

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

# **PUBLIC HEALTH DRAFT GUIDANCE**

Issue date: March 2010

## **Prevention of cardiovascular disease at population level**

NICE public health guidance x

### **Introduction**

The Department of Health (DH) asked the National Institute for Health and Clinical Excellence (NICE) to produce public health guidance on the prevention of cardiovascular disease (CVD) at population level. (CVD includes coronary heart disease [CHD], heart failure, stroke and peripheral arterial disease.)

The guidance is for government, industry, the NHS and all those whose action influences the population's cardiovascular health. This includes professionals, commissioners and managers working in local authorities, education and the wider public, private, voluntary and community sectors. It may also be of interest to members of the public.

The guidance complements, but does not replace, NICE guidance on smoking cessation, physical activity, obesity and maternal and child nutrition (for further details, see section 7). It will also complement NICE guidance on alcohol which is currently under development.

The Programme Development Group (PDG) has considered both the reviews of the evidence and the economic analysis.

This document sets out the Group's preliminary recommendations. It does not include all sections that will appear in the final guidance. NICE is now inviting comments from stakeholders (listed on our website at: [www.nice.org.uk](http://www.nice.org.uk)).

**Note that this document does not constitute NICE's formal guidance on prevention of cardiovascular disease at the population level. The recommendations made in section 4 are provisional and may change after consultation with stakeholders and fieldwork.**

The stages NICE will follow after consultation (including fieldwork) are summarised below.

- The Group will meet again to consider the comments, reports and any additional evidence that has been submitted.
- After that meeting, the Group will produce a second draft of the guidance.
- The draft guidance will be signed off by the NICE Guidance Executive.

For further details, see 'The NICE public health guidance development process 2009: An overview for stakeholders including public health practitioners, policy makers and the public (second edition)' (this document is available at [www.nice.org.uk/phprocess](http://www.nice.org.uk/phprocess)).

**The key dates are:**

Closing date for comments: 16 November 2009.

Next Group meeting: 19 November 2009.

Members of the PDG are listed in appendix A and supporting documents used to prepare this document are listed in appendix E.

This guidance was developed using the NICE public health programme process.

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## 1 Key priorities

This section will be completed in the final document.

## 2 Public health need and practice

Cardiovascular disease (CVD) is generally due to reduced blood flow to the heart, brain or body caused by atheroma or thrombosis. It is increasingly common after the age of 60, but rare below the age of 30. Plaques (plates) of fatty atheroma build up in different arteries during adult life. These can eventually cause narrowing of the arteries, or trigger a local thrombosis (blood clot) which completely blocks the blood flow. The main types of CVD are coronary heart disease (CHD), stroke or peripheral arterial disease (PAD) (British Heart Foundation 2009).

A large number of preventable illnesses and deaths are associated with CVD. Globally, it is the leading cause of death (World Health Organization 2007).

In the UK, it led to over 190,000 deaths (accounting for 40% of all deaths in the UK) in 2007. Specifically, there were 91,458 deaths from coronary heart disease (CHD) and 53,186 from stroke (Heartstats 2009). In 2006, 30% of premature deaths among men (that is, among men aged under 75) and 22% of deaths among women aged under 75 were caused by CVD, accounting for just over 53,000 premature deaths in that year.

More than 4 million people in the UK are currently affected by the condition and it costs the UK approximately £30 billion annually (Luengo-Fernandez et al. 2006).

Despite recent improvements, UK death rates from CVD are relatively high compared with other developed countries (only Ireland and Finland have higher rates). There is also considerable variation within the UK itself – geographically, ethnically and socially. For instance, premature death rates from CVD are up to six times higher among lower socioeconomic groups than among more affluent groups (O’Flaherty et al. 2009). In addition, death rates

from CVD are approximately 50% higher than average among South Asian groups (Allender et al. 2007). The reduction in CVD-related risks among younger men (and perhaps women) over previous years seems to have stalled from around 2003. This is the case in a number of countries including Scotland (O'Flaherty et al. 2009), Australia (Wilson 1995) and the United States (Ford and Capewell 2007).

The higher incidence of CVD is a major reason why people living in areas with the worst health and deprivation indicators (the Spearhead areas) have a lower life expectancy compared with those living elsewhere in England. For males, it accounts for 35% of this gap in life expectancy (70% of this is due to CHD). Among females, it accounts for 30% of the gap (63% of this is due to CHD) (DH 2008a).

In 2009, the Cardio and Vascular Coalition published 'Destination 2020', the voluntary sector's plan for cardiac and vascular health (Cardio and Vascular Coalition 2009).

### ***Risk factors***

CVD is influenced by a variety of 'upstream' factors (such as food production, access to a safe environment that encourages physical activity and access to education) and 'downstream' behavioural issues (such as diet and smoking)

In more than 90% of cases, the risk of a first heart attack is related to nine potentially modifiable risk factors (Yusuf et al. 2004):

- smoking/tobacco use
- poor diet
- insufficient physical activity
- high blood pressure
- obesity/overweight
- diabetes
- psychosocial stress (linked to people's ability to influence the potentially stressful environments in which they live)

- alcohol consumption
- high blood cholesterol.

Actions which impact on the whole population most effectively reduce these risk factors (Kelly et al. 2009). Other factors, such as maternal nutrition and air pollution may also be linked to the disease (Allender et al. 2007).

Reducing the risks by, for example, reducing cholesterol or blood pressure levels, quitting tobacco or improving dietary intake can rapidly reduce the likelihood of developing CVD. For example, it is estimated that around 70,000 premature deaths a year in the UK (the majority caused by CVD, with some deaths from cancers) could be avoided if people's diets matched nutritional guidelines (Strategy Unit 2008).

### ***Tackling the risk factors***

Some population-based prevention programmes have been accompanied by a substantial reduction in the rate of CVD deaths. However, the degree to which these are attributable to the programme is contested. This is due to a number of reasons including:

- It is difficult to design studies which evaluate entire cities, regions or countries or are of sufficient duration.
- Control sites can become 'contaminated' (that is, if the intervention affects people living in the control area).
- There may be unreasonable expectations about the speed of change.
- Behaviour change is often erratic or slow.
- Failure to address 'upstream' influences such as policy or manufacturing and commercial practices.

The crucial importance of using policy to modify population-wide CVD risk factors has been recognised on an international, European and national level. For example, the World Health Organization's (WHO) first global treaty on

health, the 'Framework convention on tobacco control' (2003) undertook to enact key tobacco control measures, such as tobacco tax increases, smokefree public places, and tobacco advertising controls. Parties to the treaty included the UK.

In 2004, WHO member states also agreed to a non-binding global strategy on diet, physical activity and health. In addition, since 1993 the European Union (EU) has legislated on issues such as advertising and the labelling of consumer products like food and tobacco.

### ***Government policy***

Government policy in many areas influences CVD, and policy documents from many departments and agencies are important. The 'Choosing health' white paper (DH 2004) set priorities for action on nutrition, physical activity, obesity and tobacco control. It was supported by delivery plans on food, physical activity and tobacco control, including the provision of NHS Stop Smoking Services.

Since that time, a wide variety of policy documents have been published to help prevent CVD, including:

- 'Commissioning framework for health and well-being' (DH 2007a)
- 'Delivering choosing health: making healthier choices easier' (DH 2005a)
- 'Health challenge England – next steps for choosing health' (DH 2006a)
- 'Healthy weight, healthy lives: a cross-government strategy for England' (DH 2008b)
- 'National stroke strategy' (DH 2007b)
- 'Our health, our care, our say' (DH 2006b)
- 'Putting prevention first – vascular checks: risk assessment and management' (DH 2008c)
- 'Tackling health inequalities – a programme for action' (DH 2003)
- 'Tackling health inequalities: what works' (DH 2005b)
- 'Tackling health inequalities: 2007 status report on the programme for action' (DH 2008a)

- 'The NHS in England: the operating framework for 2006/7' (DH 2006c)
- 'The NHS in England: the operating framework for 2008/9' (DH 2007c)
- 'Wanless report: securing good health for the whole population' (Wanless 2004).

In 2008, 10 years after publication of the first tobacco white paper, 'Smoking kills', the Department of Health held a consultation on the future of tobacco control. A new tobacco white paper is expected later in 2009.

### 3 Considerations

The Programme Development Group (PDG) took account of a number of factors and issues when developing the recommendations.

#### *Introduction*

- 3.1 Evidence was presented on how to prevent or reduce the combination of risk factors that can cause cardiovascular disease (CVD). The PDG felt it was also important to consider the key risk factors separately and so expert testimony was invited on specific topics and relevant existing NICE guidance was summarised. The reviews, together with the expert testimonies, are listed in appendix A.
- 3.2 CVD risk factors can be reduced in a number of ways. For instance, people can be directly encouraged to change their behaviours by providing them with information about health risks, advice to be more active or by prescribing a treatment. NHS and other organisations can be changed by altering the way prevention or health care services are delivered. The environment can also be changed by altering the physical layout of towns and cities. In addition, laws, taxation and national policy can be used to help change the risks faced by an entire population.
- 3.3 Epidemiological studies indicate that approximately 45–75% of the recent fall in CVD deaths in industrialised countries was as a result of prevention activities. Around 25–45% of the decrease was due to treatment.
- 3.4 The PDG noted that CVD death rates are no longer falling among young people in the UK (for instance, among those aged 35–54 in the most socially deprived groups in Scotland), the USA and Australia. This reflects a combination of adverse risk factors including smoking, a poor diet and deprivation (O’Flaherty et al. 2009).

- 3.5 The government's health checks programme ('Putting prevention first') focuses on identifying, measuring and addressing CVD risk factors (such as high blood pressure and high cholesterol) among people aged between 40 and 74. The NICE guidance complements the health checks programme by focusing on reducing the risk factors for an entire population. This will benefit the NHS, local authorities and industry, as well as individuals, by substantially reducing the number of people who need statin or anti-hypertensive medication. It will also enable services to focus on those who need treatment.
- 3.6 The falls in blood pressure and cholesterol levels seen in many Western populations are mainly attributable to changes in behaviour and the wider determinants of health, rather than to medication. Thus, preventive services alone are not likely to be sufficient unless supported by national policies and systems (Capewell and O'Flaherty 2008).
- 3.7 National policy has an important role to play in changing the risk factors faced by a population. However, developing and implementing such policy is itself a highly complex process: the PDG acknowledged that the policy process is not linear and rarely moves from design to implementation. In addition, it acknowledged that evidence alone is rarely sufficient to bring about policy change.

The way research evidence influences the policy process and gets translated into action can be explained by models such as Kingdon's (1995) 'policy windows' model. It is claimed that 'windows' open (and close) by the coupling (or de-coupling) of three 'streams': problems, policies and politics.

- 'Problem window': Only problems seen as amenable to policy solutions might be selected, many will remain unaddressed. Problems may be brought to the fore by research evidence, critical incidents, performance data or feedback.

- 'Policy window': Many strategies or initiatives may be advanced by civil servants, politicians and interest groups. To be enacted, policy must be technically feasible, congruent with dominant values and anticipate future constraints.
- 'Politics window': When lobbying, negotiation, bargaining and coalition-building is in favour of the policy.

The alignment of the three 'windows' may occur by chance, by natural cycles (for example, political or organisational) and as a result of action by 'policy entrepreneurs'. The latter use their status, reputation and influence to advance policies they favour. The 'windows' model can be applied at national and local level (Exworthy et al. 2002).

- 3.8 The PDG noted that interagency collaboration (nationally and locally) is needed to ensure policy is successfully implemented. It also noted the difficulties of both interagency and cross-government working (Strategy Unit 2008; Wanless 2004). Some of the issues addressed in this guidance have been debated by government. However, implementation of the recommendations will need to be considered further.

### ***Population versus individual approaches***

- 3.9 In the past in the UK, interventions focused on individuals have tended to dominate CVD prevention activities. However, the largest overall benefit could be achieved by making changes (albeit small ones) within the population as whole. As indicated by the Rose hypothesis, a small reduction in risk among a large number of people may prevent many more cases, rather than treating a small number at higher risk. A whole-population approach explicitly focuses on changing everyone's exposure to risk (Rose 2008). This may be best achieved through 'upstream' interventions: fiscal measures (including taxation), national or regional policy and legislation (including, for

example, legislation on smokefree public places or the way food is produced). Social and economic action can also result in a change in CVD risk (in such cases, the health outcomes are side effects – albeit desirable). Voluntary action may be effective. Sometimes, however, it may need to be supported by mandatory measures, for instance, when the pace of change is insufficient.

Data from ‘natural experiments’ in a whole population (where there were no randomised controlled trials to assess the results) provide compelling evidence. One example is the reduction in the consumption of animal fats in Eastern Europe, following the break-up of the Soviet Union (Zatonski and Willett 2005). Another example is the introduction of legislation in Mauritius to make it mandatory to use polyunsaturated oils as a substitute for highly saturated cooking oils. In such cases, there has been a remarkably rapid reduction in CVD mortality among the populations (Dowse et al. 1995). Conversely, rapid rises in CVD mortality have been seen in China and elsewhere, principally due to the adoption of a Western diet rich in saturated fats (Critchley et al. 2004).

3.10 Measures to encourage commercial markets to be health promoting could be highly cost effective (Abelson 2003; Catford 2009; Trust for America’s Health 2008; Wanless 2004). Such measures might include: improving the contents of products (re-formulation); controls on the marketing of energy dense, nutrient poor, high fat, salt and sugar processed foods; and package labelling.

