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Sir Richard Thompson
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Dear Sir Richard,

NICE draft guidance on the use of statins

Thank you for your letter, signed along with others on 10 June, expressing your concerns about the proposed recommendations on the use of statins to reduce cardiovascular risk, set out in our draft clinical guideline on lipid modification. I should say at the outset that I welcome your contribution and respect the views that you and your colleagues have put forward. I assume that these are your personal views and not those of the College which has already submitted a response to consultation to the National Clinical Guidelines Collaborating Centre. We have also received the comments of the Royal College of General Practitioners. There are important differences in both to the views set out in your letter.

I have responded to your points in the order in which they appear in your letter.

Medicalisation

The independent guideline development group (GDG) has carefully considered the evidence of benefits and harms in a systematic way, with modelling to explore areas of uncertainty. Through this work, they have addressed the three questions you pose and were able confidently to reach the conclusion that the benefits do outweigh harms and that statins are clinically and cost effective for people with a 10 year CV risk of 10% or over. The detail of the research they considered and the argument in support of their conclusions is set out in the draft guideline. It is therefore difficult to understand why you and your colleagues should take the position that the NHS should refuse people the option to have access to treatment if they wish it.

Of course, should someone decide, following an informed discussion that taking a statin is not the right choice for them, there is no compulsion for them to do so. Regarding the choice of drug, it is unlikely that each statin preparation in each dose will ever be studied in large controlled trials. It should be noted that the license for atorvastatin 20mg supports its use for prevention of cardiovascular events in adult patients estimated to have a high risk for a first cardiovascular event, as an adjunct to correction of other risk factors.

Despite the potential for a sizeable increase in the number of people who might take statins as a result of this guidance, the direct cost to the NHS will be lower than in 2012, due to the reduction in their price.

Conflicting levels of adverse events

The QALY takes account of health-related quality of life as well as length of life. It is therefore incorrect to assume that the guideline developers made the presumption that mortality reduction is the determining outcome for their recommendations. You are right to point out that there is no published evidence of a different incidence of muscle pains in statin and placebo groups in controlled trials. We cannot be sure of the reasons why the rate of these effects varies in the placebo group. Clearly, a proportion of people will discontinue a statin for whatever reason, even if this is not truly attributable to the statin itself. This rate of discontinuation was modelled in the work undertaken by the guideline development group.

Hidden data and industry bias

The guideline developers based their analyses on the best available evidence. This is what clinical guideline developers do generally. The full list of studies used is set out in the draft guideline. They reanalysed published trial reports and they did not rely solely on the work published by the Cholesterol Clinical Trialists Collaboration. Rather than speculate on the results that may or may not be found through analysing data that may or may not exist, the GDG chose to investigate the uncertainty in its decision model through a wide-ranging sensitivity analysis which showed that their conclusions on the cost effectiveness of statins remained valid on a range of adverse effect profiles. The guideline developers also investigated the implications of known side effects such as diabetes mellitus and the uncertainty around possible side effects. These effects have been subjected to sensitivity analysis in the health economics modelling.

We agree that the results of all clinical studies should be publicly available. We would prefer not to have to use data which are the subject of access restrictions for commercial reasons. We also agree that researchers should be able to access to anonymised raw trials data, and we are signatories to the AllTrials initiative. However, we do not accept that patients should be denied access to cost effective treatments supported by data to which we do have access unless there is a strong case to believe that data likely to support an alternative interpretation exists and has not been published. Selectively quoting individual studies and arguing for particular groups of researchers to have access to data which has already been credibly assessed is not in the interests of good patient care.

Loss of professional confidence

We realise there are strongly held and opposing views within the professions about this issue. You will be aware, for example, that the Joint British Societies guidance, (representing the British Cardiovascular Society, Association of British Clinical Diabetologists, British Association of Cardiovascular Prevention and Rehabilitation, British Association of Nursing in Cardiovascular Care, British Heart Foundation, British Hypertension Society, British Renal Society, Diabetes UK, Heart UK, Renal

Association and the Stroke Association) published earlier this year came to the conclusion that statins were highly effective and safe for cholesterol lowering.

We are very concerned that our guidance should carry the support of the professions. We take great care to involve them in our work, in the initial scoping and then through consultation. We advertise for members of our guideline development groups and most of our guidelines (including this one) are developed by independent collaborating centres. The methods and processes that NICE follows are respected and copied around the world. The small survey of GPs you refer to should not be ignored but since there is no indication, in your letter, of the extent of the knowledge, amongst those who responded, of the evidence and argument used to support the recommendations in our draft guideline, it cannot be right that we should regard it as the informed opinion of the GP community as a whole.

Conflicts of interest

We ask GDG members to declare any interests which might be regarded as conflicting with their membership of the group. Where conflicting interests exists, the individual concerned is either not appointed in the first place or either asked to withdraw temporarily, or to leave the group altogether, depending on the nature of the conflict. It is quite wrong to imply, as the press release which accompanied the publication of your letter did, that the GDG allowed its judgement to be influenced by the prospect of personal financial gain. This has unjustifiably damaged NICE's reputation.

Our published guideline will have taken full account of the comments we have received from wide and public consultation. Its recommendations will extend the choice currently available to people who are risk of an adverse cardiac event, holding out the prospect of a better future for those for whom it is the right choice, together with reduced NHS expenditure on avoidable morbidity in the future for a modest investment now.

Yours sincerely,

Professor David Haslam
Chair