

# National Institute for Health and Clinical Excellence

## LIPID MODIFICATION GUIDELINE

### Stakeholder Comments

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[Lipidmodification@nice.org.uk](mailto:Lipidmodification@nice.org.uk)

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<b>Name:</b>		Cardiovascular Health Working Group	
<b>Organisation:</b>		Faculty of Public Health	
<b>Document.</b>	<b>Page Number</b>	<b>Line Number</b>	<b>Comments</b>
Indicate if you are referring to the <b>Full version</b> , or the <b>NICE version</b> .	Indicate <b>Page number</b> or <b>'general'</b> if your comment relates to the whole document	Indicate <b>Line number</b>	<b>Please insert each new comment in a new row.</b>
	General		The Faculty of Public Health is the leading professional body for public health specialists in the UK. It aims to promote and protect the health of the population, and improve health services, by maintaining professional and educational standards, advocating on key public health issues, and providing practical information and guidance for public health professionals.
	General		The Faculty of Public Health (FPH) welcomes the opportunity to comment on the draft of the NICE Lipid Modification Guidelines (LMGs) released for consultation.
	General		As the LMGs mention, modelling of contributors to the fall in CH mortality suggests that person-based preventive and healthcare interventions have had a major impact (1), and that intervention based on absolute risk is the most effective way of targeting these interventions (2). As they

- 1 Unal B, Alison J, Critchley A, Capewell A. Modelling the decline in coronary heart disease deaths in England and Wales, 1980-2000: comparing contributions from primary prevention and secondary prevention. *BMJ* 2005;331:614-7.
- 2 Manuel DG, Lim J, Tanuseputro P, Anderson GM, Alter DA, Laupacis A et al. Revisiting Rose: Strategies for reducing coronary heart disease. *BMJ* 2006;332:659-62.

			set out the framework for this approach, the LMGs are therefore extremely important. Indeed, given that they should be used to guide all person-based preventive interventions, the current title is rather misleading, and the LMGs should be retitled “CVD risk reduction guidelines”.
	General		The LMGs also highlight that a clear, evidence-based policy for person-based preventive care should complement, and not replace, broad population-based interventions which are already the subject of a number of FPH policy statements (3). FPH is aware that the feasibility and cost-effectiveness of further population-based CVD prevention interventions was the subject of discussion at NICE's Public Health Consideration Panel meeting on 4 July. We understand that the Panel considered this topic to have very high priority, and therefore we hope that NICE will propose this topic to Department of Health's Referral Oversight Group for recommendation to Ministers, that NICE will issue guidance on this topic in 2009.
	4.3.2.3-7, 4.3.3.2-3, 4.3.3.5		<p><b>Use of Framingham Equations</b></p> <p>FPH strongly supports the proposal that, for person-based preventive care, absolute risk of cardiovascular disease (CVD) should be used to guide NHS intervention.</p> <p>However we share the concerns expressed about the provenance of the Framingham equations (Sections 4.3.2.3-7, 4.3.3.2-3, 4.3.3.5). For the reasons outlined, these are inappropriate for assessing CVD risk in a UK population. We consider that an appropriate set of equations for the UK population should be obtained using data from that population. The ASSIGN score is based on a Scottish cohort, but there is no comparable data for the England and Wales population. We therefore support the proposal by Hippisley-Cox et al (4) that the population covered by the QRESEARCH GP database population should be used to produce risk estimates (“QRISK”) if possible.</p> <p>However there are a number of problems associated with the use of data from a clinical database, in particular incomplete data collection (and how this is managed), and the likelihood that the population may be partially treated. In the context of QRISK, both these issues may affect the findings related to lipid ratios as a risk factor. We strongly recommend that further urgent analysis is undertaken to:</p> <ul style="list-style-type: none"> <li>determine the proportion of the population for which statins have been prescribed (all such prescriptions should be available from the database, and to stratify or adjust the data on this basis</li> </ul>

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3 Add weblinks to policy statements on salt, sugar, CAP etc  
4 Hippisley-Cox J,

