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Cardiovascular Disease - Consultation on the Draft Scope: Stakeholder Comments and Response Table

23rd April – 22nd May 2008

Stakeholder Organisation	Evidence submitted	Page Number (s)	Section	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Action on Smoking & Health			General	In general ASH supports the production of guidance to help prevent cardiovascular disease. We assume this guidance will assist in the delivery of the forthcoming vascular screening programme. However, we question why the guidance is only looking at interventions that tackle at least two CVD risk factors as this would exclude many important studies.	This guidance will be published in January 2010 so will be developed during the implementation of the vascular screening programme We agree that these issues are potentially interesting. However, this guidance is intended to consider CVD prevention activities which operate at a population level. Given the time period available to produce this guidance we have chosen to assess CVD prevention activities that are based on multiple risk factors. While we agree that it might be helpful to consider risk factors individually the workload this would entail would make the programme unachievable. In addition, there are several other pieces of NICE guidance which have addressed individual risk factors. We anticipate that this will not be the last referral relating to CVD and we would encourage stakeholders to suggest specific topics to the topic selection group – please see http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp. .
Action on Smoking & Health			4.1.1	Although the guidance is not aimed at people who are at high risk of developing CVD there will clearly be some overlap between this guidance and other NICE guidance as listed in section 6. It may be confusing for health professionals to have to cross-refer to all the various pieces of guidance in order to develop a coherent strategy and some help should be provided to resolve this matter.	Agreed. We anticipate that the final guidance will refer to other guidance as appropriate.

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Action on Smoking & Health			4.3	It is not clear from the draft scope why the guidance will only consider multi-factorial interventions. We appreciate that much work has already been done to identify individual risks and that NICE guidance has already been produced (or is under consideration) to prevent heart disease, as listed in section 6. However, studies looking at tax, for example, are most likely to focus on one risk factor at a time. Therefore ASH recommends that the scope is re-configured to allow the examination of evidence covering single risk factors.	We agree that these issues are potentially interesting. However, this guidance is intended to consider CVD prevention activities which operate at a population level. Given the time period available to produce this guidance we have chosen to assess CVD prevention activities that are based on multiple risk factors. While, we agree that it might be helpful to consider risk factors individually the workload this would entail would make the programme unachievable. In addition, there are several other pieces of NICE guidance which have addressed individual risk factors. We anticipate that this will not be the last referral relating to CVD and we would encourage stakeholders to suggest specific topics to the topic selection group – please see http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp.
Action on Smoking & Health			4.1.1 & 4.1.2	There is no explicit mention of reducing health inequalities in CVD. If this is because people in lower socio-economic groups are perceived to be at higher risk then this should be explained and linked to the guidance under development to address health inequalities and CVD – see comment below.	In line with NICE procedures, the scope will be equality assessed. Appendix B of the scope notes that issues relating to diversity and trade offs between equity and effectiveness will be examined by the PDG. The impact on equality is considered in all NICE guidance and will be in this. We anticipate that the recommendations will address inequalities in an appropriate fashion.

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Action on Smoking & Health			6	In the section: "NICE Guidance Under development", reference should be made to the draft guidance on *"Reducing the rate of premature deaths from CVD and other smoking-related diseases: finding and supporting those most at risk and improving access to services."* since this deals specifically with reducing statin prescribing and smoking cessation.	Thank you. This will be included in the final scope
Action on Smoking & Health			General	The reviewers may wish to consider the findings of a new study in the journal Circulation which is relevant to this draft scope: Hardoon, SL et al. How Much of the Recent Decline in the Incidence of Myocardial Infarction in British Men Can Be Explained by Changes in Cardiovascular Risk Factors?: Evidence From a Prospective Population-Based Study. Circulation 2008; 117: 598-604.	Thank you. We will bring this to the attention of the reviewers

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Baby Feeding Law Group (BFLG) and Baby Milk Action			General & 3	The Guidance should mention the impact of breastfeeding as a preventative measure in relation to CHD. To give just two references: **Increased risk of cardiovascular disease** ■ To confirm links between infant nutrition and health risks in later life, British researchers measured blood pressure at 13 to 16 years of age of 216 children who had been born prematurely. For those who had received preterm infant formula or routine infant formula, blood pressure was higher than for those who had received breastmilk during infancy. The authors concluded that for children born prematurely, breastfeeding lowers blood pressure in later life and that this conclusion can be extended to term infants as well. Singhal A, Cole TJ, Lucas A. **Early nutrition in preterm infants and later blood pressure: two cohorts after randomized trials**. *The Lancet 357: 413- 419, 2001* ■ This UK study looked at the cholesterol levels of 1500 children aged 13 to 16 years and determined that breastfeeding may have long term benefits for cardiovascular disease by reducing levels of total cholesterol and low-density lipid cholesterol. The research suggests that early exposure to breastmilk may program fat metabolism in later life, resulting in lower blood cholesterol levels and therefore a lower risk of cardiovascular disease. Owen GC, Whipcup PH, Odoki JA, Cook DG. **Infant feeding and blood cholesterol: a study in adolescents and systematic review**. *Pediatrics 110: 597-608, 2002* (Cont'd)	Thank you for raising this point and for these references. While breastfeeding may be a preventative measure in relation to CHD (and could be included in studies the PDG will consider) methods of promoting breastfeeding have been considered in detail in the NICE guidance on Maternal and Child Nutrition (web link). If appropriate, this guidance may link to the relevant recommendations.

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Baby Feeding Law Group (BFLG) and Baby Milk Action				■ A prospective study followed 7276 term UK infants for 7.5 years. Full data was available for 4763 children. For those not breastfed both systolic and diastolic pressures were found to be higher than for those who were breastfed at age seven years. There was a 0.2mm Hg reduction for each three months of breastfeeding. The authors suggest there may be significant benefits during adulthood as a one per cent reduction in population systolic blood pressure is associated with a 1.5 per cent reduction in overall mortality. Martin RM, Ness AR, Gunnelle D, Emmet P, Smith GD. **Does breast-feeding in infancy lower blood pressure in childhood?** *Circulation 109: 1259-1266, 2004*	Thank you for raising this and for these references
Baby Feeding Law Group (BFLG) and Baby Milk Action			4.3	Include a recommendation that the promotion of all breastmilk substitutes, including follow-on formulae, should be banned and that manufacturers and distributors of breastmilk substitutes should not be permitted to provide infant and young child feeding advice to parents, in line with the International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly Resolutions.	Thank you for your comments. However recommendations will be made based on the evidence that we find in relation to this particular piece of guidance. We would draw your attention to the recently published NICE guidance on the nutrition of pregnant and breastfeeding mothers from low income households and in particular recommendation 14 which considers infant formula.
BHF			General	The BHF welcomes this guidance and believes that it is timely given the recent emphasis on vascular screening. Vascular risk assessments have enormous potential to inform interventions that will improve the health of populations. But public health providers, commissioners and clinicians must have clear guidance on how risk factors can be modified at the population level.	Thank you.

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BHF		3		The draft scope states that the BHF identifies psychosocial stress as one of the BHF's nine modifiable risk factors. This is not completely accurate – we have not yet adopted psychosocial stress as a modifiable risk factor. However we support its inclusion in the scope as long as it is carefully defined – i.e. it is not simply linked to individuals' personal level of stress but more to their ability to influence the potentially stressful environments in which they live.	Thank you for clarifying this point. This will be amended in the final scope
BHF		4		It is an ambitious scope and understandable that it needs to be limited. However we are concerned that the guidance will only consider interventions that tackle at least two CVD risk factors. While many single risk factor interventions will be likely dealt with by other public health guidance (e.g smoking cessation, physical activity), the fiscal changes that will be investigated will arguably focus on one risk factor at a time – for example raising tobacco tax, eliminating VAT on healthy food; eliminating prescription charges for statins. For this reason, we strongly recommend the PDG reconsider the sole focus on interventions that address more than one risk factor.	We agree that these issues are potentially interesting. However, this guidance is intended to consider CVD prevention activities which operate at a population level. Given the time period available to produce this guidance we have chosen to assess CVD prevention activities that are based on multiple risk factors. While, we agree that it might be helpful to consider risk factors individually the workload this would entail would make the programme unachievable. In addition, there are several other pieces of NICE guidance which have addressed individual risk factors. We anticipate that this will not be the last referral relating to CVD and we would encourage stakeholders to suggest specific topics to the topic selection group – please see http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp

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BHF		4		There is no explicit mention of reducing inequalities in CVD. The BHF suggests adding of a third question along the lines of – what population health interventions have been shown to be particularly effective in reducing inequalities in CVD mortality and morbidity (or risk factors associated with CVD).	In line with NICE procedures, the scope will be equality assessed. Appendix B of the scope notes that issues relating to diversity and trade offs between equity and effectiveness will be examined by the PDG. The impact on equality is considered in all NICE guidance and will be in this. We anticipate that the recommendations will address inequalities in an appropriate fashion.
BHF		7		Under related "NICE Guidance Under Development", we propose that the guidance on *proactive case finding and retention and improving access to services in disadvantaged areas* should be included as it deals specifically with statin prescribing and smoking cessation.	This will be included in the final scope
BHF			General	We urge NICE to explore evidence relating to interventions by non-health related sectors (e.g. transport, environment, town planning, agriculture, business). As the PDG will be aware, these will often have a greater impact on population heart health than any health intervention. Given society's heightened awareness of -- and concern around – obesity, this is the ideal time to be introducing guidance that will assist non-health sectors implement population health interventions that promote heart health.	Agreed. Where evidence of this sort exists and can be found we would be keen for it to be assessed against our inclusion/exclusion criteria and included where appropriate.

