Evaluation of a National Cardiovascular Risk Assessment Programme

(NHS Health Check)

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Abstract

**Background:** The NHS Health Check, the largest systematic cardiovascular disease (CVD) primary prevention programme globally, aims to reduce CVD burden and health inequalities by assessing and managing CVD risk among 40 to 74 year old individuals without existing vascular diseases. I evaluated the impact of the programme at local and national levels.

**Methods:** Using electronic medical record data from general practices in Hammersmith and Fulham, I assessed CVD risk factor recording before the programme, the programme uptake in the first two years and the impact of the programme on CVD risk. National coverage of the programme in one financial year was assessed using data from Primary Care Trusts (PCTs).

**Results:** There was good recording of smoking status (86.1%) and blood pressure (82.5%), with lower BMI (59.5%) and cholesterol (47.5%) recording among Health Check eligible patients before the programme in Hammersmith and Fulham. Uptake of the Health Check was lower than the national target (75%) at 39.2% among patients with an estimated high CVD risk, but matched the national required rate at 20.0% among all remaining eligible patients. There was significant reduction in mean global CVD risk score (28.2% to 26.2%) after one year among patients with estimated high risk that had a complete Health Check. The programme uptake was higher in patients living in more deprived areas among those not at estimated high risk (adjusted odds ratio = 0.88 (0.73-106)). Mean national coverage of the programme was lower (8.1%) than anticipated (18%), with large PCT-level variation (0% to 29.8%). Coverage was significantly greater in PCTs in more deprived areas (coefficient = -0.51 (-1.88-0.00), p-value: 0.035).

**Conclusions:** Population-wide impact of the NHS Health Check may be limited by poor uptake of the programme. This and other limitations to the programme suggest that a targeted screening approach along with population-wide strategies may be a better option for more cost-effective prevention of CVD.
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Abbreviations

ABCS – Aspirin prescription, blood pressure and cholesterol control and smoking cessation
ACCF – American College of Cardiology Foundation
AHA – American Heart Association
AIC – Akaike Information Criterion
AUROC – Area Under ROC Curves
BFHS – British Family Heart Study
BMI – Body Mass Index
CDC – Centres for Disease Control and Prevention
CHD – Coronary Heart Disease
CHHS-AP – Canadian Heart Health Strategy and Action Plan
CKD – Chronic Kidney Diseases
COPD – Chronic Obstructive Pulmonary Disease
CRP – C-reactive protein
CVD – Cardiovascular Disease
DALY – Disability Adjusted Life Years
DES – Directed Enhanced Service
DPAS – Global Strategy on Diet, Physical Activity and Health
DRE – Digital Rectal Examination
DVT – Deep Vein Thrombosis
ECG-LVH – Electrocardiographic Diagnosis of Left Ventricular Hypertrophy
EMR – Electronic Medical Record
FCTC – Framework Convention on Tobacco Control
FOBT – Faecal Occult Blood Test
FSA – Food Standards Agency
FTE – Full-time Equivalent
GP – General Practitioner
hsCRP – Highly sensitive C-reactive protein
HDL – High-density Lipoprotein
ICC – Intra-class Correlation Coefficient
JBS – Joint British Societies
JBS2 – Joint British Societies 2
LDL – Low Density Lipoprotein
LES – Local Enhanced Service
LVH – Left Ventricular Hypertrophy
MI – Myocardial Infarction
MONICA – monitoring trends and determinants in cardiovascular disease
MOR – Median Odds Ratio
NCD – Non-communicable disease
NES – National Enhanced Service
nGMS – New General Medical Service
NHS – National Health Service
NICE – National Institute for Clinical Excellence
NSC – National Screening Committee
NSF-CHD – National Service Framework – Coronary Heart Disease
OR - Odds Ratio
OXCHECK – Oxford and Collaborators Health Checks
PAD – Peripheral Arterial Disease
PCT – Primary Care Trusts
PROCAM – Prospective Cardiovascular Munster
PSA – Prostate-specific Antigen
ptp – Per Thousand Population
QALY – Quality Adjusted Life Years
QOF – Quality Outcomes Framework
QOF+ – Quality Outcomes Framework Plus
ROC – Receiver Operating Characteristic
RR – Relative Risk
RRR – Relative Risk Reduction
SES – Socio-economic Status
TIA – Transient Ischemic Attack
UK – United Kingdom
US – United States
VPC – variance partitioning coefficient
WHO – World Health Organization
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Declaration of Originality

The work presented in this thesis is my own, with support from my supervisors Christopher Millett and Azeem Majeed. Andrew Dalton advised me on the management of data and the statistical analyses for modelling. I also declare that any work of others is fully cited and appropriately referenced.

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Chapter 1: Introduction

In 2008, the United Kingdom (UK) government announced the introduction of an ambitious national cardiovascular disease (CVD) prevention programme in England. This programme, named National Health Service (NHS) Health Check, aims to reduce the huge burden of CVD on the NHS by both assessing and managing CVD risk in whole eligible population in England. The general eligibility criterion for the programme is any individual aged 40 to 74 years without established CVD, diabetes, hypertension and chronic kidney disease (CKD).

The NHS Health Check programme is the largest universal systematic CVD risk assessment programme ever undertaken in the world. It is crucial to assess the effectiveness and cost-effectiveness of such an ambitious programme. Although there have recently been evaluations of the NHS Health Check at local scale, further evaluations of effectiveness of the programme at local and national levels are necessary. Thorough evaluation of the programme is essential for deriving implications for the future of the programme; the evaluation findings will also be significant for those planning to implement similar CVD prevention programmes in other countries.

1.1 Methodology of literature review

Before evaluation of the NHS Health Check programme using empirical data, I carried out an extensive literature review to detail background information on CVD and its epidemiology (Chapter 1); strategies and interventions for effective prevention of CVD (Chapter 2); global, international and national policies for the prevention of CVD (Chapter 3); and experiences from existing screening programmes (Chapter 4). I determined these areas of detailed review on the basis of the nature and scope of the Health Check programme and in order to place the results of my evaluation within the wider context of the epidemiology and prevention of CVD.

The extensive review was carried out by searching for a variety of sources of information; mainly review articles (both narrative and systematic reviews), research articles, conference proceedings and books. Research literature was identified via a number of channels, such as databases, including Science Direct, PubMed and Cochrane database; journals; Imperial College London library; bibliographies of sources reviewed; networking with colleagues; and
conferences. The searches from databases and specific journals were undertaken using a number of different keywords based on the topic of interest to be reviewed.

Given the breadth of the literature covered in my thesis, it was not feasible to carry out a systematic review, i.e. including specific inclusion and exclusion criteria and quality assessment tools. However, whilst choosing material to review, the obtained literature was assessed critically for quality. I chose materials written in English only and assessed if the literature included information related to the topic reviewed. Although the review included both peer-reviewed and non-peer reviewed literature, the type of literature was chosen based on the nature of the information to be collected. For example, for the definitions of concepts (e.g. CVDs, strategies of CVD prevention), I used non-peer reviewed sources, such as websites, as well as peer-reviewed materials of books and review articles. However, when reviewing the evidence on effectiveness of strategies and interventions, priority was given to systematic reviews and meta-analysis. In the absence of systematic reviews on a specific topic, individual empirical studies were used, with priority given to the most recent studies. When assessing the quality of literature, I also considered if the methodology of procedures used was explained exoterically; how study population was sampled and if authors treated bias appropriately.

1.2 Definition of cardiovascular disease

Cardiovascular disease is a group of disorders affecting the heart and blood vessels. CVDs include different types of diseases, e.g. heart disease and vascular disease of the brain, defined in Figure 1 (1). The most common CVDs in both sexes are coronary heart disease (CHD) and cerebrovascular disease, leading to greatest disease burden within CVDs (2).

The main cause of some CVDs, such as CHD and cerebrovascular disease, and disease of the aorta and arteries is atherosclerosis (2). Atherosclerosis occurs as a result of accumulation of fats especially cholesterol on the smooth inner linings of healthy blood vessels over many years, thickening and roughening the linings of blood vessels. The deposition of fats forms a plaque, which narrows the vessels resulting in difficulty in blood flow. Partially blocked arteries can lead to occasional chest pain, resulting a chronic condition called angina pectoris (3). Acute blockage of coronary arteries supplying oxygen rich blood to cardiac muscles can lead to shortage of oxygen in these tissues leading to a heart attack (myocardial infarction (MI) – a type of CHD). When cerebral arteries supplying the brain are blocked, the shortage
of oxygen kills the nervous tissue resulting in acute stroke (4); if the blockage disappears within some time and the stroke symptoms resolve in a day, the condition is called transient ischemic attack (TIA) (5,6). The plaque in the blood vessels can rupture and form blood clot, which could also cause MI when in the coronary arteries and stroke when in the brain (2). Peripheral arterial disease (PAD) occurs when plaque formation is in the arteries supplying limbs, head and other organs, such as kidney and stomach. PAD may, for example, block the blood supply to leg and lead to gangrene (7).

Figure 1: Types of cardiovascular diseases *(Adapted from: Mackay & Mensay, 2004 and Texas Heart Institute, 2012)* (1,8)

Rheumatic fever is an inflammatory disease of connective tissues caused by bacterial infection (Streptococcus) of the throat. Rheumatic fever can affect connective tissues particularly in the heart or the brain (9,10). If rheumatic fever is not treated, it can damage the heart valves, leading to rheumatic heart disease. Rheumatic heart diseases may further cause a fatal condition, called heart failure (10,11).
Deep vein thrombosis (DVT) is a condition that occurs due to a blood clot in a deep vein of particularly of the thigh or lower leg. If a blood clot breaks off from a deep vein and circulates in the blood through the heart to the lungs, it can block pulmonary arteries, leading to pulmonary embolism (12–14).

1.3 Epidemiology of cardiovascular disease

1.3.1 Global burden of cardiovascular disease

Non-communicable diseases (NCDs) are the main causes of global deaths (63%) (15). CVD is the leading cause of death worldwide with an estimated 17.3 million deaths, 48% of all NCDs and 31% of all global deaths, in 2008 in both sexes. The most common causes of CVD deaths are CHD and stroke, with an estimated 7.3 million and 6.2 million deaths attributable to heart attacks and stroke respectively. More than 80% of all global CVD deaths occur in low- and middle-income countries. It is projected that CVD will remain the primary cause of deaths globally and will be responsible for around 25 million deaths in 2030 (16).

According to World Health Organization (WHO), the total burden of diseases is represented by disability adjusted life years (DALYs) lost (Healthy years of life lost) (1). In 2010, the estimated burden of CVDs and circulatory diseases was 295 036 million DALYs (11.8% of all global DALYs), 129 820 million of which were due to CHD and 102 232 million to cerebrovascular disease. CVDs are among the top causes of global disease burden, with CHD and stroke ranked first and third respectively (17). It is projected that in 2030, CHD and cerebrovascular disease will be responsible for 5.5% and 4.3% of the total disease burden respectively, both ranking in the top four causes of global disease burden (18).

1.3.2 Cardiovascular diseases in the United Kingdom

CVD is the primary cause of mortality in England, accounting for about a third of all deaths (more than 147 000 deaths) in 2010; CHD is the most common cause of all CVD deaths (19). Stroke is the second commonest cause of CVD deaths, causing approximately 53 000 deaths annually in the UK (20). CHD and stroke are also the common causes of premature deaths (deaths in individuals aged 75 and under) (19,20). The estimated burden of CVDs in the UK was 2710 million DALYs in 2010, 53.7% of which was attributable to CHD and 24.5% to cerebrovascular diseases (21).
1.3.2.1 Secular trends in cardiovascular diseases

There has been a large decline in CVD mortality over the last few decades in the UK, as well as in other western countries (22–25). Although CVD remains the main cause of death, CVD mortality as a proportion of all deaths reduced from 51.1% to 32.3% from 1961 to 2009. The declines in age-standardised mortality rates of CVD and its second most common type, stroke, were similar between men and women (Figure 2). There had been more than 50% decline in deaths attributable to CHD, the most common CVD, within the same time period (22). A modelling study showed that CHD mortality declined by 54% between 1981 and 2000 in England and Wales, with 62% decline in men and 45% in women aged 25 to 84 years (26). The risk of developing first MI in British men also declined by 62% between 1978 and 2003 (27).
Figure 2: Age-standardised mortality rates for cardiovascular diseases in Great Britain between 1961 and 2009 in (a) men and (b) women (Source: British Heart Foundation, 2011) (22)
1.3.2.2 Economic burden of cardiovascular diseases

The estimated global cost of CVD in 2010 was $863 billion, 55% of which was attributable to direct healthcare costs and 45% to indirect costs (e.g. loss of productivity due to morbidity or premature death, or loss of time from work due to illness). This cost was estimated to rise by 22% to $1,044 billion in 2030. The CVD cost was greater in high-income countries than middle- and low-income countries (15). The estimated total cost of CVD, in 2010, in US was about half ($444 billion) of all global cost of CVD (28).

