Public Health Programme Guidance
Prevention of Cardiovascular Disease

Evidence Consultation – Stakeholder Response Table

12 May – 10 June 2009

Stakeholder Organisation	Evidence submitted	Document Name & Number	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Breastfeeding Network			General		*We welcome the opportunity to comment on the evidence which is informing this guidance.* Whilst breastfeeding is mentioned in the scope as related guidance (11) *Improving the nutrition of pregnant and breastfeeding mothers and children in low-income households* we cannot see any mention in the evidence gathered of breastfeeding or any studies which shows the impact breastfeeding plays on preventing CVD. The UNICEF Baby Friendly Initiative has studies highlighted and the evidence is strong for including an intervention to encourage breastfeeding since this would be one measure which could help prevent CVD. Therefore we would welcome inclusion that the NICE guidance on Ante-natal care (62), Routine postnatal care of women and their babies (37) are also related guidance documents – since good ante-natal and post-natal care sets the scene for life for the new baby. See http://www.babyfriendly.org.uk/items/search_results.asp?view=2&health_issue=18	Thank you. The PDG is aware of the importance of good fetal nutrition and the role of breastfeeding. Interventions to promote this have been included in the recent guidance on maternal and child nutrition and the current guidance makes reference to this. The aim of the reviews is to look for evidence about how to alter risk factors rather than to set out the epidemiology behind the development of CVD.

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Breastfeeding Network					Horta B.L. et al (2007) Evidence on the long-term effects of breastfeeding. WHO	The primary aim of this review by Horta et al to assess the effects of breastfeeding on blood pressure, diabetes and related indicators, serum cholesterol, overweight and obesity, and intellectual performance. While relevant to CVD, this is not the primary aim of our reviews.
Breastfeeding Network					Ip S et al (2007) Breastfeeding and Maternal Health Outcomes in Developed Countries. AHRQ Publication No. 07-E007. Rockville, MD: Agency for Healthcare Research and Quality	This report reviewed the evidence on the effects of breastfeeding on short- and long-term infant and maternal health outcomes in developed countries.
Breastfeeding Network					Singhal A et al (2004). Breastmilk feeding and lipoprotein profile in adolescents born preterm: follow-up of a prospective randomised study . Lancet 363: 1571-78	This study suggests that breastfeeding may have long-term benefits for cardiovascular health, but does not relate to a programme within the scope of the guidance.
Breastfeeding Network					http://pediatrics.aappublications.org/cgi/content/abstract/110/3/597 Christopher G. Owen et al (2002). Infant Feeding and Blood Cholesterol: A Study in Adolescents and a Systematic Review. *Pediatrics* Vol. 110 No. 3, pp. 597-608	This study suggests that breastfeeding may have long-term benefits for cardiovascular health, but does not relate to a programme within the scope of the guidance.

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Breastfeeding Network					http://www.ncbi.nlm.nih.gov/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10685933&dopt=Abstract Ravelli AC et al (2000) Infant feeding and adult glucose tolerance, lipid profile, blood pressure, and obesity. *Arch Dis Child* 82: 248-52	This study suggests that breastfeeding may have long-term benefits for cardiovascular health, but does not relate to a programme within the scope of the guidance.
Breastfeeding Network					Marmot MG et al (1980) Effect of breast-feeding on plasma cholesterol and weight in young adults. *J Epidemiol Community Health* 34: 164-7.	This study suggests that breastfeeding may have long-term benefits for cardiovascular health, but does not relate to a programme within the scope of the guidance.
Breastfeeding Network					http://www.ncbi.nlm.nih.gov/pubmed/19384111?dopt=Abstract **Duration of lactation and risk factors for maternal cardiovascular disease.** Schwartz et al	This study suggests that breastfeeding may have long-term benefits for cardiovascular health, but does not relate to a programme within the scope of the guidance.
Breastfeeding Network					http://vmj.sagepub.com/cgi/content/abstract/14/2/137?ct=ct Khan F, Green FC, Forsyth JS et al (2009) The beneficial effects of breastfeeding on microvascular function in 11- to 14-year-old children. Vascular Medicine; 14: 137-142	This study suggests that breastfeeding may have long-term benefits for cardiovascular health, but does not relate to a programme within the scope of the guidance.

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Breastfeeding Network					http://aje.oupjournals.org/cgi/content/abstract/161/1/15?ct Martin RM et al (2005). Breastfeeding in Infancy and Blood Pressure in Later Life: Systematic Review and Meta-Analysis. *Am J Epidemiology* 161:15-26	This study suggests that breastfeeding may have long-term benefits for cardiovascular health, but does not relate to a programme within the scope of the guidance.
Breastfeeding Network					http://atvb.ahajournals.org/cgi/content/abstract/25/7/1482?ct Martin RM et al (2005). Breastfeeding and Atherosclerosis: Intima-Media Thickness and Plaques at 65-Year Follow-Up of the Boyd Orr Cohort. Arteriosclerosis, Thrombosis, and Vascular Biolog 25:1482.	This study suggests that breastfeeding may have long-term benefits for cardiovascular health, but does not relate to a programme within the scope of the guidance.
Breastfeeding Network					http://highwire.stanford.edu/cgi/medline/pmid;15308954 Rich-Edwards JW et al (2004). Breastfeeding During Infancy and the Risk of Cardiovascular Disease in Adulthood. Epidemiology 15: 550-556	This study suggests that breastfeeding may have long-term benefits for cardiovascular health, but does not relate to a programme within the scope of the guidance.

