

Despite universal access entitlements to public hospital services, 44% of the population (down from a peak of 51% in 2008)² are covered by voluntary private health insurance, which typically grants faster access, greater choice of provider and superior accommodation. All of those with private health insurance have cover for public hospitals, although most also have cover for private hospitals.

Much of the care of private patients takes place in public hospitals, with insurers usually reimbursing providers on a fee-for-service basis, compared with a fixed reimbursement mechanism in the public system. This incentivises hospitals and consultants to treat private patients over public patients, and has led to criticism of the Irish system as being a two-tier system, favouring private patients. However, given that those without medical cards face substantial out-of-pocket payments for primary care services, the reality is that there is a multitiered system, benefitting private patients at hospital level and public (medical card) patients at primary care level.

In its Programme for Government 2011–16, the Government committed to introducing a single-tier health system, underpinned by UHI, by 2016. In subsequent Government policy documents, this date was pushed back to 2019, but only weeks after being appointed, the new Minister for Health acknowledged that even this timescale was too ambitious.³

Under this system, residents would be obliged to take out private health insurance, which would cover a standard basket of services (including primary and hospital care, although the composition of this basket has yet to be determined). Those on low incomes would have their premiums paid for by the State, while another cohort by income would have their premiums partially subsidised by the State.

The transition to a single-tier health system will inevitably involve changes in the relative positions of the various cohorts within the current system.

Most of those with medical cards will likely have their premiums paid for by the State, but might face changes in what they are covered for. Those with private health insurance will continue to pay premiums (although some might have their premiums partially or fully paid by the State) but receive a wider basket of care—particularly at primary care level—although they will no longer receive faster access.

However, people who currently have neither form of cover—23% of the population in 2010⁴—will fare worst. As they do not have medical cards, they are unlikely to be on sufficiently low incomes to have their premiums paid by the State, so they will be required to pay some or all of their premiums. However, since they do not currently have health insurance, this will be an additional cost for them. This cohort has the lowest usage rates of health services, suggesting that their out-of-pocket expenditures are relatively modest, and unlikely to be as much as they will have to pay under UHI.

The Government proposals have received much criticism from a range of stakeholders and analysts. Some argue that improvements could be made to the present tax-based system, to make it fairer and more efficient. Others argue that a social health insurance model would be preferable. However, there is widespread scepticism about the competition model as presently proposed.

I declare no competing interests.

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- 1 OECD. Health at a Glance 2013. Paris: Organisation for Economic Co-operation and Development, 2013.
- 2 HIA. Newsletter: May 2014 Edition. Dublin: The Health Insurance Authority, 2014.
- 3 Varadkar L. I can't solve all the problems in the health service but I will steady the ship. Dublin: Irish Independent, Aug 5, 2014. <http://www.independent.ie/opinion/comment/i-cant-solve-all-the-problems-in-the-health-service-but-i-will-steady-the-ship-30483130.html> (accessed Sept 8, 2014).
- 4 CSO. Health Status and Health Service Utilisation: Quarterly National Household Survey, Quarter 3, 2010. Dublin: Central Statistics Office, 2011.

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>

on unbiased blinded assessment of events defined in the same way for both the patients allocated active statin treatment and those allocated placebo treatment within any particular trial. The similarity of the rates in the statin versus placebo groups within each of these randomised, blinded, and controlled comparisons reported in the letter¹ provides robust unbiased evidence of an absence of adverse effects of statin therapy on each of these different adverse event measures. This important point is over-looked in the letter by Thompson and colleagues.¹

Second, there is misrepresentation of the evidence. In the comparisons of rates between trials in section 2 of Thompson and colleagues' letter to NICE,¹ it is not made clear what is meant by "effects" (by contrast with "events" used earlier in their letter), but it seems to be—in view of the rates quoted for some of the trials—something along the lines of adverse events that led to discontinuation of the active or placebo treatment. It is claimed in the letter that these "placebo adverse effect rates range from 2.7% to 80.4%, a thirty fold difference". As noted above, such comparisons are not scientifically appropriate, but the statement is also incorrect. In particular, it is stated¹ that "Total adverse effects" occurred in 80.4% of placebo-allocated patients in the METEOR trial,⁴ whereas this is actually the rate of "Total adverse events". It is misleading for Thompson and colleagues to compare the rate of "total adverse events" in METEOR with the rates of subsets of adverse events in the other trials, such as those that led to discontinuation of study treatment (ie, so-called effects). Published results for the rates of the comparable outcome of adverse events leading to discontinuation in METEOR are 11% among those allocated rosuvastatin versus 8% among those allocated placebo, and these results are entirely compatible with the rates reported for similar outcomes in the other trials (especially given that the precise definitions used in the different

trials differed, and so too did the types of patient that were included and the duration of study treatment).