CVD exerts a vast economic burden in the UK, costing a total (direct and indirect costs) of £18.9 billion to the UK economy in 2009 (29,30). £8.7 billion of this total cost was attributable to direct costs for CVD care, with 64% of this spent for hospital care and 23% for medications (29). The total costs for CHD was £6.7 billion, with £1.8 billion spending on direct costs for CVD care. Stroke cost a total of £3.7 billion to the UK economy, £1.8 billion of which was spent on direct stroke care costs (29,30).

1.3.2.3 Inequalities in cardiovascular diseases

Besides a large overall burden, CVDs are also important causes of health inequalities in the UK. Large variations in CHD mortality with different socio-economic status (SES) in British men were reported in late 1970s; men with the lowest individual level employment grade had a 3.6 times higher CHD mortality rate than men with the highest grade (31). There were also marked inequalities in CHD incidence, with again 1.5 times higher CHD incidence in men in the lowest employment grade compared with the highest (32). These variations have led to large differences in CVD mortality across populations; CHD mortality was 1.5 times greater in the most deprived areas than the least deprived in 2008 (19). Recent evidence also demonstrated that more deprived patients benefited less from the decline in CHD mortality over the last few decades (33). Stroke mortality rates were also socially patterned in England and Wales, with more than 3.5 times greater stroke mortality in men living in the most deprived areas compared to the least and more than 2.5 times greater mortality in women (20).

There are ethnic, as well as socio-economic disparities in CVD in the UK (34). CVD risk is greater in South Asian patients (35), with a particularly large CHD burden in this ethnic group (36). Although stroke mortality is also higher in South Asians, the reason for their greater risk is less clear and warrants further research (35,37). South Asians were shown to
have increased incidence of angina than white in the Whitehall-II study (38). In Scotland, Pakistani patients had higher angina prevalence than other ethnic groups, while mortality and hospital admissions due to chest pain were increased in Pakistani, Indian men and other South Asian women (39). CVD mortality rate also varies with the country of birth; individuals born in South Asian countries have higher CVD mortality compared with those born in England (34). Individuals born in Bangladesh have higher circulatory disease and CHD mortality rate compared with those born in England, whilst individuals born in China and Hong Kong have lower mortality rates (36). Men born in Bangladesh have two times higher CHD mortality rate compared with those born in England. Whilst there was a remarkable decline in CHD mortality in English-born men, CHD mortality showed no decline, but increased in men of Bangladeshi origin between 1979 and 2003 (40). Stroke mortality is the greatest in patients from an African and Caribbean background (36,41); men born in West Africa have over 2.6 times greater stroke mortality compared with men born in England (40). Using country of birth as a proxy for ethnicity has however significant limitations, because it does not reflect the country of origin of a person. For example, if children of immigrants born in the country of migration, it is not appropriate to count their ethnicity as the country of their birth. Using country of birth as a proxy of ethnicity can lead to inaccurate determination and management of inequalities in health (42).

There are also gender disparities in CVD burden in the UK. CHD prevalence was greater in men than women in 2006, with 1.3 million in men compared with 860 000 in women. More men than women had a heart attack in 2007 (>62 000 men compared with >38 000 women). CHD also accounted for more deaths in men than women in 2010 (17.0% of all deaths in men compared with 11.5% of all deaths in women were due to CHD), whilst stroke mortality was higher in women (10.3% of all deaths in women and 7.1% of all deaths in men were attributable to stroke) (19). The patterns in declining trends in mortality rates of CVDs were similar between genders from 1961 to 2009, although men experienced greater decline after 1985. Age standardised mortality rates of CHD and all CVDs, however, remain greater in men compared with women (Figure 2) (22).

There are also regional and country level variations in CVD burden in the UK. England has lower premature CHD mortality rates than three other constituent countries of the UK, i.e. about 10% less CHD mortality in both sexes in England compared with Wales in 2010 (19). Scotland have had greater (30-40%) CHD death rates compared with England since early
1960s (22). Stroke incidence rates are also greater in Scotland compared to England. The North of England has greater CHD mortality rates (43); 50% and 60% greater CHD mortality in the North West compared to South East in men and women respectively (19).

1.4 Risk factors for cardiovascular disease

There are many risk factors for CVD, which can be considered in two categories of non-modifiable (fixed) and modifiable risk factors. Fixed risk factors are those that cannot be modified, namely family history of CVD, gender, age and ethnicity. Age is the strongest predictor of CVD: the damage to cardiovascular system increases with age, thus older individuals have greater CVD risk (44). CHD risk is greater in men than pre-menopausal women; however, differences in CHD risk profiles between women and men reduce after menopause (45,46). Having a family history of CVD is another risk factor for CVD; having a first-degree relative who had suffered from CVD at a premature age (e.g. below 55 years in men and below 65 years in women) increases the risk of developing CVD (47,48). Ethnicity is a complex risk factor for CVD (47), since it acts as a determinant for the other risk factors of CVD, as well as overall CVD risk (49,50).

Modifiable risk factors can be considered in two categories: clinical and behavioural risk factors. Modifiable risk factors play significant role in the prevention of CVDs, since they can be changed (behavioural) or treated (clinical) (47). The most significant clinical risk factors for CVD are high blood pressure and blood lipid levels. High blood pressure is the major independent risk factor for diseases globally (51) and is also independently associated with CVD mortality (52). Evidence suggests that even a small reduction in blood pressure can provide substantial public health benefits, with significant reductions in CVD prevalence in a population (53). For example, 5 and 10 mmHg decrease in diastolic blood pressure in long-term is associated with at least 34% and 56% reduction in stroke risk respectively and at least 21% and 37% reduction in CHD risk (54). There is also evidence demonstrating that in those aged 40 to 69 years, a 20 mm Hg change in systolic blood pressure and 10 mm Hg decrease in diastolic blood pressure can produce more than two times difference in the risk of stroke mortality and two times difference in the risk of CHD and other vascular diseases mortality. For example, a 20 mm Hg increase in systolic blood pressure increases the risk of death from stroke by two times (52).
Lipid levels are also strongly associated with CVD risk: increased total cholesterol (hypercholesterolemia), low-density lipoprotein (LDL) cholesterol and triglycerides, and reduced high-density lipoprotein (HDL) cholesterol levels increase the risk of CVD (48). Lewington et al. (55) reported that 1 mmol/L increase in total cholesterol increases the risk of CHD mortality by about 50% in 40 to 49 year old individuals and the risk decreases by increasing age. A meta-analysis also showed that 1 mmol/L decrease in LDL cholesterol is associated with 12% reduction in deaths from all causes, with 19% reduction in CHD deaths (56). High triglyceride levels also act as independent predictors of CVD risk, with increased triglyceride levels associated with moderate increase in CHD risk (57). Decreased levels of HDL cholesterol increase the risk of CVD. Gordon et al. (58) demonstrated that a 1 mg/dl increase in HDL cholesterol reduced CVD risk by 3.7% in men and 4.7% in women.

Diabetes mellitus is another major independent clinical risk factor for CVD (59,60). Evidence suggests that patients with diabetes are more than two times more likely to have CVDs than those without diabetes, with 2.1 times greater CVD incidence in diabetic men and 2.7 times greater incidence in women (61). Wannamethee et al. (62) also showed that men with early onset diabetes are more than two times more likely to have CHD and CVD than those without. Evidence also suggests that patients with diabetes have poorer prognosis after myocardial infarction than those without (63).

Kidney disease is also another factor that is significantly associated with increased risk of CVD (64), especially in diabetic patients (59). Evidence suggests that in CKD patients, CVDs cause more deaths than problems due to renal function (e.g. kidney failure) (65). Obesity and adiposity are independent risk factors for CVD, but also have negative effect on other clinical risk factors like blood pressure, lipid levels and diabetes (48,60,66). It was shown that in men aged 50 years and below, men with the highest weight are two times more likely to have CHD than the thinnest, whilst CHD risk is 2.4 times greater in the heaviest women patients compared with the thinnest (67). A number of other novel clinical risk factors for CVD have been identified; these include highly sensitive C-reactive protein (hsCRP), fibrinogen, homocysteine, lipoprotein-a and others. However, these risk factors are not managed in routine clinical practice (68,69).

The main behavioural risk factors for CVD are physical inactivity, smoking and unhealthy diet with excess salt, trans fats and alcohol. These risk factors have a complex association with CVD, since they could affect both CVD risk directly and other CVD risk factors, such
as diabetes and hypertension (48). Physical inactivity is an independent risk factor for CVD, with about 30% lower CVD mortality risk associated with light, moderate or more vigorous physical activity (70). A meta-analysis supported that physical activity is associated with 35% decrease in CVD mortality risk (71). Physical activity is recommended as a significant intervention in preventive strategies (48).

Smoking is one of the most significant preventable CVD risk factors (72); smokers are about two times more likely to develop stroke than non-smokers (73). Age is significantly associated with smoking attributable CVD risk; for example, whilst persons aged 60 years and older have more than two times greater risk of heart attack, those aged 50 years and younger have more than five times greater risk (74). Passive smoking, breathing second hand smoke, also acts as a risk factor for CVD (75,76).

Diet is very crucial for CVD risk. Salt-intake has strong and well-known association with blood pressure (77); elevated levels of salt-intake increase blood pressure and accordingly the risk of CVD (78,79). Reduction in consumption of salt levels is therefore important to reduce blood pressure; for example, a 6 gram reduction in salt intake per day can reduce systolic blood pressure by 5.8 mmHg (80). Reduction in salt-intake lowers CVD risk, as well as blood pressure (79,81,82). Evidence suggests that a 6 gram reduction in salt intake per day is associated with 24% reduction in stroke and 18% reduction in CHDs (79).

Trans fatty acids (trans-fats) are one of the significant nutritional risk factors that need to be tackled for cardiovascular protection (83). There are both industrial trans-fats, which are created by partially hydrogenating vegetable oils to obtain semi-solid fats, and naturally occurring trans-fats, which are very small in amount in natural diet. Industrial trans-fats are more commonly consumed and harmful for health, although naturally occurring trans-fats have no major harm implications for health (84). Trans-fats have strong adverse impact on levels of blood lipids, with decreasing effect on HDL cholesterol and increasing effect on LDL cholesterol and triglycerides. They may also lead to systemic inflammation, insulin resistance and consequently diabetes. Trans-fats are therefore strongly associated with the increased risk of CHD (84–86). Even a small increase in trans-fat consumption leads to increase in CHD risk; it was estimated that an increase in trans-fat consumption by 2% of total energy intake (approximately 5 g per day trans-fat) increases the risk of CHD by 23% (86).
The relationship between alcohol and CVD risk is complex. Evidence suggests that light to moderate consumption is effective in reducing CVD risk, with 25% lower CVD risk in alcohol drinkers compared with non-drinkers (87). However, excess consumption increases the risk, with two times greater CVD mortality risk in those having excess alcohol consumption (having three or more drinks within one to two hours) compared with those having light to moderate consumption (88).

1.4.1 Secular trends in cardiovascular risk factors

Reductions in CVD mortality are highly attributable to population level reductions in CVD risk factors (26,89–94). Population level CVD risk factor reductions have had a greater contribution to the decline in CVD mortality compared to improvements in health care and treatment of patients with existing CVDs (90,94,95); for instance, 58% of the decline in CHD mortality was attributable to population level risk factor reduction in England and Wales between 1981 and 2000 (26). A review demonstrated that interventions to manage risk factors can generate rapid reductions in CVD mortality (96). However, it is important to note that the CVD mortality decline is not only attributable to reduction in CVD risk, but also to improvements in modern treatment for CVDs, which have enhanced survival rates after CVD events (91).

The decline in CVD mortality rates is attributable to reduction in CVD incidence rates and improvement in survival after established CVD events. The CVD incidence decline is attained when CVD risk factors reduce. Reductions in three major risk factors, smoking, blood pressure and lipid levels, explain the majority of decline in CVD incidence (27). Smoking is responsible for the largest proportion of decline, for instance 23% of all MI incidence decline was attributable to decline in cigarette smoking between 1978 and 2000 in Britain (27). Smoking prevalence has shown a decline in a number of high-income countries since 1970s (97), including the UK (98,99). There was a significant drop in non-HDL cholesterol levels in Britain by 0.28 mmol/L between 1978 and 2004 (27). This reflect the trends elsewhere (100,101). Finally, a global reduction in blood pressure was observed between 1980 and 2008; systolic blood pressure decreased by 0.8 mm Hg in men and 1.0 mm Hg in women per decade. There were variations in the decline in blood pressure, with greater decline in high-income regions, e.g. 3.5 mm Hg systolic blood pressure decline per decade in women in Western Europe and Australasia (102). Systolic blood pressure declined by 6.6
mmHg between 1978 and 2004 in Britain, which contributed to 13% of reduction in MI incidence (27).

