EDITOR'S CHOICE

Statins for all over 50? No

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Should you prescribe statins to everyone over the age of 50, even those at low cardiovascular risk? A new Cochrane review seems to suggest that you should. An article in this week *BMJ* cries caution (doi:10.1136/bmj.f6123).

Current guidance from the UK's National Institute for Health and Care Excellence (NICE) and the American Heart Association recommends statins only when the 10 year risk of cardiovascular disease is 20% or greater. But since these guidelines were written, a large meta-analysis of individual patient data reached a different conclusion. Published in the *Lancet* in 2012, the Cholesterol Treatment Trialists (CTT) Collaboration meta-analysis found that statins significantly reduced major cardiovascular events and all cause mortality in people at low risk, a benefit which, the paper said, "greatly exceeds any known hazards of statin therapy."

As John Abramson and colleagues explain, it's this meta-analysis that led the Cochrane reviewers to embrace the idea that statins should be used far more widely, even perhaps to everyone over 50, as a *Lancet* editorial suggested at the time.

But Abramson and colleagues' detailed critique of the CTT meta-analysis should give us pause. Their own analysis of the data finds no evidence of a reduction in all cause mortality or in the total number of serious events. They also highlight the failure of the trials included in the CTT analysis to adequately report important harms of statin treatment, including myopathy and diabetes. They conclude that broadening the use of statins to low risk individuals "will unnecessarily increase the incidence of adverse events without providing overall health benefits."

There is a concern underlying their critique that will be familiar to *BMJ* readers. It is that all of the trials included in the CTT meta-analysis were funded by the manufacturer of the statin

being studied. They list the various ways in which these trials might have exaggerated the benefits of statins and minimised the harms, and they summarise what low risk patients need to know. Top of the list is the benefit of lifestyle change, something that the dominance of industry sponsored clinical trials too often obscures.

None of this does much to bolster confidence in the published literature. Nor am I reassured by discussions at two recent meetings co-hosted by the European Federation of Pharmaceutical Industry Associations (EFPIA). Drug company AbbVie is suing the European Medicines Agency to stop summary reports of its clinical trials becoming publicly available (doi:10.1136/bmj.f1636). AbbVie's lawyer made clear that the company considers even the data on adverse events to be commercially confidential. Despite industry's claims to be in favour of greater transparency, EFPIA and its American counterpart PhRMA are supporting AbbVie. The *BMJ* and BMA have joined forces to intervene on behalf of the EMA (doi:10.1136/bmj.f4728).

As for a way forward, I can't improve on the list of solutions proposed by Richard Lehman when emailing out his journal review blog this week (<http://bit.ly/HcKvjy>): "All phase 3 trials to be designed and conducted independently of manufacturers, using the best available comparator. Research priorities to be determined by patients (James Lind Alliance). Value-based pricing. All data available from all trials, with meta-data: IPD [individual patient data] level for qualified independent centres. Big increase in comparative effectiveness research, much more research into non-pharmacological treatments."

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