3.11 Advertising and promotion activities have an important influence on consumption patterns. The PDG felt that children are particularly vulnerable and need to be protected from commercial pressures. The ‘Sydney principles’ (from Sydney, Australia) provide an example of the type of issues that should be addressed. These state that any action to reduce marketing to children should: support the rights of children; afford substantial protection to children; be statutory in

nature; take a wide definition of commercial promotion; guarantee commercial-free childhood settings; include cross-border media; and be evaluated, monitored and enforced. Closer to home, the Ofcom/Food Standards Agency TV advertising restrictions on foods high in salt, fat and sugar to children are an example of UK action to put such principles into practice.

- 3.12 Interventions which rely on people deciding to change their behaviour are likely to vary in effectiveness. For example, people who are disadvantaged might find it more difficult to change than affluent people. As a result, some interventions that focus on changing behaviour may inadvertently increase health inequalities. To overcome this, the recommendations do not, in the main, rely on individual choice but, rather, aim to make the healthy choice the easy choice. Hence, the emphasis is on changing policies, systems, regulations and other similar 'upstream' factors. This approach is likely to reduce, rather than increase, health inequalities and is congruent with NICE's guidance on behaviour change (see section 8).

### ***Private, regional and community action***

- 3.13 Public, private, voluntary and community sector organisations all have a role to play in preventing CVD at EU, national, regional, sub-regional (for instance county-wide) and local level. Those preparing, manufacturing and selling food have a particularly important role. Such organisations must consider their commercial interests. However, the PDG considers it reasonable to expect them to work with others to help prevent CVD. It takes this view in light of the diseases and deaths caused by CVD (and the consequent costs to the exchequer and society). The PDG noted Brownwell and Warner's comments (2009) that some responsible commercial organisations are already taking positive action. However, these authors also point out that other parts of the food industry have sometimes defended

their market by adopting similar strategies to those used by the tobacco industry in the 1950s and 1960s. They state: 'Certainly, there is an opportunity if the industry chooses to seize it – an opportunity to talk about the moral high ground **and** to occupy it'

- 3.14 The success of legislation banning tobacco advertising and smoking in public places has demonstrated the effectiveness of national government action to improve the public's health. In terms of CVD prevention, government offices and strategic health authorities could make an important contribution at regional level. For example, they could negotiate local area agreements (LAAs) that include 'stretched' targets related to CVD. They could also ensure that the DH's world class commissioning strategies for health and social care adequately address CVD prevention at both a population and individual level. There is also scope for effective action by public sector bodies at a sub-regional level. This was the case in Merseyside where, in the run up to the national workplace ban on smoking, local smoking restrictions had been considered in the absence of national legislation.
- 3.15 Local authorities and primary care trusts, working with the private and voluntary sector in local strategic partnerships, have demonstrated their commitment to CVD prevention. For example, they have established health and wellbeing partnerships. In addition, 5 of the 15 most popular improvement targets included in local area agreements for England relate directly or indirectly to CVD prevention.
- 3.16 The role of voluntary and community sector groups and organisations in CVD prevention is important. Nationally, the campaigning activities of charities such as the British Heart Foundation, the National Heart Forum and others focused on chronic diseases are particularly influential. Local advocacy is also important and may be supported by the voluntary sector. For example, it could have an impact on planning applications for fast-food outlets.

3.17 Addressing the needs of deprived groups involves working beyond geographical boundaries with community groups. The leaders of some communities may be able to deliver CVD prevention programmes effectively. However, it should not be assumed that all community leaders will be able or willing to participate – or that it would be appropriate.

3.18 The PDG recognised that smoking cessation and other services that aim to help people who are trying to change their behaviour have an important role to play in preventing CVD. Many of these services or approaches have been the focus of earlier NICE guidance (see section 7).

### ***Single risk factors***

3.19 Key CVD risk factors are: smoking, a poor diet, obesity, lack of physical activity and high alcohol consumption.

3.20 The PDG noted that approximately 100,000 people die from smoking-related diseases in the UK every year (it accounts for 29% of deaths from cancer, 13% of cardiovascular deaths and 30% of deaths from respiratory disease) (Action on Smoking and Health 2008). It also acknowledged that smoking accounts for over half the disproportionate burden of illnesses experienced by deprived groups and strongly endorsed the national tobacco control measures set out in 'Beyond smoking kills' (Action on Smoking and Health 2008). Approaches to helping people to quit smoking, or to stop using other forms of tobacco, are covered by recommendations made in NICE guidance on: 'Smoking cessation services' (NICE public health guidance 10); 'Brief interventions and referral for smoking cessation' (NICE public health guidance 1); and 'Workplace interventions to promote smoking cessation' (NICE public health guidance 5). As a result, tobacco issues are not covered in this guidance.

- 3.21 The PDG noted that nicotine replacement therapy (NRT) can help to reduce CVD among people who are addicted to nicotine. The PDG fully endorses the Tobacco Advisory Group's recommendations on the regulation and marketing of NRT (Royal College of Physicians 2007). The report advocates making NRT more acceptable and accessible to people who smoke and who find it impossible to quit.
- 3.22 In response to feedback from stakeholders, the PDG felt it was important to also consider single risk factors and to make recommendations on the use of salt and saturated, unsaturated and trans fats in food. Policies to promote physical activity were also considered.
- 3.23 Much of the observational evidence that links diet to CVD is based on individual nutrients. However, the PDG recognised that their impact should be considered in the context of the whole diet. A 'healthier' diet based on fruit, vegetables, wholegrain foods, fish and poultry is associated with a reduction in CVD risk factors (Fung et al. 2001; Lopez-Garcia et al. 2004) and lower CVD mortality (Heidemann et al. 2008; Osler et al. 2001). Interventions promoting this type of 'healthier' diet have also been shown to be highly effective in reducing blood pressure (Appel et al. 1997) and the risk of cardiovascular disease (de Lorgeril et al. 1999). While a number of the recommendations relate to single nutrients, the PDG recognises that a 'healthier' diet is likely to comprise a balance of nutrients and a reduction in the intake of harmful elements. In a typical Western diet, the latter include saturated fat and salt (Hu 2008).
- 3.24 The PDG agreed with the 2009 WHO review of industrial trans fatty acids (TFAs) that they are unnecessary and 'toxic' and should be eliminated. Assuming a linear dose response, a reduction in energy from TFAs to less than 1% of food energy might save between 4500 and nearly 7000 lives. It would also help reduce health inequalities. It noted that bans have been successfully implemented in Denmark

and New York City. The review states: because TFAs produced by partial hydrogenation are not normally present naturally in foods and have no known health benefits, the group considered them as industrial additives'. It recommends that, food services, restaurants, and food and cooking fat manufacturers should avoid their use as well (Uauy et al. 2009).

The WHO review noted that people who use partially hydrogenated vegetable oils (PHVO) for cooking or consume a high proportion of industrially processed or restaurant food, would have mean trans fatty acids intakes considerably higher than the national average.

The review noted that '...replacing TFAs with vegetable oils high in polyunsaturated fatty acids (PUFA) and monounsaturated fatty acids (MUFA) is the preferred option for health benefits... eliminating use of TFA-containing PHVO [partially hydrogenated vegetable oils] should be considered as hazard removal, in line with risk management models used to address many other food safety issues.'

- 3.25 The PDG discussed the benefits of substituting low-fat for high-fat products. Evidence suggests that reducing saturated fat intake from 14% to 6% of energy intake (as in Japan) might prevent around 30,000 CVD deaths annually. High levels of sugar may be used to replace the fat, thereby losing some of the benefit in terms of calorie reduction. It was also concerned total fat intake would not be reduced but rather moved from one product to another.
- 3.26 Salt intake is a major determinant of CVD in the UK, mainly due to its effect on blood pressure. Between 10 and 30% of a person's salt intake comes from adding it to food and using it in cooking, 70–90% is added to food during the manufacturing process. Reducing the population's salt intake will therefore involve encouraging the food processing industry to reduce the salt in processed foods – as well as changing people's use of 'discretionary' salt. The PDG believes the

former can only be achieved by using a combination of voluntary and regulatory action.

The PDG also noted that the UK population's daily salt intake has fallen by 0.9g in the last 5 years (a reduction of around 2% per year). This means people are consuming an average of 8.6g of salt per day. The PDG noted that this reduction has come about as a result of public awareness campaigns and a voluntary code of practice for industry, led by the Food Standards Agency.

3.27 Evidence shows that large reductions in the salt content of foods are feasible; a 10% reduction in items like bread and soups is not detected by consumers and does not, therefore, affect consumer choice. A reduction in mean salt intake of 3g per day for adults (to achieve a target of 6g daily) would lead to around 20,000 fewer deaths from CVD annually. That means approximately 130,000 quality-adjusted life years (QALYs) would be gained and around £350 million would be saved in healthcare costs. A reduction of 6g per day would lead to twice the gain: some 260,000 QALYs and a saving of £700 million in healthcare costs.

3.28 NICE has made recommendations on helping people to be physically active in: 'Four commonly used methods to promote physical activity' (NICE public health guidance 2); 'Physical activity and the environment' (NICE public health guidance 8); 'Promoting physical activity in the workplace' (NICE public health guidance 13); and 'Promoting physical activity for children and young people' (NICE public health guidance 17). As a result, although these issues are important in helping to prevent CVD, they are not covered in this guidance.

3.29 The PDG discussed whether calorie content could be presented on food labels in terms of the hours of physical activity required to use them up. It was noted that there was no evidence to support this

approach. However, the PDG was aware of evidence to support the idea that presenting the total calorific content on food labels could help reduce intake (Ludwig and Brownell 2009).

- 3.30 The PDG discussed the links between sedentary behaviour and CVD, and the need to encourage people to be more physically active. However, evidence on how to address sedentary behaviour is not well developed and remains an area for further study.

### ***Children***

- 3.31 Maternal and fetal nutrition has an important influence on whether or not people develop CVD later in life. There is a growing body of evidence that suggests breastfeeding may protect against the development of risk factors for CVD. For example, it is associated with small reductions in blood pressure (Martin et al. 2005), serum cholesterol (Owen et al. 2008), a reduced risk of being overweight (Harder et al. 2005) or having type 2 diabetes (Owen et al. 2006). However, the evidence on breastfeeding per se as a means of preventing CVD is unclear (Martin et al. 2004; Rich-Edwards et al. 2004). While the PDG recognised the benefits of breastfeeding, it concluded that there was insufficient evidence to make a recommendation related to CVD prevention. However, NICE's guidance on maternal and child nutrition is referred to in the recommendations.

- 3.32 The PDG noted the importance of taking action to prevent the development of CVD risk factors among children by ensuring they have a healthy, balanced diet and are physically active. This supports the principle of 'primordial prevention' to maintain low cholesterol and blood pressure throughout life.

### ***Evidence***

- 3.33 Many studies considered in the reviews of effectiveness were carried out some years ago. The majority were published before 2000, with a

substantial number published before 1990. This reflects, in part, the decision to include studies such as the North Karelia and HeartBeat Wales CVD population-level programmes which took place in the 1970s and 1980s. The age of the studies means a number of factors have to be taken into account when considering effectiveness. In particular:

- The different risk factor levels for CVD are likely to have changed. For instance, intake of salt and saturated fat and the prevalence of smoking may have fallen, while a sedentary lifestyle and rates of obesity may have increased.
- The political and cultural environments which affect the effectiveness of interventions may have changed substantially.

3.34 There are a number of difficulties when considering evidence of the effectiveness of population-level interventions:

- Changes may have come about inadvertently, for instance, as a result of a change in agriculture practice following economic developments – and unrelated to CVD prevention. Any evaluation of such changes are likely to have been carried out after the event, using proxy data.
- It is often difficult to find a suitable control population where conditions are relatively similar to those in the intervention group. Where a control group is used, there are often difficulties with contamination between the two groups which can lead to an underestimation of any beneficial effects.
- It is ethically and practically impossible to use randomised controlled trials with country-wide populations. The best evidence available has to be gleaned from other research designs in particular, natural experiments, epidemiological models and cost effectiveness and cost benefit analyses.

- 3.35 The potential effect of any intervention may change according to the initial level of risk. For instance, it may be easier to reduce salt intake among a population with a high intake than among a population where intakes of salt are lower. However, epidemiological modelling suggests that substantial reductions in CVD rates can be achieved by further reducing the major risk factors as much as possible. This is the case even in countries where CVD mortality rates are initially lower, such as Italy (Palmieri et al. 2009).
- 3.36 The economic modelling was based on conservative assumptions. Nevertheless, it suggested that the recommended population-based approaches are likely to be consistently cost saving. .

### ***Other issues***

- 3.37 Many of the risk factors that the PDG considered are significant for a number of other health-related conditions – not just CVD – including some common cancers, respiratory diseases, obesity, diabetes, kidney diseases and mental wellbeing. The prevention strategies discussed in this guidance are likely to help prevent some of these other health conditions. (Certainly, they are not likely to increase the risk of any other common chronic diseases.) However, it was not possible to consider each of these other health conditions in detail.
- 3.38 This guidance focuses on salt, trans fats and saturated and poly unsaturated fats. However, the PDG emphasised its support for a healthy diet, as advocated in the ‘eatwell’ plate (Food Standards Agency 2007).
- 3.39 Daily consumption of products containing plant sterols and stanols may reduce blood cholesterol by about 10% – and so may have a substantial impact on CVD mortality. However, it was not clear how a recommendation on their use might impact on inequalities in health. The PDG believes this issue deserves further attention.
- 3.40 Agricultural and transport policy and practice (and other similar

issues) have a powerful impact on people's diet and physical activity levels. They also impact on climate change and sustainable development (which, in turn, can affect health). The PDG did not consider either climate change or sustainable development as these issues were beyond the scope of this guidance.

This section will be completed in the final document.