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British Heart Foundation	 NICE paper on so marketing.doc		General		The BHF is the nation's heart charity. We welcome the opportunity to respond to this consultation on the evidence for guidance on the prevention of cardiovascular disease. The BHF contributes to the prevention of cardiovascular disease in a range of ways including research to provide the evidence base for prevention strategies, education, information, awareness raising and campaigning for change to ensure that the regulatory and legislative framework is conducive to healthy choices. The Cardio and Vascular Coalition, an alliance of 41 voluntary organisations' including the BHF, has recently published *Destination 2020*, a vision for tackling heart and circulatory disease in England over the next ten years. While this vision addresses the full range of areas where action is needed, prevention is identified as a key gap from the existing National Service Frameworks where further action is needed.	Thank you.

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Stakeholder Organisation	Evidence submitted	Document Name & Number	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
British Heart Foundation		Expert Paper 4	Annex A		The independent evaluation on food labelling mentioned in this paper has now been published confirming that a combination of traffic light colours, guideline daily amounts and interpretative words best meet the needs of the whole population. Qualitative research with consumers carried out by the BHF in 2006 indicated that traffic light colours allow for 'at a glance' interpretations of nutritional content while guideline daily amounts can help with more detailed analysis and relative judgement between products.	Thank you..
British Heart Foundation		Expert Paper 4	Annex A		The BHF has undertaken research which indicates that, since the restriction of marketing HFSS foods to children came into force, food companies are marketing children's food directly to parents. In addition, aspects of such marketing actively exploit wider societal concerns about poor eating habits amongst children to make health associations for HFSS products.	Thank you.

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British Heart Foundation		Expert Paper 7	5	4	The paper notes that the Heart of Mersey is a member of the Cardio and Vascular Coalition. This is an alliance of 41 voluntary organisations with an interest in promoting and protecting cardiac and vascular health in England, chaired by the British Heart Foundation. In April 2008, the coalition published an independent review of the opportunities and challenges facing cardiovascular disease in the coming decade, undertaken by the York Health Economics Consortium. The project comprised interviews with experts, a modelling exercise and a survey of people who care for, or live with somebody diagnosed with a cardiovascular condition. While the comprehensive nature of the coalition's work means that this research covers a range of areas, key messages include the need for improved public health campaigns, education in schools, progression of screening services and efforts to ensure that culturally and socially sensitive services are developed for marginalised groups. Further information is available at bhf.org.uk/cvc	Thank you.

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Department of Health			1	General	Because this guidance will relate to prevention of cardiovascular disease at a population level, could you please highlight the importance of sighting *NHS Health Check* and the supporting documents that we have for the programme. The *NHS Health Check* programme is a universal and systematic programme for everyone between the ages of 40-74 that will assess people's risk of heart disease, stroke, kidney disease and diabetes, and will support people to reduce or manage that risk through individually tailored advice. Phased implementation of the programme began in 2009/10 and is expected to be fully implemented in 2012/13. We believe that the following documents are relevant to the *NHS Health Check* programme. Could you please therefore consider these as evidence in preparing the new guidance. We confirm that this view is supported by colleagues at NHS Improvement. - **The Handbook for Vascular Risk Assessment, Risk Reduction and Risk Management. A report prepared for the UK National Screening Committee.** University of Leicester. March 2008.  - VascularRiskAssessment[1].pdf Cont'd	Thank you. The PDG is aware of the importance of the vascular screening programme and hope that the final recommendations will complement this.

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Stakeholder Organisation	Evidence submitted	Document Name & Number	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Department of Health					**Putting prevention first - Vascular checks: risk assessment and management**. DH. April 2008. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_083822 (This document has been included in NICE's draft scope) - **Putting prevention first - Vascular checks: risk assessment and management: Impact Assessment.** DH. November 2008.http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_090351 - **Putting prevention first. Vascular Checks: risk assessment and management. 'Next Steps' Guidance for Primary Care Trusts.** DH. November 2008. www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyandGuidance/DH_090277 - **Putting Prevention First - NHS Health Check: Vascular Risk Assessment and Management. Best Practice Guidance.** DH. April 2009. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_097489	Thank you for these references.

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Stakeholder Organisation	Evidence submitted	Document Name & Number	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Diabetes UK		**Evidence Review**	General		Diabetes UK would like to highlight the following study: Primary prevention of CVD: physical activity, BMJ Clin Evid 2007; 12:218. This study looks at whether counselling people in the general population increases physical activity, which subsequently has an effect on CVD risk factors. The study found that counselling people to increase physical activity may reduce BMI and blood pressure.	Thank you for all your comments. However, while this study indicates that counselling may be a useful part of a multi-component population programme to prevent CVD, the article does not directly consider the effectiveness of these programmes, and would hence not be included in any of the evidence reviews. NICE is currently developing on guidance on diabetes. We have passed your comments on to the relevant team to help in the development of that piece of work as well. NICE has also already published guidance on brief advice on physical activity ('four commonly used interventions to promote physical activity NICE PH2') and this will be referenced in the guidance.

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Diabetes UK		**Evidence Review**	General		Diabetes UK would also like to highlight the following study: Primary prevention of CVD: diet and weight loss, BMJ Clin Evid 2007; 10:219. This study focuses on interventions to improve diet and promote weight loss. The outcomes of the study lead to changed behaviour, and these changes may prevent CVD. The results showed that advice to reduce sodium intake, saturated fat and increase fruit and vegetable intake reduced cardiovascular risk factors, which may subsequently reduce CVD. Combined interventions ie physical activity plus dietary advice plus behavioural change are more effective than simpler interventions to help an individual lose weight, thereby reducing their CVD risk.	Thank you for asking us to consider this. Although it importantly indicates that various dietary messages like salt reduction may be a useful part of a multi-component population programme to prevent CVD, the article does not directly consider the effectiveness of these programmes, and would hence not be included in any of the evidence reviews. We will however note the article for possible use as part of our general considerations section