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BHF HPRG			4.3 Q 1)	Please could you explain the rationale for inclusion criteria – particularly in reference to an intervention must tackle at least two risk factors. This might exclude interventions that have focussed on single risk factors	This guidance is intended to consider CVD prevention activities which operate at a population level. Given the time period available to produce this guidance we have chosen to assess CVD prevention activities that are based on multiple risk factors. While, we agree that it might be helpful to consider risk factors individually the workload this would entail would make the programme unachievable. In addition, there are several other pieces of NICE guidance which have addressed individual risk factors. We anticipate that this will not be the last referral relating to CVD and we would encourage stakeholders to suggest specific topics to the topic selection group – please see http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp.
BHF HPRG			General	Will the guidance focus on children and adults or just adults?	The guidance will cover both adults and children
BHF HPRG			General	What will be the search dates for the literature review? A number of large scale community CVD prevention interventions were delivered in the 1970s and 1980s.	Search dates will cover 1970 - current
BHF HPRG			4.3 Q 2)	What types of evidence will be used to answer this question? Correlates (quantitative)? Qualitative? Expert opinion?	We intend to review primary qualitative studies looking at barriers and facilitators and to carry out primary research to gather qualitative data

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Blood Pressure Association			3 a)	Since the guidance relates to at-risk groups it may be more appropriate to speak of the numbers of people at risk where quantifiable, rather than the numbers of people with CVD. For example, there are approximately 16 million people in the UK with high blood pressure – around a third of these are undiagnosed, and only a minority have their blood pressure controlled to acceptable levels through medication and lifestyle (Health survey for England 2006).	Thank you.
Blood Pressure Association			3 a)	What is a 'premature illness'? Are you presuming that CVD is ultimately unavoidable, and is there therefore an age limit on the potential beneficiaries of this programme?	Thank you. This sentence has been amended to read 'A large proportion of the risk of a first heart attack (over 90%) comes from nine easily or potentially modifiable risk factors'
Blood Pressure Association			3 b)	Inequalities persist not only in relation to mortality rates from CVD, but also in overall prevalence of risk factors. For example, people of African-Caribbean origin are more likely to develop high blood pressure, and people from South Asian groups are at a higher risk of developing diabetes. The scope refers to inequalities in mortality only, but prevalence of CVD risk factors is equally, if not more important.	Agreed.
Blood Pressure Association			3 c)	A more appropriate reference for the identification of the nine modifiable risk factors for CVD might be the INTERHEART study, referenced earlier in the scope.	Thank you.
Blood Pressure Association			3 d)	Direct attribution of effect may be difficult, as you state, and quantifying effect may be even more so. There may be a need for flexibility in interpretation of effect – instead of a simple yes or no there could be levels of interpretation, such as "no effect", "insufficient evidence of effect" and "evidence of effect", etc.	Agreed. This is common practice in public health work.

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Blood Pressure Association			4.1.1	Populations are identified only geographically, whereas earlier in the scope you state that differences in mortality from CVD can be identified along social and ethnic as well as geographical lines. Similarly, age is a contributing factor to CVD incidence. There may be a need to define populations more clearly, and not just on geographical lines.	The aim of the guidance is to consider populations within a geographical area. However, there may be sub-populations within these areas (such as specific ethnic groups) that will be covered. NEEDS REWORDING
Blood Pressure Association			4.1.2	How is risk defined and quantified in this scope? There needs to be clarity over which any groups will not be included in the scope, besides those already diagnosed with CVD.	High risk is taken to be where there is a clinical diagnosis of increased risk of developing CVD beyond what would be expected based on factors such as age, lifestyle and gender. While these higher risk groups are not the focus of the guidance, as part of a population, the guidance may be relevant to some.
Blood Pressure Association			4.2.1 a)	There needs to be some flexibility with regard to single risk-factor interventions, as there is a risk of missing out on important learning. Further, a single-target intervention may comprise different approaches – for example, an intervention to lower blood pressure could look at diet, physical activity, overweight, and alcohol consumption, tackling five CVD risk factors under the banner of a single factor.	There is a need to make the guidance process compatible with the time and resources available, which inevitably means excluding some material. We feel we have achieved the right balance to be able to produce population level CVD guidance. A programme which included approaches aimed at diet, physical activity, overweight and alcohol consumption would be included in the scope for this guidance..
Blood Pressure Association			4.2.1 b)	Interventions involving a pharmacological element should include programmes to increase patient concordance with medication – in other words, support to help them continue to take their medicines as prescribed. This can be difficult for people with high blood pressure in particular, and many people stop taking their medication within a year of being prescribed.	Consideration of measures to address concordance with prescribed regimes is outside the scope of this guidance. We will consider interventions where there is a pharmacological element, but only where this is part of a broader approach and where the primary prevention element can be extracted.

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Blood Pressure Association			4.2.3	If screening needs to include modification, it is important that modification is defined – is information provision modification, for example? The Blood Pressure Association's Know Your Numbers! campaign tests the blood pressures of hundreds of thousands of people annually, providing them with information on diet and lifestyle changes to manage their blood pressure, as well as referring people with high readings to their GP for further testing and treatment. Where successful, this intervention could be seen as a modification of health behaviour, depending on definition.	Interventions which alter only knowledge or attitudes with no measure of behaviour identified would not be included. However, where such outcomes reported in a study addressing multiple risk factors (such as diet and physical activity) it would be included.
Blood Pressure Association			4.3	A further question should be whether particular populations were more likely to benefit from programmes, and whether this might actually increase health inequalities between populations. Furthermore, there could be consideration of what support or further interventions might be required in order to counteract this effect.	Agreed. The PDG will be asked to consider these issues.
Blood Pressure Association			4.3	As well as barriers to effective implementation, there should be discussion of barriers to access in the first place, as this is a first step to implementation.	Noted. It is likely that issues relating to access to interventions or to services (such as healthy diets) will be considered in addressing the second question.
Breastfeeding Network		1	2 b)	We welcome the inclusion "NICE public health programme guidance supports implementation of the preventive aspects of national service frameworks." We hope the guidance will make use of the NSF on Children, Young People and Maternity.	Thank you for raising this
Breastfeeding Network		1	2 c)	We welcome the inclusion that the guidance will support related policy documents.	Thank you
Breastfeeding Network		2	2 d)	We welcome the inclusion that voluntary and community sector groups will be included in the scope alongside health professionals and others.	Thank you

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Breastfeeding Network		3	3 b)	We welcome the acknowledgement of the variations in premature CVD deaths between affluent groups and lower socio-economic groups.	Thank you
Breastfeeding Network		3	3 c)	We welcome the reference to upstream and downstream factors which may influence CVD, as well as the nine key factors including maternal nutrition. We would also like to see breastfeeding included in this section. There is a growing body of evidence about breastfeeding and the crucial role this plays in the short and long term health of the mother and infant. Many of these are risk factors known to influence CHD (obesity, cholesterol, diabetes). This is an important preventative measure. Life should begin with as healthy a diet as possible. Studies and research on the UNICEF Baby Friendly Initiative website support this:- http://www.babyfriendly.org.uk/items/search.asp?library=2 Breastfeeding is also specifically mentioned in the National Service Framework, the Choosing Health documents, and Tackling health Inequalities, all of which are mentioned in this document.	

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Breastfeeding Network		4	4.2.1	We welcome the inclusion of legislative changes and the need to look at multiple risk-factor approaches. We would also like food advertising and sponsorship to be included and the part it plays with regard to people's food choices. Examples of these are junk foods adverts aimed at both children and adults and adverts for breastmilk substitutes. This is building on work already done by NICE on "Improving the nutrition of pregnant and breastfeeding mothers and children in low income households" See Recommendation 14. Sponsorship can be more subtle but is described on one website as "the fastest growing marketing tool". This description shows how companies, some of whom profit from sales of unhealthy foods, may use sponsorship as a way of gaining publicity, credibility and recognition. Ultimately to increase their sales. An example of this is sponsorship of school materials. This creates a conflict of interest as it gives children mixed messages about healthy eating. Some companies offer reward schemes, where parents and children are encouraged to purchase and consume certain products in order for the school to receive rewards (some offer financial rewards and others offer material rewards, such as books). The products being promoted are not always the healthiest option. Another example is sponsorship of conferences and study days for health professionals and others.	Thank you. If material relating to sponsorship and advertising arises in the review of effectiveness it will be considered. It is possible that these influences will also be mentioned in the qualitative work on barriers and facilitators.