## **4 Recommendations**

When writing the recommendations, the Programme Development Group (PDG) (see appendix A) considered the evidence of effectiveness and cost effectiveness. Note: this document does not constitute NICE's formal guidance on these programmes. The recommendations are preliminary and may change after consultation.

The evidence statements underpinning the recommendations are listed in appendix C.

The evidence reviews, supporting evidence statements and economic analysis are available at [www.nice.org.uk/guidance/PHG/Wave17/26](http://www.nice.org.uk/guidance/PHG/Wave17/26)

### ***Population versus individual approach***

Changes in cardiovascular disease (CVD) risk factors can be brought about by intervening at a number of different levels. Although interventions focused on changing individual behaviour have tended to dominate in recent years, population-level changes could lead to the greatest overall benefit. Such changes may be achieved through 'upstream' interventions: national or regional policy and legislation and action aimed at improving the physical, social and economic environments. (For more on the importance of interventions aimed at the whole population, see considerations 3.2, 3.3, 3.5, 3.6 and 3.9.)

The policy recommendations (recommendations 1 to 11) are based on extensive and consistent evidence which suggests that these changes are

likely to be the most effective and cost effective way of reducing CVD among the population.

Government has addressed – and continues to address – cardiovascular disease at a population and individual level. The recommendations in this guidance are based on a robust analysis of the evidence for action and provide a national framework for action. Implementation will involve government, industry and key non-governmental organisations. Any action to be taken by government will be prioritised following the usual processes.

The recommendations for practice (recommendations 12 to 24) support and complement – and are supported by – these policy changes.

## ***Recommendations for policy***

### ***Who should take action?***

The following officials, government departments and national agencies should be involved:

- Chief Medical Officer
- National Clinical Director for Coronary Heart Disease
- Chief Scientist
- Department for Business, Innovation and Skills
- Department for Culture, Media and Sport
- Department for Children, Schools and Families
- Department for Environment, Food and Rural Affairs
- Department for Transport
- Department of Communities and Local Government
- Department of Health
- Food Standards Agency
- HM Treasury
- National Institute for Health Research
- Ofcom

- Other research organisations (for example, the Medical Research Council and the Economic and Social Research Council).

Other key players include:

- food and drink manufacturers
- food and drink retailers
- caterers
- the farming sector
- national, non-governmental organisations including, for example, the British Heart Foundation, Cancer Research UK, Diabetes UK, National Heart Forum, the Stroke Association and other chronic disease charities.

### **Recommendation 1: common agricultural policy**

The common agricultural policy (CAP) is the overarching framework used by European Union member countries to form their own agricultural policies. However, it introduces a number of significant distortions, including on certain food prices in the EU. Ongoing reform of the CAP should remove such distortions and provide a basis for supporting other government action on preventing CVD in the UK. There is sufficient evidence to suggest that the CAP could now be reviewed to support the prevention of CVD. The evidence suggests that the following are among the measures that could be considered.

#### ***What action could be taken?***

- Negotiate to amend the common agricultural policy (CAP) to ensure it takes account of public health issues. Specifically, food growing and production should be linked to healthy eating guidelines, such as the ‘eatwell plate’<sup>1</sup>.
- Negotiate to ensure the European Commission’s (EC) impact assessment procedure (part of its strategic planning and programming cycle) takes the effect on cardiovascular health into account.

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<sup>1</sup> Food Standards Agency (2007) Eatwell plate [online]. Available from [www.eatwell.gov.uk/healthydiet/eatwellplate](http://www.eatwell.gov.uk/healthydiet/eatwellplate)

- Ensure fiscal incentives and disincentives for industry support the production of low saturated, as opposed to full-fat, dairy products and fruit, vegetables and cereals for human consumption.
- Ensure reduced-fat dairy products are cheaper than their full-fat equivalents.

### **Recommendation 2: product labelling and marketing**

A framework of legislation and regulation affects consumer behaviour. The evidence suggests that, in the context of product labelling and marketing, the following measures could be considered.

#### ***What action could be taken?***

- Develop legislation to implement the Food Standards Agency's Integrated Label for products sold in England. This includes traffic light colour-coding, text to indicate 'high', 'medium' or 'low' content of particular ingredients and the percentage guideline daily amount (GDA). Implement the system in advance of legislation.
- Restrict advertising for products that fall into the amber and red categories of the Food Standards Agency's food labelling system.
- Clearly label products requiring a high salt content (such as some cheeses and meat products) to indicate that they are high in salt and should only be considered for occasional consumption.

### **Recommendation 3: salt**

High levels of salt in processed food have a major impact on the total amount consumed by the population. This, in turn, can cause high blood pressure which is a CVD risk factor. Industry has made considerable progress in reducing salt in everyday foods. However, the rate of progress is too slow and, as a matter of priority, needs to be accelerated. The evidence suggests that the following are among the measures that could be considered to reduce salt content further.

***What action could be taken?***

- Reduce population salt intake to no more than 6g per day initially (and to a lower level in the longer term). This can be achieved by promoting the benefits to the EU and introducing national legislation.
- Continue to reduce the salt content of commonly consumed foods (bread, meat products, cheese, soups and breakfast cereals) by persuading manufacturers to progressively change their recipes and production methods. All food products available throughout the EU should be subject to these changes, including low cost, standard and luxury goods.
- Agree EU salt targets for processed foods. Ensure salt levels are monitored in commonly consumed foods. Monitoring should take place at EU level and nationally.
- Reinforce national targets for salt intake among the population and review them at regular intervals. This includes developing a timetable to meet the voluntary targets on the level of salt used in common foods. Set a deadline for the development of mandatory regulations if progress is not being achieved.
- Develop fiscal incentives and disincentives to encourage manufacturers to make low salt products cheaper than their higher salt equivalents.
- Impose VAT at the standard rate on culinary quality salt, as part of a consistent policy to ensure taxation is used to reduce the risk of CVD.

**Recommendation 4: saturated fats**

Halving the average intake of saturated fats (from 14% to 7% of total energy) might prevent approximately 30,000 CVD deaths annually. The evidence suggests that the following are among the measures that could be considered.

***What action could be taken?***

- Offer subsidies to encourage manufacturers to make low saturated fat products cheaper than the higher saturated equivalent.

- Introduce legislation (for example in relation to VAT) to make high saturated fat products more expensive than the lower saturated fat equivalent.
- Introduce legislation (for example, in relation to VAT) to make fruit and vegetables and other foods that make up a healthy diet cheaper than less healthy products.
- Reformulate all products (particularly those sold as low priced 'value' ranges) to reduce the amount of saturated fat they contain and remove trans fats.

### **Recommendation 5: trans fats**

Trans fats constitute a significant health hazard. As part of the proposed CVD prevention framework, it would be beneficial to eliminate them altogether from the national diet. The evidence suggests that the following are among the measures that could be considered.

#### ***What action could be taken?***

- Ban the use of industrial trans fats for human consumption throughout the EU.
- Revise the current UK and international recommendation on trans fatty acids, so that they account for less than 0.5% of daily energy value for **all** groups – not just for the population mean. Develop a timetable for action that includes the introduction of legislation if there is no other way to achieve this in a timely fashion.
- Replace trans fatty acids with vegetable oils high in polyunsaturated and monounsaturated fatty acids. Ensure saturated fats are not used to replace trans fats.
- Independently monitor the level of trans fats in processed and take-away food to identify consumption in all sectors of the population, rather than relying on an average figure.

**Recommendation 6: catering guidelines**

Public sector organisations are important providers of food and drink to large sections of the population. An effective way to reduce the risk of CVD would be to improve the nutritional quality of the food and drink they provide. The evidence suggests that the following are among the measures that could be considered.

***What action could be taken?***

- Ensure Food Standards Agency-approved dietary guidelines in publicly-funded settings such as schools, hospitals and public sector work canteens are achieved.
- Develop a timetable to implement the voluntary 'Healthy Food Mark' scheme. Set a deadline for the development of mandatory regulation if progress is not being achieved.

**Recommendation 7: take-aways and other food outlets**

Food from take-aways and other outlets comprises a significant part of many people's diet. Local planning authorities are able to control fast-food outlets and it is up to them to use their powers to take effective local action.

Regulation of the outlets selling this food would provide another opportunity to tackle the risk of CVD. The evidence suggests that the following are among the measures that could be considered.

***What action could be taken?***

- Ensure local planning authorities understand existing legislation which enables local authorities to refuse planning permission for take-aways and other food retail outlets in specific areas (for example, near schools). Ensure the legislation is widely implemented. (See also recommendation 12.)
- Link this legislation to licensing and food hygiene regulations.

**Recommendation 8: active travel**

Travel offers an important opportunity to help people become more physically active. However, inactive modes of transport have increasingly dominated in recent years. The evidence suggests that the following are among the measures that could be considered.

***What action could be taken?***

Use fiscal incentives and disincentives to promote physical activity including physically active travel to and at work. For example:

- exempt VAT on sports and exercise equipment, cycles and related equipment used at work
- place direct taxes on the provision of car parking used as a benefit.

**Recommendation 9: health impact assessment**

Health impact assessment is a well-developed method of determining the likely health consequences of particular policies, initiatives or actions. It is important to ensure this approach is applied as a routine part of the policy development process. The evidence suggests that the following are among the measures that could be considered.

***What action could be taken?***

- Assess all public policy for its potential impact (positive and negative) on cardiovascular disease and other related chronic diseases. In addition, assess its potential impact on health inequalities. Assessments should be carried out using health and policy impact assessment and other similar, existing tools.
- Make health impact assessments mandatory for all public policy. Monitor the outcomes of policy following the assessment and use them to follow up and amend future plans.
- Regularly and independently monitor the consumption of salt, trans fatty acids, saturated fatty acids, mono and polyunsaturated fatty acids. Use industry data (including consumer purchasing data) and population

surveys. Ensure there is continuous progress towards a healthy level of consumption of these nutrients.

### **Recommendation 10: commercial interests**

Food and drink manufacturers and retailers have a particularly important role in helping to prevent CVD. Some responsible commercial organisations are already taking positive action. The evidence suggests that the following are among the measures that could be considered.

#### ***What action could be taken?***

- Introduce a similar framework for food and drink production to that adopted by the World Health Organization for tobacco control (that is, 'Framework convention on tobacco control' [2003]).
- Develop an international public health information system (resembling GLOBALink<sup>2</sup>) for CVD prevention.
- Ensure all meetings, including lobbying, between the food and drink industry and government and government agencies are conducted in a transparent way.
- Ensure disclosure rules are followed including declarations of interests (for example, on past employment and consultancy work).

### **Recommendation 11: children**

Eating and drinking patterns get established at an early age, so measures to protect children from the dangers of a poor diet should be given serious consideration. The evidence suggests that the following are among the measures that could be considered.

#### ***What action could be taken?***

Vigorously protect children and young people from marketing which promotes an unhealthy diet by:

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<sup>2</sup> [www.globalink.org](http://www.globalink.org)

- Developing an agreed framework of principles for food marketing aimed at children. This could be similar to the ‘Sydney principles<sup>3</sup>’. The framework should be comprehensive and should be based on children’s rights to a healthy diet.
- Banning the advertising of foods high in fat, salt and sugar (as determined by the Food Standards Agency nutrient profile) on TV and other broadcast media including new technologies (such as the Internet or mobile phones).
- Developing standards, supported by legislation, to provide controls for non-broadcast media.

### ***Recommendations for practice***

#### **Recommendation 12: take-aways and other food outlets**

##### ***Who is the target population?***

Take-aways and other food outlets.

##### ***Who should take action?***

Local government.

##### ***What action should they take?***

- Introduce bye-laws to regulate the opening hours of take-aways and other food outlets near schools.
- Use existing powers to set limits for the number of take-aways and other food outlets in a given area. Directives could specify the distance from schools and the number that can be located in certain areas.

#### **Recommendation 13: health impact assessment**

##### ***Who is the target population?***

Whole population.

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<sup>3</sup> Swinburn B, Sacks G, Lobstein T et al. (2007) The ‘Sydney principles’ for reducing the commercial promotion of foods and beverages to children. *Public Health Nutrition*: 11 (9): 881–6.

***Who should take action?***

- Regional and local government.
- Local policy makers.

***What action should they take?***

- Assess the potential impact (positive and negative) that all local plans will have on rates of CVD and related chronic diseases, including any potential impact on health inequalities. Use existing tools such as health impact assessments.
- Monitor the outcomes following a health impact assessment and use this to follow up and amend plans.

**Recommendation 14: training*****Who is the target population?***

Caterers.

***Who should take action?***

- Local authorities.
- Providers of hygiene training.

***What action should they take?***

Ensure the links between nutrition and health are a mandatory part of hygiene training for caterers. In particular, training should cover the adverse effect that salt, industrial trans fats and saturated fats can have on health. It should also cover the healthy alternatives to these ingredients, based on the 'eatwell plate'<sup>4</sup>.

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<sup>4</sup> Food Standards Agency (2007) Eatwell plate [online]. Available from [www.eatwell.gov.uk/healthydiet/eatwellplate/](http://www.eatwell.gov.uk/healthydiet/eatwellplate/)

**Recommendation 15: public sector food provision*****Who is the target population?***

Anyone who eats meals provided by public sector organisations.

***Who should take action?***

- Local authorities.
- NHS organisations.
- Education authorities.
- Prison services.
- Emergency services.

***What action should they take?***

Procure and provide meals for people working in the public sector (and for others in receipt of meals provided by public services) that:

- are low in salt and saturated fats
- are nutritionally balanced and varied, in line with recommendations made in the 'eatwell plate'<sup>5</sup>,
- do not contain industrial trans fats
- are clearly labelled.