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Stakeholder Organisation	Evidence submitted	Document Name & Number	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Diabetes UK		Evidence review	General		Whereas Diabetes UK recognises the following studies are aimed at populations already at high risk of developing Type 2 diabetes and subsequent CVD (people diagnosed with impaired glucose regulation (IGR), we have included the following lifestyle intervention studies for consideration: 1. Chinese Da Qing Study – showed a 42% relative risk reduction (RRR) in Type 2 diabetes over a 6 year period (Pan XR, Li GW, Hu YH, Wang JX, Yang WY, An ZX, et al. Effects of diet and exercise in preventing NIDDM in people with impaired glucose tolerance. The Da Qing IGT and diabetes study. Diabetes Care 1997; 20:537-44) 2. Finnish diabetes prevention study – there was a 58% RRR in Type 2 diabetes over a 3 year period (Tuomilehto J et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med. 2001 3;344(18):1343-50) 3. US Diabetes Prevention Programme – there was a 58% RRR in Type 2 diabetes over a 3 year period. There was also a reduction in CVD (Knowler WC et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. N Engl J Med. 2002 Feb 7; 346(6):393-403.)	Thank you for asking us to consider these articles We can confirm that although each study offers useful indirect evidence on ways to prevent CVD, the papers do not directly address the effectiveness of multi-component population programmes to prevent CVD. An important feature of the populations in our evidence reviews was that the population should be low risk. In these studies individuals at higher than normal risk of diabetes/cvd were randomised to alternative strategies.

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Diabetes UK					4. Japanese prevention study – 67% RRR in Type 2 diabetes over a 3 year period. (Kosaka K, Noda M, Kuzuya T. Prevention of type 2 diabetes by lifestyle intervention: a Japanese trial in IGT males. Diabetes Res Clin Pract 2005; 67: 152-162.) 5. Indian Diabetes Prevention Programme – 29% RRR in Type 2 diabetes over a 2.5 year period (Ramachandran A et al. The Indian Diabetes Prevention Programme shows that lifestyle modification and metformin prevent type 2 diabetes in Asian Indian subjects with impaired glucose tolerance (IDPP-1). Diabetologia. 2006 Feb;49(2):289-97)	

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Diabetes UK		Evidence Review	General		The way messages about risk are communicated to people is important. For example, communicating the risk of CVD in intervention programmes. Therefore, those delivering services should be aware of these uncertainties and needs and tailor care to support and shape perceptions to enhance health-maintaining behaviours**:** **Troughton J, Jarvis J, Skinner C, Robertson N, Khunti K and Davies M. Waiting for diabetes: Perceptions of people with pre-diabetes: A qualitative study. Patient Education and Counselling, July 2008; 72 (1):88-93** The WAKEUP study successfully piloted an educational package to encourage effective communication of key 'health alert' messages between health professionals and people with IGR**:** **Evans PH, Greaves C, et al. Development of an educational toolkit for health professionals and their patients with pre-diabetes: The WAKEUP study (Ways of Addressing Knowledge Education and Understanding in Pre-diabetes. Diabetic Medicine 2007;24:770-7**	We agree that these are both useful studies to help consider the most useful components of a multi-component population programme to prevent CVD. They do not however directly evaluate the effectiveness of such programmes, and so were not included in the evidence reviews.

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Diabetes UK		Evidence Review – Phase 2	General		In reference to the effect of programmes on salt intake, the following intervention aimed at reducing salt intake in school children maybe of interest: http://www.diabetes.org.uk/Professionals/Shared_Practice/Care_Topics/Children_and_Young_People/Frankies-leap-to-health--Aug-2008/	This describes an interesting approach to reducing salt intake, but does not evaluate the effect of this on CVD. Thus although the study might inform the design of a new multi-component population programme to prevent CVD, it does not directly evaluate such a programme and so would not be included in our evidence reviews.
Diabetes UK		Evidence Review	General		Diabetes UK supports the Food Standards Agency (FSA) Traffic Light Food labelling, as this helps the public make informed healthy choices about the food that they buy. A recent FSA report highlights the efficacy of Traffic Light Food Labelling, identifying that people use this particularly when trying to lose weight or reduce their intake of certain nutrients, such as salt and fat. The report Report on comprehension and use of UK nutrition signpost labelling schemes can be found at http://www.food.gov.uk/news/newsarchive/2009/may/pmp	It is very important that food labelling is understood by the public, but this does not equate reduction in CVD, and this is not claimed in the link referred to. Thus, this work although again indicating a possible contributor to a new multi-component population programme to prevent CVD, does not directly evaluate such a programme and so would not be included in our evidence reviews.

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Diabetes UK		Evidence Review	General		Diabetes UK seeks clarification of how NICE intends this guidance to link with the Government's NHS Health Check programme which aims to identify people at risk of CVD through health checks aimed at 40 – 74 year olds. Diabetes UK welcomed the Vascular Risk Assessment and Management Programme and has been calling for proactive and systematic programmes to ensure early identification of people at high risk of Type 2 diabetes and subsequently CVD. Modelling has estimated that the Programme has the potential to prevent at least 4,000 people a year from developing diabetes[1]. 1. http://www.diabetes.org.uk/Documents/Professionals/040908early_identification_positionand%20VRAM%202008%20FINAL.doc A link to the recent NHS Health Check report can be found at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_097489	We agree that the NHS Health Check programme is an important intervention which complements the approach taken in this guidance. We will ensure that there is adequate linkage to the programme in the published guidance.

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Diabetes UK		Evidence Review	General		Will NICE be considering the following examples of mass media campaigns? Change for Life http://www.nhs.uk/change4life/Pages/Default.aspx Measure Up campaign This Diabetes UK campaign raises awareness of the risk factors for Type 2 diabetes, including obesity and overweight http://www.diabetes.org.uk/Measure_Up_-_are_you_at_risk_of_diabetes/	We agree that mass media campaigns may be important. However, we are not aware of evaluations of these two particular campaigns.