Despite decreasing trends in these risk factors, two other major CVD risk factors have shown opposite trends. Body mass index (BMI) has shown an increase globally, by about 0.5 kg/m² per decade in both sexes. The trends vary between regions, with especially large increases in BMI in high-income regions (103). In England, there was an increasing trend in the obesity prevalence between 1993 and 2011, with 10.4% increase in men and 9.5% in women (104). Diabetes has also shown increasing trends over years globally, with more than the double of number of people with diabetes in 2008 compared with 1980 (105). In the UK, there was a 54% increase in the prevalence of diabetes (from 2.8 to 4.5%) between 1996 and 2005 (106).

Evidence apparently supports that reduction in CVD risk factors have played important role in the decline of CVD incidence (27,107). The question now is that what has played the major role in the reduction of these risk factors; two possible factors are changes in lifestyle behaviour (e.g. healthy diet) and increased use of pharmacological agents. It is crucial to answer this question, since it has important implications for CVD prevention. Many current evidence failed to establish the underlying reason for reduction in risk factors (27). Present evidence is limited and inconsistent; there is lack of longitudinal data, which are required for accurately establishing the major drivers behind the risk factor changes.

In a Swedish study, which reported substantial decline in serum total cholesterol levels, there was limited increase in pharmaceutical interventions for lowering serum cholesterol within the study period, suggesting that changes in diet were possibly responsible from the declining trends in total cholesterol (107). In US, reduction in total cholesterol and LDL cholesterol was reported in both lipid-lowering drug users and non-users, which implies that improvement in lifestyle factors may play crucial role in lipid level reduction (108). A study using worldwide data, but mainly from European countries (MONICA - monitoring trends and determinants in cardiovascular disease - Project data) demonstrated significant blood pressure reduction, with no association between patterns in blood pressure and medication use. The study suggests that lifestyle changes carry crucial importance in lowering blood pressure at population level (109).

In contrast to these studies, a British cohort study on randomly selected men aged 40 to 59 years showed greater blood pressure reductions between 1998 and 2000 in those using blood
pressure lowering medications, suggesting that treatment was probably the major factor enhancing the blood pressure reduction (110). However, it is important to note that these study participants were old men and the findings may not be generalizable to whole population. In a Japanese study, increased use of antihypertensive medications accounted for a part of the reduction in mean systolic blood pressure between 1986 and 2002, particularly in older individuals. The study reported minimal effect of lifestyle factors like physical activity, dietary salt intake and alcohol drinking on systolic blood pressure reduction, but the driver behind the significant part of systolic blood pressure reduction remained unexplained (111).

It is very important to determine the major driver behind the reductions in CVD risk factors for the future of CVD prevention, but it is apparent that this is a complex issue. Evidence indicates that the association between CVD risk factors and both drug therapy and lifestyle factors varies over time. In developed countries, initial large reductions in cholesterol were observed before the introduction of lipid reducing agents (e.g. statins), implying that changes in health behaviours, particularly diet, were associated with the cholesterol reduction. The cholesterol reductions have recently been modest, but they are mainly attributable to lipid-lowering medications (112). These suggest that improvement in healthy lifestyle have been slowed down in recent times, leaving drug therapies as a larger contributor in the risk factor reduction. Public health professionals may need to focus on the factors that facilitated the risk factor reduction at early times, when the risk factor reduction rates were at the highest levels.

Although the major driver of the risk factor reduction has not been exactly explained yet, evidence shows that behavioural changes have played some role. There is evidence that prescribing levels have not reached the level at which they contribute to larger proportion of the CVD risk reduction (113). In high-income countries, the therapeutic interventions are not high enough yet for large CVD risk reductions. There are a number of factors that can limit the use of drug therapy, e.g. statins, such as costs and drug adherence in healthy looking individuals (114,115). These may, therefore, limit effective reduction of CVD risk factors. The evidence showing large CVD risk reductions have used data before statins are at low-cost and commonly used; thus, therapeutic agents may play larger role in the recent CVD risk trends.
1.4.2 Inequalities in cardiovascular disease risk factors

Inequalities in CVD, discussed earlier, are often partially explained by disparities in CVD risk factors (116). There are marked differences in smoking between socio-economic groups in England, with greater smoking rates among the most disadvantaged. Although those more disadvantaged did not experience reduction in smoking prevalence between 2001 and 2008, there was reduction in other groups. This is possibly due to an increase in those not ever starting smoking, but not an increase in smoking cessation rates (117). Socio-economic inequalities in risk factors are parallel to inequalities in CVD burden in many countries (118). The socio-economic variation in smoking prevalence and smoking cessation rates are directly proportional to socio-economic disparities in CVD burden, suggesting that smoking has an important role in the generation of socio-economic inequalities in CVDs (118,119). Alcohol consumption is greater in lower socio-economic groups, which is also a determinant of higher CVD mortality in these groups (119). Diabetes is also more prevalent in more deprived individuals compared with less (120,121). In those with diabetes, more deprived patients are more likely to have greater BMI (121) and less likely to control their cholesterol than less deprived (120). Diabetes, therefore, is an important predictor of greater CVD mortality in more deprived populations and effective interventions are essential to control risk factors (e.g. obesity and cholesterol) in these groups for the management of inequalities in CVD burden (120).

Although south Asians have lower obesity prevalence than other ethnic groups (e.g. whites and blacks) (50,122), obesity associated health problems can appear at a lower BMI in this ethnic group (122). For example, they have greater insulin resistance (123,124), even in those with lower levels of BMI and central obesity (determined by abdominal fat) (125). South Asians are also less physically active; lower levels of physical activity are associated with greater BMI, waist measurement, blood pressure and blood glucose levels (126). These can all explain greater diabetes (50,124,127) and CHD prevalence in south Asian population compared with other ethnic groups (126). Blood pressure is higher in Afro-Caribbeans compared with Europeans (128); this pattern explains the raised stroke prevalence in the black population, particularly in women (35). There might be other explanations for ethnic inequalities in CVD, including disparities in health behaviours, psychosocial factors and genetics (129). Ethnic differences in CVD cannot be fully explained by differences in levels
of known risk factors: there might be other undetermined factors that play role in ethnic inequalities (35).

1.5 Challenge of funding cardiovascular disease care

Age is the strongest predictor of CVD. In England, despite declining CVD incidence and mortality rates, CVD prevalence is increasing, particularly in older individuals (19). This is because aging populations, who have greater CVD risk than younger, are increasing and survival is also increasing in CVD patients due to improved CVD care (130). In the western world, since the proportion of aging populations keeps increasing, the prevalence of CVD cases is expected to increase dramatically leading to a huge burden on health care, which will in turn increase the costs of CVD care (130,131). In US, CVD spending is projected to triple within the next twenty years (131).

A similar cost projection in the UK would put NHS under a disastrous pressure irrespective of its financial situation. However, the English health system shows little sign of financial growth in the following years and may be exposed to significant cutbacks in public health care spending (132), similar to other European countries that are suffering from the financial crisis (133).

Evidence supports that reduction in CVD risk factors play a significant role in reducing CVD burden. Capewell and O’Flaherty (96,134) suggest that for effective and cost-effective reduction of CVDs, policies addressing risk factors (such as population level reductions in salt-intake) at population-level are important. This may imply that when population-level interventions for managing risk factors are accompanied by clinical management of high-risk patients will be paramount way of effectively preventing the projected increase in the burden of CVD (134,135) and consequently, lessening the risk of increase in CVD spending in the NHS. This is also valid for other high-income countries, which are also in need for effective strategies for CVD prevention.

1.6 Key points from Chapter 1

CVD is the major cause of mortality worldwide; CHD and stroke are the most common contributors of CVD deaths. CVD accounts for the majority of the deaths in the UK, although there has been decline in its mortality during the second half of the 20th century and early 21st century. As well as causing a huge total burden, CVD is one of the major contributors of
health inequalities in the UK; for instance individuals living in more deprived areas tend to have greater CVD rates than those living in affluent areas.

A number of risk factors, categorized as fixed (e.g. age, sex, ethnicity) and modifiable risk factors (e.g. smoking, lipid levels, blood pressure, etc.), are associated with CVDs; inequalities in CVD risk factors in different population groups explain the large proportion of CVD disparities. There have been declines in CVD burden since the last century, which are largely attributable to reduction in CVD risk factors as well as improvements in treatment of CVD cases. This suggests that strategies to manage CVD risk factors at population level accompanied by interventions to manage risk in high-risk individuals can play a significant role in effectively and cost-effectively reducing CVD burden. This is important in this era of increasing prevalence of CVDs due to rising aging population, and consequently increasing health care expenditure.
Chapter 2: Prevention of Cardiovascular Diseases and Evidence of Effectiveness of Cardiovascular Disease Prevention Programmes

2.1 Disease prevention

Disease prevention can be classified in three categories: primary prevention, secondary prevention and tertiary prevention:

*Primary prevention* aims to prevent the occurrence of a disease or facing an injury in healthy individuals either by individuals’ own efforts, such as by having immunization against an infectious disease, having healthy diet, doing regular exercise and using helmet, or communal efforts, e.g. legislations about smoking, seatbelts and controlling water supplies (136,137).

*Secondary prevention* targets individuals with already developed illness or a serious risk factor. Secondary prevention interventions aim to cease or slow down disease progress at early stages for preventing reoccurrence of disease or reduce morbidity. Examples for these interventions can be given as prescriptions to reduce risk factors, aspirin for heart attack and regular examinations, and screening of individuals with a chronic condition (137).

*Tertiary prevention* includes measures that aim to manage chronic conditions and their associated complications. These interventions aim to diminish adverse effects of a disease, i.e. physical disabilities, and maximize potential years of useful life. Examples for tertiary prevention measures can be given as programmes for managing chronic pain and CVD disease rehabilitation programmes (138). Although tertiary prevention is an important prevention area, I am not going to discuss on it further, since it is outside the scope of my thesis.

*Quaternary prevention* is a new concept of disease prevention that has recently been discussed in the literature. Quaternary prevention is defined by the world organization of family physicians (WONCA) as: “action taken to identify patient at risk of over-medicalization, to protect him from new medical invasion, and to suggest to him interventions, which are ethically acceptable” (139). However, a number of scholars defined the term differently to explicate various ideas (140). Because of this reason and since the concept is not widely adopted, I shall not consider it further.
Primordial prevention is another concept of disease prevention that has recently been widely adopted. Primordial prevention includes measures and actions that aim to inhibit the development of predisposing conditions, such as economic, environmental, social, behavioural, cultural, that can lead to risk factors for diseases (141). In other words, primordial prevention is actions taken to prevent populations from epidemics of risk factors that cause diseases (142). The concept of primordial prevention has been confused in the literature. Some scholars have explained the term differently from the above; the primordial prevention is for preventing the development of risk factors starting from an early stage in life course. They, for example, suggested that primordial prevention involves maintaining optimal CVD risk factor levels from childhood to adulthood to protect individuals from CVD events (142,143). Giampaoli (144) implied that healthy eating habits can be attained in childhood, which would continue to adulthood, by ensuring that cheap and healthy food is available in schools to avoid the effects of socio-economic circumstances on risk factors.

One of the concerns discussed about primordial prevention in the literature is that whether it differs from the traditional concepts of primary prevention. It is strongly argued that two concepts are fundamentally different. Whilst primordial prevention inhibits incidence of risk factors in a population by managing conditions that lead to risk factors, primary prevention aims to manage risk factor levels by either targeting individuals or groups after they appear in the population (144). Therefore, the difference between two concepts is that primordial prevention acts more distally from disease outcomes compared to primary prevention. For example, changing the environment to promote physical activity in populations is significantly separate from CVD risk factor reductions.

The definitions of primordial prevention above may downplay the importance of primary prevention. Geoffrey Rose’s (145) explanations of primary prevention indicate that non-medical interventions like environmental planning to enhance physical activity are also covered under the primary prevention concept. The scope of mass or population primary prevention strategies explained by Rose is wide as the primordial prevention. Therefore, having a separate concept of primordial prevention may cause unnecessary confusion to the discussion of disease prevention. Although this is the case, primordial prevention is still being used occasionally in the literature.

The examples of interventions for primordial prevention above clearly illustrate that it may be only important in emphasizing the consequences of the life-course on CVD risk (146). The
evidence demonstrates that life-course carries crucial importance in CVD and the primordial prevention is, therefore, a significant area in disease prevention. This thesis focus is on the evaluation of the NHS Health Check programme that is a CVD primary prevention programme covering population aged 40 to 74 years. Therefore, I will not further discuss on primordial prevention strategy, since a life-course approach in preventing CVDs is beyond the scope of my study.

2.2 Prevention of cardiovascular disease

The different divisions within disease prevention were outlined above in a general context. I shall now consider primary and secondary prevention specifically relating to CVD.