**Recommendation 16: children and young people*****Who is the target population?***

Children and young people under the age of 16 years.

***Who should take action?***

- Parents and carers of children and young people under the age of 16 years.

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<sup>5</sup> Food Standards Agency (2007) Eatwell plate [online]. Available from [www.eatwell.gov.uk/healthydiet/eatwellplate/](http://www.eatwell.gov.uk/healthydiet/eatwellplate/)

- Nursery nurses and workers in pre-school day care settings such as nurseries.
- Local authorities.
- Schools (governors and teachers).
- Catering staff.

***What action should they take?***

- Help children to have a healthy diet and to develop positive, life-long habits in relation to food. This can be achieved by ensuring the messages conveyed about food, the food and drink available and where it is consumed is conducive to a healthy diet. (For more details, see NICE public health guidance 11 on maternal and child nutrition at [www.nice.org.uk/PH11](http://www.nice.org.uk/PH11))
- Local authorities should ensure cinemas, fun parks and other places where children congregate for entertainment and recreation provide a range of affordable healthy snacks and drinks. This includes the food and drinks provided in vending machines.

**Recommendation 17: local and regional policy**

***Who is the target population?***

Whole population.

***Who should take action?***

- Local authority planning departments.
- Government regional offices.

***What action should they take?***

Align Section 106 funding ('planning gain') with the promotion of heart health to ensure there is funding to support physically active travel and to give people in disadvantaged areas access to affordable fruit and vegetables.

**Recommendation 18: physical activity*****Who is the target population?***

Whole population.

***Who should take action?***

Local authorities.

***What action should they take?***

- Ensure cycle tracks are part of the definitive map (the legal record of public rights of way).
- Prioritise the needs of pedestrians and cyclists over motorists when developing or redeveloping streets.
- Make it mandatory for public sector employers to provide staff with workplace travel plans incorporating physical activity. Make it a voluntary option for other large employers.
- Audit and abolish bye-laws that prohibit physical activity in public spaces.
- Consider offering free swimming to parents and carers who accompany children aged under 5 years (children under 5 already go free).
- Allocate part of the budget for road building to promote walking, cycling and other forms of travel that involves physical activity.

***Recommendations for practice: regional CVD prevention programmes (19–24)******Who is the target population?***

Whole population.

***Who should take action?***

- Primary care trusts.

- Local authorities.
- Directors of public health.
- Local partnerships (such as those responsible for local area agreements).
- Government regional offices.
- Non-governmental organisations including charities and community groups.

### **Recommendation 19: key elements**

#### ***What action should they take?***

- Introduce a programme of intense, multi-component interventions to reduce the risk of cardiovascular disease. This should comprise five elements: preparation, programme development, resources, leadership and evaluation.
- Introduce CVD programmes to coincide with the introduction of national policies, as identified in recommendations 1 to 10.

### **Recommendation 20: preparation**

#### ***What action should they take?***

- Gain a good understanding of the nature and extent of CVD in the community and any previous CVD prevention initiatives that have been run in the area (including any positive or negative experiences). This includes the community's exposure to current (and potential) risk factors.
- Gauge the community's level of knowledge about CVD risk factors and people's confidence in their ability to change their behavior to reduce those risks.
- Identify groups of the population who are disproportionately affected by CVD and develop strategies to address their needs.

- Take into account the community's exposure to risk factors (those currently facing adults and those emerging for children and younger people).

### **Recommendation 21: programme development**

#### ***What action should they take?***

- Develop a population-based approach, as well as strategies for targeting people at particularly high risk of CVD.
- Take account of ongoing, accredited screening activities by GPs and other healthcare professionals.
- Only develop, plan and implement a strategic, integrated media campaign as part of a wider package of interventions to address CVD risk factors. This should be based on an acknowledged theoretical framework.

When developing CVD programmes, take account of NICE recommendations within the following guidance: 'Brief interventions and referrals for smoking cessation' (NICE public health guidance 1); 'Four commonly used methods to increase physical activity' (NICE public health guidance 2); 'Workplace interventions to promote smoking cessation' (NICE public health guidance 5); 'Behaviour change' (NICE public health guidance 6); 'Physical activity and the environment' (NICE public health guidance 8); 'Community engagement' (NICE public health guidance 9); 'Smoking cessation services' (NICE public health guidance 10); 'Maternal and child nutrition' (NICE public health guidance 11); 'Promoting physical activity in the workplace' (NICE public health guidance 13); and 'Physical activity and children' (NICE public health guidance 17).

### **Recommendation 22: resources**

#### ***What action should they take?***

- Ensure CVD prevention programmes are adequately staffed. Avoid adding CVD prevention activities to the workload of existing staff without relieving them of other tasks.

- Ensure interventions are sustainable beyond the end of the research or evaluation period by providing adequate resources.
- Ensure volunteers are an additional (rather than a core) resource and that support for volunteers is adequately resourced.
- Ensure steps are taken to retain effective staff.
- Ensure recruitment of staff and volunteers from the community is sensitive to local culture and needs.

### **Recommendation 23: leadership**

#### ***What action should they take?***

- Implement a leadership structure within the CVD programme. This includes identifying links with the leaders of other relevant organisations.
- Identify people to lead the programme, including people from the local community. Identify in advance – and provide for – the training and other needs of these potential leaders.
- Develop systems to ensure the CVD programme works effectively with other organisations involved in CVD prevention. This includes ensuring senior staff are involved, as appropriate.

### **Recommendation 24: evaluation**

#### ***What action should they take?***

- Ensure evaluation is an integral part of the CVD programme.
- Ensure appropriate methods are used to evaluate its processes, outcomes and measures or indicators. Ensure the results of evaluation are incorporated into future activities.

The PDG considers that all the recommended measures are cost effective.

For the research recommendations and gaps in research, see section 6 and appendix D respectively.

## 5 Implementation

NICE guidance can help:

- National and local organisations within the public sector meet government indicators and targets to reduce health inequalities and improve health.
- NHS organisations, social care and children's services meet the requirements of the DH's 'Operating framework for 2009/10' and 'Operational plans 2008/09–2010/11'.
- NHS organisations, social care and children's services meet the requirements of the Department of Communities and Local Government's 'The new performance framework for local authorities and local authority partnerships'. This includes reducing levels of childhood obesity (PSA delivery agreement 12). It also includes promoting better health and wellbeing for all, by reducing all-age, all-cause mortality rates and reducing smoking prevalence (PSA delivery agreement 18).
- Local authorities, NHS and national organisations to fulfill their responsibilities under the 'National service framework for coronary heart disease' (DH 2000).
- NHS organisations implement the 'NHS health check: vascular risk assessment' and 'Management best practice guidance' (DH 2009).
- National government, local authorities and national organisations fulfill their responsibilities regarding restricting the availability of tobacco as part of the Tobacco – Health Bill 2009, the Health Act 2006 (smokefree premises, places and vehicles), and the Children and Young Persons (Sale of Tobacco etc.) Order 2007.

- Local authorities and NHS organisations fulfill their responsibility to increase local opportunities for physical activity, as outlined in ‘Choosing health – making healthy choices easier’ (DH 2005), ‘Choosing activity: a physical activity action plan’ (DH 2005) and the ‘Walking and cycling: an action plan’ (Department for Transport 2004).
- NHS organisations and other local public sector partners fulfil their remit to promote the economic, social and environmental wellbeing of communities. It can also help them to benefit from any identified cost savings, disinvestment opportunities or opportunities for redirecting resources.
- NHS and local authority organisations meet the requirements of ‘Delivering choosing health – making healthy choices easier’ (DH 2005).

NICE will develop tools to help organisations put this guidance into practice. Details will be available on our website after the guidance has been issued ([www.nice.org.uk/PHxx](http://www.nice.org.uk/PHxx)).

## 6 Recommendations for research

This section will be completed in the final document.

More detail on the gaps in the evidence identified during development of this guidance is provided in appendix D.

## 7 Updating the recommendations

This section will be completed in the final document.

## 8 Related NICE guidance

### ***Published***

Promoting physical activity for children and young people. NICE public health guidance 17 (2009). Available from [www.nice.org.uk/PH17](http://www.nice.org.uk/PH17)

Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease. NICE clinical guideline 67 (2008). Available from [www.nice.org.uk/CG67](http://www.nice.org.uk/CG67)

Identifying and supporting people most at risk of dying prematurely. NICE public health guidance 15 (2008). Available from [www.nice.org.uk/PH15](http://www.nice.org.uk/PH15)

Preventing the uptake of smoking by children and young people. NICE public health guidance 14 (2008). Available from [www.nice.org.uk/PH14](http://www.nice.org.uk/PH14)

Promoting physical activity in the workplace. NICE public health guidance 13 (2008). Available from [www.nice.org.uk/PH13](http://www.nice.org.uk/PH13)

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Smoking cessation services. NICE public health guidance 10 (2008). Available from [www.nice.org.uk/PH10](http://www.nice.org.uk/PH10)

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### ***Under development***

Alcohol use disorders (prevention). NICE public health guidance (publication expected March 2010).

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## **Appendix A Membership of the Programme Development Group (PDG), the NICE project team and external contractors**

### ***Programme Development Group***

PDG membership is multidisciplinary, comprising public health practitioners, clinicians (both specialists and generalists), local authority officers, teachers, social care professionals, representatives of the public, patients, carers, academics and technical experts as follows.

**Pamela Ashton** Community Member

**Andrew Briggs** Chair of Health Policy and Economic Evaluation, University of Glasgow

**Simon Capewell** (Vice Chair) Professor of Clinical Epidemiology, University of Liverpool; Honorary Consultant in Public Health, Liverpool PCTs

**Francesco Cappuccio** Chair of Cardiovascular Medicine and Epidemiology, Clinical Sciences Research Institute, University of Warwick Medical School; Honorary Consultant Physician, University Hospitals Coventry and Warwickshire NHS Trust, Coventry

**Martin Caraher** Reader in Food and Health Policy, Centre for Food Policy, City University

**Charlie Foster** Senior Researcher, Health Promotion Research Group, British Heart Foundation

**Paramjit Gill** GP and Clinical Reader in Primary Care Research, Primary Care Clinical Sciences, University of Birmingham; Honorary Consultant in Primary Care, Heart of Birmingham Teaching PCT

**Robin Ireland** Chief Executive, Heart of Mersey

**Paul Lincoln** Chief Executive, National Heart Forum

**Klim McPherson** (Chair) Visiting Professor of Public Health Epidemiology,  
University of Oxford

**Madeleine Murtagh** Senior Lecturer in Social Science and Public Health,  
School of Population and Health Sciences, Newcastle University

**Margaret O'Mara** Community Member (attended meetings 1 to 3 only)

**Kiran Patel** Consultant Cardiologist and Honorary Senior Lecturer in  
Cardiovascular Medicine, University of Birmingham, Sandwell and West  
Birmingham NHS Trust

**Suzannah Power** Community Member

**Ian Reekie** Community Member

**Sian Robinson** Principal Research Fellow, Medical Research Council  
Epidemiology Research Centre, University of Southampton

**John Soady** Public Health Principal, Directorate of Public Health, NHS  
Sheffield

**Margaret Thorogood** Professor of Epidemiology, Warwick Medical School,  
University of Warwick

**Valerie Woodward** Senior Lecturer, University of Wolverhampton

***NICE project team***

**Mike Kelly**  
CPHE Director

**Jane Huntley, Catherine Swann**  
Associate Directors

**Hugo Crombie**  
Lead Analyst

**Andrew Hoy**

Analyst

**Patti White**

Analyst

**Susan Murray**

Analyst

**Lorraine Taylor**

Analyst

**Caroline Mulvihill**

Analyst

**Bhash Naidoo**

Technical Adviser Health Economics

***External contractors***

**Evidence reviews**

Review 1: 'Prevention of cardiovascular disease at population level (Question 1; phase 1)' was carried out by the West Midlands Health Technology Assessment Collaboration (WMHTAC), University of Birmingham. The principal authors were: Mary Pennant, Wendy Greenheld, Anne Fry-Smith, Sue Bayliss, Clare Davenport and Chris Hyde.

Review 2: 'Prevention of cardiovascular disease at population level (Question 1; phase 2)' was carried out by WMHTAC, University of Birmingham. The principal authors were: Mary Pennant, Wendy Greenheld, Anne Fry-Smith, Sue Bayliss, Clare Davenport and Chris Hyde.

Review 3: 'Prevention of cardiovascular disease at population level (Question 1; phase 3)' was carried out by WMHTAC, University of Birmingham. The

principal authors were: Mary Pennant, Wendy Greenheld, Anne Fry-Smith, Sue Bayliss, Clare Davenport and Chris Hyde.

Review 4: 'Barriers to, and facilitators for, the effectiveness of multiple risk factor programmes aimed at reducing cardiovascular disease within a given population: a systematic review of qualitative research' was carried out by the Peninsula Technology Assessment Group at the Peninsula Medical School, Universities of Exeter and Plymouth. The principal authors were: Ruth Garside, Mark Pearson, Kate Ashton, Tiffany Moxham and Rob Anderson.

### **Primary research**

Review 5: 'Population and community programmes addressing multiple risk factors to prevent cardiovascular disease: A qualitative study into how and why some programmes are more successful than others' was carried out by the Peninsula Technology Assessment Group at the Peninsula Medical School, Universities of Exeter and Plymouth. The principal authors were: Ruth Garside, Mark Pearson, Tiffany Moxham, and Rob Anderson.

### **Economic analysis**

Review 6: 'Prevention of cardiovascular disease at population level (Question 1; cost-effectiveness)' was carried out by WMHTAC, University of Birmingham. The principal authors were: Lazaros Andronis, Pelham Barton, Sue Bayliss and Chris Hyde.