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Stakeholder Organisation	Evidence submitted	Document Name & Number	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Diabetes UK		Evidence Review	General		Diabetes UK would like to highlight the following local examples of practice aimed at CVD prevention. We have also included an example of a toolkit which empowers local community leaders to raise awareness and increase understanding of diabetes and its management amongst the South Asian community: http://www.diabetes.org.uk/Professionals/Shared_Practice/Care_Topics/Black_and_Minority_Ethnic_Communities/Apnee_Sehat_Our_HealthbrMay_2006/ http://www.diabetes.org.uk/Professionals/Shared_Practice/Care_Topics/Black_and_Minority_Ethnic_Communities/Toolkit_to_Support_the_Running_of_Diabetes_Awareness_Events_for_the_South_Asian_Communities/ An example of a film made to raise awareness of heart disease in the South Asian community. Further details can be obtained from the South Asian Health Foundation. http://www.sahf.org.uk/Members.aspx?id=16	Thank you. These resources are useful to local practitioners. We will ensure that the references are forwarded to our implementation team.

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Stakeholder Organisation	Evidence submitted	Document Name & Number	Section Number	Page Number	Comments Please insert each new comment in a new row.	Response Please respond to each comment
Diabetes UK		Evidence Review	General		This article may be of interest for the following reasons: • The study makes recommendations about improving services for people from BAME communities. • Amongst other recommendations the study identifies the need: • To have a culturally competent workforce through staff training • To provide bi-lingual services for effective communication • To engage the local community in the development of services • The study shows the efficacy of local programmes that have been aimed at ethnically diverse populations GYH Lip, AH Barnett et al (2007) *Ethnicity and Cardio Vascular Disease Prevention in the UK: A practical approach to management* Journal of Human Hypertension 21, 183-211	This is indeed an interesting paper which considers issues relating to equity, including between ethnic groups. However unfortunately it does not provide direct evidence on the effectiveness of multi-component population programmes to prevent CVD, or differential effectiveness depending on the ethnic mix of the populations in which the programmes were implemented and so cannot be included in our evidence reviews.

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McNeil Nutritionals Ltd		**Paper 10**	General/ paper		Plant stanols and sterols We wish to highlight that It is particularly noteworthy in relation to this consultation that the **European Food Safety Authority** has recently provided two separate positive opinions in relation to the cholesterol lowering effect of plant stanols and sterols after reviewing comprehensive scientific dossiers and concluded that, as an example in the case of plant stanols, "***Plant stanol esters have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of coronary heart disease"*** *(1.* Plant stanol and sterol esters have been proven to reduce cholesterol in various populations (2,3) and several clinical studies show that the serum cholesterol lowering effect is sustained as long as consumption is maintained. Miettinen et al. 1995 (2) studied the effect of plant stanol ester margarine on serum blood lipids in a mildly hypercholesterolemic population for 12 months. The cholesterol lowering effect was sustained as long as the study subjects consumed the plant stanol ester margarine and led to a significant reduction in low density lipoprotein (LDL) cholesterol. Similarly, De Jong et al. 2008 (4) studied the long-term effects of plant sterol or stanol ester consumption on lipid and lipoprotein metabolism in subjects on statin treatment for 85 weeks. LDL-cholesterol was decreased by 11.6 % after 45 weeks in the plant sterol group and by 8.7 % after 85 weeks. For the plant stanol ester group LDL-cholesterol was decreased by 8.7 % after 45 weeks and by 13.1 % after 85 weeks. Cont'd	Thank you for this information. The studies do not fit into the scope of our literature review, as they did not examine the effectiveness of a programme addressing multiple risks

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McNeil Nutritionals Ltd					For the plant stanol ester group LDL-cholesterol was decreased by 8.7 % after 45 weeks and by 13.1 % after 85 weeks. As plant stanol ester margarine has been on the Finnish market since 1995 blood lipid data from individual subjects that have used plant stanol ester margarine for more than 10 years exist and show a sustained lowering of blood cholesterol with consumption of plant stanol (5). Subjects consuming these ingredients consistently observe significant reductions in LDL cholesterol, a proven risk factor for cardiovascular disease (CVD) (3). These data demonstrate a diet based approach to reducing the burden of CVD risk in various specific populations. Cont'd	See comments above.

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McNeil Nutritionals Ltd					The burden of CVD is also reduced in the broader community where these ingredients are available. The Doetinchem Cohort Study (6), examined the customary use and effects of phytosterol consumption over a five year period in 4505 subjects. Subjects reported intakes using food frequency questionnaires and blood samples were collected. The data indicate that while the customary use of phytosterol enriched products was below recommended levels, increases in cholesterol levels were halted in those reporting the ingredients use. A 0.26 mmol/L increase in serum cholesterol was observed in those participants not reporting use of phytosterols. Stabilization of cholesterol can be equally important because the burden of CVD risk is still effectively minimized. Based on these data and data from clinical studies with better compliance and use of the recommended levels of the ingredients would further enhance the benefit to the community, moving from maintenance to reduction. A follow up study (7) in this population indicates cholesterol lowering versus maintenance can be achieved. The population of users being studied had a lower cholesterol (0.24 mmol/L) vs. baseline. The non user group, as it did in the previous study, had increased cholesterol levels.	See comments above.