2.2.1 Secondary prevention of cardiovascular disease

Secondary prevention of CVD involves management of CVD risk factors in individuals who have already suffered from a CVD event; this could be acute such as a MI or stroke, or chronic like angina. The only aim of reducing risk factors in these patients is to reduce the risk of recurrent CVD events or deaths (147). Although this definition is specific to CVD, it still fits into the broader definition of disease prevention, which consists of the management of diseases and reducing associated disabilities.

About half of all CVD events in individuals aged 35 to 74 years occur in patients with pre-existing CVD; this equals to a relatively small proportion, around 5 or 6%, of the population (148–150). A cohort study of 35 760 patients demonstrated that 42% of all CVD events occurred in those with existing CVD, which represent 10% of all population (148). Individuals with established CVD are therefore at a greater risk than the general population and have the greatest need for risk reduction (149).

Interventions targeting patients with existing CVD to manage risk factors and prevent recurrent events generate a clinically and cost effective prevention strategy. This is because, the number of patients in this high-risk group is low and the prevention approach can cover a relatively large proportion of the total population risk using limited resources. These patients with chronic conditions are easily accessible in the health care system (151); tend to be more motivated to reduce their future risk (114); and the benefits of pharmacological interventions in this group is high (150,152). The other strength of the secondary prevention strategies is
that since the target population is clearly defined and there is no need for additional stratification, the process is simple and easy to implement (151).

Besides the strengths above, there are concerns about the secondary prevention. As stated earlier a large proportion of CVD events are secondary occurrences, however the majority of these are first events. For example, according to Kerr et al. (148), 58% of CVD events occur in the population without a pre-existing condition. This therefore denotes that if interventions focus only on secondary prevention, most people to have a CVD event would not receive any preventative care. Among patients with no previous history of CVD event, low to moderate risk patients have also potential to develop CVDs and they even produce more cases than high-risk patients. The reason for this is that although these individuals have lower risk, since they are in greater number than high-risk populations, the cumulative risk of CVD events in low to moderate risk groups is greater (145).

There are other weaknesses of secondary prevention. Patients targeted by secondary prevention are regarded as at high CVD risk. The concern is that if these patients are indubitably at a higher risk than remaining non-CVD population. This dogma has recently been upturned; it was established that patients to have clinical CVD tend to have a high global risk, which means that the reason for increased risk in CVD patients is the combination of present risk factors (153). In addition, there is evidence that atheroma and arterial calcification can be present, although an individual has not developed a CVD event (154). Secondary prevention, therefore, will miss these high-risk patients yet to have a CVD event.

2.2.2 Primary prevention of cardiovascular diseases

The aim of the primary prevention of CVD is to manage CVD risk in populations without a pre-existing CVD, therefore, who do not have any disease symptoms and can be considered as “well”. Primary prevention strategies can be divided into two approaches, which were first proposed by Geoffrey Rose in 1981 in his study entitled “Strategy of prevention: lessons from cardiovascular disease” (145). These two approaches are namely ‘high-risk’ and ‘mass or frequently termed population’ strategies.
2.2.2.1 High-risk approach

High-risk approach targets individuals at the highest risk in a population. This approach aims to reduce the CVD risk in this targeted sub-population, in other words to truncate the risk factor distribution (Figure 3) (109). Primary phase in high-risk prevention strategy is screening of a population to identify high-risk group. This phase is then followed-up by appropriate interventions provided to manage risk in the identified group (135). High-risk approach in CVD prevention can be considered as similar to clinical practice process; a patient must be intervened for cure, when they are encountered as ‘ill’ by clinicians (145).

![Figure 3: Impact of high-risk and population strategies on a population distribution for systolic blood pressure (109)](image)

“*This image has been reproduced from Tunstall-Pedoe et al., Pattern of declining blood pressure across replicate population surveys of the WHO MONICA project, mid-1980s to mid-1990s, and the role of medication, p.2, 2006* with the permission from BMJ Publishing Group Ltd.”

Both high-risk and population strategies have strengths and weaknesses. Rose (135) defined these in his work, ‘*Sick Individuals and Sick Populations*’, which has generated a significant debate in disease prevention area. The main advantages of high-risk strategy are based on the fact that it targets a smaller population group. Although the target group in high-risk based primary prevention is different from secondary prevention, both of them are nevertheless
targeted. The strengths of high-risk based primary prevention are, therefore, parallel to those of secondary prevention.

![Comparison of high-risk and population strategies](image)

**Figure 4: Advantages and disadvantages of high-risk and population-based strategies in primary prevention (Adapted from tables 1, 2, 5, 6 in Sick Individuals and Sick Populations in Rose, G.) (135)**

The first benefit of high-risk approach associated with limited number of the target population is greater overall benefit per individual (135). There is evidence that benefit gained from an intervention is proportional to absolute risk of CVD event: the higher the risk the greater the benefit (56). The greater benefit per individual produces a favourable cost to benefit ratio and consequently a more cost-effective strategy. Small target population in high-risk strategies also allows a better quality of care, with individually tailored intervention, compared to strategies targeting the whole population (135) and also expose fewer individuals to any potential harms of the intervention (155).

Another area associated with strengths of high-risk strategies is motivation to participate and intervene. Considering the motivation to participate in high-risk individuals: high-risk strategies involve screening of individuals and management of their risk using individualized interventions, which enhance participants’ awareness about their risk and therefore their motivation. Interventions provided under high-risk strategies aim to reduce already existing high-risk; the knowledge of greater potential of getting benefit from the process can therefore
motivate individuals to comply (135). Although this is the case, there are still questions over the motivation of participants without a clinical condition; there is limited evidence on how the levels of motivation differ between high-risk individuals and those with diagnosed diseases. Final advantage of the high-risk approach is increased motivation in practitioners. Since there is a problem to deal with in high-risk approach, practitioners are not diverging from routine care. Additionally, because the care of high-risk individuals will produce a gain, practitioners have chance to see the benefit of the prevention, which motivates and encourages them to be more involved.

Moving on to weaknesses of the high-risk prevention strategies, difficulties and costs of screening will be considered first. A prevention strategy could be beneficial for population health, if it aims to modify prevalence of risk factors in a population rather than managing risk factors in each individual (145,156). This is particularly important in the case of CVDs, since major risk factors of CVDs, namely blood pressure, cholesterol levels and BMI are all widespread in the UK. High-risk approach only targets individuals at the highest risk and provide large benefit to only this sub-group in the population, therefore limiting the modification of prevalence of risk factors in the whole population. Many CVD events occur in people without elevated risk factor levels (145). A low-risk individual at the time of screening may be at high risk in the next generation, screening should therefore be repeated regularly to detect new high-risk patients and manage their risk factors. This would explain the increased cost essential for screening in the high-risk prevention strategies (135).

A prevention strategy must have an effective mechanism to modify risk factors. The high-risk approach identifies individuals to be targeted by screening; as a result of screening, a large number of people could be identified as having increased risk for which there is no appropriate treatment to manage risk. In the case of reducing CVD risk, there are efficacious ways of reducing risk, such as using statins for lowering lipid levels in high-risk individuals without a pre-existing disease (152) and aspirins for reducing CVD events (157).

The last requirement for a prevention approach to improve the health of a population is to cover a large proportion of the population with a risk factor. This is very important for the success of a high-risk strategy to prevent CVD events; uptake of the screening programme or intervention and continued adherence to interventions can rigorously limit the effectiveness of a high-risk based prevention process (135). Considering high-risk CVD prevention programmes, poor uptake of initial risk assessment (screening process) and poor attendance
to risk management interventions, such as weight loss programmes or statins, can limit the effectiveness of programmes.

Another considerable disadvantage of the high-risk prevention strategy is being palliative and temporary. This approach aims to identify individuals with present causes (risk factors) of diseases rather than changing underlying causes of diseases in the population. For example, high-risk prevention strategies can be largely accompanied with pharmacological interventions and as in secondary prevention; an identified cohort can be prescribed medications, such as lipid lowering drugs, statins, anti-hypertensive and aspirin to lower CVD risk. Although these interventions can be effective in lowering risk in the targeted group, they do not resolve the underlying societal causes of the risk in the population. Treating a high-risk group with medications will not prevent generation of other high-risk groups requiring treatment in the future and population risk factor distribution will remain the same until a further intervention targeting the whole population risk. This therefore indicates that high-risk approach in CVD prevention aims to prevent the establishment of CVDs in those susceptible to it, rather than solving the source of the problem, e.g. by reducing salt intake in the population to prevent the future establishment of hypertension (135).

The potential of the high-risk prevention approach for population, as well as individuals is limited. It is not possible to predict a future disease accurately, an individual with actual high-risk might not be identified during screening under high-risk prevention approach and might develop a disease right after the examination. Although the accuracy of prediction tools and diagnostic tests are improving everyday, 100% accurate absolute level of risk cannot be obtained. In CVD prevention, high-risk strategies use CVD risk prediction tools, such as Framingham risk score explained in details in Chapter 2.4. The accuracy of risk prediction tools used in the assessment of CVD risk is limited (158).

The other reason of limited potential of this strategy for population is analogous to the major weakness of secondary prevention. The high-risk approach focuses on a small proportion of the population identified as high-risk, which produces a higher rate of CVD cases. However since the number of people in the remaining lower risk population is larger, this group generates a high prevalence of CVD. Rose highlighted this by: “a large number of people at a small risk may give rise to more cases of disease than the small number who are at a high risk” (135).
A final weakness of the high-risk approach in primary prevention to be considered is its behaviourally inappropriate nature. In this approach, symptomless people are medicalized, creating new patients from healthy individuals. This can cause the loss of high-risk patients’ self-efficacy and they would end up with simply relying on their practitioner and medications to reduce their risk. This may therefore lead patients to continue their risk taking behaviours, such as consumption of unhealthy food or smoking (159).

2.2.2.2 Population approach

Population strategies in primary prevention do not target individuals as high-risk strategies do, but they aim to reduce CVD risk in the entire population. If we consider CVD risk or a risk factor as a frequency distribution, the population strategies aim to shift the entire distribution along the x-axis (Figure 3), which, therefore, means they aim to reduce CVD risk or a risk factor in the entire population. Population approach aims to reduce the exposure of everyone to risk factors of diseases at an earlier stage than the high-risk approach for preventing them to become at high-risk in the future. Rose (135) suggested that small reduction in risk factors in a large population can be more effective in preventing more cases than managing risk factors in a small high-risk population. There has not been an extensive implementation of the population level prevention strategies. This is because population based prevention strategies are less popular in the policy and clinical domains, although they have been strongly supported by the public health community (160).

The strengths and weaknesses of population based prevention strategies are highlighted in Figure 4. Population based prevention approaches have a number of strengths that help to overcome the weaknesses of high-risk prevention approaches. The first considerable advantage of this prevention strategy is that it is radical; it possesses a potential for long lasting changes across the whole population. Population based interventions aim to change social norms and consequently the environment. This would prevent the generation of high-risk individuals, therefore the continued need for further interventions (135). For example, the UK salt reduction programme aims to reduce the salt intake in the whole population, with an aim to prevent the generation of new high blood pressure patients and consequent CVD cases. This intervention aims to protect population from adverse impacts of sodium intake as long as the legislation is in place, not only when it is first implemented (161).
The major strength of the population approach is that it has a potential of producing benefit in the whole population. Modelling studies have confirmed this (162). Although one of the concerns about the population strategies that they are slow processes, with a significant lag between the interventions and health gain (163), recent evidence supports the opposite of this indicating faster effect of population strategies in reducing CVD risk (96). There is especially strong evidence on the rapid declines in CVD events following the population level dietary changes (134); e.g. enhanced consumption of vegetable oils facilitated the rapid declines in CHD events (164).

Although population-wide strategies have robust potential in managing CVD risk, they also have weaknesses. Several weaknesses of the strategies are surrounding the “prevention paradox” that Rose suggested. Rose defined the paradox as “a measure that brings large benefits to the community offers little to each participating individual” (145). In the population approach, small reductions in each individual accumulate to generate large reductions in the whole community. Although the population strategies have large potential to produce health gain in the whole population, no one receives individual considerable, even sometimes any noticeable benefit.

In addition to little gain per individual, the motivation of the individuals to participate can be low in the population strategies. This is because the majority of individuals participating in the population strategies are healthy individuals and they may not comprehend the need for change. This indicates that it can be difficult to motivate the individuals to participate. This is particularly acceptable in the case of a potential harm involved in the interventions, because participants would be less motivated to accept the risk for very little gain (135,145). In this type of strategies involving potential harm, the benefit to risk ratio can be low (135): the clofibrate trial of the World Health Organization initiated in 1965 can be given as an example for this, where the population saved by the cholesterol-lowering intervention was less than it harmed (165).

Most interventions involving the whole population aim to change the environment without a need for direct public involvement, minimizing the limitations. These interventions, for instance, involve reducing salt or trans fat content in industrialized foods for passive modification of the diet in the population (83,161,166). To reduce the impact of possible limitations, such as low motivation to participate in population approaches, the interventions
can be accompanied by approaches targeting individuals, such as incentives and deterrents to aid behaviour change (167).