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Breastfeeding Network		6	6	In the section on Related NICE guidance we would welcome inclusion of the Maternal and Child Nutrition Guidance, since this highlights the socio-economic factors and also recognises the crucial role breastfeeding plays in the short and long term health of both mothers and their infants. This touches widely on CVD.	Thank you. This guidance has been added to the appropriate section.
British Cardiovascular Society			4.3	The key questions are very confused. Why should the group consider only 2 or more interventions applied simultaneously? Surely it would be sensible to start by looking at single risk factor interventions e.g. smoking cessation, weight loss, cutting saturated fat, cutting salt etc. Then look at them in combination.	This guidance is intended to consider CVD prevention activities which operate at a population level. Given the time period available to produce this guidance we have chosen to assess CVD prevention activities that are based on multiple risk factors. While we agree that it might be helpful to consider risk factors individually the workload this would entail would make the programme unachievable. In addition, there are several other pieces of NICE guidance which have addressed individual risk factors. We anticipate that this will not be the last referral relating to CVD and we would encourage stakeholders to suggest specific topics to the topic selection group – please see http://www.nice.org.uk/getinvolved/suggestatopic/suggest_a_topic.jsp
British Hypertension Society			3 c)	It is important under 'diet' to clearly specify 'dietary salt reduction' and 'increase in fruit and vegetable intake' as priorities.	Noted -Thank you.
British Hypertension Society			4.2.2 a)	If excluding high risk groups, does that include the elderly? The scope seems to be a little vague on who and what is going to be included.	All age groups will be considered

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CTC – The National Cyclists' Organisation			4.2.1 & 4.3	We believe that "multiple risk-factor approaches" will exclude many of the interventions which deal with active travel – walking and cycling schemes. Where active travel interventions occur, they often deal with physical activity alone and none of the other risk factors suggested and are reported only in the grey literature. Environmental, fiscal or legislative changes to promote active travel projects are often primarily motivated to reduce congestion or casualties, not to tackle the risk factors that affect CVD. These will be lost under the current arrangement.	This guidance is intended to consider population level CVD programmes. As these address a problem that is based on multiple risks, they address, almost by definition, generally multiple risk factors. While it might be helpful to consider risk factors individually the workload this would entail would make the programme unachievable. In addition, there are several other pieces of NICE guidance which have addressed individual risk factors which will be incorporated as appropriate into this guidance.
CTC – The National Cyclists' Organisation			4.2.2	Where interventions to promote active travel do tackle multiple risk factors, they occasionally are targeted at those in bad health. An example would be exercise referral.	Noted.
CTC – The National Cyclists' Organisation			General	We were deeply disappointed that the limited scope adopted for NICE public health guideline 2 – Four commonly used methods to increase physical activity, failed to address more widely the overwhelming and obvious contribution that cycling makes to improving public health.	Noted.
Department of Health			General	In order that the guidance can add value to government policy, it would be helpful if you could highlight and consider recent additional evidence-based Public Health policy initiatives relating to CVD prevention; some specific examples are provided below: please see section 2 (c).	Noted. We will be keen to consider evidence relating to the outcomes of these initiatives. It may also be appropriate to include those responsible for programmes such as these in the qualitative work to answer question 2.
Department of Health			General	Would you consider highlighting the reduction of health inequalities as a key theme within the draft scope. Specific examples of how we believe this could be done are provided below.	Thank you. The impact on inequalities in cardiovascular disease will be considered by the PDG.

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Department of Health			General	From a Public Health policy perspective, a clear focus on CVD prevention interventions that are as upstream as possible would be helpful, as would be a longer-term timeframe for the measurement of impact. We recognise however that a focus on more upstream interventions could present significant implementation difficulties for local authorities, and the wider public, private and voluntary sectors.	It is our intention to include both 'upstream' and 'downstream' factors. The timeframe for measurement of impact will be determined by the studies identified, but we agree that it will be helpful if these include longer term measurement of impact. This may be an issue that is raised in the consideration of qualitative factors relating to success.
Department of Health			General	We suggest it would be helpful to further clarify the underlying paradigm/conceptual approach to the development of this guidance. For example it would be helpful to further clarify whether, and/or how, high risk individuals and pharmacological interventions would fall within the scope of evaluation of population-wide approaches to CVD prevention.	The aim of the guidance is to address whole populations and not to focus on individuals at high risk. Recommendations for the population are likely also to benefit these groups when taking a population approach. Similarly, pharmacological interventions may be considered where they are part of a broader approach to reducing risk and where information can be disaggregated.

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Department of Health			2 a)	In order to strengthen the health inequalities focus, could you please consider the following addition at the end of this paragraph: *"It should support overall improvement in health, and tackling health inequalities."*	Thank you. This paragraph relates to the referral from the Department of Health. The potential impact on inequalities is indicated elsewhere by the inclusion of relevant policy docments.
			2 b)	We suggest that it would be helpful if you could clarify what *'programme guidance'* means in this context, and how this is different to a clinical guideline or intervention guidance on CVD prevention.	Thank you. This information is referenced in the 'further information' section (5). It is not possible to go into detail in the scope itself which is restricted in size.
			2 c)	*Could you please consider adding the following to the list of policy documents that the guidance will support;* • "Tackling Health Inequalities – A Programme for Action" *(DH 2003)* • "Tackling Health Inequalities: 2007 Status Report on the Programme for Action" *(DH 2008)* • "Commissioning framework for health and well-being" *(DH 2007)* • "The NHS in England: The operating framework for 2008/9" *(DH 2007)* • *"Healthy Weight, Healthy Lives: A Cross Government Strategy for England"* (DH 2008)	Thank you. These documents have been added.

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			3 b)	To strengthen the health inequalities focus in this paragraph, could you please consider the inclusion of a reference to the contribution that circulatory disease makes to the gap in life expectancy between the Spearhead areas (the areas with the worst health and deprivation indicators, and a focus for the life expectancy element of the 2010 health inequalities target) and England. For males, this is 35% of the gap (70% of which are CHD), and for females this is 30% of the gap (63% of which are CHD). You may be aware that these data are in the 2007 *Status Report on the Programme for Action* (DH 2008).	Thank you. This information will be included.
			3 d)	Given the problematic nature of evaluative evidence on complex changes between populations, it would be helpful if you could comment at an early stage on the feasibility of producing practical programme guidance that could add value to a review of the evidence, and consider other product options if appropriate.	Thank you. We are aware of the difficulties in evaluating these types of interventions and of producing guidance. However, we have been asked to produce programme guidance on this topic.

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			3 d)	Given the problematic nature of evaluative evidence on complex changes between populations, we suggest that the following considerations may be important in developing guidance: ▪ the methodology selected would, in our opinion, need to command wide credibility among Public Health epidemiologists and other key stakeholders. ▪ we feel that the modelling approach selected would need to balance individual and population risk assessment/risk management considerations. ▪ policy options would, we consider, need to be modelled in a UK context: for example, where smoke-free legislation came into effect from 1 July 2007, and where current risk factor levels are much lower than in some other countries. ▪ in some instances, information about the public acceptability of population-based prevention approaches will, in our view, be very limited.	We agree that there are difficulties in evaluating complex interventions and that the issues you indicate are important.
			4.1.1	It would be helpful if you could clarify the reasons why a geographical approach to population coverage is proposed, rather than a population sub-group approach. In section 3 (b), it is already noted that the considerable variation in CVD death rates within the UK is geographical, ethnic and social.	The background to this referral is to examine the effectiveness of geographical population approaches. This will not exclude consideration of the variable impact of social factors, ethnicity etc.
			4.1.1	Reference has been made in the draft scope to ethnicity, so we suggest that ethnicity is included as a sub-group o the populations to be covered. We also suggest that gender should be included as a sub-group.	We have included an example within this paragraph. Please note that the differential effectiveness of interventions in various groups is highlighted as an area for consideration in appendix B.

Stakeholder Organisation	Evidence submitted	Page Number (s)	Section	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			4.1.1	Could you please clarify whether evidence from international studies will be considered and set in context.	International studies will be considered and their applicability to England at this time taken into account. To enable us to complete the work in the time available we will need to limit the scope of these studies to those which will provide most useful information. All studies are considered for their applicability to the situation here and now when being used to develop recommendations.
			4.2.1	From a health improvement perspective, a broad scope – looking as far upstream as possible – will be beneficial. It would be helpful if you could clarify this. For example, under fiscal changes we consider that there would be interest in considering financial incentives/disincentives (such as reward schemes) for healthy living behaviour.	Noted.
			4.2.1 a)	In our opinion, the multiple risk-factor approaches to preventing CVD among a given population currently listed are very broad. Could you please consider highlighting some specific examples of regulatory levers, such as the primary care Quality and Outcomes Framework (QOF). There is some mapping that appears to show some limited evidence of a disparity between CHD standardised mortality ratios and QOF scores (average clinical achievement) across Birmingham, which we feel may be worth pursuing.	Noted. We would hope to include regulatory levers in the consideration of qualitative factors which influence the success and 'implementability' of recommendations, either through the qualitative review or through the fieldwork on draft recommendations. We also hope (anticipate) that the PDG will include those with experience in working with these factors.

