Date: January 16, 2013.....

Addendum related to work of the panel Member BMJ editorial advisory board

Adviser to BMJ on state of the art reviews

Cindy Mulrow

I declare that that I have read and understood the BMJ Group policy on declarations of interest. I hereby declare the following interests, according to the policy.

I have the following interests to declare:

Personal

- Senior Deputy Editor, Annals of Internal Medicine
- Receive travel and small remuneration for Patient Center Outcome Research Institute (PCORI) Advisory Panel
- Cancer Prevention Research Institute of Texas Oversight Board Member
- Receive travel only for Institute of Medicine committee meetings
- Past Member Editorial Board, British Medical Journal 1995-2000

Organisational

Current research grants from

None

Unpaid positions (current)

- Member, PCORI Advisory Panel
- Member, Institute of Medicine
- Master, American College of Physicians
- Member, American Society Clinical Investigation
- Member, CONSORT, PRISMA, STROBE, TRIPOD groups

Name: Cynthia Mulrow

Signature

ynthia Mulion

Date:5/22/2014

Paul Wicks

http://www.bmj.com/about-bmj/advisory-panels/editorial-advisory-board/paul-wicks

Competing Interests

Have you in the past five years accepted the following from an organisation that may in any way gain or lose financially from the publication of papers in the BMJ? YES

Reimbursement for attending a symposium? YES

A fee for speaking? YES

A fee for organising education? YES

Funds for research? YES

Funds for a member of staff? YES Fees for consulting? YES

Have you in the past five years been employed by any organisation that may in any way gain or lose financially from the publication of papers in the BMJ? YES

Do you hold any stocks or shares in an organisation? Do you have any other competing financial interests?

YES

I have the following competing interests.

Paul Wicks is an employee of PatientsLikeMe and holds stock/options in the company. The PatientsLikeMe R&D Team has received research funding (including conference support and consulting fees) from Abbvie, Accorda, AstraZeneca, Avanir, Biogen, Boehringer Ingelheim, Genzyme, Janssen, Johnson & Johnson, Merck, Novartis, Sanofi, and UCB. The PatientsLikeMe R&D team has received research grant funding from Kaiser Permanente, the Robert Wood Johnson Foundation, Sage Bionetworks, The AKU Society, University of Maryland, and University of Michigan.

Addendum related to work of the panel

* I have published one observations paper in the BMJ (<u>http://www.bmj.com/content/348/bmj.g368</u>) and one blog post (<u>http://blogs.bmj.com/bmj/2014/03/14/paul-wicks-patients-take-centre-stage-at-the-4th-nhs-expo/</u>)

* As of 2014 I serve on the editorial advisory board and receive a BMJ subscription to help stay on top of the BMJ's activities

* I have supported the BMJ's patient partnership work, for instance by helping to identify patient advocates, and working with BMJ editors on the patient peer review program (e.g. I did the voiceover on how to sign up <u>http://www.bmj.com/about-bmj/resources-reviewers/guidance-patient-reviewers</u>)

Jane Smith (secretary to the panel)

I declare that that I have read and understood the BMJ Group policy on declarations of interest. I hereby declare the following interests, according to the policy.

I have the following interests to declare:

<u>Personal</u>

I was employed by the BMJ for many years, latterly as a deputy editor. I retired in 2012. I continued to do read submitted articles on a freelance basis until the summer of 2013.

<u>Organisational</u> None

<u>Unpaid positions (current)</u> Member of research ethics committee

Name:

Date: 28 July 2014

Addendum related to work of the panel

I was one of the associate editors who read the paper by Abramson et al when it was first submitted, though I do not remember it or the discussions about it clearly.

I prepared the timeline of what happened from the time of submission of the papers by Abramson et al and Malhotra up to the time of the publication of the corrections (SP14) for the BMJ's Editor in Chief and for the Panel. I was paid by the BMJ for preparing it.