The last considerable weakness of the population based prevention strategies is difficulty in motivating practitioners to involve in the intervention, associated with the fact that the gain per individual is too little. As well as low individual health gain, the other reason that reduce the practitioner motivation is that primary prevention approaches alienate practitioners from medical practice, since health is no longer an individual but population problem and these approaches prevent practitioners to focus on a single patient to expect the patient to get better (135). The individual practitioner motivation is, however, less of a concern in the most population strategies, because instead of clinical involvement, they generally require broader public health and legislative changes.

2.2.2.3 Weaknesses of primary prevention of cardiovascular diseases:

The first considerable weakness of the population prevention is around the number of eligible population; the population eligible for primary prevention is large. Population based primary prevention approaches target the entire population: This therefore makes the primary prevention strategies less cost-effective compared to secondary prevention strategies. High-risk based prevention strategies target only a particular population: this in turn needs extra workload and cost for screening populations to determine the eligible population (135).

Individuals eligible for high-risk based primary prevention strategies include those with high risk of developing CVD and the cumulative number of CVD events in these individuals is greater than the group with previous CVD experience (156). However, individuals with the highest risk are those who will gain the most from interventions. Patients who developed a CVD previously and possess symptoms of diseases are at the highest risk; this therefore causes high-risk primary prevention strategies to be less cost-effective compared to secondary prevention (147,168).

Another weakness of primary prevention strategies is that the motivation of participants in primary prevention is limited. In secondary prevention, since the strategies are targeting populations with a previous experience of disease, participants may be more motivated to take actions to change their risk factors. In contrast, primary prevention targets the general population, who have no experience of a CVD (135). This, therefore, can reduce the
motivation of the general population to change; for example, statin uptake and adherence tends to be lower in primary prevention than secondary prevention (114).

Despite the weaknesses of the primary prevention, it is important for global management of CVD. CVD prevention is vital across the whole population; it is therefore essential to employ a combination of secondary and primary CVD prevention strategies. The important concern in the area of CVD prevention is the form of primary prevention strategies to be implemented: high-risk versus population based strategies (Chapter 2.9) (143).

2.2.2.4 The changing face of high-risk based prevention strategies

There have been continuous efforts to improve the CVD prevention strategies. Identifying the high-risk population is a critical issue in the high-risk based prevention strategies. During the period that Rose wrote his seminal paper, prediction of CVD risk was reliant on the level of individual risk factors. However, there have been constant advancements in the CVD prevention field. The largest change occurred with the development of global risk factors, which moved the focus from targeting individuals with raised single CVD risk factors to those with high global CVD risk (169–171). The development in understanding of the cumulative effect of risk factors on CVD risk (172) and the linear correlation between risk factors and risk (173) has facilitated the shift from single risk factor approach to global risk in the CVD prevention. Because of these advancements in the prediction of CVD risk, some have argued that the conclusions drawn by Rose are out-dated (149).

There is considerable evidence suggesting that managing risk based on global CVD risk provides larger benefits to a population than controlling only single risk factors, such as the levels of lipid and blood pressure (174). For instance, controlling blood pressure in individuals with elevated global CVD risk is more effective in reducing life years lost from CVD compared to strategies targeting only those with high blood pressure (175).

The concept of global risk has been further maintained with the advancements in the understanding of the causative mechanism (aetiology) of CVDs; CVDs have complex aetiology and they have no direct relationship with any single risk factor (170). For example, patients with the same level of single risk factors, such as blood pressure or lipid levels, can have different levels of global CVD risk depending on the presence or level of other risk factors. Therefore, based on this relationship, it is possible to observe low CVD risk in an individual with elevated blood pressure or lipid levels or inversely, high CVD risk in those
with low levels of these risk factors (170,176). Assuming that all risk factors, such as blood pressure, lipid levels and smoking status, stays the same but the patient is diagnosed with diabetes, the 5-year global CVD risk of a 50-year old women would increase from 10% to 20% (170). This dramatic change in global risk illustrates how a single risk factor affects the overall risk of an individual and therefore suggests that a single risk factor measurement, for example, solely blood pressure or lipid measurements, cannot act as good predictors of CVD risk.

In primary prevention programmes that use global CVD risk for identifying patients eligible for interventions, a threshold value at which an individual becomes high risk, therefore, eligible for having risk management interventions, must be set (177). When setting up a threshold, it is essential to obtain a balance between a high threshold unable to capture the most of the high-risk population and a low threshold that produces high expenses for interventions (178). Currently, in the UK, the recommended threshold for determining individuals at high risk and therefore those eligible for risk management interventions is 20% ten-year CVD risk. The threshold used for defining high risk has changed over years, Joint British Societies (JBS) guideline primarily recommended a cut-off point of 30% ten-year CHD risk, equivalent to 40% ten-year CVD risk (179), and this was then reduced to 15% CHD risk, equivalent to 20% CVD ten-year risk, with the introduction of the second JBS guideline (153). Lowering the threshold for defining CVD high-risk from 40% to 20% has been estimated to generate 5 million more people as eligible for interventions, including statin therapy (180).

Although CVD risk scores have flaws, as outlined in Chapter 2.4.4, they are becoming more embedded in practice and there have been improvements in their methodologies. With the advancements in their methodologies, their ability to predict global risk has been improving and this may therefore play a role in enhancing the power of high-risk based CVD prevention strategies (181,182). The advancements in risk scores with a potential to improve the effectiveness of the high-risk based prevention strategies have also influenced the Rose debate.

It is important to effectively intervene and manage risk in the CVD prevention strategies and there have been considerable advancements in developing effective therapeutic agents; for example, statins. Statins are today both clinically- and cost- effective agents in reducing lipid levels in individuals without pre-existing CVD conditions: this can, therefore, improve the
power of the high-risk based primary prevention programmes (183). Advancements in therapeutic agents with a potential in promoting effectiveness of the high-risk primary prevention programmes have, therefore, produced implications conflicting with the Rose debate.

The development of risk scores able to effectively predict CVD risk and advancements in therapeutic agents effective in reducing CVD risk lead to arguments that there is less need for the population-wide strategies for prevention of CVD (149). The effectiveness of CVD risk scores would be overestimated, if we propose that they cover the weakness of high-risk prevention strategies and reduce the need for the population-based CVD prevention strategies. This can be explained by two main weaknesses of risk scores. CVD risk scores are able to generate accurate prediction of future CVD events in the highest risk individuals; however their power to predict future events in those with low to moderate risk is limited (148). Another weakness of the CVD risk scores is that they are unable to manage risk in the population other than high-risk population identified for interventions. Therefore, even if a risk score has 100% predictive accuracy, there is still need to employ strategies to control CVD risk in the whole population. Although there have been improvements in CVD risk scores, they are still unable to predict risk flawlessly (184). Risk scores are, therefore, likely to fail detecting high-risk patients; relying only on the high-risk based prevention can limit the scope of CVD prevention.

2.3 Clinical guidance for cardiovascular disease prevention

Following the adoption of strategies for tackling rising burden of NCDs worldwide by WHO (Chapter 3.1.1), guidelines specifically on the prevention of CVDs have been introduced. These guidelines include recommendations on the secondary and primary prevention of CVDs, using evidence-based and cost-effective approaches in different settings (i.e. health care or community settings), for policy-makers and health care professionals of member states (185,186).

Close to the end of the last millennium, a crucial shift from targeting single risk factor to overall CVD risk occurred in the field of the CVD prevention. As discussed earlier in Chapter 2.2.2.4, the CVD disease prevention was previously dependent on management of individual risk factors; a clinician was, therefore, aiming to manage elevated individual risk factors to reduce the CVD risk of patients. Mainly adopted approach in controlling CVD risk
was to reduce blood pressure below the determined threshold (187). The collation of strong evidence has facilitated the modification of clinical guidance on the CVD prevention (170), shifting the focus of clinical guidance to controlling global cardiovascular risk (179,188,189).

In the UK, the CVD prevention has recently been adopted as a health policy (Chapter 3.2). Although the CVD prevention was included in clinical guidance prior to its manifestation in health policy, it is also not been long since the provision of guidance on CVD risk reduction. Since the switched attention from controlling single risk factors to global CVD risk, the clinical guidance on the CVD prevention has evolved in the UK (153,190), as well as Europe (48). The guidance, specifically on the prevention of CVD, is now used, besides the hypertension management guideline that is constantly revised (191). The revised version of the clinical guidance on hypertension management currently used in the UK now includes aspects relative to overall CVD risk (188,189).

There are many overlapping clinical guidelines on CVD prevention, which can be inconsistent and have little harmonisation. This leads to potential challenges in patient care (192). In the UK, the guidance on CVD prevention by the Joint British Societies (latest revised version in 2005) was followed by two guidelines published by National Institute for Clinical Excellence (NICE) in 2008. These two guidelines played crucial role in embedding global risk assessment and management firmly into clinical and public health practice (190,193). One of these NICE guidelines was on lipid level modification in both primary and secondary prevention of CVDs and one of the major recommendation of the guideline was considering global CVD risk, not level of lipids, when prescribing statins at clinical practice (190). The revised version of this guideline was issued in 2010; the decision of the type of CVD risk score used was left to clinical practitioners with this re-issued document (further described in Chapter 2.4.2) (180). Another CVD prevention related NICE guideline introduced in 2008 (193) emphasized the use of global risk scores for identification of high-risk disadvantaged populations, including deprived populations. CVD risk of these high-risk individuals in disadvantaged populations is recommended to be managed using statins, based on the lipid modification guideline recommendations; this is important to reduce CVD mortality in these populations and thus improve the health inequalities (193).

The UK National Screening Committee (NSC) prepared thorough guidance on vascular risk assessment, following the announcement of plans of developing a national vascular risk assessment programme (194). The guidance was issues in 2008 parallel to the Putting...
Prevention First document that introduced the NHS Health Check programme (195). This NSC guidance brought existing guidance on the prevention of CVD, diabetes and CKD (vascular risk assessment and management) together and extended the work of the committee on the screening of diabetes and heart diseases. The document, which provides approved evidence-based best practice, aimed to guide the NHS Health Check programme (194). The guidance was updated with new evidence on the assessment and management of risk of vascular disease, and published in 2012 (196).

In 2010, NICE published the first guidance on the population-level prevention of CVDs, combining evidence from population-based interventions for reducing CVD risk (160). The guidance provides a range of considerable recommendations for policy makers on the interventions for reducing risk at population level. Although most recommendations were targeted at national government, the document also included some recommendations for local authorities that are responsible from taking local actions against risk factors (160).

### 2.4 Cardiovascular disease risk scores

Predicting risk of a disease is a process of estimating probability of developing a future disease based on pre-existing information. The prediction of CVD risk is a major constituent in the CVD prevention. Predicting and communicating risk of CVD, a major cause of morbidity and mortality, of an individual can help to increase disease awareness and motivation to take action for reducing risk and future CVD events (177). CVD risk prediction is important in the high-risk based prevention approaches: CVD risk scores can be used to categorise patients based on their risk levels and high-risk patients, once identified, can be provided with more intensive risk-lowering interventions (197).

As mentioned earlier in *Chapter 2.2.4*, approaches targeting only a single risk factor are not effective as approaches for managing risk in those with high total (global) risk (198); a small number of risk factors with a large predictive power can be combined to produce predictive models, called CVD risk scores, for potential CVD events (197). These models are derived from longitudinal data: baseline data on traditional CVD risk factors (e.g. age, total cholesterol, blood pressure, etc.) are initially recorded for patients; the patients are then followed up for a certain time period; and disease outcome is recorded after the follow-up. The CVD risk prediction models are built based on baseline risk factor data and are mostly proportional hazard or multivariate regression models. The risk prediction models include
risk factors that are significantly correlated with disease outcome and the first step in building prediction models is to assess relative risk (RR) for each baseline risk factor at population level, rather than at individual level. These population level model coefficients are then transformed into the risk prediction models to calculate individual level risk scores. The final predicted risk score is in the form of a percentage probability of developing a CVD event within a fixed time period, commonly ten years; the greater risk score means the individual has higher risk of developing a CVD event (199).

Apart from the derivation of a risk prediction model, it is also important to assess the accuracy of the risk score in the prediction of risk and its clinical effect using an appropriate method. This is essential when directing the improvement of tools and also when developing guidelines for the use of the most efficient risk score. A variety of methods can be used to evaluate the performance of the risk prediction models, but the ability of discrimination and calibration are the most common measures used for this purpose (200). Discrimination is the ability of a risk prediction tool to distinguish individuals who will have a CVD event from those who will not. Discrimination of the risk prediction tools is mainly measured using receiver operating characteristic (ROC) curves (201). These curves are plots of sensitivity (true positive rate) against specificity (false positive rate) across all probable cut-off values for predicting binary outcomes. The area under these ROC curves (AUROC) is used to measure the discrimination ability of a risk score (202,203). Calibration is the comparison between predicted risk and observed event rates: calibration is measured by the ratio of the predicted CVD events to observed events; therefore, the closer the predicted risk to observed outcome, the better calibration is obtained for a risk score (184,203).