Stakeholder Organisation	Evidence submitted	Page Number (s)	Section	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			4.3, Q1)	In order to strengthen the focus on health inequalities, and to cross-reference the sub-groups flagged up earlier, could you please consider the addition of a new sentence at the end of the first sentence in Question 1, as follows: *"which interventions are most effective at addressing health inequalities geographically, ethnically and by gender."*	Noted. Where available data allow, the impact on inequalities will be considered (as indicated in appendix B), and we anticipate this will form part of the deliberations of the PDG.
			4.3, Q1)	Please could you clarify the proposal to limit the number of CVD risk factors within scope to a minimum of two. We are not clear why this is appropriate when the purpose is to produce guidance on the prevention of CVD in different populations. A rationale for exclusion of interventions that focus on only one risk factor (for example, smoking), or that combine with approaches not listed here, would be useful.	This guidance is intended to consider population level CVD programmes. As these address a problem that is based on multiple risks, they address, almost by definition, generally multiple risk factors. While it might be helpful to consider risk factors individually the workload this would entail would make the programme unachievable. In addition, there are several other pieces of NICE guidance which have addressed individual risk factors which will be incorporated as appropriate into this guidance.
			4.3, Q1)	Given the above, could you please clarify what smoking cessation (or prevention) interventions will fall within the scope of this work.	Smoking cessation and prevention interventions delivered to populations together with an intervention to reduce at least one other risk factor for CVD (such as physical inactivity) would be included.
			4.3, Q1)	We feel that population-wide multi-component interventions to improve diet would be expected to include "5 a day", salt reduction and saturated fat reduction. In our view, assessment could also be made of the impact of individual components such as the Food Standard Agency's population-wide salt campaign, which we would welcome.	Noted -thank you

Stakeholder Organisation	Evidence submitted	Page Number (s)	Section	Comments Please insert each new comment in a new row.	Response Please respond to each comment
			4.3, Q2)	To strengthen the focus on health inequalities, and to cross-reference the sub-groups flagged up earlier, could you please consider the addition of the following to the end of the sentence in Question 2: *"… including sub-groups experiencing health inequalities."*	Noted. We will include additional wording on addressing inequalities.
			6	Could you please consider the addition of the following to the list of related NICE guidance: • the most appropriate means of generic and specific interventions, to support attitude and behaviour change at population and community levels. • an assessment of community engagement and community development approaches, including the collaborative methodology and community champions. • guidance for midwives, health visitors, pharmacists and other primary care services, to improve the nutrition of pregnant and breastfeeding mothers and children in low income households.	Noted. We will add these documents to the list.
			Appendix B	Regarding the third bullet point *("whether it is effective and cost-effective")*, we feel that it would be advantageous to be clear on what these studies can tell us about the time period over which we could expect to see an impact (or not) i.e. the rate of change.	Noted. We would anticipate that the evidence about the time period over which an effect occurred or was looked for would be considered in the reviews of effectiveness.

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			Appendix B	Regarding the fourth bullet point *("critical elements")*, you may be aware that there is also interest in understanding the impact of political, cultural and organisational factors on the effectiveness of interventions. Could you please therefore consider the addition of *"or organisations"* to the line *"the status of the person (or organisations) delivering it and the way it is delivered."*	Noted. This may be an important element and we would want to consider this in our qualitative reviews of factors influencing success
Department of Health			General	Email comment from DH: In addition to comments from the Department of Health in the attached document, it would be helpful if you could consider referencing "Putting Prevention First", in order to be much clearer about the complementarity of the two pieces of work. We feel that, as it stands, there may be scope for confusion between them, especially as (although the draft states that it is concerned not with people either with CVD or at high risk of developing it) it proposes to cover pharmacological interventions where they are for primary prevention. The NHS will not prescribe statins for anyone under a 20% risk, which is "high risk". Therefore, we consider that that this could be disregarded, leaving just hypertension treatment (as far as we can see). We feel that it is important to stress the principal objective of the guidance, i.e., is it mainly to look at whole population measures (including such things as potential Government action in the fields of reducing deprivation, inequalities, increasing exercise, food labelling, changing taxation/legislation to favour CV risk reduction measures, reducing pollution etc.) or is it a review of known risk factors, and how to manage/intervene on these (in which case, it would seem to have a considerable overlap with other guidance)?	Noted. We will include thjs reference The guidance is aimed at considering whole population approaches to reducing CVD risk rather than a consideration of how to reduce individual risk factors. As you indicate, this would overlap with other guidance.

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Diabetes UK			2 e)	It is important that reference is made to the Type 1 and Type 2 diabetes clinical guidelines as these contain relevant guidance for people with diabetes. Emphasis on people with diabetes is important as CVD is a major cause of mortality for people with diabetes. Furthermore diabetes is the second leading cause of CVD after smoking in the UK. **Reference** Diabetes UK (2007) Diabetes Heartache	While we appreciate that diabetes is important as a cause of CVD (and type II diabetes has a number of similar factors associated with it as CVD) it is important to be aware that this guidance is not about the clinical management of diabetes or CVD.
Diabetes UK			3 c)	Owing to the prevalence of CVD in people with diabetes, it is important that Hba1c (blood glucose levels) and overweight are mentioned as modifiable risk factors that are particularly pertinent to people with diabetes.	Changes in Hba1c and changes in glucose tolerance etc are significant. However, it is not possible to list all the possible biochemical or physiological measures relating to risk of developing CVD. As noted in section 4.3, where these are used as outcomes in included studies they will be reported.
Diabetes UK			4.1.1	It would be valuable here to identify particular sub sets of the population in recognition of the different approaches that may need to be taken to support CVD prevention in these populations. The scope needs to consider populations that are at higher risk of developing CVD, particularly as mentioned previously diabetes is the second leading cause of CVD after smoking in the UK. **Reference** Diabetes UK (2007) Diabetes Heartache	is not the intention to address in this guidance issues such as management in specific populations at high risk of developing CVD, such as those with diabetes. However, modification of risk factors such as smoking, diet or inactivity will have relevance to these groups as well as the population as a whole.
Diabetes UK			4.2.1 a)	Add lifestyle interventions to the “educational and behavioural” approaches.	“Lifestyle” interventions are covered by the current list

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Diabetes UK			4.2.2 a) & b)	The scope refers to the Diabetes NSF and how this guidance will support its implementation. In order for this guidance to achieve this, the scope needs to reflect approaches and interventions that are focussed at people that are at high risk of developing CVD such as people with diabetes. The guidance needs to support people holistically. Whereas people with diabetes may receive CVD prevention interventions and support that are applicable to the population as a whole, they also benefit from interventions that are suitable because they are at high risk. The guidance needs to consider the holistic needs of individuals who are at increased risk of CVD, particularly as diabetes is a major cause of CVD.	As indicated, this guidance is intended to address whole populations rather than focus on those with clinical conditions that raise their risk of developing CVD. We agree that these groups may benefit from specific interventions, however these are outside the scope of this work.
Diabetes UK			6	Add the following NICE guidelines to the list of related guidance: Type 1 diabetes – clinical guideline 15 http://www.nice.org.uk/guidance/index.jsp?action=byID&o=10944 Type 2 diabetes (update publication due soon) http://www.nice.org.uk/guidance/index.jsp?action=byID&o=11635	Although relevant as control of diabetes is important for reduction of risk of cardiovascular disease in individuals, these documents beyond the scope of this work.
EARNEST			3 c)	We welcome the recognition in the draft scope that maternal nutrition may be linked to cardiovascular disease (CVD) but believe that both maternal and infant nutrition should be given greater prominence. Evidence is accumulating that a mother's diet during pregnancy and an infant's early growth pattern can have long term implications for the infant's future risk of cardiovascular disease and its concomitant risk factors. Evidence that early nutrition or breastfeeding can "programme" future metabolism suggests that intervening at an early stage could reduce future susceptibility to disease risk factors.	Thank you. As you may be aware, maternal and child nutrition is the subject of a separate NICE guidance.