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McNeil Nutritionals Ltd			General/ Paper		Using other population data (the National Health Survey for England) the potential benefit of a more global approach to heart health with these ingredients (i.e. phytostanols/phytosterols) has been simulated (8). The CVD levels of the populations were estimated using the Framingham equation applied to the data from the National Health Survey for England. The population simulated was one that was free of atherosclerosis and diabetes. Modeling this population free of high risk individuals provides a better sense of how a community would benefit from public health programme based on these ingredients. The models built were successful in replicating the epidemiology data that has indicated the benefits of universally lower cholesterol levels. Models of universal use of phytosterols (target goal of total cholesterol being reduced 0.5 mmol/L) resulted in a 11.8 percent reduction in CVD events. Not only is this significant from a CVD perspective, it would also represent a large economic savings. While there are limitations to the methodology, the models still give good insight into how tools available in the community can be leveraged with potentially large benefits. It is also safe to assume that public health programmes including these ingredients would be easy to execute. The supply of these products in the market is stable, the science behind the benefits is robust (tested in many populations and approved by scientific and regulatory bodies), the ingredients are safe for ages 5 and older and are available in foods that people are familiar with (the ingredients are flexible and can be put in a large variety of matrices). These foods could easily fit into healthy balanced diets.	See comments above.

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McNeil Nutritionals Ltd					Reference List 1. Plant stanol esters and blood cholesterol. Scientific substantiation of a health claim related to plant stanol esters and lower/reduced blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006. EFSA Journal 2008, 852,1-13 2. Miettinen TA, Puska P, Gylling H, Vanhanen H, Vartiainen E. Reduction of serum cholesterol with sitostanol-ester margarine in a mildly hypercholesterolemic population. N Engl J Med 1995;333:1308-12. 3. Law MR. Plant sterol and stanol margarines and health. West J Med 2000;173:43-7. 4. de Jong A, Plat J, Lutjohann D, Mensink RP. Effects of long-term plant sterol or stanol ester consumption on lipid and lipoprotein metabolism in subjects on statin treatment. Br J Nutr 2008;100:937-941. 5. Gylling H, Miettinen TA. The effect of plant stanol- and sterol-enriched foods on lipid metabolism, serum lipids and coronary heart disease. Ann Clin Biochem 2005;42:254-263	See comments above.

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McNeil Nutritionals Ltd					6. Wolfs M, de JN, Ocke MC, Verhagen H, Monique Verschuren WM. Effectiveness of customary use of phytosterol/-stanol enriched margarines on blood cholesterol lowering. Food Chem Toxicol 2006;44:1682-8. 7. de JN, Zuur A, Wolfs MC, Wendel-Vos GC, van Raaij JM, Schuit AJ. Exposure and effectiveness of phytosterol/-stanol-enriched margarines. Eur J Clin Nutr 2007;61:1407-15. 8. Reynolds TM, Mardani A, Twomey PJ, Wierzbickid AS. Targeted versus global approaches to the management of hypercholesterolaemia. J R Soc Promot Health 2008;128:248-54.	See comments above.
MRC Collaborative Centre for Human Nutrition Research		**Evidence Reviews 1, 2, 3**	General	N/A	We recognise the large amount of work that has gone into conducting these systematic reviews in a relatively short timeframe. Nevertheless we have general concerns about the review methods and interpretation of the findings, which are outlined below:	Thank you.

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MRC Collaborative Centre for Human Nutrition Research		**Evidence Review 3**	3.3 – Summary of the evidence	124	The graphs do not include estimates of variability (e.g. 95% confidence intervals) for point estimates and thus it is not possible to determine statistical or clinical significance of the effect sizes. Further, equal weighting is given to all studies whereas a more appropriate method to reduce bias would be to weight results by study size.	Thank you for drawing our attention to an important limitation in our review. However we do acknowledge this and discuss its implications, particularly in section 4.5 of review 3 Specifically 95% CI cannot be constructed because the majority of the included studies do not have the appropriate statistical information in the papers. It may have been possible with more time to infer 95%CIs or gain information from authors directly, but this was not possible in the time available, particularly taking into account that this was only one of series of evidence reviews. Concerning weighting, as we have not formally meta-analysed the data we have not given any weight to any of the studies. The idea of weighting by study size is interesting but would not receive much support from the text-books, a further complexity being that it is not clear whether the weight by size of the controlled before-after studies should be based on the size of the population subjected to the programme or the size of the population/s used to evaluate outcomes.

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MRC Collaborative Centre for Human Nutrition Research			3.3 - Evidence statement	146	The approach taken in the three evidence statements is to describe the direction of effect of individual studies (positive or negative) rather than providing a quantified effect size. Thus it is impossible to determine how statistically or clinically significant the findings of studies really are. This “vote counting” approach is misleading and fails to provide a robust summary of the evidence necessary for the development of appropriate guidance.	The lack of usable information on dispersion mentioned in the previous response also explains our inability to meta-analyse the results. Without this it is difficult to reliably incorporate estimates of size of effect into conclusions. The poverty of reporting/analysis of the results of the included studies also affected our confidence in the meaning of tests of statistical significance offered in many papers. We were only left with the option of vote-counting. We acknowledge its limitations but believe we have been suitably cautious in our interpretation. We are also clear that not offering the PDG any summary because of the shortcomings of “vote-counting” was a worse alternative. We would definitely welcome your thoughts on how the problem we encountered could have been overcome as it is an issue likely to be encountered by NICE again in the future.

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MRC Collaborative Centre for Human Nutrition Research			3.3 - Evidence statement	146	Findings from different study designs (e.g. controlled before and after studies, and randomised controlled trials [RCT]) have been combined. Such grouping fails to acknowledge the higher quality of RCTs and gives equal weighting to studies of variable quality. We believe studies of different designs should be considered separately.	We believe the separation between RCTs and CBAs is completely transparent already. We have not attempted to combine the results of RCTs with CBAs. Further an interesting feature which we observed was the high degree of inter-dependence between study design and type of programme evaluated. Individually randomised RCTs are not feasible when evaluating population level programmes; we only encountered these in the large scale screening initiatives we included. Thus separating, and possibly excluding studies on the basis of "quality", itself potentially introduces bias by excluding a particular type of intervention, which was in fact the one of particular interest to NICE.
MRC Collaborative Centre for Human Nutrition Research			4.3 – Outcomes	191	The self-reported nature of most dietary measures (as compared with physiological measures of other risk factors e.g. BP, cholesterol, BMI) means dietary findings are at particular risk of reporting bias due to the unblinded nature of the interventions. Thus we believe more caution should be applied to interpreting self-reported dietary results.	Again we acknowledge this and discuss the limitations of the results based on these outcome measures. We believe we have already been highly, and appropriately, cautious in our interpretation of them.