2.4.1 Framingham risk scores

The first CVD risk prediction model comparable to today’s modern risk scores originated from the Framingham Study, which was a longitudinal study established in 1949 in the United States (US) with an aim to investigate the main risk factors for CVDs (204,205). The risk score to be first used in routine practice was again derived from the Framingham Study and the model was published in 1976 (172). This composite risk model included a number of risk factors associated with CVDs to obtain an effective prediction of risk. These risk factors were age, sex, smoking status, systolic blood pressure, total cholesterol, electrocardiographic diagnosis of left ventricular hypertrophy (ECG-LVH) and glucose intolerance test as a measure for diabetes. This model allows prediction of category of one’s CVD risk (lowest to
highest) (172). This risk score demonstrated a significant relationship that risk factors with a continuous nature, such as blood pressure, have continuous association with CVD risk. This indicates that a patient with blood pressure within normal limits (e.g. lower than 140/100 mmHg) can have high CVD risk and even greater overall CVD risk than a patient with high blood pressure (206).

The Framingham group, establishing the Framingham risk scores using the Framingham Study longitudinal data, became the pioneers in building methods to develop CVD risk scores. The early Framingham risk scores were replaced with risk scores developed in the following years and the most remarkable development in risk scores was observed in the early 1990s. A number of algorithms for predicting risk of developing CHD, stroke, MI, combined CVD events and CVD mortality were produced in this period (207,208). These risk scores, particularly the one for predicting combined CVD events, the Framingham-Anderson risk prediction model, are the most commonly used risk scores. These risk scores, entrenched in clinical practice, have been in routine use for more than two decades.

The Anderson risk score uses a number of risk factors to predict CVD events. These risk factors are, namely, age, sex, smoking status, systolic blood pressure, lipid ratio (total cholesterol to HDL ratio), diabetic status and ECG-LVH. As outlined before, blood pressure and lipid ratio recordings are entered as continuous variables and the other risk factors are entered as categorised variables; for example, diabetes status and LVH status are coded as Yes or No and if there is no information on disease diagnosis, the status is assumed as negative (No) (207,208).

The Framingham groups developed another risk score called the “Framingham-Wilson Score” in 1998. The Wilson Score replaced the continuous variables, blood pressure and cholesterol measurements, with categorical variables to predict CHD risk. The blood pressure categories of Joint National Committee (JNC-V) and cholesterol categories of National Cholesterol Education Programme (NCEP) were incorporated in the CHD risk prediction score instead of continuous blood pressure and cholesterol measurements. This CHD prediction model is simpler to use, but has similar performance compared to earlier Framingham risk prediction models (209). Although this is the case, the Wilson score has never been used as frequently as the Anderson risk score.
The Framingham risk scores have a number of weaknesses, although they remain the most frequently used risk scores in clinical practice. The reason for wider use of the Framingham risk scores is most probably due to the familiarity of clinicians in using these risk scores, but not the accuracy of the risk scores in estimating CVD risk. There are two considerable weaknesses of the Framingham risk scores. The first one is; the accuracy of the scores in estimating CVD risk varies in different populations. Since the risk scores originate from US, they usually overestimate risk in populations with lower CHD mortality rates. These risk scores also overestimate CVD risk in the UK; for example, in British men, sample from British Regional Study, the Framingham risk scores predicted 47% more CHD deaths and 57% more CHD events than the observed. The overestimation in the risk of CHD events and deaths differed between geographical regions of the UK, with greater overestimation in the Midlands and Wales and the south of England compared to the north of the England (210). The overestimation and the accuracy of risk scores are also not consistent and show significant differences between settings (158,211). The Framingham risk scores generally underestimate risk in populations with higher CVD risk, such as in socio-economically deprived populations (158,212).

The Framingham risk scores were produced using risk factor data recorded in 1970s (207). The CVD risk has undergone population-wide changes over the second half of the 20th century. The prevalence of CVD risk factors and CVD incidence had shown considerable reductions in US, as well as the UK (Chapter 1). This reduction therefore has led to the overestimation of the CVD risk by the Framingham based risk scores. The other reason for overestimation of risk by the Framingham risk scores is that the Framingham cohort study population had greater absolute risk compared to any present population (210).

There have been efforts to overcome the above explained problems in risk estimation by recalibrating the Framingham risk scores. Risk scores can be recalibrated at a national level (213,214), local level (215) or for specific population groups, e.g. ethnic minorities (216,217). In the recalibration process, the Framingham risk algorithm to be recalibrated is first chosen and predicted CVD mortality rates by the chosen risk algorithm, therefore, the mortality rate of derivation population, are compared with the mortality rates of a population of interest. The risk score is then adjusted for the population of interest accordingly (213). Recalibration of existing risk scores is an appealing process since it allows the use of an existing risk score in a wide range of settings. This, therefore, reduces the need for generating
novel algorithms that involve an expensive and complex process. Recalibration of risk scores also has limitations; for example, in a study recalibrating a Framingham risk score to the Swiss population, there was overestimation in predicted number of events after recalibrating the risk score based on the national mortality and local incidence rates data (213).

The second weakness of the original Framingham risk scores, apart from inadequate estimation of risk, is that they lack a number of independent predictors of CVD: these risk factors are namely deprivation, ethnicity, family history of CVD and obesity. This weakness of the risk scores affect the risk prediction of individuals and tends to change RR ranking of patients, in contrast to the first outlined weakness above, which has an equal impact on the whole population. There have been attempts to modify the risk scores to address this weakness. In the UK, the JBS have modified the *Framingham-Anderson score* to take family history of CVD (179) and ethnicity (153) into account when predicting CVD risk. These risk scores are called Joint British Societies 1 (JBS1) and Joint British Societies 2 (JBS2) respectively.

### 2.4.2 Risk scores derived for the UK population

The Framingham risk scores have been widely used in the UK, but there have been attempts to develop risk scores for compensating the weaknesses of these scores and to provide more accurate prediction of CVD risk in the UK. Deprivation has been shown to have a considerable impact on CVD risk and it is accepted as an independent risk factor for CVD (*Chapter 1.3.2*). The CVD risk difference between the population in the highest fifth of deprivation in the UK and the lowest fifth is comparable with the difference between diabetic and non-diabetic and those with 10 years or over age difference (218). There are differences in risk estimation by Framingham risk score between socio-economic groups; while the risk score overestimates risk in the least deprived population, it underestimates risk in the most deprived. This leads the risk score to be more sensitive, but less specific to CVD events in the affluent and vice versa in the most deprived (219). The Framingham-Anderson risk score underestimated risk in deprived populations in the UK, meaning that the most deprived would receive only half of the care to manage their risk relative to their need compared to the least deprived (219). Deprivation can be included into a CVD risk score to counteract the differences in risk estimation between socio-economic groups. This inclusion will improve
the equity in prediction of CVD risk across all social groups, although it may not have an effect on the overall accuracy of risk prediction in the population.

A number of CVD risk scores have been developed, apart from Framingham risk score. They are derived in different populations using different vascular endpoints and a variety of methods. The ASSIGN risk score (220) was derived from a Scottish population of men and women aged 30 to 74 years participated in the Scottish Heart Health Study and the Scottish MONICA Project. This risk score included socio-economic deprivation as a risk factor and the Scottish Index of Multiple Deprivation was used to rank social deprivation based on the postcode of residence. This risk score incorporated family history of CVD as well as deprivation, in addition to predictors included in the original Framingham risk scores. The ASSIGN risk score improved discrimination compared to the Framingham-Anderson score. Considering that it added two independent risk predictors, this improvement was minor. The ASSIGN risk score provides more equitable CVD risk prediction than the Framingham-Anderson risk score: observed to expected risk ratio varied with deprivation using the Framingham-Anderson risk score and it overestimated risk in the most deprived social group, however there was no variation between deprivation groups using the ASSIGN score (220).

The ASSIGN score was demonstrated as overestimating risk in other populations (e.g. English population), although it had good discrimination ability given that it takes family history of CVD and deprivation into account. The reason for this overestimation is again the fact that the ASSIGN score was derived using data back from 1980s, when the CVD incidence was greater in the Scotland compared to other populations and since then England has seen substantial reductions in CVD incidence (221).

The Framingham and the ASSIGN risk scores overestimate risk in the English population, as well as in populations at a lower risk compared to the derivation population. They, therefore, lead to unnecessary treatment of patients who are in reality at a low risk and also expose them to probable side effects (222). These already developed risk scores can be recalibrated to improve their discrimination performance in the UK, but this may not still adequately improve their performance (221). These reasons grounded the work for developing risk scores to obtain more accurate risk predicting in the UK. Two risk scores, QRISK (222) and QRISK2 (182) developed using the QRESEARCH database are among the significant contemporary risk scores to be considered. The risk scores developed prior to the QRISK risk
scores had been developed using data from cohort studies, such as the Framingham cohort study. In cohort studies, baseline risk factors and CVD events at final point are both well recorded, with few missing data. Data quality is therefore one of the many strengths of the cohort data. However, cohort studies are costly and time-consuming. The establishment and management of cohorts require considerable resources. Sample size in cohort data is another problem; small sample size can reduce the power of the derived risk scores.

The QRESEARCH database, data source of the QRISK scores, was created using a different method compared to these previous studies. This database is produced by longitudinal data extracted from routine UK primary care records and it currently incorporates data for more than 13 million patients (223). In contrast to cohort data used to derive previous risk scores, the dataset is extremely large in sample size, data extraction is not costly and no extra resources are needed for the management of participants. The major problem with this dataset is that it contains a large amount of missing data; for example, only about 40% of patients in the dataset used to derive the QRISK risk score had lipid measurements recorded (222).

The QRISK score, the primary risk score from QRESEARCH database, was derived from a cohort of 1.28 million patients who were registered at 318 general practices between 1st January 1995 and 1st April 2007. The derivation population was aged between 35 to 74 years and excluded those with a diagnosis of diabetes and CVDs (222). The risk of first CVD event was estimated for the derivation population using the Cox proportional hazard models. The final QRISK model included deprivation (the Townsend deprivation score) (224), family history of premature CVD, BMI and anti-hypertensive therapy, in addition to risk factors included in the Framingham. The performance of the QRISK score was validated using a separate validation dataset of 0.61 million patients registered in 160 general practices against the Framingham-Anderson and the ASSIGN scores: the QRISK score provides lower CVD risk estimates and better discrimination of risk than the ASSIGN and Framingham-Anderson scores. It was also shown as better calibrated to the UK population compared to the other two (222). The QRISK score was also validated using external datasets. These validations again showed that the QRISK score has better performance than the Framingham-Anderson score in the UK. It provides better discrimination and calibration in a population representative of the national population, with a slight underestimation of risk but this underestimation is smaller than the overestimation of risk produced by the Framingham-Anderson score (225,226).
In 2008, the QRISK was updated to produce the second version called QRISK2 (182). This risk score was derived using 2.3 million 35 to 74 year old patients registered with 531 general practices from 1st January 1993 to 31st March 2008. In addition to risk factors in QRISK, QRISK2 incorporated self assigned ethnicity and diagnosis of chronic conditions, namely renal disease, atrial fibrillation and rheumatoid arthritis. The validation of the developed risk score using the derivation population showed that the QRISK2 score provides improved discrimination and calibration compared to the QRISK score; both scores had better performance than the Framingham-Anderson score (182).

The QRISK2 score produced in 2008 (QRISK2-2008) has been updated in 2010 (QRISK2-2010), 2011 (QRISK2-2011) and 2012 (QRISK2-2012) to reflect the progress in quality of the derivation data (227,228). External validations of the QRISK2 score have been performed (228,229); QRISK2-2008 and QRISK2-2011 were validated using external cohorts against the first version of QRISK score (QRISK1) and the modified Framingham-Anderson (the risk score recommended by NICE) scores (190).

These validations have shown that QRISK2 models perform better, with better discrimination and calibration, compared to the Framingham-Anderson score (228,229). QRISK2-2008 was also shown to perform better than the primary version of the score (QRISK1), although the difference was small (229).

The development of the QRISK scores for the UK has made the debate surrounding the choice of CVD risk score to predict CVD risk in the NHS Health Check programme inevitable (230,231). Initially in 2008, the NICE guidance recommended the use of modified version of Framingham equation (JBS2), despite a number of weaknesses. This was because it was published just before the external validation of the QRISK score and it is not possible for NICE to approve a clinical tool before assessing the validation independent of the derivation group (190). Following the independent validation of the QRISK score, NICE reviewed the decision on the use of CVD risk tool in practice. With the revised version of the NICE guidance, the previous guidance recommendation for using the JBS2 score was withdrawn and practitioners were given autonomy to choose which risk score, either JBS2 or QRISK/QRISK2 to use based on their needs (180).