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EARNEST			4.3 Q 1)	**Recommended Intervention** The promotion of breastfeeding, though already acknowledged as important for its short-term benefits, should also be included as part of a strategy for the prevention of CVD because of strong evidence that it can reduce the subsequent risk of several adverse CVD risk factors. **Evidence base** The evidence that breastfeeding confers long term benefits on cardiovascular risk comes from longitudinal observational studies and follow up studies of randomised controlled trials (reviewed in Singhal, 2008). Observational studies have found that breast fed babies subsequently have a lower risk of high cholesterol (Owen et al, 2002), high blood pressure (Martin et al, 2005) and obesity (Arenz et al, 2004). Although it is possible that these studies might have been confounded by social patterning in the breast fed and formula fed groups, evidence from randomised controlled trials suggests that they are real effects. (Cont'd)	Thank you. If evidence is available in included papers it will be considered. However, as noted there is a separate NICE guidance on maternal and child nutrition. Thank you for providing these references

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EARNEST			4.3 Q 1)	Studies in pre-term babies have found that infants assigned to breast milk versus formula, for an average of 4 weeks, had marked benefits up to 16 years later for the major components of the metabolic syndrome (blood pressure, leptin 'resistance' suggestive of future obesity, insulin resistance and lipid profile) (Singhal and Lucas 2004). There were also dose-response associations between the volume of breast-milk intake and later cardiovascular benefit (Singhal and Lucas 2004). Singhal and Lucas have suggested that the cardiovascular advantages of breast-feeding may be due to slower growth in breast-fed versus formula-fed infants - the growth acceleration hypothesis (Singhal and Lucas 2004). Consistent with this hypothesis, they found that small for gestational age infants randomly assigned to a standard formula for the first 9 months had lower blood pressure 6 - 8 years later than infants fed a nutrient-enriched formula that promoted growth (Singhal et al. 2007). Faster growth in healthy term infants has also been linked with higher blood pressure (reviewed in Singhal et al. 2007) and obesity later in life (Ong and Loos 2006). A possible explanation for the slower growth seen in breast fed babies is the lower protein content of breast milk compared to infant formulas. One of the trials in the Early Nutrition Programming Project is the Childhood Obesity Project. This trial randomly assigned mothers who had chosen to formula feed to a high or lower protein content formula. After two years, those who had been fed the high protein formula had significantly higher BMI than those fed the lower protein formula (Koletzko, 2008). The growth rates of the lower protein group were more similar to those of a reference group of breast fed babies. The results of this trial provide further evidence that the growth pattern of breast fed babies confers long term protection against metabolic changes which increase the risk of obesity and CVD.	

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EARNEST			6	**Inclusion in current policies for the reduction of obesity** Although not included in the 2006 NICE guidance on obesity, the long term advantages of the pattern of growth seen in breastfed infants is now recognised in health strategies for reducing obesity in England. The joint Report by the Royal College of Paediatrics and Child Health and the Scientific Advisory Committee on Nutrition recommended the introduction of the WHO growth standards in the UK as they are based on the growth pattern of breast fed babies and that current evidence suggests that such a pattern of growth could potentially reduce the risk of later obesity (SACN/RCPCH 2007). The cross-government strategy, Healthy Weight, Healthy Lives (DH/DCSF 2008) also recognises the importance of the pattern of growth in early life in contributing to the risk of obesity. It includes the promotion of breastfeeding and the use of the WHO growth standards as part of its strategy for reducing childhood obesity rates in England. The implementation of this policy has been consolidated by the updating of the Child Health Promotion Programme (DH/DCSF 2008). This programme sets out the early intervention and prevention public health programme for children and families. It has been updated to reflect changing public health priorities and now has a greater focus on the early identification and prevention of obesity through, among other things, the promotion of longer breastfeeding.	Noted thank you

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EARNEST			General	**References** Arenz S, Ruckerel R, Koletzko B, von Kries R. Breast-feeding and childhood obesity--a systematic review. Int J Obes Relat Metab Disord. 2004 Oct;28(10):1247-56. Review. Koletzko B. Early feeding and later growth: the European Childhood Obesity Project. Advances in Experimental Medicine and Biology. Accepted for publication Martin, R.M., Ben-Shlomo,Y., Gunnell,D., Elwood,P., Yarnell,J.W.G., & Davey Smith,G. (2005) Breast feeding and cardiovascular disease risk factors, incidence, and mortality: the Caerphilly study. *Journal of Epidemiology and Community Health* **59**, 121-129. Ong KK and Loos RJ. (2006). "Rapid infancy weight gain and subsequent obesity: systematic reviews and hopeful suggestions." *Acta Paediatrica* **95**: 904-8. Owen CG, Whincup PH, Gilg JA, & Cook DG. (2003) Effect of breast feeding in infancy on blood pressure in later life: systematic review and meta-analysis. *BMJ* **327**, 1189-1195. Singhal A (2008). Early origins of cardiovascular disease. Advances in Experimental Medicine and Biology. Accepted for publication Singhal A and Lucas A. (2004). "Early origins of cardiovascular disease: is there a unifying hypothesis?" *Lancet* **363**: 1642-5. Singhal A, Cole TJ, Fewtrell M, Kennedy K, Stephenson T, Elias-Jones A, Lucas A. (2007). "Promotion of faster weight gain in infants born small for gestational age: is there an adverse effect on later blood pressure?" *Circulation* **115**: 213-220. (Cont'd)	

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EARNEST				SACN/RCPCH (2007). Application of WHO Growth standards in the UK. Report prepared by the joint SACN/RCPCH Expert Group on growth standards. Department of Health and Department for Children, Schools and Families. (2008). Healthy weight, healthy lives: a cross-government strategy for England. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_082378 Department of Health and Department for Children, Schools and Families. (2008). The child health promotion programme. Pregnancy and the first five years of life. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/DH_083645	
Faculty of Public Health			General	The Faculty of Public Health welcomes this planned Programme Guidance scoping document. It is extremely important that a population approach is taken to reducing cardiovascular risk. It is the most cost-effective approach and can yield the greatest returns. It is important to acknowledge that many, perhaps most, of the factors determining people's risk of developing or dying from cardiovascular disease lie outside the health services and need to be tackled by society-wide changes to the environment in which individuals live, the range of options available to them, and what decisions they therefore make. Much has been written about 'the obesogenic environment' in which we now live and we look forward to reading the NICE guidance in March 2010 on effective steps to tackle this.	Thank you
Faculty of Public Health			General	There needs to be a clear distinction between "evidence of no effect" and "no evidence".	Agreed. It is important to make this distinction in the evidence reviews and to take it into account in developing recommendations.

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Faculty of Public Health			General	Where there is no evidence of the effects of interventions, we would ask NICE to examine the evidence on factors that facilitate or impede healthier lifestyles (such as transport policies that act as barriers to physically active transport) so that when policy decisions are taken by local, regional or even national government in such areas, what is known can be used, even if that information is incomplete. Recognising that there will not always be experimental evidence we recommend that NICE adopts a criteria to seek out the best available evidence.	Noted.
Faculty of Public Health			General	Please cite primary sources even in the introduction. If there is no time to go back to the primary sources, perhaps you could reference it as (eg Health Survey for England 2005, cited by Allender et al 2007)	Thank you. This will be amended
Faculty of Public Health			General	We understand that the brief is as given to NICE by the Department of Health. We are not concerned that it is 'limited' to cardiovascular disease and excludes cancers because several primary prevention interventions that reduce cardiovascular risk will also impact on many cancers, albeit with a much longer timescale. This is particularly the case where they share major risk factors (such as tobacco use, physical activity, diet, obesity, high alcohol consumption).	Agreed. Risk factors such as diet, tobacco use, alcohol and inactivity are significant for many non communicable diseases.
Faculty of Public Health			General	Similarly, we assume that interventions that help reduce or prevent obesity, diabetes, and metabolic syndrome would be included because of their impact on cardiovascular risk.	Agreed. To be included, these interventions would need to be part of a programme addressing multiple risk factors (such as diet and activity).
Faculty of Public Health			3 b)	Whilst we agree that CVD risk is higher in *some* South Asian groups, it is important to acknowledge that this is a heterogeneous group. There is much variation in risk of obesity, diet and physical activity levels between for example, Bangladeshi compared with Indian communities. Given that "South Asians" comprise a large and growing minority population in the UK, it would be useful to make such distinctions where possible.	Agreed. If it is possible to make distinctions from the evidence considered we will do so.

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Faculty of Public Health			4.1	We agree that it should focus on local, regional and national populations and not on individuals with or at high risk of developing CVD. Population-wide changes, such as making a healthier diet or physically active transport easier and reducing public exposure to tobacco smoke, should also benefit these groups. It is important that all ages are included in this guidance, and where appropriate, a life course approach is adopted. However, where an intervention has been tried only on one age group or been found to be effective only for certain age groups, it should not be excluded on the grounds of not being tested or effective for all ages, provided the age limits are specified (and any adverse effects on other age groups mentioned, if applicable).	Thank you. All ages are included. The PDG may feel it appropriate to adopt a life course approach to developing recommendations. Agreed. When considering developing recommendations from evidence of effectiveness, the degree to which such evidence is applicable beyond the original study population in terms of personal and organisational characteristics (which would include differences between countries and over time) is crucial
Fit For Sport			General	I would like to comment on the conference and the discussion around the NICE guidelines for Cardiovascular Disease I attended on the 1st of April. While there was discussion about prevention, I was a little confused of how and who will give families the education on prevention of this disease. I believe that if we educate our families on prevention, we will reduce the impact of such diseases like this one! The obesity levels in children and adults will accelerate this disease if we do not act and put in the guidance for education in schools and households across the UK.	Thank you. Recommendations generally include information on who should act, as well as what they should do. However developing these recommendations is the role of the PDG, carried out following consideration of the evidence.
Food Standards Agency			2 c)	Suggest including Healthy Weight, Healthy Lives (2007), although this document is primarily about obesity there are key associations between obesity and cardiovascular disease.	Thank you – we will include this in the final scope

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Food Standards Agency			3 d)	Text includes phrase 'and failure to address 'upstream' influences such as policy or manufacturing practices.' However, this fails to take account to the activity to reduce salt content of foods and development of plans to address saturated fat/energy. nor does it take into account guidance from FSA in relation to catering in general or specific to major institutions in particular. Note FSA salt activity has resulted in reductions in salt in many food categories the extent to which food industry is meeting salt targets is currently being collated.	Section 3d of the scope is making a general point about the difficulties of evaluating interventions and making comparisons between populations such as cities or regions where upstream influences may impact on both intervention and control populations We are aware of the programmes of work the FSA is leading on salt reduction, institutional catering and the plans to address saturated fat and energy intakes. Within our scope would consider these type of programmes to be 'environmental' interventions . Information such as this would be very helpful in setting the context in which the recommendations will be developed.