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MRC Collaborative Centre for Human Nutrition Research			4.5 – Limitations of the review	203	There is inadequate discussion of likely publication bias, particularly with respect to studies with positive findings being more likely to be published than those with negative results. Thus we believe the evidence presented is likely to have a positive bias.	We recognise and discuss the possibility of publication bias in several places. Unfortunately it is not self-evident that publication bias is likely to have a major impact on the results: a) searching was not confined to published studies, although we acknowledge that given more time further searches for grey literature could have been done b) the results are near to the null, so it is as likely that disappointing positive results may not have been published to a similar degree as negative results (we have one anecdotal case where this may have occurred) c) the clarity of presence or absence of statistical significance (a further aspect of publication bias) is also blurred in this topic On balance we believe appropriate emphasis has been placed on publication bias, and the related phenomenon of selective reporting of outcomes with positive results.

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MRC Collaborative Centre for Human Nutrition Research		**Evidence reviews 1, 2, 3**	General	N/A	We are concerned that the focus on multiple risk-factor interventions means that important findings from relevant single-factor intervention studies have been overlooked. For example, there is no discussion of the DASH (Dietary Approaches to Stop Hypertension) trials[1]. Furthermore it is unclear why some multiple risk factor interventions that appear directly relevant, such as PREMIER[2] and DPP[3], are missing. Restricting the scope of the evidence review to this extent may have made it manageable but ultimately less useful.	The evidence reviews addressed the scope requested. We acknowledge that single-factor population programmes may be important but this was outside the scope of the guidance and the evidence reviews. We comment on this in section 4.5 p203 Concerning the missing studies none directly address the effectiveness of multi-component population programmes to prevent CVD. In 1 (DASH) meals were supplied to a relatively small number (459) individually randomised participants. It is debatable whether this is either multi-component or scalable to a point where it could be considered part of a population programme. We freely acknowledge that this study provides important information on what the components of such a programme might be, but this does not make it eligible for the evidence reviews in question.

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MRC Collaborative Centre for Human Nutrition Research		**Expert papers**	General	N/A	The rationale for the various expert papers is vague. It is unclear why these particular topics were chosen for expert review and on what basis the expert authors were selected.	The expert papers were requested by the PDG. Where suitable expertise was not available within the group itself, papers were requested from outside experts.

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MRC Collaborative Centre for Human Nutrition Research					[1] Appel LJ, et al. A clinical trial of the effects of dietary patterns on blood pressure. *New England Journal of Medicine* 1997;336(16):1117-24 [2] Appel LJ, et al. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial. *Journal of the American Medical Association* 2003;289(16):2083-93 [3] Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *New England Journal of Medicine* 2002;346(6):393-403	Reference 1) looks at a single factor intervention in a small population of volunteers rather than in the general population. The intervention was to compare blood pressure in groups fed one of three diets prepared in research kitchens In 2. (PREMIER) one of the interventions evaluated is much more convincingly multi-component, but the scale is again small with just 810 subjects being randomised between three different interventions. Thus although the study contributes to an understanding of what might be effective components of a population level programme, it is not a direct evaluation of one, and hence was not included. Finally in 3. as already discussed in a response to Diabetes UK the main issue limiting relevance to addressing the scope question on effectiveness of multi-component population programmes to prevent CVD is that the population in this study is at much higher risk of CVD than an average general population. This is again not to understate the indirect value of this study.

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NHS Sefton		The Handbook for Vascular Risk Assessment, Risk Reduction and Risk Management	Section 1	7	The terms 'Health Check' and 'Screening' need to be clarified, especially as what is being proposed is NOT population level screening for CVD.	Terms such as 'health check' and 'screening' are used in the evidence reviews within the context of the studies that report on them.

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NHS Sefton		Putting Prevention First NHS Health Check: Vascular Risk Assessment and Management Economic Modelling for Vascular Checks	Section 11 Appendix C	25	Clarification on which Framingham derivative or QRISK2: There are several Framingham based including CVD (BNF) CVD Framingham and JBS2. There seems to be a variation between the scores given (for example same patient, CVD Framingham 29, JBS2 21 and QRISK 2, 19). Result: possible confusion for patients and also the number requiring a review. In one practice locally, CVD Framingham approx 230 pt, JBS2 168 and QRISK 158. QRISK estimates 8% as high risk where Framingham 13%!	This comment appears to be about 'putting prevention first' rather than the NICE reviews and expert papers produced for the production of NICE guidance on prevention of CVD at population level.

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NHS Sefton		Primary Care Service Framework: Vascular Checks	3. Scope and Definition of the Service	2	Age range: 40 – 74 with flexibility to include wider age range. What is the rationale for 40-74 when much of Framingham was based on 32 – 74 and so is QRISK.	This comment appears to be about 'primary care service framework: vascular checks' rather than the NICE reviews and expert papers produced for the production of NICE guidance on prevention of CVD at population level.
NHS Sefton		Primary Care Service Framework: Vascular Checks (also CVD_EF3v1)	10. Integrated Governance	10	Guidance needed as to skill sets required for different patient groups. I.e. for patients that are thought to be low risk, could they be managed by a health trainer while those that are known to be high risk may need to be managed by a general practitioner?	This comment appears to be about 'primary care service framework: vascular checks' rather than the NICE reviews and expert papers produced for the production of NICE guidance on prevention of CVD at population level.
NHS Sefton		Primary Care Service Framework: Vascular Checks	10. Integrated Governance	10	Support in writing of patient group directives.	This comment appears to be about 'primary care service framework: vascular checks' rather than the NICE reviews and expert papers produced for the production of NICE guidance on prevention of CVD at population level.