Modelling report: 'Prevention of cardiovascular disease at population level: modelling strategies for primary prevention of cardiovascular disease' was carried out by WMHTAC, University of Birmingham. The principal authors were: Pelham Barton and Lazaros Andronis.

### **Expert reports**

Report 1: 'The effectiveness of physical activity promotion interventions' was carried out by Charlie Foster, British Heart Foundation Health Promotion Research Group.

Report 2: 'Health policy analysis' was carried out by Mark Exworthy, School of Management, Royal Holloway University of London.

Report 3: 'Expert testimony on salt and cardiovascular disease' was carried out by Francesco Cappuccio, Clinical Sciences Research Institute, University of Warwick Medical School.

Report 4: 'The relationship between commercial interests and risk of cardiovascular disease' was carried out by Jane Landon, National Heart Forum.

Report 5: 'Regional development of a population-based collaborative CVD prevention strategy: the experience of NHS West Midlands' was carried out by Kiran Patel, University of Birmingham and West Midlands Strategic Health Authority.

Report 6: 'NICE guidance on the prevention of CVD at population level: evidence from the Co-operative Group' was carried out by Cathryn Higgs, the Co-operative Group.

Report 7: 'Population and community programmes addressing multiple risk factors to prevent cardiovascular disease (CVD): addendum to qualitative study produced by Peninsula Technology Assessment Group for NICE: CVD programme – Heart of Mersey (HoM)' was carried out by Robin Ireland, Heart of Mersey.

Report 8: 'Expert testimony paper on the independent evaluation of "have a heart Paisley" phase one (Scotland's national CHD prevention demonstration project)' was carried out by Avril Blamey, Avril Blamey and Associates.

Report 9: 'Expert testimony on the public health harm caused by industrially produced trans fatty acids and actions to reduce and eliminate them from the food system in the UK' was carried out by Paul Lincoln, National Heart Forum.

Report 10: 'Prevention of cardiovascular disease at a population level: evidence on interventions to address dietary fats' was carried out by Modi Mwatsama, Heart of Mersey.

Report 11: 'CVD risk factors: paradigms and pathways' was carried out by Simon Capewell, University of Liverpool.

Report 12: 'CVD prevention in populations: lessons from other countries' was carried out by Simon Capewell, University of Liverpool.

Report 13: 'Will CVD prevention widen health inequalities?' was carried out by Simon Capewell, University of Liverpool.

Report 14: 'Food manufacturer's perspective' was carried out by Frances Swallow and Nicola Currie, Greencore.

## **Appendix B Summary of the methods used to develop this guidance**

### ***Introduction***

The reviews, expert reports and economic analysis include full details of the methods used to select the evidence (including search strategies), assess its quality and summarise it.

The minutes of the PDG meetings provide further detail about the Group's interpretation of the evidence and development of the recommendations.

All supporting documents are listed in appendix E and are available at [www.nice.org.uk/guidance/PHG/Wave17/26](http://www.nice.org.uk/guidance/PHG/Wave17/26)

### ***Guidance development***

The stages involved in developing public health programme guidance are outlined in the box below.

1. Draft scope released for consultation
2. Stakeholder meeting about the draft scope
3. Stakeholder comments used to revise the scope
4. Final scope and responses to comments published on website
5. Evidence reviews, expert testimony and economic analysis undertaken
6. Evidence and economic analysis released for consultation
7. Comments and additional material submitted by stakeholders
8. Review of additional material submitted by stakeholders (screened against inclusion criteria used in reviews)
9. Evidence and economic analysis submitted to PDG
10. PDG produces draft recommendations
11. Draft guidance released for consultation and for field testing
12. PDG amends recommendations
13. Final guidance published on website
14. Responses to comments published on website

## ***Key questions***

The key questions were established as part of the scope. They formed the starting point for the reviews of evidence and were used by the PDG to help develop the recommendations.

The overarching questions were:

- Which multiple risk-factor interventions are effective and cost effective in preventing the onset of cardiovascular disease (CVD) within a given population (primary prevention)?
- How does effectiveness and cost effectiveness vary between different population groups?

The subsidiary question was:

What barriers and facilitators influence the effectiveness of multiple risk-factor programmes aimed at reducing CVD (or the risk factors associated with CVD) among a given population (including subgroups experiencing health inequalities, where the data allows)?

These questions were made more specific for each review (see reviews for further details).

Single risk factors were considered using expert testimony. See appendix C for details.

## ***Reviewing the evidence***

Three reviews of effectiveness (reviews 1,2,3), one qualitative review (review 4), one primary study of barriers and facilitators (review 5) and one review of cost effectiveness (review 6) were conducted.

## ***Identifying the evidence***

The following databases were searched for randomised controlled trials (RCTs); controlled before-and-after trials; cohort studies; case-control

studies; before-and-after studies; and interrupted time series (from 1970 onwards):

- ASSIA (Applied Social Science Index and Abstracts)
- CINAHL (Cumulative Index of Nursing and Allied Health Literature)
- Cochrane Database of Systematic Reviews (CDSR)
- Cochrane Library (Wiley)
- Database of Abstracts of Reviews of Effects (DARE)
- DH-Data
- EMBASE
- Health Management Information Service (HELMIS)
- Health Technology Assessment (HTA)
- HMIC (Health Management Information Consortium)
- King's Fund Database
- MEDLINE
- MEDLINE In Process
- PsycINFO

The following websites were also searched:

- Centre for the Evaluation of Public Health Interventions, London School of Hygiene & Tropical Medicine [www.lshtm.ac.uk/cephi](http://www.lshtm.ac.uk/cephi)
- Cochrane Public Health Group [www.ph.cochrane.org/en/index.html](http://www.ph.cochrane.org/en/index.html)
- Health evidence <http://health-evidence.ca>
- The Campbell Collaboration [www.campbellcollaboration.org](http://www.campbellcollaboration.org)
- The Evidence for Policy and Practice Information and Coordinating Centre <http://eppi.ioe.ac.uk/cms>

Further details of the databases, search terms and strategies used are included in the review reports.

### **Selection criteria**

Studies were included in the effectiveness reviews if they:

- Involved a population at least the size of one covered by a UK primary care trust.
- Were based in an Organisation for Economic Co-operation and Development (OECD) country, another developed country or within a World Health Organization region.
- Included primary prevention strategies to tackle at least two of the key risk factors for CVD.

Studies were excluded if they were:

- Confined to populations clinically diagnosed as being at high risk of CVD or diagnosed with CVD.
- Published before 1970.
- Not published in English.

### **Quality appraisal**

Included papers were assessed for methodological rigour and quality using the NICE methodology checklist, as set out in the NICE technical manual 'Methods for the development of NICE public health guidance' (see appendix E). Each study was graded (++, +, –) to reflect the risk of potential bias arising from its design and execution.

### ***Study quality***

- ++ All or most of the methodology checklist criteria have been fulfilled. Where they have not been fulfilled, the conclusions are thought very unlikely to alter.
- + Some of the methodology checklist criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.

- Few or no methodology checklist criteria have been fulfilled. The conclusions of the study are thought likely or very likely to alter.

### ***Economic analysis***

The economic analysis consisted of a review of economic evaluations (review 6) and a cost effectiveness analysis.

#### **Review of economic evaluations**

The same protocol was used to conduct the literature reviews for all phases of the review. In a minor departure from the protocol, the list of included study designs was extended to include cost-consequences.

The following databases were searched from 1970 to August 2008:

- ECONLIT
- EMBASE
- MEDLINE
- NHS EED database (Cochrane Library, Wiley).

The search was limited to articles published from 1970 onwards and in the English language.

In addition to the general bibliographic database searches, specific searches were conducted for each programme found during the general searches to ensure all published evaluations, particularly economic evaluations, were identified.

Study quality was assessed using an evidence form based on the 'Methods for the development of NICE public health guidance' (second edition 2009) and adapted to reflect the parameters of this review. It was supplemented with questions from the Drummond checklist (Drummond MF [1996] Guidelines for authors and peer reviewers of economic submissions to the BMJ. London: BMJ).

The selection criteria were the same as for the effectiveness reviews (see pages 53–54). The following study types were included: cost–benefit, cost-effectiveness and cost–utility analyses.

### **Modelling**

An economic model was constructed to incorporate data from the reviews of effectiveness and cost effectiveness. The results are reported in: ‘Prevention of cardiovascular disease at population level: modelling strategies for primary prevention of cardiovascular disease’. It is available on NICE's website at [www.nice.org.uk/guidance/PHG/Wave17/26](http://www.nice.org.uk/guidance/PHG/Wave17/26)

### **Fieldwork**

This section will be completed in the final document.

### ***How the PDG formulated the recommendations***

At its meetings between September 2008 and July 2009, the PDG considered the evidence of effectiveness, expert reports and cost effectiveness to determine:

- whether there was sufficient evidence (in terms of quantity, quality and applicability) to form a judgement
- whether, on balance, the evidence demonstrates that the intervention is effective, ineffective or equivocal
- where there is an effect, the typical size of effect.

The PDG developed draft recommendations through informal consensus, based on the following criteria:

- Strength (quality and quantity) of evidence of effectiveness and its applicability to the populations/settings referred to in the scope.
- Effect size and potential impact on the target population's health.
- Impact on inequalities in health between different groups of the population.
- Cost effectiveness (for the NHS and other public sector organisations).

- Balance of risks and benefits.
- Ease of implementation and any anticipated changes in practice.

Where possible, recommendations were linked to an evidence statement(s) (see appendix C for details). Where a recommendation was inferred from the evidence, this was indicated by the reference 'IDE' (inference derived from the evidence).

## Appendix C The evidence

This appendix lists the evidence statements from four reviews, a cost-effectiveness review and a primary research study provided by external contractors (see appendix A) and links them to the relevant recommendations. (See appendix B for the key to quality assessments.)

The evidence statements are presented here without references – these can be found in the full reviews (see appendix E for details).

The appendix also sets out a brief summary of findings from the economic analysis.

The four reviews (reviews 1–4), the primary research study (review 5) and the cost-effectiveness review (review 6) are:

- Evidence reviews:
  - Review 1: ‘Prevention of cardiovascular disease at population level (Question 1; phase 1)’
  - Review 2: ‘Prevention of cardiovascular disease at population level (Question 1; phase 2)’
  - Review 3: ‘Prevention of cardiovascular disease at population level (Question 1; phase 3)’
  - Review 4: ‘Barriers to, and facilitators for, multiple risk factor programmes aimed at reducing cardiovascular disease within a given population: a systematic review of qualitative research’
- Primary research:
  - Review 5: ‘Population and community programmes addressing multiple risk factors to prevent cardiovascular disease: A qualitative study into how and why some programmes are more successful than others’

- Cost-effectiveness review:
  - Review 6: ‘Prevention of cardiovascular disease at population level (Question 1; cost-effectiveness)’

**Evidence statement R3.E1a** indicates that the linked statement is numbered E1a in review 3. **Evidence statement R5.12** indicates that the linked statement is numbered 12 in the primary research study (review 5). **Evidence statement ER1** indicates that the linked statement is from expert report 1. **Evidence statement CE1** indicates that the linked statement is numbered 1 in in the cost-effectiveness review (review 6). ‘

The reviews, economic analysis and additional evidence are available at [www.nice.org.uk/guidance/PHG/Wave17/26](http://www.nice.org.uk/guidance/PHG/Wave17/26) Where a recommendation is not directly taken from the evidence statements, but is inferred from the evidence, this is indicated by **IDE** (inference derived from the evidence).

Where the PDG has considered other evidence, it is linked to the appropriate recommendation below. It is also listed in the additional evidence section of this appendix.