Stakeholder Organisation	Evidence submitted	Page Number (s)	Section	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Food Standards Agency			4.21 a)	It is not clear where you would include activity/intervention on food provision and procurement. They could be included within 'environmental changes' however this could result in the impact being swamped by other activities etc. The impact of procuring food lower in salt, fat (particularly saturated fat) and sugars can be high (see secondary analysis of school meals in secondary schools in England using FSA's Target Nutrient Specifications for manufactured products used in school meals, Gibson 2005 see www.food.gov.uk/multimedia/pdfs/modellingchanges.pdf) Potential impact of a consistent procurement approach with a standardised contract which links to criteria that help lower salt, fat (particularly saturated fat) and sugars [perhaps referring to FSA criteria] would have major benefit. It would be important for this not to be lost among other 'environmental' issues.	Thank you. Depending on the availability of evidence, this may be considered in studies of effectiveness of programmes. However, it may also be an issue that arises in the consideration of barriers to the effective implementation of programmes (see question 2, para 4.3)
Food Standards Agency			4.2.1 b)	Unclear how the GDG will be able to look at pharmacological benefits when screening will not be part of the remit. It is difficult to see how pharmacological approaches would be appropriate for the stated population group who are not at high risk of CVD, nor how they will be identified.	There are a number of interventions which involve pharmacological elements which have also included population level interventions in terms of e.g. diet and physical activity. We hope to be able to include these broader elements of such programmes rather than to exclude them simply on the grounds that they have included a pharmacological intervention for some.

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Food Standards Agency			4.3 Q1)	The FSA have undertaken and are undertaking or have been involved with a range of activity which will be relevant to consider as part of this question. this includes: • Healthy eating advice (see eatwell.gov.uk pus FSA communication via leaflets, interventions (see N09/N14), work with teen girls, education activity/interventions, nutrient standards in care homes for older people) • SACN salt and health report (2003) • FSA salt campaign (phases 1-3)(2003 – 2008) • Salt targets for manufactured food (see general comment below about the review of salt targets) • Evidence on reduction of population salt intake (see http://www.food.gov.uk/science/dietarysurveys/urinary http://www.food.gov.uk/news/newsarchive/2007/mar/saltresearchmar07 • Saturated fat/energy strategy • FSA catering strategy (2008) • Target Nutrient Specifications for manufactured products used for school lunch (see above) • Guidance for food served in major institutions (2006/7) • Food behaviour research (N09/N14 programmes) including weight prevention during smoking cessation, Tees on the Move, 5 a day the Bash street way, etc • Cardiovascular research (N02 programmes) • Front of pack signposting (R&D to report….) • Nutrient Profiling • Food competency framework In addition note that there is likely to be considerable information in the NICE GDG Obesity evidence papers.	Noted thank you

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Food Standards Agency			4.3 Q2)	See comments above re 4.3Q1. Also consider that in addition to qualitative information it would be useful to look for quantitative information which may be available about success of different approaches to overcome barriers.	Thank you
Food Standards Agency			General	NICE have previously considered the issue of salt intake – see FSA briefing note Jan/Feb 07 'salt reduction as a strategy to reduce hypertension (NICE ID topics 1833 and 1817)	Thank you
Food Standards Agency			General	Not clear what the timeline for this work is, activity underway which will be of interest include salt survey currently being concluded with results anticipated in July 08 evaluation of	The first meeting of the PDG to consider evidence is in September 2008, with final publication in March 2010
Food Standards Agency			General	FSA review of salt targets (see comment in 43Q1 above). Please note: The review of the salt targets will consider what further reductions are necessary to maintain progress towards the daily population average intake target of 6g. Having run a programme of stakeholder meetings earlier this year to discuss the targets for each category, we are now considering the outputs of these meetings, as well as information on reductions achieved so far, levels in products, technical constraints, independent advice and data on current intakes, and reviewing each target and category as appropriate. We will issue a full public consultation on the revised targets in the summer, with the aim of publishing the final revisions by the end of the year.	Thank you

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Food Standards Agency			General	Impact of front of pack labelling of packaged foods will also impact on the CVD prevention area if consumers re able to choose products lower in salt, and saturated fat. A study to assess consumer preferences and use of front of pack labels is being managed by an independent Project Management Panel and conducted by BMRB and University of Surrey. The study will assess how labels contribute to healthier eating choices and which elements of the different schemes best help people to correctly interpret nutritional information on food. Qualitative fieldwork in a number of locations across the UK now almost complete. Quantitative work to assess consumer understanding will commence shortly. Headline results will be available by the end of the year. It is unclear whether the reporting of this study will fit within the timeline of the GDG, however, the impact of this study will be of significance to the outcome of the GDG work in consumer information aspects of the CVD prevention programme.	Thank you. The consultation on the evidence for this programme of work will take place in between 12th May and 10th June 2009, with the publication being due in March 2010
GE Healthcare			General	We applaud the focus on the prevention of cardiovascular disease. How will this guidance support the Department of Health's announcement and imminent programme of vascular checks for 40 – 74 year olds? Will there be specific aspects of the guidance for GP's who are the main "port" of call for patients?	Thank you. It will be important to ensure that the guidance takes account of the current policy environment, however we cannot prejudge what recommendations the PDG will make.
GE Healthcare			4.2	In the section on interventions that will be covered, you state that interventions that include a pharmacological element will be covered. However, interventions that include diagnostic elements which in some cases would help prevent cardiovascular diseases have not been added. We think it is important in reviewing interventions to prevent cardiovascular diseases that a whole systems approach is used. It would therefore be necessary to include interventions that have a diagnostic element.	The aim of the guidance is to consider population level interventions to change risk factors linked to CVD. Included interventions will address more than one risk factor, and these could include diagnostic elements. However, we would need the outcomes to include changes beyond simply changes in knowledge or attitudes.

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GE Healthcare			4	Would there be work done with the Food Standards Agency and relevant industry to review the nutritional value and content of the different foods available on the market since diet is an important factor?	While we welcome the FSA's work with the food industry, we don't anticipate taking this particular approach as part of the guidance development process
Greater Manchester & Cheshire Cardiac/Stroke Network			4.2.1 a)	The work from Dr Fosters in Greater Manchester confirmed that, when using the mass media, it was important to have messages that attracted the public's attention. This could use the cigarette in a syringe and needle (first developed in California), which created an emotional response and is now being used as a national warning. It can also be by giving new information eg the April Be Healthy, Be Happy supplement of the Manchester Evening News showing that a Pizza Mediterranean Meat Feast stuffed crusts contains 3,096 calories and 22.4 g salt. The programmes whereby takeaways and restaurants discourage the use of salt eg by offering salt cellars with smaller and fewer holes in exchange for existing ones, should be encouraged. Where they feel they need to use salt in their cooking, they should be encourage to use salt that replaces most of the sodium with potassium which will then decrease, rather than increase, blood pressure.	Thank you. It would be useful to have details of this evidence and we would be grateful if you could forward details so it can be considered for inclusion in the evidence reviews.
Greater Manchester & Cheshire Cardiac/Stroke Network			4.2.1 a)	All products are elastic to some extent. The rising cost of cigarettes has an effect on smoking but the effect has been reduced by the availability of smuggled and counterfeit cigarettes. So more activity by Customs and Excise, Police and trading Standards will reduce smoking. Other measures would include removing VAT from nicotine replacement therapy (requiring EU changes) and putting tax on food products with excess salt content.	Thank you.

