

Misrepresentation of statin safety evidence

We are writing to draw attention to serious errors in "Concerns about the latest NICE draft guidance on statins", a letter that was sent by Richard Thompson and colleagues to the National Institute for Health and Care Excellence (NICE) and the Secretary of State for Health,¹ and to the media with a press release.² The letter¹ was covered extensively in the media and increased confusion about the effects of statins, despite the robust response from NICE.³ As a consequence, it might well lead patients who are at high risk of heart attacks and strokes to stop statin therapy or not start it, thereby substantially increasing their risks of death and disability.

There are two major types of scientific error in the letter by Thompson and colleagues (see annotated version of the letter).

First, there are errors of interpretation. Much is made in the letter about differences in the rates of adverse events that were recorded in different statin trials. However, it is not scientifically appropriate to make such non-randomised comparisons between trials of the rates of events that are defined very differently in different trials (which also involved different types of patient with different underlying risks of adverse events). For example, the rates of adverse events given as reasons for discontinuation in one trial should not be compared (as was done in the letter¹) with the rates of all adverse events, or of discontinuations for any reason, in another trial. Moreover, since the results quoted relate to the numbers of events that are recorded during a particular trial (and should more properly be referred to as cumulative incidence rather than rates), they will also be affected by differences in the duration of different trials. By contrast, it would have been entirely appropriate to make direct comparisons of event rates between randomised groups within each trial since these are based



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For the annotated version of the letter see <http://www.ctsu.ox.ac.uk/research/meta-trials/ctt/annotated-thompson-letter-ms-word>