**Recommendation 1:** evidence statements R3.E5b–h, R4.4.a, R5.10; additional evidence ER 2, ER 4, ER 7, ER 8, ER 9, ER 10

**Recommendation 2:** evidence statements R3.E5b–h, R4.9c; IDE

**Recommendation 3:** evidence statements R3.E1c, R3.E1m, R3.E5b–h, R5.10; additional evidence ER 3, ER 11, ER 12

**Recommendation 4:** evidence statements R3.E1b, R3.E1h, R3.E1i–k, R3.E5b–h, R5.10; additional evidence ER 10, ER 11, ER 12

**Recommendation 5:** IDE

**Recommendation 6:** evidence statements R3.E5b–h, R5.10; additional evidence ER 9, ER 10, ER 11, ER 12

**Recommendation 7:** evidence statements R3.E3c, R3.E5b–h, R4.18b

**Recommendation 8:** evidence statements R3.E3c, R3.E5b–h, R5.10

**Recommendation 9:** evidence statements R3.E5b–h

**Recommendation 10:** evidence statements R3.E5b–h, R4.3a, R4.3b;  
additional evidence ER 4

**Recommendation 11:** evidence statements R3.E5b–h, R4.3a, R4.3b, R5.10;  
additional evidence ER 4

**Recommendation 12:** evidence statements R3.E3a, R3.E3c, R4.18a,  
R4.18b; additional evidence ER 3, ER 4, ER 9, ER 10

**Recommendation 13:** IDE

**Recommendation 14:** evidence statements R4.9e; additional evidence ER 3,  
ER 9, ER 10

**Recommendation 15:** evidence statements R3.E1a–m, R3.E3c, R4.4a,  
R4.9e, R4.18a, R4.18b, R4.25e; additional evidence ER 3, ER 9, ER 10

**Recommendation 16:** evidence statements R3.E5c, R4.18a–c; additional  
evidence ER 4

**Recommendation 17:** additional evidence ER 5, ER 7, ER 8

**Recommendation 18:** evidence statements R4.1b, R4.3a, R4.3b, R4.7a–c,  
R4.8a–d, R4.16a–c, R4.17a–d, R5.3, R5.7, R5.8, R5.9, R5.11, R5.12

**Recommendation 19:** evidence statements R3.E2a–f, R4.2a–c, R4.17a–d,  
R4.18a–c, R4.19a, R4.20a, R4.21a–c, R4.22a, R4.23a–b, R4.24a–d, R4.25a–  
d, R4.26a–d, R5.2

**Recommendation 20:** evidence statements R3.E1a–o, R3.E2a–f, R3.E3a–c,  
R4.14a–b, R5.5, R5.7, R5.10, CE 1–9; additional evidence ER 7, ER 8, ER 13

**Recommendation 21:** evidence statements R4.3a, R4.3b, R4.10a–d,  
R4.11a, R4.11b, R4.12a, R4.13a–d, R4.15a, R4.15b, R5.2, R5.4, R5.6, R5.7

**Recommendation 22:** evidence statements R4.1b, R4.7c, R4.10d, R5.2, R5.3

**Recommendation 23:** evidence statements R4.16a–c, R5.12

**Recommendation 24:** evidence statements R3.E1n, R3.E3c, R4.4a, R4.9f, R4.18a, R4.18c; additional evidence ER 1

### ***Evidence statements***

#### **Evidence statement R3.E1a**

CVD mortality and morbidity: Limited evidence from 3 out of 38 programme evaluations using different summary effect measures demonstrate a mixed effect of multiple risk factor interventions (MRFI) on CVD mortality (the majority of programmes were beneficial) with two controlled before-and-after (CBA) studies demonstrating a net decrease in CVD mortality and one randomised controlled trial (RCT) demonstrating no net change. Limited evidence from 4 out of 38 programme evaluations, using different summary effect measures, demonstrate a mixed effect of MRFI on CVD morbidity (the majority disbeneficial) with one CBA study and one RCT demonstrating a net increase in morbidity and one RCT demonstrating no net change in morbidity. The effect of one programme on morbidity and mortality is unclear.

#### **Evidence statement R3.E1b**

Blood cholesterol: A large body of evidence from 15 CBA studies and 5 RCTs demonstrates a mixed direction of effect (majority of programmes beneficial) of MRFI programmes on blood cholesterol. Fourteen studies (nine CBA and five RCTs) demonstrate a beneficial net effect. Four CBA studies demonstrate no net effect or inconclusive net effects and two CBA studies demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study, reporting a 0.7mmol/l net reduction in blood cholesterol. The least optimistic result was from a CBA study, reporting a +0.5mmol/l net increase in blood cholesterol.

**Evidence statement R3.E1c**

Diastolic and systolic blood pressure: A large body of evidence demonstrates a mixed direction of effect (majority of programmes beneficial) in favour of MRFI programmes on diastolic and systolic blood pressure. Fourteen CBA studies and five RCTs demonstrate a mixed direction of effect (majority of programmes beneficial) on diastolic blood pressure. Twelve studies (seven CBA studies and five RCTs) demonstrate a beneficial net effect. Five CBA studies demonstrate no net effect or inconclusive net effects and two CBA studies demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study, reporting a 5.5mmHg net reduction in diastolic blood pressure. The least optimistic result was from a CBA study, reporting a 6mmHg net increase in diastolic blood pressure. Fourteen CBA studies and five RCTs demonstrate a mixed effect (majority of programmes beneficial) on systolic blood pressure. Ten studies (five CBA studies and five RCTs) demonstrate a beneficial net effect. Five CBA studies demonstrate no net effect or inconclusive net effects and four CBA studies demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study, reporting an 11.8 mmHg net reduction in systolic blood pressure. The least optimistic result was from a CBA study, reporting a 5mmHg net increase in systolic blood pressure.

**Evidence statement R3.E1d**

Smoking: A large body of evidence from twenty CBA studies and four RCTs demonstrate a mixed effect of MRFI on smoking prevalence (the majority of programmes beneficial). Twelve studies (nine CBA studies and three RCTs) demonstrate a beneficial net effect. Seven studies (six CBA studies and one RCT) demonstrate no net effect or inconclusive net effects and five CBA studies demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study, reporting an 18.6% net reduction in smoking prevalence. The least optimistic result was from a CBA study, reporting a 12.8% net increase in smoking prevalence.

**Evidence statement R3.E1e**

BMI: A large body of evidence from fourteen CBA studies and three RCTs demonstrate a mixed effect of MRFI programmes on body mass index (BMI) (the majority of programmes beneficial). Ten studies (seven CBA studies and three RCTs) demonstrate a beneficial net effect. Four CBA studies demonstrate no net effect or inconclusive net effects and three CBA studies demonstrate a disbeneficial net effect. The most optimistic result was from a CBA study, reporting a 1.3kg/m<sup>2</sup> net reduction in BMI. The least optimistic result was from a CBA study, reporting a 0.7kg/m<sup>2</sup> net increase in BMI.

**Evidence statement R3.E1f**

Blood glucose: Limited evidence from 3 out of 38 programme evaluations, using different summary effect measures, demonstrate a mixed effect of MRFI on blood glucose. One RCT and one CBA study report mixed results: net decreases in men and net increases in women, whilst one CBA study demonstrates no net effect.

**Evidence statement R3.E1g**

Triglyceride levels, high-density lipoprotein/low-density lipoprotein (HDL/LDL) ratio or lipid levels: No evidence has been identified on the effects of MRFI programmes on triglyceride levels, HDL/LDL ratio or lipid levels.

**Evidence statement R3.E1h**

Dietary change – low versus high fat spreads: Five CBA studies and one RCT (+) demonstrate a mixed effect of MRFI programmes on consumption or low versus high fat spreads (the majority of programmes beneficial). Four studies (three CBA studies and one RCT) demonstrate a beneficial net effect. One CBA study demonstrates an inconclusive net effect and one CBA study demonstrates an unfavourable net effect. The most optimistic result was from a CBA study, reporting a 24% net reduction in the number of people with high consumption of fat spread on bread. The least optimistic result was from a CBA study, reporting a 3.3% net decrease in the use of unsaturated spreading fats.

**Evidence statement R3.E1i**

Dietary change – vegetable versus animal fats for cooking: Four CBA studies demonstrate a mixed effect of MRFI programmes on the use of vegetable versus animal fat for cooking (the majority of programmes beneficial). Three CBA studies demonstrate a beneficial net effect and one CBA study demonstrates an inconclusive net effect. The most optimistic result was from a CBA study, reporting a 6% net increase in the use of unsaturated fats for cooking. The least optimistic result was from a CBA study, reporting a 2% net decrease in the use of vegetable fats for cooking.

**Evidence statement R3.E1j**

Dietary change – low versus high fat milk: Five CBA studies and one RCT (+) demonstrate a mixed effect of MRFI programmes on the consumption of low-versus high-fat milk (the majority of programmes beneficial). Three CBA studies and one RCT demonstrate a beneficial net effect and two CBA studies demonstrate an inconclusive net effect. The most optimistic result was from a CBA study, reporting a 9% net increase in the use of low fat milk in men. The least optimistic result was from a CBA study, reporting a 1% net decrease in the use of low fat milk in women.

**Evidence statement R3.E1k**

Dietary change – consumption high fat foods: Six CBA studies demonstrate a mixed effect of MRFI programmes on the percentage of high-fat foods in the diet (the majority of programmes beneficial). Three CBA studies demonstrate a beneficial net effect, two CBA studies demonstrate no net effect or inconclusive net effects and one CBA study demonstrates a disbeneficial net effect. The most optimistic result was from a CBA study, reporting a 24% net decrease in saturated fat intake. The least optimistic result was from a CBA study, reporting a 3.4% net increase in high-fat/junk food consumption.

**Evidence statement R3.E1l**

Dietary change – consumption of fruit and vegetables and wholemeal bread: Limited evidence is available on the effects of MRFI programmes on the

consumption of fruit and vegetables and wholemeal bread (the majority of programmes beneficial). Three CBA studies demonstrate a mixed effect of MRFI programmes on the consumption of fruit and vegetables. Two CBA studies demonstrate a beneficial net effect and one CBA study demonstrates an inconclusive net effect. The most optimistic result is from a CBA study, reporting a 9% net increase in the number of people consuming five portions of fruit and vegetables per day. The least optimistic result is from a CBA study, reporting a 0.2% net decrease in fruit consumption. Two CBA studies demonstrate a mixed effect on the consumption of wholemeal bread. One CBA study demonstrates a beneficial net effect and one CBA study demonstrates an inconclusive effect. The most optimistic result is from a CBA study, reporting a 3% increase in children. The least optimistic result is from the same CBA study, reporting a 0.3% net decrease in adults.

#### **Evidence statement R3.E1m**

Dietary change – salt intake: Two CBA studies (one [+] and one [-]) provide mixed results for the effects of MRFI programmes on salt intake. One CBA study demonstrates a beneficial net treatment effect and one CBA demonstrates an inconclusive net treatment effect.

#### **Evidence statement R3.E1n**

Physical activity: Evidence from 11 CBA studies and one RCT (+) provide a mixed pattern for the effect of MRFI programmes on physical activity (the majority of studies are disbeneficial). Three CBA studies and two RCTs demonstrate a favourable net effect. Three CBA studies demonstrate inconclusive net effects and four CBA studies demonstrate a disbeneficial net effect. The most optimistic result is from a CBA study, reporting an 11.5% net increase in the number of people doing strenuous physical activity more than three times per week. The least optimistic result is from a CBA study, reporting a 6% net decrease in the number of people who were physically active.

**Evidence statement R3.E1o**

Attitudes, knowledge and intentions relating to CVD risk factors: Limited evidence is available on the effects of MRFI programmes on CVD risk factor attitudes, knowledge and intention to change. One CBA study and one uncontrolled before-and-after study suggest beneficial changes in CVD knowledge following MRFI programmes. One of these studies showed a net increase in the number of individuals intending to lose weight. No evidence has been identified on the effects of MRFI programmes on CVD risk factor attitudes.

**Evidence statement R3.E2a**

General: Evidence for variation in effectiveness in subgroups of the population is limited and inconsistently reported across included programmes. There is no clear pattern with respect to gender, age, ethnicity or measures of deprivation which may be the result of the limited information available, confounding and selective reporting.

**Evidence statement R3.E2b**

Ethnicity: Three programmes report the results of subgroup analysis of effectiveness according to ethnicity. One uncontrolled before-and-after study reports lower effectiveness in ethnic minorities in acquisition of CVD knowledge. One CBA study reports lower effectiveness in ethnic minority groups for reducing smoking prevalence, reducing BMI and increasing fruit and vegetable intake and one CBA study reports no difference in effectiveness according to ethnic group.

**Evidence statement R3.E2c**

Age: Six programmes report results of subgroup analysis according to age. Two uncontrolled before-and-after studies report a reduction in effectiveness in acquisition of CVD knowledge in younger participants and one uncontrolled before-and-after study reports a reduction in effectiveness in reducing salt intake in younger participants. One CBA study reports a reduction in

effectiveness in promoting CVD awareness in older participants. Two CBA studies report no differences in effectiveness according to age.

#### **Evidence statement R3.E2d**

Gender: Seven programmes report results of subgroup analysis according to gender. Four programmes report a reduction in effectiveness in women compared to men. One RCT reports a reduction in effectiveness in increasing physical activity in women compared to men. One uncontrolled before-and-after study and two CBA studies report a reduction in effectiveness in reducing smoking prevalence in women compared to men. One CBA study reports a reduction in effectiveness in reducing cholesterol in women compared to men. One CBA study reports a reduction in effectiveness in drinking low-fat compared to high-fat milk in women compared to men. Two programmes report a reduction in effectiveness in men compared to women. Two CBA studies report a reduction in effectiveness in promoting CVD awareness and acquisition of CVD knowledge in men compared to women and one CBA study reports a reduction in effectiveness in reducing CVD morbidity and mortality in men compared to women. One CBA study reports no differences in effectiveness according to gender.

#### **Evidence statement R3.E2e**

Social class: Two programmes report results of subgroup analysis according to social class. One CBA study reports a reduction in effectiveness in reducing smoking in lower social classes compared to higher social classes. One CBA study reports no differences in effectiveness according to social class.

#### **Evidence statement R3.E2f**

Level of education: One programme reports results of subgroup analysis according to level of education. One CBA study reports a reduction in effectiveness in CVD awareness in those relatively more educated.

#### **Evidence statement R3.E3a**

Nature of the interventions: Thirty one programmes were concerned with the effectiveness of population programmes using education and mass media,

and seven with screening programmes directed at large populations in the community or primary care. However, 16 of the education and mass-media programmes contained screening components. Counselling was a key process in many programmes, undertaken individually in 24 programmes and amongst groups in 16 programmes. The 38 programmes varied in many other ways. Programme length ranged from one to over 20 years. The size of the population addressed ranged from approximately 2500 to over 1 million. Fourteen of the programmes implemented changes to the environment. Health departments (n=23) [where n is the number of programmes in which the organisations indicated were involved], local health committees (n=12), voluntary organisations (n=11) and community volunteers (n=9) had roles in programme delivery. Programmes were delivered in a variety of settings including workplaces (n=12) and schools (n=18).

### **Evidence statement E.3b**

Education and mass-media based programmes compared to screening based: As indicated this was the most marked contrast between the programmes. However comparing the effectiveness of the two groups is complicated:

- Many of the education and mass-media based programmes contain elements of screening.
- There are many CVD screening programmes, particularly focused on moderate or high-risk populations which are not included in this review.
- The comparison between the two groups is likely to be confounded by other factors, a very important one of which is that CBA studies are used to evaluate most of the education and mass-media based programmes, and RCTs all the screening based programmes.

