Science Media Centre

Expert reaction to review of evidence on efficacy and safety of statins, as published in the *Lancet**

Dr Tim Chico, Reader in Cardiovascular Medicine / consultant cardiologist, University of Sheffield, said:

"This paper summarises the risks and benefits of statins, and highlights the damage done by irresponsible or uninformed scare stories that exaggerate their risks. Many people are reluctant or completely opposed to taking statins but cannot explain why, other than they feel statins are dangerous or ineffective, neither of which is correct. Most inaccurate messages about statins come from observational studies. Scientific journals and newspaper articles are littered with observational studies that are later shown to be incorrect, but they get reported on because they make interesting headlines and confirm people's existing biases.

"The current study restricts itself to summarising comprehensively the findings from properly conducted, randomised controlled trials, where patients received statin or placebo pills, with neither patient nor doctor knowing which they were taking. Although even these studies aren't without disadvantages, they are the only reliable evidence on which to base the benefits and risks of a particular treatment.

"I often meet people who don't want to take statins yet are happy to take other drugs with greater risks of side effects, or take supplements with no benefit at all. Statins have been unfairly demonised, and this prevents a sensible discussion of the risks and benefits of their use. Statins can cause side effects, but the chance of developing these is low, while the effects of suffering the heart attack that a statin might have prevented can be fatal or life-long.

"It is clear that statins reduce the risk of a heart attack, not completely, but sufficiently to recommend taking them in people with a higher risk of heart disease. Statins also increase the risk of some side effects, particularly muscle pain, bleeding into the brain and diabetes. As a doctor, it's not my role to tell people to take any drug; my job is to tell people openly the risks and benefits of a particular treatment and for them to decide for themselves. Unfortunately, the confusion over the risks of statins means many people have made up their mind without being told the proper facts.

"Some critics of statins justify their position by saying that a healthy lifestyle can reduce the risk of heart disease more than statins, and it is true that much more should be done to improve our diet, exercise habits and other factors such as smoking and obesity. However, these are complex and difficult factors to alter, and doctors have only a limited ability to help our patients improve their lifestyle."

Prof David Webb, Professor of Therapeutics & Clinical Pharmacology, University of Edinburgh, and President, British Pharmacological Society, said:

"In recent years, those of us who manage the large number of patients at excess risk of heart disease and strokes have been fighting an uphill battle to persuade them to take statins, a class of medicines that have been repeatedly shown to save lives. The problem has largely related to concerns about muscle aches and potentially more serious side effects (muscle damage, diabetes and haemorrhagic stroke) that have been very well publicised on the internet. Many patients who have much to benefit from statins, and many of those at more modest risk, have been persuaded not to take them because of exaggerated claims of harm, and some research suggesting that the benefits have been overestimated. It is likely that many lives have been lost, based on a received view that statins are dangerous and ineffective.

"This comprehensive review, by a broad group of leading international academics, of robust and unbiased evidence from randomised controlled trials and systematic reviews, confirms that statins are both effective and cost effective, and that the benefit rises with the level of pre-treatment risk. It also confirms that any rare harms are substantially outweighed by solid benefits, in terms of a reduction of heart attacks and strokes.

"So long as the public still have trust in experts, this work provides the evidence needed to justify providing the substantial cardiovascular protection to patients that they deserve."

Prof Jeremy Pearson, Associate Medical Director at the British Heart Foundation, said:

"This comprehensive review reiterates the lifesaving benefits of statins, which vastly outweigh the rare side effects associated with the medicine. Evidence, from many objective clinical trials, shows that statins are a safe and effective way of reducing heart attack and stroke risk. And there is certainly no debate that people who have had a heart attack or stroke should be taking statins to reduce their risk of another, potentially deadly event.

"Medicine should be guided by evidence and this review will help clinicians to consider the available evidence and judge its strengths and weaknesses. Clinicians, and particularly GPs, play a vital role in advising patients so it's important that if a person has concerns about their medication, they discuss this with their GP first."

Prof Sir John Tooke FMedSci, former President of the Academy of Medical Sciences and Chair of the 'How can we all best use evidence to judge the potential benefits and harms of medicines' oversight group, said:

"This study has added much needed clarity into the heated debate on the safety and efficacy of statins. Most importantly it highlights the relative value of different ways of generating evidence.

"It is essential that patients and the public have access to the best evidence when it comes to making decisions about the management of their health, whether these concern lifestyle changes or the use of medication. Clear, accurate and trustworthy information is vital to empower people to make treatment choices.

"This review provides a clear summary of the evidence to date which will help healthcare professionals and patients have more informed conversations about the benefits and harms of statins.

"Following a request from the Chief Medical Officer, the Academy has been exploring the best ways of generating and communicating evidence about the benefits and harms of medicines, and how to

ensure this evidence is trustworthy so that all stakeholders – patients, the public but also healthcare professionals – can use it to inform their decisions about medicines.

"Throughout our evidence gathering for the project we have repeatedly heard calls for communications about scientific evidence to present absolute risk and so I am pleased to see that this study has presented data in this way."

* 'Interpretation of the evidence for the efficacy and safety of statin therapy' by Rory Collins *et al.* will be published in the *Lancet* at 23:30 UK time on Thursday 8 September 2016, which is also when the embargo will lift.

Declared interests

Dr Tim Chico: "I am a committee member and Treasurer of the British Atherosclerosis Society, a charity established in 1999 to promote UK atherosclerosis research."

Prof David Webb: "I have no relevant conflicts of interest, but should say that although I am a member of the MHRA Board, this is my personal view and has not been discussed with MHRA."

Prof Jeremy Pearson: "The BHF funds several of the authors of this review, including Rory Collins and John Danesh, who are BHF Professors."

Prof Sir John Tooke: "Professor Sir John Tooke FMedSci (Chair of the Oversight Group) is Co-Chair of the Centre for the Advancement of Sustainable Medical Innovation, a joint initiative between Oxford University and University College London (UCL). His research interests relate to the pathogenesis of diabetic complications and their management, and the development of academic health science systems. He was Vice Provost (Health) at UCL until July 2015 and Academic Director of UCL Partners, and in the past has served as Chair of the Medical Schools Council. He is a Non-Executive Director of Bupa and Executive Chairman of Academic Health Solutions, a company that offers advice to international governments, universities and other agencies on the development of Academic Health Science systems. He has served as President of the Academy of Medical Sciences for four years until December 2015. He was in receipt of a National Institute of Health Research grant for the UCL Hospitals Biomedical Research Centre. He serves on the International Advisory Boards for both the Qatar Academic Health System and the National University of Singapore Medical School."

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The SMC has asked the experts in the above Roundup to declare any interests which may be regarded by a reasonable and objective third party as giving rise to a conflict, and their responses are included above.

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