A study published after the NICE revision and recommendations on the choice of risk scores suggested that JBS2 is likely to produce double the number of high-risk individuals by
QRISK2. This therefore implies that the cost of preventative care would be more than double with JBS2 compared to QRISK2. These differences caused by using two different risk scores based on the preference are likely to widen inequalities in the CVD risk (232). These findings therefore suggest the revision of recommendations on providing autonomy in the choice of risk score; the extra workload and cost to be generated by the use of JBS2 may be avoidable.

2.4.3 Including novel biomarkers in cardiovascular disease risk scores

A variety of CVD risk scores have been developed using different populations, methods and CVD endpoints (181,233–236). A number of novel biomarkers found in plasma are correlated with CVD risk; C-reactive protein, fibrinogen, apolipoproteins and lipoprotein-associated phospholipase A2 are some of the examples for these novel biomarkers. It is an important concern in the area of CVD risk prediction that if CVD risk can be better estimated if these biomarkers are taken into consideration (237).

There have been attempts to include these novel risk factors in risk prediction tools for improved estimation of CVD risk; C-reactive protein is one of these novel biomarkers that have been incorporated in the risk scores, especially in US. C-reactive protein (CRP) acts as an important predictor of CVD risk, despite a non-causative association between CRP and CVD based on the Bradford-Hill criteria (238). When CRP is added into risk prediction models, it fails to add evident improvement in discrimination of risk, although it is a crucial independent predictor of CVD risk (181,239). It is, therefore, questionable if CRP or other novel biomarkers are useful in the prediction of CVD risk (69,239).

Not only novel biomarkers add a little to the predictive performance of risk scores, but also other predictors like socio-economic deprivation (220) and even well-established risk factors such as blood lipid levels can contribute little to the accuracy of the risk prediction models (240). The evidence suggesting that the ability of additional risk factors to improve the accuracy of risk prediction is poor can be clarified with two contradicting proposals. The first reason can be the fact that the models already include risk factors, such as age and sex, which have considerable predictive power. The inclusion of additional risk factors, therefore, provides relatively minor improvement in discrimination of risk compared to the strong risk factors and contributes little to the accuracy of the model (240,241). The second reason for the apparent poor ability of additional risk factors in improving the accuracy of models can be a shortcoming in the tool used to measure the discrimination ability of the model. As
outlined before (Chapter 2.4), AUROC is commonly used to measure the discrimination ability of the models. This method was originally developed to discriminate between binary outcomes, e.g. yes/no; therefore, might not be suitable to compare continuous data, as in discrimination between CVD risk scores (240). It is suggested that measuring discrimination ability of a risk score is not the most suitable tool to compare the risk scores. Calibration is suggested as a better measure for more accurate prediction of risk (200). A number of methods other than calibration, such as reclassification table and predictiveness curve, have also been proposed as alternatives to AUROC (199).

2.4.4 Weaknesses and limitations to cardiovascular risk scores

CVD risk scores are only models used to predict the probability of developing a future event. CVD diseases are complex in nature and it is not possible to measure the actual CVD risk. Risk prediction models are simple tools to aid understanding and attempts to reduce risk. Because of their nature, they are therefore not expected to be flawless tools and risk scores have a number of unavoidable weaknesses and limitations.

CVD risk scores are not diagnostic tools to assess the presence of a condition, in contrast to many other screening tests, which act as tools to detect presence of diseases (e.g. cancer). CVD risk prediction models are instead prognostic tools. In contrast to diagnostic tools aiming to detect the actual presence of diseases, prognostic models, with a stochastic nature, aim to predict the incidence of future events (199,242). This should not be regarded as a weakness of risk scores and their scope should be recognized when they are used.

Population-level RR s are translated to predict the likelihood of an event in an individual; this therefore shows that risk scores are exposed to ecological fallacy (243). Risk scores determine risk of individuals based on their risk factor profile, but since all individuals in a population do not have mean characteristics of that population, all individuals cannot have the same risk score (244). This is demonstrated in Figure 5; both the QRISK2 and Framingham risk scores have limited ability to discriminate between high-risk and lower risk patients. Only 40% of CVD events occur in men with predicted high-risk using QRISK2 and 54% of events using the Framingham score; while for women only 26% of events occurred in high-risk individuals using both the QRISK2 and Framingham risk scores (229).
Figure 5: Proportions of men and women who were classified as high risk of cardiovascular events (≥20% cardiovascular disease risk within next 10 years) by QRISK2 and the NICE version of the Framingham equation, and who actually had a subsequent cardiovascular event (229)

"This image has been reproduced from [Collins & Altman, An independent and external validation of QRISK2 cardiovascular disease risk score: a prospective open cohort study, p.6, 2010] with the permission from BMJ Publishing Group Ltd."

CVD risk scores are developed using statistical modelling as described before and therefore the weaknesses of risk scores surround around technical and mathematical errors. It is essential to balance between predictive accuracy and parsimony when developing a risk prediction model. Including more risk scores during statistical modelling increases the accuracy of the risk prediction model (245). Statistical procedures, for instance estimation of mean, are generally liable to cause error in risk estimation. Therefore, addition of more risk factors have limitations, since each additional risk factor leads to additional measurement error and total of individual errors from each variable results in a large overall error in the risk prediction models. The error in CVD risk scores is generally disregarded; the confidence intervals are usually not quoted (246,247). The artefact that each risk factor includes missing data, especially when routine data is used to derive risk scores, leads to a further weakness in addition of more risk scores in the CVD risk prediction models. The reason for this is that
addition of more variables leads to an increase in the missing data in the derivation dataset and this reduces the accuracy of prediction by the derived risk score (248).

The number of events observed in a derivation dataset affects the accuracy of prediction models (249). In the case of CVD risk scores, the power of risk scores is extremely limited with low number of CVD events. This association in CVD risk scores leads to difference in accuracy of prediction between sexes. Women, particularly younger than 75 years, experience fewer CVD events than men; this therefore reduces the accuracy of risk prediction in women compared to men (240). The accuracy of risk scores is also associated with number of measurements of clinical risk factors, such as blood pressure. Using the mean of multiple measurements when predicting risk in risk scores reduces measurement error (246).

The accuracy of risk scores is limited, when they are applied to populations with different disease profiles compared to the derivation population (240,250). For example, both Framingham risk score, derived in US (207) (Chapter 2.4.1), and Prospective Cardiovascular Munster (PROCAM) risk score, derived in Germany (234), overestimated CHD risk in a UK population (251). Different risk estimates are produced for the same patient using different risk scores for predicting same CVD outcome. The concordance of identification of high-risk patients between different risk scores can also be poor (252). Although there is agreement between different risk scores in predicting average CHD risk in a population, this may not be true for risk prediction in individuals (253).

Risk scores including more risk factors require greater workload and cost to collect data. The usage of these risk scores, therefore, can be limited because of the workload of the practitioners to perform risk assessment (241,254). The importance of using simple CVD risk scores has therefore been increasing. The simple risk scores are especially important in low and middle-income countries, where the global burden of CVDs has been substantially increasing and the capacity to assess and measure many risk factors is limited. Laboratory measurements, for instance blood lipid tests, are costly measures. The previous literature has proposed that simple scores not including laboratory measurements provide as strong risk prediction as those using laboratory based data. These simple risk scores might therefore act as alternatives in settings with limited resources (255,256). Another alternative can be use of partial data, including risk scores already available in medical records (257,258).
It is crucial to have a good understanding of weaknesses and limitations to CVD risk scores, when taking decision on the use of CVD risk scores. There are unavoidable weaknesses that should be carefully considered when using risk scores: since CVD risk scores are prognostic, but not diagnostic models, they are prone to significant errors in discrimination of risk and because of their nature, they include errors.

The accuracy and usefulness of risk prediction models is important for clinical decisions to manage risk and prevent events. Many of the weaknesses and limitations to CVD risk prediction models outlined earlier are avoidable. First, when selecting a risk score for risk prediction in a population, it is important to question the quality of its derivation: use of a good quality methodology and adequate CVD endpoints is important in the derivation process. Second, it is crucial to use risk scores derived from populations with similar characteristics, e.g. similar disease profiles.

### 2.4.5 Evidence for effectiveness of cardiovascular disease risk scores in clinical practice:

Although there is broad information behind the derivation and accuracy of risk prediction scores, the academic literature surrounding their impact in clinical practice is sparse. The present literature suggests evidence on the effectiveness of risk scores is limited (158). A systematic review on the impact of providing CVD risk score information to patients suggested that risk scores can be effective in increasing accuracy of patients’ perception of risk and also may improve willingness to have preventive therapy in patients with moderate or high risk. However, the study showed that there is no evidence on the effectiveness of risk scores on long-term outcomes, such as adherence to interventions (259). A recent systematic review examined for the first time the effect of selecting participants for risk management interventions using risk scores followed by multifactorial lifestyle interventions on CVD risk and mortality. Although using CVD risk scores for the clinical decision on multifactorial interventions in primary prevention was suggested as improving individual risk factors, there was again limited evidence on their effectiveness on CVD risk or mortality (260). Evidence base demonstrates that there is a shortage of supporting evidence on the effectiveness of using risk scores in primary prevention. The clinical guidance recommendations (Chapter 2.3) on use of risk scores for screening of the population to determine individuals eligible for risk lowering treatments are, therefore, questionable (158).
One of the challenges in deriving a conclusion from the studies around the impact of risk scores is the inconsistency in terms of designs, interventions and controls used between the studies (259). As well as the quantity of and inconsistency within the literature, the weaknesses of individual studies are concerning. There are a number of weaknesses within the literature, which limit the interpretation of the findings. The first considerable problem with the literature is that many studies lack a control group (259). In the studies incorporating a control group, there was mainly intervention within the control group, receiving usual care (158,259,260). This therefore limits the understanding of the effect of the risk score alone.

The literature on the impact of risk scores on improving health outcomes has mainly incorporated high-risk individuals, those with diagnosed hypertension or diabetes, excluding individuals at low to moderate risk who are in need of CVD risk assessment for therapeutic intervention decisions (158,184). This therefore acts as a limitation in commenting on the effectiveness of risk scores. The other concern is that risk scores are used as part of complex interventions together with education, lifestyle counselling and other risk management interventions (259). This therefore averts the isolation of the effect of the risk score on the achieved improvements.

Risk scores are truly more likely to be used along with interventions in clinical practice (260). Risk scores seem to be effective in improving CVD risk only when combined with interventions for risk management. This relation is suggested to be stronger with repeated provision of CVD risk followed with supporting interventions, such as education and counselling (259).

There is again limited evidence on the impact of clinicians’ knowledge of global risk on improving clinical outcomes; including improvement in CVD related prescriptions and also reductions in risk factors (261). There is also limited information surrounding effective strategies to promote the use of risk scores in clinical practice. However, existing evidence suggests that nurse-led clinics, use of smart software and strong teamwork have potential to improve the use of risk scores (262).

Clinical judgement for identification of high-risk individuals to be managed for reducing their risk can be poor when clinicians only refer to single risk factors. This is especially true for patients with moderate CVD risk (263). Integrating CVD risk factor information can help clinicians make more accurate decisions for treating patients against CVD risk (264).
presence of CVD risk scores on medical records has potential in improving anti-hypertensive and lipid lowering medication use in high-risk individuals (265). The communication of CVD risk scores is also likely to promote actions for reducing CVD risk, again particularly in high-risk patients (266,267).

The other concerning issue in the use of risk scores in the clinical practice is the way of effective communication of global CVD risk to patients. The different methods of presentation of CVD risk to individuals translate into different effects on outcomes. There are limited good-quality studies on the effectiveness of methods used in communication of CVD risk; evidence therefore supports the need for further well-designed research on examining effective methods for communication of risk to promote preventive actions by patients (267).

It may be difficult for clinicians to effectively communicate CVD risk scores to patients (267) and indeed for patients to comprehend the communicated risk information (268). The understanding of global risk concept among clinicians can be also poor (269). Clinicians may not find risk scores useful in practice; evidence suggests that they may believe numerical CVD risk information does not add to clinical decisions (270,271). The literature on the negative impacts of providing patients with CVD risk scores is scarce. Based on the existing literature, there is very little evidence that providing patients with risk score information causes clinical harm. However, the evidence suggests that if risk communication is combined by clinical support, it does not cause harm (261).

2.4.6 Universal and targeted approaches to cardiovascular risk assessment

Evidence suggests that using routine medical records to estimate CVD risk scores can be as effective as universal screening of whole population in targeting interventions to all population with a potential of developing future CVD events. Effective and cost saving prevention can therefore be obtained without a need for screening all population (272). The literature supporting the targeted high-risk strategies in primary prevention of CVD, compared to universal screening approach, has been growing (273). Targeted approach for systematic screening can be based on the CVD risk estimated using risk factor information already existed in electronic medical record (EMRs). It was shown that more than 85% of patients likely to experience CVD events can be targeted with preventative therapeutic interventions by only screening 20% of the population with estimated high-risk (257). Evidence suggests determining high-risk patients for a targeted prevention approach using
risk scores with already existing EMRs can be more efficient in preventing CVD, consuming fewer resources, at a lower cost than universal screening (274,275). A more recent study further suggested that identification of a target population for CVD primary prevention using incomplete EMRs provide similar risk prediction using additional methods to replace missing data with estimated risk factors. This study also supported that targeted strategies using pre-existing data in medical records may be a better alternative than a universal screening approach (276).