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NHS Sefton		Putting Prevention First NHS Health Check: Vascular Risk Assessment and Management	13. Risk Management and lifestyle interventions	28	It is important to emphasise that "*everyone* who has a NHS health check, regardless of their risk score, should be given lifestyle advice, where clinically appropriate, to help them manage their risk"	This comment appears to be about 'putting prevention first' rather than the NICE reviews and expert papers produced for the production of NICE guidance on prevention of CVD at population level.
NHS Sefton		Economic Modelling for Vascular Checks	41 Link Simulation results with cost effectiveness data	18	Cost benefit analysis of annual reviews for those known to be at high risk.	This comment appears to be about 'economic modelling for vascular checks' rather than the NICE reviews and expert papers produced for the production of NICE guidance on prevention of CVD at population level.
NHS Sefton		Economic Modelling for Vascular Checks	15. Interventions offered	9	Combination of interventions and more information as to which are cost effective and the numbers who will require one or more intervention. How to plan services accordingly for a 5 year rolling programme.	This comment appears to be about 'economic modelling for vascular checks' rather than the NICE reviews and expert papers produced for the production of NICE guidance on prevention of CVD at population level.

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NHS Sefton		Economic Modelling for Vascular Checks	C. Workforce impact (results section)	34	Capacity considered only if both vascular checks and subsequent interventions are managed in general practice. More detail needed on how to break down costing. For example: phlebotomy services (increased blood tests), use of Gym and other physical activity and weight management programmes, how about costing of pharmacists or health trainers' offering the checks.	This comment appears to be about 'economic modelling for vascular checks' rather than the NICE reviews and expert papers produced for the production of NICE guidance on prevention of CVD at population level.
Novo Nordisk Ltd		Prevention of CVD EP4 – Commercial Interests	Annex A Row heading 'Pharmaceutical Companies', column heading 'Lobbying'	10	As a point of clarification, Novo Nordisk (not Novartis) is one of the corporate partners of the Oxford Health Alliance. Novo Nordisk's mission is to defeat diabetes by supporting primary prevention of the development of diabetes, improving secondary prevention of the complications of diabetes and by researching new technologies that will ultimately yield a cure for diabetes. In doing so, we aim to engage collaboratively with other stakeholders from the public, private and voluntary sector who share our vision.	Thank you
Royal College of Nursing		General	General		There does not seem to be any reference to clinical networks. We would suggest that such bodies would have potential value in this area, specifically cardiac, stroke and diabetes networks.	Thank you. These networks may be important in implementing recommendations.

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Servier Laboratories Ltd		General	General		There is a wealth of evidence demonstrating that resting heart rate independently predicts all-cause and cardiovascular mortality in the general population (see Draft Scope comments). Heart rate can be easily measured and recorded, and provide clinicians with important information when evaluating patients. There is also good evidence that reducing heart rate is an effective secondary preventative measure, as demonstrated in BEAUTIFUL for example in a sub-group of patients with resting heart rate greater than 70bmp. Whilst lifestyle adaptations that are associated with a reduction in resting heart rate are generally felt to be beneficial, we acknowledge that the effects of pharmacologically lowering resting heart rate in the general population are unknown.	Thank you. This guidance does not cover clinical interventions. Use of heart rate may be a useful technique but is outside the scope of this work.

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UK Faculty of Public Health		Reviews 1,2 & 3: Effectiveness	General		This systematic review represents an exhaustive trawl through the literature on multifactorial interventions in community settings. It is thus useful within this narrow context, which sadly now looks rather dated. As stakeholders consistently emphasised when commenting on the scope in 2008, the issue in the 21st century will be the effectiveness and cost-effectiveness of interventions targeting SINGLE important risk factors (such as smoke free bans, FSA programmes to reduce dietary salt etc). The widening of the original (over-narrow) scope is thus very welcomed. The decision to commission relevant evidence from experts is also very valuable.	Thank you.

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UK Faculty of Public Health		Review 4: Cost-Effectiveness	General		This is a disappointing paper. It confines itself to the original (over-narrow) scope. Much of the reviewing work was apparently done by researchers not experienced in CVD epidemiology or health economics. Furthermore, this general review has missed key papers from Australia and the USA. These are appended. Failing to review the cost-effectiveness of single interventions is a major limitation. Happily that crucial issue has been addressed in most of the expert papers.	These reports do not meet the inclusion criteria for the cost-effectiveness review. However, the PDG is aware of these reports and they are referenced in the modelling report.
UK Faculty of Public Health		Review 5: Qualitative studies	General		This is an outstanding review of the key factors which facilitate or obstruct the success of community-based multifactorial risk factor programmes. A corresponding review of single factor interventions would be equally valuable.	Thank you.
UK Faculty of Public Health		Review 6: Primary Qualitative study	General		No comment	Noted
UK Faculty of Public Health		Expert papers	General		These are mostly excellent. The inclusion of cost-effectiveness issues in many is very welcome.	Thank you.

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UK Faculty of Public Health			General		We understand that papers have also been produced on cardiovascular risk factor pathways, lessons from CVD trends in other countries, and the potential effects of CVD prevention programmes on inequalities. These latter papers are not currently provided on the NICE consultation website; they will also need to be exposed to peer review and public scrutiny.	Additional expert papers have been consulted on during the second consultation period.