With these provisos (and reference to pages 127–31 in report 3), the pattern of results for the risk factors of cholesterol, blood pressure (BP), smoking and BMI in the two different groups of programmes are summarised in the table below:

Programme type (n=38)	Programme result, based on direction of effect			
	Beneficial	Inconclusive	Disbeneficial	No data
	Net change in mean total cholesterol in mmol/L			
Educ & MM 9	4	2		16
Screening 5	0	0		2
	Net change in systolic BP in mmHg			
Educ & MM 6	4	4		17
Screening 5	0	0		2
	Net change in diastolic BP in mmHg			
Educ & MM 7	5	2		17
Screening 5	0	0		2
	Net change in BMI in kg/m <sup>2</sup>			
Educ & MM 8	3	3		17
Screening 3	0	0		4
	Net change in smoking prevalence in %			
Educ & MM 9	6	5		11
Screening 3	1	0		3

Although the results are similar, there does appear to be a more consistent pattern of benefit in the programmes focusing on screening. As well as the provisos mentioned above, the following also need to be borne in mind when taking this observation at face value:

- Whether this difference could be accounted for by chance alone.
- Whether the difference would persist if the size of the effects could be taken into account.
- Vote counting as a method of summarising the results in a systematic review is recognised to be the weakest approach.

### Evidence statement R3.E3c

Possible variations in effectiveness by other aspects of the nature of the intervention: Over the three reports, many other plausible reasons for the noted variation in effectiveness have been identified. These include:

- duration of programme
- intensity of programme
- use of an underlying theoretical model to inform the design of the programme
- pre-programme investigation of particular risk factors operating in a population
- community involvement in planning and/or design of programme
- adaptability of the programme as new challenges emerge
- level of integration of the separate components of the programme
- inclusion of environmental changes as part of the programme.

Whether any of these factors account for differences in effectiveness which could not arise by chance alone has not been fully explored, and their potential importance can neither be confirmed nor refuted. Unfortunately, the extent to which the differences could ever be satisfactorily explored using the results from these evaluations is debatable given noted limitations in the reporting of the precise differences in nature of the programmes and the amount of statistical information available.

#### **Evidence statement R3.E5b**

Gender: Twelve programmes report participation in programme interventions and/or programme evaluation surveys according to gender. One uncontrolled before-and-after study, seven CBA studies and two RCTs report lower participation in evaluation surveys or programme interventions by males. While two programmes, one CBA study and one RCT, report no gender differences in participation rates.

#### **Evidence statement R3.E5c**

Age: Fifteen programmes report participation in programme interventions and/or programme evaluation surveys according to age. One uncontrolled before-and-after study and 13 CBA studies report lower participation in evaluation surveys or programme interventions by those of younger age whilst one CBA study reports no difference in participation according to age.

**Evidence statement R3.E5d**

Level of education: Seven programmes report participation in programme interventions and/or programme evaluation surveys according to level of education. Six CBA studies report lower participation by those relatively less well educated while one CBA study reports lower participation by those relatively better educated.

**Evidence statement R3.E5e**

Social class: Three programmes report participation in programme interventions and/or programme evaluation surveys according to social class. One CBA study and two RCTs report lower participation by those of lower social class.

**Evidence statement R3.E5f**

Ethnicity: Three programmes report participation in programme interventions and/or programme evaluation surveys according to ethnicity. Two CBA studies and one RCT report lower participation by ethnic minority groups.

**Evidence statement R3.E5g**

Marital status: Three programmes report participation in programme interventions and/or programme evaluation surveys according to marital status. Two CBA studies and one RCT report lower participation by those unmarried or divorced.

**Evidence statement R3.E5h**

CVD risk: Twelve programmes report participation in programme interventions and/or programme evaluation surveys according to CVD risk. One uncontrolled before-and-after study, six CBA studies and three RCTs report lower participation by individuals at relatively higher CVD risk while one RCT reports relatively lower participation by individuals at relatively lower CVD risk.

**Evidence statement R4.1b**

These suggest that factors influencing success include: time limitations for projects, leadership, (including difficulties engaging community members at strategic levels), and cooperation between partner organisations.

**Evidence statement R4.2a**

Four study reports show conflicting evidence about the degree and methods of community engagement important for success.

**Evidence statement R4.2b**

For programmes that were successful, one study reports that positive community expectations about the potential of the programme to effect wider change facilitated community engagement. It is suggested that insufficient community engagement did not significantly impact on another programme's success.

**Evidence statement R4.2c**

For programmes that were unsuccessful, one study reports that previous negative experiences of community programmes discouraged community engagement. Conversely, another study reports engagement in the programme increased willingness for future involvement.

**Evidence statement R4.3a**

There is evidence from five study reports that community programmes to address heart health can be affected by the broader political context.

**Evidence statement R4.3b**

This can effect diverse organisational elements such as: the availability of project funding, the development of partnerships between organisations and a sense of shared purpose at different administrative levels. Individual responses may also be affected through legislation incentives to healthier behaviours.

**Evidence statement R4.4a**

There is evidence from four study reports that high pricing can impact on people's ability and willingness to adopt healthy eating behaviours and to participate in organised physical activity.

**Evidence statement R4.7a**

Six study reports discuss factors relating to organisational and strategic issues.

**Evidence statement R4.7b**

There is evidence from four studies that short time frames limit the ability to plan and develop the programme, engage the community, develop partnerships and communication, meet targets and leave a positive legacy.

**Evidence statement R4.7c**

Leadership was identified as a key organisational benefit of programmes by three studies. It is required to develop partnerships and collaborations within communities, and is important at all levels, from volunteers to with senior administrators. One study failed to see the desired shift in leadership to the community itself.

**Evidence statement R4.8a**

Evidence from six study reports is related to the organisational culture and partnerships of those involved in CVD programme services.

**Evidence statement R4.8b**

Three studies note differences in culture between partner organisations including frames of reference, terminology and programme expectations although this didn't always lead to conflict.

**Evidence statement R4.8c**

Four studies suggest that CVD programmes are enhanced where partner organisations have aligned values, priorities, focus and goals between organisations.

**Evidence statement R4.8d**

Partnerships may have positive effects through interagency learning, increasing the visibility of smaller organisations and enhanced funding opportunities.

**Evidence statement R4.9c**

Promotional materials need to be accessible in terms of terminology and language used.

**Evidence statement R4.9e**

Two studies note that to sustain the provision of healthier food options, communities need to take them up and so they need to be made attractive and clear.

**Evidence statement R4.9f**

One study found that community projects were largely unwilling address smoking, preferring to promote physical activity.

**Evidence statement R4.10a**

Five studies reported on staffing successful programmes.

**Evidence statement R4.10b**

Three studies report difficulties in recruitment and retention.

**Evidence statement R4.10c**

Positive staff contributions were defined in three studies where successful networking allowed staff to use their time effectively because they were not duplicating activities; where they were assisted by structures that focus on heart health issues and where flexibility allowed them to spend significant periods of time with participants.

**Evidence statement R4.10d**

Positive staff characteristics included knowledge and interest in heart health and being upbeat and friendly. A range of specialist staff should be involved.

**Evidence statement R4.11a**

Six study reports make specific comments about funding and resource requirements.

**Evidence statement R4 11.b**

Five study reports note the need for those with existing roles and responsibilities to be given resources to take on additional CVD programme work, or for dedicated positions to be created. Limited time for school-based staff may be a particular problem.

**Evidence statement R4.12a**

Two studies identify effective communication between organisations, staff and the community, to be important, but use different mechanisms to achieve this: lay health advisers or having a full time project coordinator.

**Evidence statement R4.13a**

Four study reports discuss recruiting and retaining programme volunteers.

**Evidence statement R4.13b**

Volunteers need adequate resourcing and leadership, and may be motivated by witnessing positive changes in the community.

**Evidence statement R4.13c**

One study suggests that volunteers find health promotion less satisfying than traditional patient service roles.

**Evidence statement R4.13d**

Two study reports about the same programme note that lay health advisers, recruited from the target community, were key.

**Evidence statement R4.14a**

Two study reports mention the role of GPs in community CVD projects.

**Evidence statement R4.14b**

GP uptake was slow and it is suggested that GPs may be less comfortable in health promotion roles than their traditional role of secondary prevention.

**Evidence statement R4.15a**

Evidence relating to staff training were identified by six study reports.

**Evidence statement R4.15b**

While skills training is needed, involvement in the programme itself increases skills and knowledge through sharing information and implementing theoretical knowledge.

**Evidence statement R4.16a**

Five study reports relate to the evaluation of CVD prevention programmes.

**Evidence statement R4.16b**

Two study reports found that process evaluation and action research raised self-awareness among staff and promoted programme improvement. While a third reports that time limited projects limit the possibility of such learning.

**Evidence statement R4.16c**

Data management was a challenge in long-term projects and those with multiple strands across a number of organisations.

**Evidence statement R4.17a**

There is evidence from eight study reports about community engagement in CVD prevention programmes.

**Evidence statement R4.17b**

Two study reports suggest that successful community engagement requires multiple approaches across populations.

**Evidence statement R4.17c**

Two study reports suggest that successful programmes need to be sensitive to communities' habits and cultural patterns, while a further three describe the

important of matching programme staff to the social and/or ethnic characteristics of the target communities.

**Evidence statement R4.17d**

Challenges to community engagement include engaging community representatives at strategic levels; building confidence in community leaders; difficulties breaking into existing networks; competing with other community events; reaching young people; reluctance due to the legacy of negative experiences with previous initiatives; lack of enthusiasm in the community.

**Evidence statement R4.18a**

Seven studies report that the local physical environment had important effects on the ability of community CVD risk-reduction projects to be successful.

**Evidence statement R4.18b**

Five studies reported that access to healthy food options was limited, while unhealthy food was more visible, both in the community and in school-based programmes.

**Evidence statement R4.18c**

Local barriers to physical activity including no sidewalks, unmetalled roads or loose dogs; lack of school provision to secure bikes or store kit which discourages extra-curricular exercise; and local availability of gyms or other facilities.

**Evidence statement R4.19a**

Community and familial norms: There is evidence from one study report among British Asians that stress from a variety of sources was a noted problem among both men and women and this might lead to inability to access essential services or to communicate with professionals.

**Evidence statement R4.20a**

Attitudes to food and cooking: There is evidence from three study reports that specific foods and eating patterns may be regarded as important expressions

of cultural identity. Cultural norms about food types and their preparation may not be the most healthy from a CVD prevention perspective.

**Evidence statement R4.21a**

There is evidence from three study reports about cultural attitudes to weight and exercise.

**Evidence statement R4.21b**

These suggest that, among some groups, understandings of greater weight as a sign of wealth and health may persist which may challenge successful adoption of CVD prevention activities.

**Evidence statement R4.21c**

Further, specific connotations of language used to describe weight and physical activities may exist, so shared understandings between clinical and community meanings should not be assumed.

**Evidence statement R4.22a**

Fatalism and health: There is evidence from three study reports, among three different ethnic groups, of fatalistic attitudes where one's state of health is the will of God.

**Evidence statement R4.23a**

There is evidence from six study reports to suggest that a benefit of community CVD programmes is in providing leadership that encourages local attitudes to change for the better.

**Evidence statement R4.23b**

As well as making personal changes, such 'social health' encouraged changes within the family, within the local community and within the wider social and political community. Despite this, one study suggests that men remain less likely to use health services.

**Evidence statement R4.24a**

Nine studies discuss community perceptions of CVD risk factors.

**Evidence statement R4.24b**

Six studies report high levels of understanding about CVD risk among the target population while two suggest limited understanding and two suggest challenges in turning knowledge into action.

**Evidence statement R4.24c**

One study suggests that different types of knowledge are at play (theoretical, practical, experiential and intuitive), and where there is a discrepancy between theoretical and experiential knowledge, the latter influences what participants do. These links might be challenged by cues to action (health belief model) – most significantly breakdown of self-image and social networks.

**Evidence statement R4.24d**

One study develops a typology of six ‘ideal types’ of functional and dysfunctional attitude among programme participants who see it as a blessing, an opportunity, a confirmation, a watchman, a disappointment or an insult. The latter two are negative or ‘dysfunctional’ in terms of positive health choices and more men have these attitudes.

**Evidence statement R4.25a**

Nine study reports discuss people’s motivations for, or resistance to, adopting risk reduction behaviours.

**Evidence statement R4.25b**

Two studies report that health concerns, sometimes serious, were motivating factors to participate and two that feedback of physiological test results was motivating.

**Evidence statement R4.25c**

Women may be targeted to take heart health practices home, however, two studies report on difficulties initiating or maintaining family interest and that resistance from family members was a barrier to adopting healthier behaviour. It is difficult to maintain behaviour changes amidst the usual business of family commitments.

**Evidence statement R4.25d**

One study suggests that there is a need for ongoing support in order for behavioural changes to be made and maintained.

**Evidence statement R4.25e**

One study found that secondary school pupils enjoyed the freedom to make food choices not available at primary school – pupils' food choices, and those of the wider population, may reflect issues other than health.

**Evidence statement R4.26a**

Six studies report on participant perceptions of programmes in which they were involved.

**Evidence statement R4.26b**

In two studies participants reported improving heart health through weight loss, increased exercise, as well as increased awareness and use of services and programme activities. One study also suggests that networks providing community support was a benefit.

**Evidence statement R4.26c**

One study found that practical demonstrations were much more successful than information provision alone.