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Greater Manchester & Cheshire Cardiac/Stroke Network			4.2.1 a)	The ready access to goods makes a difference. So tobacco products should be removed from the entrances of supermarkets initially but eventually tobacco products should only be allowed to be sold from licensed premises only selling tobacco with no advertising or displays apart from a simple sign. The sale of confectionary at supermarket check-out counters should also be discontinued.	Thank you. We cannot prejudge what recommendations the PDG will make from the evidence.
Greater Manchester & Cheshire Cardiac/Stroke Network			4.2.1 a)	Tobacco products should only be allowed to be sold from licensed premises only selling tobacco with no advertising or displays apart from a simple sign. Children should be protected from second-hand smoke (this affects their risk in later life) by banning smoking in cars when children are present (as proposed in British Columbia) and in children's playgrounds	Thank you. We cannot prejudge what recommendations the PDG will make from the evidence.
Greater Manchester & Cheshire Cardiac/Stroke Network			4.2.1 b)	Folate should be added to flour. This will definitely reduce neural tube defects but there is some evidence that it will also reduce heart disease. There is no reason to restrict the over the counter sale of simvastatin to one market brand ie zocor.	Thank you. We cannot prejudge what recommendations the PDG will make from the evidence.
HEART UK			General	We welcome the development of new guideline as a pro-active step to reducing the incidence of cardiovascular disease.	Thank you.
HEART UK			3 c)	The interventions studied should include exercise as a lifestyle therapy though it is often prescribed allied with dietary modification e.g. OXCHECK, MRFIT, Diabetes Prevention Projects/Programmes (Finnish, USA, India).	It is hoped to include these types of programmes.

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HEART UK			4.2.1 b)	The interventions covered should include diets e.g. OMNIHEART study or DASH diet and nutriceuticals for which there is some lipid surrogate evidence (e.g. sitostanol/sitosterol products)	If evidence relating to these diets comes from programmes which cover multiple risk factors it will be possible to consider the material. However, as noted elsewhere, it is not possible to consider all the evidence relating to all risk factors, hence the restriction to multiple risk factor interventions.
HEART UK			4.2.1 c)	Interventions to be covered should include statins for ultra-low risk patients in light of the licence for pharmacist prescription for simvastatin 10mg.Relevant trials include MEGA (10mg pravastatin) and JELIS (omega-3 (EPA) added to 5-10 mg simvastatin/10-20mg pravstatin).	Unfortunately consideration of these interventions would be outside the scope of this guidance. However, we anticipate that it will be necessary to make reference to other related NICE guidance which may include that relating to the use of pharmaceuticals such as statins.
National Heart Forum			General	Consider as primary prevention of CVD and cancer prevention or avoidable and linked chronic diseases guidance. The review needs to be mindful of the usefulness to practitioners and the synergies between overlapping work in the prevention of a wide range of chronic diseases with the same or similar prevention interventions.	The referral relates to prevention of CVD. However, as many of the risk factors for CVD also influence other non communicable diseases it will be relevant to others working in related fields. We hope to make these connections in the guidance.
National Heart Forum			General	Review by single risk factor and multiple risk factor (MRF) intervention. Compare the effectiveness and applicability of holistic disease prevention and healthy lifestyle programs compared to individual risk factor interventions. Rationale - Not much recent research on MRF interventions available -this will considerably narrow the scope and usefulness of the review. Given the paucity of MRF research extrapolate learning from interventions on individual risk factors.	Noted. This is an interesting suggestion, however comparing the effectiveness of holistic programmes to individual risk factor interventions would involve reviewing the full range of potential interventions which would not be possible in the timescale available. It would also duplicate work carried out in other NICE guidance.
National Heart Forum			General	Major focus should be tackling CVD inequalities	Noted. The guidance will consider inequalities.

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National Heart Forum			General	Need to identify the specific contribution of particular health technologies such as social marketing and their combinational value with other interventions.	Noted. It is hoped that the available evidence will include these types of approaches.
National Heart Forum			General	Need to consider the level of intervention and how upstream or downstream and synergies.	Thank you.
National Heart Forum			General	Need to identify the contributions of different sectors and settings and target groups	Thank you.
National Heart Forum			General	Need to consider methodological issues about population public health approaches and social change attributions. Especially natural experiments.	Thank you.
National Heart Forum			General	Given the paucity of research need to make detailed recommendations about the research and development agenda	Research recommendations are routinely included in the full guidance, however it is premature to comment on what these might be.
National Heart Forum			General	Need to consider how this work compliments and compares with the cardiovascular risk screening program for 40-74 year olds and secondary prevention and its economic and social consequences on pursuant morbidity and disability.	Thank you. The guidance will need to take into account the current policy background.
National Heart Forum			General	Include adults and children. Need to consider a lifecourse approach from the beginning of life.	All ages are included. The PDG may feel it appropriate to adopt a life course approach to developing recommendations.
National Heart Forum			General	Need to consider implications for the organisation of public health services at all levels and professional training and development	Thank you.
National Heart Forum			General	Need to develop the application of public health intervention modelling methodology to aid judgements on investment to take account of evidence deficits.	Thank you.
National Heart Forum			General	Need to consider premature mortality and not just all deaths.	Thank you.
National Pharmacy Association			general	The NPA welcomes NICE's intention to produce public health guidance for the prevention of cardiovascular disease in different populations	Thank you.

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National Pharmacy Association			general	The Government white paper *Pharmacy in England Building on strengths – delivering the future*[1] published in April 2008 recognises the roles for community pharmacy in improving public health including: • Becoming 'Healthy Living' centres providing support for self care which will include promoting healthy living • Offering advice when selling stop smoking and dietary products • Vascular checks, discussions with stakeholders groups, regarding implementation will include community pharmacies. It is recognised that pharmacies offer an excellent point of contact for the general population and also offer a place of access for groups who may not be registered with GPs. • Raising awareness of the effects of harmful drinking and informing people of recognised sensible limits • Information about increasing physical exercise • Information about healthy diet • Accelerating and expanding pharmacy's ongoing contribution to public health and how it contributes to reducing health inequalities • Strengthen contractual arrangements so that stop smoking services provided in pharmacies show clear evidence of close partnership with local NHS stop smoking services	Thank you.

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National Pharmacy Association			general	Community pharmacies are well placed to offer advice and support for self-care as they see patients when they are well as well as when they are ill. They are accessible being located where people live and work. 99% of the population, even those in the most deprived areas, are able to get to a pharmacy within 20 minutes by car and 96% by walking or using public transport[1]. Pharmacy staff frequently live in the community in which they work, know and understand the cultural needs of the community and in areas of ethnic diversity speak languages(s) other than English.	Noted.
National Pharmacy Association			General	Many community pharmacies already provide services which help reduce the risk of CVD including; • Stop smoking • Weight Management Screening for diabetes, blood pressure and cholesterol	Noted.
Newcastle University			6	The NICE programme guidance on behaviour change is also relevant to this draft scope and should be referenced here.	This has been included in the final scope
Nottingham City PCT			4.1.1	The draft scope states: “local, regional or national populations”. It is important for Nottingham City PCT that the guidance looks into the available evidence with regard to deprived communities and in particular the need to target communities at high risk of CVD in order to reduce inequalities in CVD. This is in line with government policy such as the Spearhead group in England.	Thank you. We anticipate that there will be an important focus on inequalties. We would be interested if you have any evidence related to differential impact in deprived communities. We would also anticipate that these issues may be addressed in the work to answer question 2.

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Nottingham City PCT			4.2.1	Section 4.2.1 refers to "multiple risk factor approaches to preventing CVD among a given population" and 4.3 refers to "multiple risk-factor interventions [that address at least two risk factors]". We are very interested to know what intervention improves risk factors in a given population, but we are also interested to know what 'intervention mix' is most effective to improve CVD outcomes at a population level (e.g. city or state). For instance if an intervention is put in place in primary care to identify and manage patients at risk of CVD, are population outcomes better achieved, if this is supported by a range of community interventions addressing different CVD risk factors as well.	Noted. We hope the PDG will be able to consider issues such as this in its deliberations.
RCN			General	With a membership of over 400,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector. The RCN promotes patient and nursing interests on a wide range of issues by working closely with the Government, the UK parliaments and other national and European political institutions, trade unions, professional bodies and voluntary organisations. The RCN welcomes proposals to develop this guidance. It is good to see the planned inclusion of qualitative analysis of the influencing factors of participation.	Thank you.