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Unilever UK	7. Poli et al Non-pharmacologi 6-AHA - Lichtenst AH and Arterioscle 5-NCEP Expert Pa JAMA 2001 2486- 4-IAS executive summary.pdf 3-AbuMweis et a Food and Nutr Re 2-Demonty 2009 Nutr.pdf 1.EFSA Opinion pl sterols.pdf	European Food Safety Authority (EFSA) review – Plant Sterols and Blood Cholesterol. (1)	General		This EFSA opinion confirms the cholesterol lowering efficacy of plant sterols, and agrees with established evidence that lowering cholesterol has been shown to reduce the risk of coronary heart disease. The panel considers that the following wording reflects the available scientific evidence: "Plant sterols have been shown to lower/reduce blood cholesterol. Blood cholesterol lowering may reduce the risk of coronary heart disease".	Although of general interest in prevention of CVD, the information provided is outside the scope of the guidance.

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Unilever UK		Recent meta-analysis on plant sterols – Demonty et al (2)	General		This meta-analysis confirms the dose-dependent LDL-cholesterol lowering efficacy of phytosterols in various food formats. This meta-analysis strengthens the evidence that 2g/day of phytosterols lower LDL-cholesterol.	See comments above
Unilever UK		Recent meta-analysis on plant sterols – AbuMweis et al. (3)	General		This meta-analysis confirms the dose-dependent LDL-cholesterol lowering efficacy of phytosterols in various food formats evaluating response according to baseline LDL-cholesterol, food carrier and the frequency and time of intake.	See comments above
Unilever UK		International Atherosclerosis Society – 'Harmonized Guidelines on Prevention of Atherosclerotic Vascular Disease' (4)		18	2g a day of plant sterols included in dietary advice for preventing cardiovascular disease.	See comments above

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Unilever UK		National Cholesterol Education Program ATP III guidelines (5)		2490	Plant sterols are included in the list of dietary changes that aim to enhance lowering of LDL cholesterol concentrations.	See comments above
Unilever UK		Summary of American Heart Association (AHA) Diet and Lifestyle Recommendations Revision 2006 – Lichtenstein et al. (6)		2189	In this summary, plant sterols are seen as a therapeutic option in addition to diet and lifestyle modification for individuals with elevated LDL-cholesterol levels.	See comments above

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Unilever UK		Nutrition Foundation of Italy - consensus document on non-pharmacological control of plasma cholesterol levels. Poli et al (7)		S10-S11	The document shows that plant sterols are included in this Italian consensus document and recommended for cholesterol lowering.	See comments above
Unilever UK		General			Endpoint studies with clinical outcomes are unlikely ever to be performed due to the large scale required, design difficulties (e.g. opportunities for confounding), ethical considerations and cost. Almost all dietary recommendations are based on epidemiological data or intervention studies on surrogate biomarkers such as LDL- cholesterol.	Thank you for this very relevant observation, which we have noted.

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Unimedic Ltd	 ajh 2004 17 118.  AJH 2002 15 445.  AIx CAD Weber.  A. Simon J Hypertens 2005.  Arteriograph invasive validation  Miklos_Illyes-Caro Arteriograph.pd	**General**	General		As the performance of risk assessment is crucial in achieving population-level primary prevention of CVD, improving the identification of asymptomatic but high risk individuals has to be a priority. The advancement of technology already made ultra-non-invasive Central Blood Pressure, Aortic Pulse Wave Velocity and Augmentation Index measurement routinely available even in the everyday clinical practice. Medical evidence shows that compared to regular, peripheral blood pressure the central, aortic one is more accurate in terms of predicting cardiovascular risk. Aortic Pulse Wave Velocity is also proven to have huge importance, as it is the direct measure of the functional and structural changes of the aorta, due to arteriosclerosis. Augmentation Index is an early stage marker, reflecting the impairment of small arteries' vasodilation - endothelial dysfunction. The mentioned parameters (most of them already included as an independent risk factor in the latest ESC & ESH Guidelines) represent the combined effects of the classical risk factors thus identifying the stage of arteriosclerosis. Cont'd	Although of general interest in prevention of CVD, the information provided is outside the scope of the guidance

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Unimedic Ltd	 CentralBP-consen -JHypert'07.pd  CentralAorticBP-A o-Hypert'08.pd  Better Manageme of Cardiovascular  Baulmann validation-J-Hyper  ASCOT CAFE.pd  ArtStiff&DRUX-Ma ud-ArtRes.pdf				Unfortunately the current approach does not take these small and large arterial function and structure measures into account at all, although reportedly they perform significantly better on the level of the individual in predicting CVD, than the estimation by statistics based QRISK or Framingham. Health inequalities could be easily reduced too, as point of care testing in primary care, community and pharmacy based settings are all available in this respect, fulfilling the priorities of the program. If arteriosclerosis in this way would be diagnosed at the early (potentially reversible) stage, the load and cost of secondary care could be significantly reduced. On the other hand the feasibility, clinical and cost effectiveness of a validated system (Arteriograph) in different population groups and settings is just being piloted by Ealing PCT. Please find attached some additional evidence for your consideration.	The current guidance deals with primary prevention before the development of atherosclerosis. Clinical assessment and possible pharmacological interventions such as those discussed here are outside the scope of this guidance.

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	Mayo_Ca_score_I V.pdf Jupiter - statins non-hypercholest ESRD_prognstic-H 2005.pdf ESHguidelines200 df Diabetes.pdf Danish_popul_PW CIRC2005.pdf					

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	Subclin_detection-P2006.pdf StrongHeartStudy oman-Hypert'07.p SHAPE-TaskForce 0III%202006.pd RotterdamStudy-(-'06.pdf McEniery SBPao.p					