**Evidence statement R4.26d**

Two studies suggest that the participants may doubt the credibility of health messages, with so many sources of, sometimes contradictory, information available. Matching the characteristics of the community may be important.

**Evidence statement R5.2**

Community engagement: Positive community engagement requires trusting, respectful relationships to be built which motivate and support change. Community engagement should be an ongoing and dynamic partnership which responds to community needs.

As CVD may not be seen as an immediate concern within targeted communities, staff may first need to listen and respond to the existing concerns of the community. This may be done through participating in existing networks and forums, or creating forums that have more open agendas, at least to start with.

Sufficient time is needed to ensure that this is done appropriately and also to ensure that changes become adopted by the community so that they are empowered to continue, even if the project itself comes to an end.

Information and education is likely to be more effective if it relates to the experiences of the community, and if those that deliver it are seen as part of that community. Appropriately skilled staff are needed for effective community engagement.

Greater levels of participation, that involve community members as partners or devolve power to them, may have additional benefits – ensuring that programmes are truly responsive to community needs, involving local people in the complexities of planning and delivering such programmes and so facilitating understanding within the community.

Done well, community engagement may create a positive feedback loop which motivates change, improving health which produces greater motivation. However, care needs to be taken to ensure that those adopting behaviour change are not just those already motivated to change, thereby increasing, rather than lessening, health inequalities.

### **Evidence statement R5.3**

Staffing – leadership: Strong, inspirational leadership may be important to initiate, coordinate and drive complex programmes and motivate and encourage cooperation among multiple staff across a number of agencies with a range of responsibilities.

To fulfil this, staff are needed whose role is dedicated to the programme and those with multiple roles need to have appropriate time freed up.

Leaders may be needed for the project over all, but also for specific elements of the project, for example, to encourage primary care participation or ensure local political or funding support. Leaders from within the community are also needed to champion the project and facilitate engagement.

Expectations of leadership roles should be matched by appropriate control and responsibility, and given the necessary training and support.

#### **Evidence statement R5.4**

Staffing – staff engagement: To ensure that staff are engaged with the aims of a CVD prevention programme, they require appropriate training and resources, a good understanding of how their role fits into the programme overall and a clear understanding of the extent of their roles and responsibilities.

#### **Evidence statement R5.5**

Staffing – GPs: The role of primary care was complicated and sometimes contradictory. Some GPs may be more comfortable with a secondary, rather than primary, prevention role, which may explain why some participants found it difficult to engage them in CVD prevention programmes. Conversely, other participants viewed primary care as crucial partners in CVD prevention.

Advocacy among other local organisations may be a key role.

Where primary care is involved in CVD prevention programmes, they need to receive appropriate resources to free-up staff time.

Engaging primary care and keeping them appropriately informed may require tailored approaches.

#### **Evidence statement R5.6**

Staffing – volunteers: Volunteers from within the community may be particularly effective at informing, motivating and engaging their peers in the community and enhance community empowerment.

Volunteer workers need to be properly trained and supported to ensure that they continue to be involved and don't get burnt out.

The issues of paying those involved should be considered carefully.

#### **Evidence statement R5.7**

Staffing – multi-agency, multi-disciplinary teams: Public health work to reduce CVD is likely to require the involvement of multiple agencies and disciplines.

Coordination and cooperation is required to build trust and a sense of shared purpose through aligning the goals and activities of different agencies involved, and assigning clear roles and responsibilities to participating organisations and staff within them. Joint appointments may facilitate this. Ongoing feedback and communication is vital.

Sufficient time is needed to successfully negotiate and accommodate different expectations and bureaucracies.

#### **Evidence statement R5.8**

Legacy: CVD reduction programmes may enhance their longer-term impact through ensuring that programme activities are embedded within organisations and the community.

Appropriate training and support for key staff, and community members, from project inception may help to ensure activities become ‘institutionalised’. Ongoing sources of funding should also be identified.

Programme impacts should be regularly assessed and results fed back to staff and organisations so that successful activities are recognised and adopted. This will require the identification of appropriate resources.

Early and ongoing community engagement may ensure ongoing changes in healthy behaviours, empowering the community to maintain positive changes. Short-term projects often fail to leave lasting benefits to a community as their short-term goal setting may preclude the necessary engagement required.

#### **Evidence statement R5.9**

Short time frames: Short time frames for CVD prevention programmes may threaten success at a number of levels: implementation, staff engagement

and training, community engagement, evaluation and legacy. It is difficult for such programmes to meet community needs, staff needs or to permit changes to become embedded in the community. This may lead communities and local agencies to lose faith in such interventions, further hampering the ability of future work to be successful in those areas.

**Evidence statement R5.10**

Structural barriers: At a macro-level, changes in the broader political environment can have dramatic effects on the adoption and continuation of prevention activities.

Support for CVD prevention programmes may be affected by changing political priorities around prevention and treatment of illness.

**Evidence statement R5.11**

Piloting and monitoring: Cyclical approaches to monitoring and evaluation, such as piloting, process evaluation and action research, allow project to be responsive to local needs, adapting or removing inappropriate projects and allowing successful projects to be rolled out.

Information from this process fed back to staff in a timely way can help develop a sense of ownership and cooperation and motivate good practice.

Organisations and individuals should also learn from the experiences of previous projects.

**Evidence statement R5.12**

Challenges of evaluation: Commissioners and funders may need to allow flexibility in programme evaluation designs to allow them to adapt to local needs, rather than requiring fixed plans prior to funding. In addition, programmes and evaluations should allow sufficient time for outcomes to be achieved.

Multiple methods may be needed to evaluate important aspects of CVD prevention programmes, such as community empowerment, that are not all easily captured through numerical outcome data.

Programmes that measure only population-level changes may not capture large impacts for some individuals, and this may be important, especially where health inequalities are addressed.

#### **Evidence statement CE1**

Three studies gave results in cost per life-year gained for population-based programmes compared to no intervention. The results ranged from cost-saving to £240,000 per life-year gained.

#### **Evidence statement CE2**

Two studies gave results in cost per QALY or DALY (disability-adjusted life years) for population-based programmes compared to no intervention. Results ranged from £10 per QALY to £96 per DALY.

#### **Evidence statement CE3**

Two studies gave results in cost per case prevented for population-based programmes compared to no intervention. Results ranged from cost saving to £22,000 per case prevented.

#### **Evidence statement CE4**

Five studies reported results in cost per life-year gained for some form of screening strategy compared to no intervention. Results ranged from cost saving to £140,000 per life-year gained.

#### **Evidence statement CE5**

Two studies gave results in cost per case prevented for screening compared to no intervention. Results ranged from £10,000 to £730,000 per case prevented.

**Evidence statement CE6**

Two studies gave results per 1% reduction in coronary risk for screening compared to no intervention. Results ranged from £2.25 to £5.30 per 1% reduction for one person.

**Evidence statement CE7**

One study gave a result of £0.80 per pound weight lost for a screening programme compared to no intervention.

**Evidence statement CE8**

One study gave results ranging from £12,000 to £120,000 per life-year gained and £100,000 to £230,000 per QALY for screening compared to a population-based approach.

**Evidence statement CE9**

One study gave results from cost saving to £39,000 per life-year gained for some form of exercise training.

***Additional evidence***

- Expert reports:
  - ER 1: 'The effectiveness of physical activity promotion interventions'
  - ER 2: 'Health policy analysis'
  - ER 3: 'Expert testimony on salt and cardiovascular disease'
  - ER 4: 'The relationship between commercial interests and risk of cardiovascular disease'
  - ER 5: 'Regional development of a population-based collaborative CVD prevention strategy: the experience of NHS West Midlands'
  - ER 6: 'NICE guidance on the prevention of CVD at population level: evidence from the Co-operative Group'
  - ER 7: 'Population and community programmes addressing multiple risk factors to prevent cardiovascular disease (CVD):

addendum to qualitative study produced by Peninsula Technology Assessment Group for NICE: CVD programme – Heart of Mersey (HoM)

- ER 8: ‘Expert testimony paper on the independent evaluation of ‘have a heart Paisley’ phase one (Scotland’s national CHD prevention demonstration project)’
- ER 9: ‘Expert testimony on the public health harm caused by industrially produced trans fatty acids and actions to reduce and eliminate them from the food system in the UK’
- ER 10: ‘Prevention of cardiovascular disease at a population level: evidence on interventions to address dietary fats’
- ER 11: ‘CVD risk factors: paradigms and pathways’
- ER 12: ‘CVD prevention in populations: lessons from other countries’
- ER 13: ‘Will CVD prevention widen health inequalities?’
- Report 14: ‘Food manufacturer’s perspective’

### ***Cost-effectiveness evidence***

The economic analysis consisted of a review of economic evaluations and a cost-effectiveness analysis.

- ‘Prevention of cardiovascular disease at population level (Question 1; cost-effectiveness)’
- ‘Prevention of cardiovascular disease at population level: modelling strategies for primary prevention of cardiovascular disease’.

Some primary prevention programmes involving education, mass media and screening with a general population were found to be effective and cost effective. They may reduce some of the risk factors for CVD, including changing behaviours which increase the risk. However, when the findings from all programmes were summarised, the overall effect on health outcomes

was uncertain. In addition, as these programmes were conducted many years ago, the findings may not be generally applicable in the UK now.

The cost-effectiveness analysis strongly suggests that legislation likely to reduce the risk of CVD can be expected to produce a net cost saving to the public sector – as well as improving health. (Unless a very large sum of money needs to be spent on implementation.)

For example, implementing a CVD prevention programme based on the North Karelia project would result in an incremental cost-effectiveness ratio of approximately £7000 per quality-adjusted life year (QALY). For the Stanford Five City Project, the total healthcare cost savings almost equal the estimated cost of the project. The benefits of reducing the prevalence of smoking would also make the programme cost saving.

At the request of the Programme Development Group (PDG), the scope of the modelling was extended beyond programmes for which there was direct evidence of effectiveness. Interventions modelled included:

- The North Karelia project – including the effect of a net percentage reduction in serum cholesterol of 3% for men and 1% for women, and a reduction in systolic blood pressure of 3% for men and 5% for women.
- The Stanford Five City Project – the effect of a 4% reduction in systolic blood pressure and a 2% decrease in serum cholesterol among the general population.
- Legislation to ban trans fats and so reduce trans fatty acid (TFA) levels in the population so that it only accounts for approximately 0.7% of total fat consumed.
- Legislation to reduce the population's salt intake by 3g and 6g per day.

## Appendix D Gaps in the evidence

The PDG identified a number of gaps in the evidence related to the programmes under examination based on an assessment of the evidence. These gaps are set out below.

1. There is a lack of UK studies on the effectiveness of programmes to prevent CVD among black and minority ethnic groups living in the UK.
2. There is a lack of evidence on the effectiveness of interventions targeting those with high risk factors who believe their health is bad.
3. There is a lack of evidence on the effectiveness of providing emotional support and help to develop general coping skills as part of interventions to prevent CVD.
4. There is a lack of evidence on the effectiveness of CVD prevention programmes involving the families of those at risk.
5. There is a lack of controlled comparison studies looking at the effectiveness of lay health advisers in helping to prevent CVD.

## Appendix E: supporting documents

Supporting documents are available at

[www.nice.org.uk/guidance/PHG/Wave17/26](http://www.nice.org.uk/guidance/PHG/Wave17/26) These include the following.

- Evidence reviews:
  - Review 1: 'Prevention of cardiovascular disease at population level (Question 1; phase 1)'
  - Review 2: 'Prevention of cardiovascular disease at population level (Question 1; phase 2)'
  - Review 3: 'Prevention of cardiovascular disease at population level (Question 1; phase 3)'
  - Review 4: 'Barriers to, and facilitators for, multiple risk factor programmes aimed at reducing cardiovascular disease within a given population: a systematic review of qualitative research'.
  
- Primary research:
  - Review 5: 'Population and community programmes addressing multiple risk factors to prevent cardiovascular disease: A qualitative study into how and why some programmes are more successful than others'.
  
- Economic analysis:
  - Review 6: 'Prevention of cardiovascular disease at population level (Question 1; cost-effectiveness)'
  - 'Prevention of cardiovascular disease at population level: modelling strategies for primary prevention of cardiovascular disease'.
  
- Expert reports:
  - Report 1: 'The effectiveness of physical activity promotion interventions'
  - Report 2: 'Health policy analysis'

- Report 3: ‘Expert testimony on salt and cardiovascular disease’
- Report 4: ‘The relationship between commercial interests and risk of cardiovascular disease’
- Report 5: ‘Regional development of a population-based collaborative CVD prevention strategy: the experience of NHS West Midlands’
- Report 6: ‘NICE guidance on the prevention of CVD at population level: evidence from the Co-operative Group’
- Report 7: ‘Population and community programmes addressing multiple risk factors to prevent cardiovascular disease (CVD): addendum to qualitative study produced by Peninsula Technology Assessment Group for NICE: CVD programme – Heart of Mersey (HoM)’
- Report 8: ‘Expert testimony paper on the independent evaluation of “have a heart Paisley” phase one (Scotland’s national CHD prevention demonstration project)’
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- Report 12: ‘CVD prevention in populations: lessons from other countries’
- Report 13: ‘Will CVD prevention widen health inequalities?’
- Report 14: ‘Food manufacturer’s perspective’.

For information on how NICE public health guidance is developed see:

- ‘Methods for development of NICE public health guidance (second edition, 2009)’ available from [www.nice.org.uk/phmethods](http://www.nice.org.uk/phmethods)

- 'The NICE public health guidance development process: An overview for stakeholders including public health practitioners, policy makers and the public (second edition, 2009)' available from [www.nice.org.uk/phprocess](http://www.nice.org.uk/phprocess)