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RCN			General	Target audience is not clearly identified throughout. The document seems to focus on particular strata of society (people with known risk factors) rather than those who may be unaware of being at risk due to social class, unemployment, and ethnicity.	The audience is primarily those who will develop interventions to address CVD. However, it is intended to look at interventions that will influence the whole population risk of CVD, not those who are known to be at high risk.
RCN			General	The document could have a stronger focus on young people, particularly relating to primary prevention – overall, children and young people are not mentioned, which is surprising as this is aimed at prevention. It would be useful to refer to weaning, toddler diets, nutrition in school age children & school food policies, schools where healthy eating and physical activity is a key theme. It could link to extended school services, health visitors' role in pre-school nutrition, school nurses' role in delivering healthy eating and activity health promotion – these professionals could do a lot more with additional capacity and resources. This would strengthen the need for focused and disease specific education at school age where it can impact.	Children will be included in the search for evidence. However it is too early to speculate on what this evidence will say.
RCN			General	The recent National Cardiac Conference addressed the value of identification of Atrial Fibrillation for example in the elderly who attend for flu vaccines and having a radial pulse check. This significantly reduces the incidence of stroke. Such strategies should be taken into consideration.	Thank you.
RCN			2 b)	Does not mention Children's NSF.	Noted.
RCN			2 c)	No mention of key DH obesity documents such as Foresight Report 2007, National Obesity Strategy 2007, Children's Plan 2007, Healthy Schools 2005, Healthy weight, healthy lives 2007.	Noted. Additional documents will be referenced

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RCN			Appendix B	Although there is a slight mention of ethnic and social class groups in appendix B this could be made clearer and be included in the main body.	The influence of factors such as social class and ethnicity is covered in section 3b.
Servier Laboratories Ltd	Word document providing background evidence and supporting references. Letter which originally was submitted to Professor R Hobbs and endorsed by several expert Cardiologists.			Please find attached a word document providing background evidence and supporting references. In addition, please find attached a letter which originally was submitted to Professor R Hobbs and endorsed by several expert Cardiologists. The content of this letter is in support of our submission. All persons whose signature is present on the form have provided their consent for this letter to be submitted to NICE on this occasion.	Thank you. Resting heart rate is a relevant measure and might well be an appropriate outcome measure in an included study.
Servier Laboratories Ltd			3 c)	Significant and robust evidence from large epidemiological studies exists, which demonstrates the strong association between heart rate and cardiovascular risk. This association has been repeatedly reported in several different study populations, and has been reported to be independent of other cardiovascular risk factors. Heart rate can be simply and inexpensively measured and recorded, and provides a great deal of information about an individual's health. Changes to lifestyle such as smoking cessation and taking exercise can influence heart rate. Consideration should be given to including heart rate as a modifiable risk factor in this section of the document. Please see the attached evidence summary to inform your review of heart rate and its role in cardiovascular risk.	Thank you. Where included studies use heart rate as an outcome measure this will be included.

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Sheffield PCT			General	Comment also made at the consultation event: The CVD focus is perhaps too narrow in view of the nature of public health cardiovascular prevention programmes in practice. It would be very apt to extend the definition of CVD to encompass 'cardio-metabolic' disease prevention. In the context of this guidance, for example, diabetes prevention evidence should not be excluded by reason of drawing too narrow a definition. Although the end-point of these studies may not be cardiovascular, the end-point of the disease pathology is cardiovascular.	The referral is about CVD. However, many of the risk factors are significant for other non communicable diseases, such as some cancers and metabolic diseases and so the guidance may be significant for these conditions.
Sheffield PCT			General	Although not explicitly stated in the draft scope it was made clear at the consultation event that the guidance will be concerned only with population-wide approaches. This will not be as relevant as it could be for PCTs since almost all of our prevention programmes have a targeted element by design, vis-à-vis addressing health inequalities. Purely population-wide approaches can introduce incentives that are perverse to the task of improving inequalities – i.e. can actively exacerbate inequalities – since uptake / risk modification is likely to be more rapid and more complete in the more affluent communities. An appraisal of the evidence for targeted vs. undifferentiated approaches would be helpful. It was agreed at the consultation event that social marketing, which is a differentiated approach, would fall within the scope of the guidance and so it would not be consistent to exclude other targeted modalities.	Thank you. The definition of population used in the final scope is "People of all ages living within certain geographical areas who may or may not have other characteristics in common (such as ethnic origin). Usually these areas will cover at least a region of a country (such as Merseyside) and could be urban or rural. In the UK, they will not be smaller than an area currently covered by a primary care trust".
South Asian Health Foundation			General	It would be prudent to not only consider smoking of tobacco but also other forms of tobacco consumption, as there is evidence that other modalities of consumption are also linked to CVD and BME groups do have increased rates of smokeless tobacco intake	Thank you. This will be changed in the final scope.

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South Asian Health Foundation			General	There are ongoing strategies in several areas at several levels which must be accommodated for consideration in the scope e.g. Investing for Health (W Midlands SHA), the Vascular risk assessment strategy (DH) etc.	Noted. It will be important to set the guidance in the correct policy framework.
South Asian Health Foundation			General	Access is not the sole issue to increase rates of provision, but awareness and acquisition of services must occur in parallel with increased access to services	Agreed.
South West Regional PH Groups			2 c)	The guidance will also support the delivery of the obesity strategy.	Agreed. This has been added to the list of relevant policy documents.
South West Regional PH Groups			4.2.1 a)	Should also include marketing and involvement of business sector as multiple risk factor approaches.	These issues may be considered in the recommendations developed by the PDG.
South West Regional PH Groups			4.2.1 b)	This section should include programmes of screening for CVD risk factors as primary prevention where the intervention involves management by primary care.	Where there is a relevant intervention that meets the inclusion criteria these programmes will be included.
South West Regional PH Groups			4.2.2 b)	Excluding cholesterol screening as a primary prevention activity will not be helpful. Most general population cholesterol screening testing includes referral to GP or management in primary care if result is above a threshold level.	Noted. Where a population level intervention includes screening as part of an intervention to address multiple risk factors it will be included in the evidence considered.
Sustrans			General	We welcome the references in the draft scope to physical activity levels as influencing the risk of CVD and protecting against it.	Thank you.
Sustrans			3 c)	Still more we welcome the acknowledgement of the importance of environmental factors. These are all too often overlooked or undervalued, but we believe them to be of primary importance. I have appended the pdf of "Creating the environment for active travel" (Sustrans 2007) which, although it is not specifically focused on CVD, illustrates the issue.	Thank you.

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Sustrans			General	When you come to review evidence relating to physical activity, we have confidence that you will spread the net to include all forms of "lifestyle" physical activity, and take care to avoid undue concentration on sport and active recreation.	Thank you.
Sustrans			General	In the area of physical activity, we urge you to seek evidence relating to interventions implemented by non-health sector organisations and, in many cases, without specific health objectives. We understand that it will often be extremely difficult to determine the impact of this type of intervention on CVD – or even on physical activity levels – but we believe that many of the most significant interventions will be of this kind, in areas such as transport and planning.	Agreed. Where this evidence is available we will consider it.
Sustrans			General	Further to the above, we urge you therefore to consider including evidence relating to intermediate outcomes – such as increases in levels of walking and cycling – where it may not be possible to find studies of the final impact of such interventions on CVD levels.	These outcomes will be considered if covered by the included studies.

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Syner-Med (PP) Ltd			General	The management and treatment of iron deficiency and anaemia in the general population may help to reduce CVD rates. Better diets are a good start point. Oral iron supplements are the gold standard but often have limited success due to poor tolerance and compliance and sometimes absorption. Three IV iron agents are available on the UK market which are being increasingly utilised in the primary care setting. Over the past decade there has been ever increasing evidence of the relationship between iron deficiency, anaemia and CVD. Following the widespread use of iv iron and erythropoietin in patients with CKD to reduce CVD, the association between CVD and anaemia has received increasing attention of late. The aggressive management of anaemia in renal medicine has been driven by the desire to reduce CVD where anaemia has been established as a risk factor. Current management strategies in CKD patients are based on early detection and correction to avoid CVD developing. This approach could serve the general population and health service well where iron deficiency and anaemia are very prevalent but largely ignored. The introduction of eGFR reporting with all U & Es in the UK has dramatically increased the detection of patients with CKD. NICE has evaluated their anaemia and their guidance states that if Hb <11g/dl then treatment should be with IV Fe +/- ESA. Many of the patients being identified are patients with existing morbidity such as high blood pressure and diabetes.	Thank you. Where included studies involve changes to iron deficiency these issues will be considered.

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The British Dietetic Association			General	The BDA wishes to highlight the necessity for the involvement of a dietitian or public health nutritionist in the GDG or as an co-opted expert.	We agree that this is very important and are hoping to include a community dietitian and/or a registered public health nutritionist in the Programme Development Group. We contacted both the BDA and the Nutrition Society to draw their attention to the advertisement calling for applications for members of the Programme Development Group and are hoping that their members have responded.
The British Dietetic Association			4.2.1	Within the intervention to be covered, the area of the food environment needs to be highlighted: food production, manufacturing, marketing, affordability, and access have a huge impact on diet.	We agree and envisage that these are examples of the environmental changes noted under section 4.2.1 in the scope
The British Dietetic Association			Appendix B	Potential considerations include, whether 'partnership working' across different organisations, at a strategic level, is effective	We envisage that issues such as partnership working will be covered under 'factors which may prevent or support effective implementation'
The Nutrition Society			General	The Nutrition Society supports this initiative and considers that the 'Draft Scope' is appropriate and comprehensive. The main issues have been considered and incorporated and there is no obvious oversight.	Thank you
The Nutrition Society			General	It is hoped that the Nutrition Society will have an opportunity to make a contribution to the guidance development.	We would welcome the Nutrition Society's comments when we consult on the draft evidence from 12 May to 10 June 2009 and on the draft guidance from 14 September to 12 October 2009