Another serious error in Thompson and colleagues' letter¹ relates to their misrepresentation of the results from the WOSCOPS trial.⁵ It is stated that "the cumulative incidence of myalgia was 0.06% in the statin arm, and 0.06% in the placebo arm". However, in the paper referenced in support of that claim,⁵ it is reported that myalgia was recorded in 20 of the 3302 patients allocated pravastatin and 19 of the 3293 patients allocated placebo: these numbers translate into percentages of 0.6% and 0.6%, respectively (ie, a ten fold error). Moreover, in the same section of the WOSCOPS paper,⁵ it was reported that another 97 patients allocated statin and 102 allocated placebo reported other muscle aches, yielding an overall rate of 3.5% and 3.7%, respectively. The METEOR trial classified adverse events using the MedDRA coding system, which includes all muscle aching in the definition of myalgia. Consequently, comparison of the placebo rates of myalgia defined more similarly in METEOR of 12.1% and in WOSCOPS of 3.7% yields a difference that is not 200-fold (as claimed in the letter to NICE), but is only about three fold (ie, more than a 60-fold error).

Errors in the rates quoted by Thompson and colleagues for these and other trials (see supporting material) invalidate their main points about the adverse effects of statins, undermining conclusions that were widely disseminated.

A debate about offering statin therapy to patients who are not at high risk of heart attacks and strokes (as has now been recommended by NICE⁶) is entirely appropriate. However, in making a case against such a strategy, it is not at all appropriate to misrepresent evidence in ways that mislead doctors, patients and the wider public.

The Clinical Trial Service Unit receives grants from the pharmaceutical industry (including manufacturers of statins) for independent research and has a patent for a statin-related myopathy genetic test ([http://www.ctsuo.ox.ac.uk/about-ctsuo/documents/independent-](http://www.ctsuo.ox.ac.uk/about-ctsuo/documents/independent-research)

<http://www.ctsuo.ox.ac.uk/about-ctsuo/documents/guidelines>). It has a staff policy of not accepting any payments directly or indirectly from the pharmaceutical industry, except for reimbursement of the costs of travel and accommodation to participate in scientific meetings (<http://www.ctsuo.ox.ac.uk/about-ctsuo/documents/guidelines>).

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- 1 Thompson R, Gerada C, Haslam D, et al. Concerns about the latest NICE draft guidance on statins. <http://www.nice.org.uk/Media/Default/News/NICE-statin-letter.pdf> (accessed Sept 17, 2014).
- 2 Kendrick M, Malhotra A. Leading doctors reject latest statin guidance from the National Institute for Health and Care Excellence. <http://www.ctsuo.ox.ac.uk/research/meta-trials/ctt/thompson-press-release-pdf> (accessed Sept 25, 2014).
- 3 Haslam D. NICE draft guidance on the use of statins (response to Thompson et al). <http://www.nice.org.uk/Media/Default/News/NICE-response-to-statin-letter-June-2014.pdf> (accessed Sept 17, 2014).
- 4 Crouse III JR, Raichlen JS, Riley WA, et al, for the METEOR Study Group. Effect of rosuvastatin on progression of carotid intima-media thickness in low-risk individuals with subclinical atherosclerosis. The METEOR Trial. *JAMA* 2007; **297**: 1344–53.
- 5 Shepherd J, Cobbe SM, Ford I, et al for the West of Scotland Coronary Prevention Study Group. Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia. *N Engl J Med* 1995; **333**: 1301–07.
- 6 NICE. Lipid modification: cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease. NICE guidelines [CG181], July 2014. <http://www.nice.org.uk/guidance/CG181/> (accessed Sept 17, 2014).

Department of Error

Sedrakyan A. *Precarious innovation of anti-infective coated devices*. *Lancet* 2014; **384**: 111–13—In this Comment (July 12), the fourth sentence of the third paragraph should have read "Some evidence suggests that newer second-generation cephalosporins are inferior to first-generation cephalosporin or metronidazole." This correction has been made to the online version as of Oct 3, 2014.

Papageorgiou AT, Ohuma EO, Altman DG, et al. *International standards for fetal growth based on serial ultrasound measurements: the Fetal Growth Longitudinal Study of the INTERGROWTH-21st Project*. *Lancet* 2014; **384**: 869–79—The supplementary appendix of this Article (Sept 6) has been corrected as of Oct 3, 2014.

Siva N. *Crowdfunding for medical research picks up pace*. *Lancet* 2014; **384**: 1085–86—In this World Report (Sept 20), the affiliation for Jai Ranganathan has been amended. This correction has been made to the online version as of Oct 3, 2014.

For supporting material see
<http://www.ctsuo.ox.ac.uk/research/meta-trials/ctt/annotated-thompson-letter-ms-word>