		<ul style="list-style-type: none"> <li>• determine the pre-statin lipid ratios (which should have been performed, at least in recent years, on all patients prescribed statins)</li> </ul> <p>There is very little cohort-based information on CVD risk in South Asians, and the method used by QRESEARCH previously to examine ethnic effects (area-based proportion of ethnic minority population) is relatively insensitive. We also suggest that an urgent analysis of QRESEARCH data is undertaken to determine the proportion of patients with ethnic group coded, and to attempt to estimate CVD risk in this subgroup.</p> <p>An alternative source of data would be the Health Survey for England, among the majority of participants who gave permission for flagging of their mortality records at the NHS Central Registry. This has the advantage of being a nationally representative random sample of the general population, not a clinical population, although not all relevant factors are enquired about or measured each year. This could also be used for the six largest minority ethnic groups that were the focus of the HSE in 1999 and 2004.</p> <p>It would be unfortunate if the Framingham equations are used in the final version of the NICE guidance when a better alternative could be available. Every effort should be made to undertake further analyses of the QRESEARCH database before the final guidance is released in the winter.</p>
	General	<p><b>Non-Pharmacologic vs Pharmacologic Interventions</b></p> <p>The draft LMGs make appropriate and extensive reference to pre-existing NICE (“public health”) and other guidance on lifestyle modification including smoking cessation, physical activity and weight management/obesity (6.2.1 primary prevention care pathway, and Section 6 Lifestyle modification for prevention of CVD). However we are concerned at the lack of guidance about the timing of non-pharmacologic versus pharmacologic interventions.</p> <p>There should be a clear statement specifying the time between lifestyle modification interventions and consideration of pharmacologic interventions to ensure that the former have been attempted (or not) and the impact assessed. Given the time constraints in general practice, there is a risk that, in higher risk patients, lifestyle modification interventions will either be delivered at the same time that statin is commenced, or worse, not delivered at all. The LMGs should also specify an optimal number of sessions/attendances for intervention.</p> <p>The timing of pharmacologic vs non-pharmacologic would probably differ depending on the degree of cardiovascular risk and / or diagnosis.</p>

			<ul style="list-style-type: none"> <li>▪ for diabetics requiring glycemic control, statins should be started at the same time as glycemic control;</li> <li>▪ BP at 145/95 or above should be treated immediately;</li> <li>▪ essentially all others at high risk, but without clinical evidence of CVD, should be started on a three month trial of lifestyle modification, with review at the end of this, with further review after another three months, if there is evidence of some improvement in risk factors.</li> </ul> <p>However, this is not enough: there needs to be careful thought given to the nature of the lifestyle modification advice given by clinicians, especially in relation to diet, and how this should be modified (this should be included as a part of any lipid guidelines). Much of the current problem with lifestyle modification at individual level relates to "tick box" approach, without sufficient careful advice being given to each patient.</p>
			<p>The difficulties in undertaking RCTs of lifestyle interventions are well known. However the LMGs could have looked more broadly than just CVD outcomes. For example, the LMGs do not refer to the large US and Finnish RCTs of diabetes prevention interventions (5,6). While these were undertaken in people with abnormal glucose tolerance, this is a large, higher risk subgroup within the population the LMGs will identify. In addition, a re-analysis of the MRFIT intervention programme also showed that it resulted in a statistically significant 18% reduction in the incidence of diabetes during a 6-year period (7). The cost-effectiveness of these interventions has also been demonstrated (8).</p> <p>The impact of these interventions on practice capacity should also be assessed as part of the implementation process, and the input staggered as necessary to ensure that neither patients nor practices are overloaded.</p>

Please add extra rows as needed

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- 5 Diabetes Prevention Program Research Group. Reduction in the Incidence of Diabetes with Lifestyle Intervention or Metformin. N Engl J Med 2002; 346: 393-403.
  - 6 Jaakko Tuomilehto, Jaana Lindstrom, Johan G Eriksson, Timo T Valle, et al Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med 2001; 344: 1343-52.
  - 7 Davey Smith G, Bracha Y, Svendsen KH, Neaton JD, Haffner SM, Kuller. LH. Incidence of type 2 diabetes in the randomized Multiple Risk Factor Intervention. Trial. Ann Intern Med. 2005;142:313-22.
  - 8 Herman WH, Hoerger TJ, Brandle M, Hicks K, Sorensen S, Zhang P, et al. The cost-effectiveness of lifestyle modification or metformin in preventing type 2 diabetes in adults with impaired glucose tolerance. Ann Intern Med. 2005;142:323-32.