2.4.7 Lifetime risk scores and future of risk scores

In clinical practice, risk scores predicting absolute risk within a short to medium time period have been adopted; 10-year risk scores are the most commonly used risk prediction tools. The use of medium-term risk scores in young patients is currently limited (177). Despite the presence of multiple risk factors and thus a very high RR, the risk scores can predict a low absolute CVD risk for younger individuals; risk scores, therefore, tend to underestimate CVD risk in younger individuals (277). Estimated CVD risk may be low in patients with elevated risk factors, e.g. those with diabetes and/or high cholesterol (241,278,279). For example; in a study assessing the JBS2 risk in different age groups, although over 20% of young and middle aged men (below 50 years) had high blood pressure and over 50% had high lipid ratio, only about 15% of those had high estimated CVD risk (10-year CVD risk greater than 20%) (279). In another study using Framingham and ATP III risk scores, both risk scores failed to identify high-risk individuals (10-year CVD risk greater than 20%) among those aged below 30 years, despite high prevalence of risk factors in the population (278). These results are not because the risk scores are inaccurate, but are caused by the limited scope of the medium-term risk scores. These risk scores have been modelled to predict risk within a specific medium-term, therefore have limited ability to predict high-risk young individuals, who actually have low medium-term risk (177). This limits the scope of high-risk based CVD prevention strategies; since if the risk in young individuals is identified earlier, the early provision of risk management interventions, particularly those targeting lifestyle change, has potential to reduce the risk of future events (277,280).

The limitations of medium-term risk scores in predicting risk in younger individuals can be improved with a number of alternative methods. The first and simplest method to improve the risk prediction in young adults can be lowering the threshold for identification of high-risk patients eligible for treatment in the young populations, when using the same medium-term
risk score (177). In Norway, such an approach has been adopted; drug therapy is recommended for 40 to 49 years old patients with a 10-year risk greater than and equal to 1%; 50 to 59 years old patients with a risk greater and equal to 5%; and 60 to 69 year old patients with a risk greater and equal to 10% (281). The considerable weakness in this approach is that medium-term risk scores have poor ability to discriminate between low risk levels. It was shown that 10-year Framingham risk score for predicting CHD outcomes has poor ability to discriminate between levels of lifetime risk, particularly in younger men (282). Another concern on lowering threshold for treatment in younger individuals is that early onset of treatment for risk management has little potential to produce benefit (reduction in CVD risk) (283). This is consistent with the previously outlined evidence suggesting that risk scores may produce benefit in individuals at the highest risk of CVD (Chapter 2.4.4).

Another alternative in predicting CVD risk in younger individuals can be calculating CVD risk score using the same risk factor information, but with an older age. This can be assumed as providing an estimate of the future risk of an individual if their risk profile stays the same. This approach can expose young patients to unnecessary treatment and may cause harm (281).

The third approach to be considered is the comparative approach. Risk tables can be used to predict the RR, instead of absolute risk, of an individual comparative to the average person at the same age and sex (48,284). Risk management interventions targeting the RR can also manage the absolute risk to increase in the future (285). The poor discrimination ability of risk scores at the low levels of risk can again limit this approach.

More recently, European guidelines have proposed an approach called “risk age” as an alternative to comparative approach. Risk age is predicted by comparing the estimated risk of a person with multiple risk factors to the risk of an older person with a normal risk profile (277). Cardiovascular risk age is not dependent on the baseline CVD profile and therefore it can be used in any setting without a need for recalibration. Another strength of cardiovascular risk age is independent of CVD end point to be predicted; thus it can be used to predict any CVD end point: e.g. when assessing the risk of fatal, non-fatal and combined fatal and non-fatal CVD events. A limitation of the risk age is that it is not an appropriate measure for decisions on therapeutic interventions for risk reduction. Risk age is, therefore, not recommended for decisions on the need for therapeutic risk factor management, but is
suggested as a useful tool for effective risk communication and encouraging lifestyle change in young people (48,277).

The most popular suggestion for improving the risk prediction in younger individuals is considered as the use of lifetime risk scores, instead of medium term (10-year) risk scores. Due to various limitations of medium-term CVD risk scores, there has been a growing focus on prediction of lifetime risk (177,286,287). Elevated levels of risk factors lead to accumulation of atherosclerosis and these physiological changes, caused by CVD risk factors, can start at a very young age. For example, it was shown that in the 33 to 50 year old population with a low to moderate 10-year CVD risk and high lifetime CVD risk, the prevalence of coronary artery calcification was high (288). This therefore suggests that high-risk patients can be identified at a younger age using lifetime CVD risk scores. Preventive clinical interventions targeting young individuals based on the lifetime CVD risk can prevent atherosclerosis, which in turn help to reduce risk of future CVD events. As well as the clinical use of lifetime risk scores to prevent the development of CVD disease, lifetime risk scores can play crucial role in public health practice when planning population-level prevention strategies as they can be used to assess population level disease burden and the future burden of diseases (177,289).

The main problem about the lifetime risk estimation is that CVD incidence is homogenously high in the entire population and therefore lifetime risk scores will predict high lifetime risk for the majority of the population. Early studies assessing the use of lifetime risk prediction showed that risk scores vary with different levels of risk factors at some extent (286,290). For example, the lifetime risk score of a 40-year-old person with low cholesterol levels was about half the lifetime risk of a person with high risk (290). Using more recently derived QRISK model for lifetime risk estimation, lifetime risk of a men aged 40 years drops by 10% if he quits smoking, and his weight, blood pressure and lipids ratio reduces (248,291). Lifetime risk scores have, therefore, some ability to discriminate between levels of risk, however, for the lifetime risk scores to be useful for targeting people for risk management, risk scores must vary sufficiently throughout the population (291).

A problem about the use of lifetime risk scores is that the best method for managing risk following the identification of population at high-risk of CVD at a very young age is concerning. This is because the individuals identified with high lifetime risk are likely to be intervened with medications to reduce risk, the same approach used when using medium term
risk scores. The lack of tailored risk management interventions to follow lifetime risk prediction has limitations. The statin treatment of patients with high lifetime risk does not address the underlying causes of risk and does not provide substantial benefits. This can also over-medicalize patients, exposing them to potential side effects (159,292). There are also financial implications of medicalizing large populations for lifetime (293). Lifetime risk is, therefore, likely to be supported by the pharmaceutical industry.

Although there has been growing literature on lifetime risk prediction and its association with risk factor change in different populations, the evidence behind the effectiveness of lifetime risk scores is limited (even more limited than medium-term risk scores) (287,294–296). A study demonstrated that high lifetime risk knowledge of clinicians increases the prescription of risk lowering medications, such as aspirin and lipid-lowering drugs. This increase in prescriptions was due to high risk scores generated to a large number of individuals (297). A study examined the cost-effectiveness of statin use in patients based on the lifetime risk suggested that statin use in large populations is more cost-effective than its use in current routine practice (298).

Lifetime risk scores can be useful in demonstrating the long-term impact of risk management interventions; for example, controlling blood pressure decreases the lifetime CVD risk in the remaining life (294). This, therefore, indicates lifetime risk scores may be useful in motivating change. Another strength of lifetime risk scores to be considered is that they may help to communicate CVD risk more effectively in clinical practice. It was suggested that lifetime risk scores may be useful when combined with medium-term risk scores in clinical practice (177). The importance of controlling lifetime CVD risk and the need for effective lifetime risk scores to be used in young adults has recently been emphasized in clinical guidelines (48,299).

Identification of young individuals with high long-term CVD risk is important to tackle the huge burden of CVDs. Currently used medium-term risk scores seem to be ineffective in targeting young individuals and lifetime risk scores is one of the most promising methods among the efforts to target young population with high long-term risk. Lifetime risk prediction is a newly developing method in risk prediction field. There are still concerns surrounding their ability to discriminate between risk levels and to stratify risk in populations. There is limited evidence on their effectiveness, in both clinical and public
health practice, and cost-effectiveness of intervening patients based on lifetime risk scores; more data on their effectiveness and cost-effectiveness is, therefore, warranted.

2.5 Evidence for effectiveness of secondary prevention strategies

There has been far greater focus on secondary prevention strategies in practice compared to primary prevention strategies. The evidence of effectiveness of secondary prevention strategies is well established. Evidence surrounding the effectiveness of secondary prevention strategies can be explored examining the clinical trials and their reviews on the impact of secondary prevention processes; namely medical therapy (medication for controlling risk factors, e.g. blood lowering drugs for hypertension), surgical procedures (e.g. coronary artery bypass grafting for patients coronary artery stenosis) and therapeutic lifestyle changes (e.g. weight management interventions) on CVD outcomes (300). The evidence from these studies has largely proved the effectiveness of secondary prevention strategies on CVD outcomes.

Considering the effectiveness of secondary prevention strategies as a whole not as single processes involved in secondary prevention, the evidence suggests secondary prevention programmes are effective in practice. A systematic review of trials showed that multidisciplinary secondary prevention programmes for management of CVDs are effective in improving probability of receiving care for managing risk factors, (e.g. increased prescription of lipid lowering drugs), reducing hospital readmissions, improving quality of life and reducing risk of recurrent CVD events (301). Another study demonstrated that a variety of secondary prevention programmes, including lifestyle counselling, education and medical treatment of risk factors can be effective in managing CVD outcomes (302). A systematic review suggested that interventions for lifestyle change in secondary prevention of CHDs are effective in improving diet and exercise habits, reducing all-cause and CVD mortality, and preventing recurrent CVD events (303).

Evidence also supports that individual processes and interventions involved in secondary prevention are effective. Interventions for smoking cessation in patients with CVD are effective in reducing all-cause mortality (304); stopping smoking in patients with CHD can reduce all-cause mortality by up-to 36% (305). Exercise-based cardiac rehabilitation interventions are also effective in reducing cardiovascular risk factors (306) and all-cause and CVD mortality (307). Medical therapy for controlling clinical risk factors has been also shown as effective: antiplatelet agents, such as aspirin, are effective in preventing recurrent
CVD events (308). Antihypertensive agents reduce the risk of further stroke and other CVD events (309–311); this effect of reduced recurrent CVD events is similar in both hypertensive and non-hypertensive patients with a previous CVD experience (309,311); Statins (lipid-lowering agents) are also effective in reducing recurrent CVD events and the need for surgical operations of revascularisation (180).

The evidence surrounding the effectiveness of secondary prevention of CVDs is very comprehensive. Since this thesis mainly focuses on the primary prevention of CVD, I shall not go into very much detail on the effectiveness of secondary prevention strategies but will discuss a few of the more important trials in primary care. Although these trials might not reflect the current secondary prevention in practice, since they were administered before the introduction a pay-for-performance framework called quality outcomes framework (QOF) scheme, (Chapter 3.3.1), it will be useful to examine these trials for the purpose of comparison because the Health Check programme is mainly administered in general practice. A trial in Scotland assessed the impact of nurse-led clinics on management of CHD patients in general practice. After one year the intervention was effective in improving aspirin use, physical activity and diet, and reducing CVD risk factors, such as blood pressure and lipid levels, but not smoking (312). These gains in the first year of the programme resulted in improved health of the patients and reduced hospital admissions (313). After four years, the early benefits of the programme were translated into reduction in further CVD events and all-cause mortality after four years (314). These reductions in CVD events and mortality were not maintained after ten years, however this could be due to large crossover between control and intervention groups, dilution effect caused by randomisation and the study design that reduced the capability of detecting significant changes in outcomes (315). The nurse-led secondary prevention programme was cost-effective, with a cost of £1,097 per QALY gained (316).

Another clinical trial in North England, Leicester, trained nurses delivered a CHD and chronic heart failure (CHF) management programme in primary care practices. Nurses effectively managed medications of patients who experienced an MI. The nurse-led management programme also improved the referrals to appropriate services, such as echocardiography or smoking cessation services. In the short term, the programme improved risk factor profiles of patients, with significant increase in the number of patients having their blood pressure and cholesterol levels managed (317). Although this trial was less cost-
effective than the previous trial in Scotland, with a cost of £13,158 for each quality-adjusted life year (QALY) gained, it was cost-effective based on the recommendations of NICE (set a threshold of £30,000 for cost-effectiveness). The programme was less cost-effective, because it generated substantial additional costs to NHS (for example, increased prescription costs) (318).

Based on the presented evidence, secondary prevention strategies are recognised as vastly clinically effective and cost-effective. However although secondary prevention provides definite benefits for health, evidence suggests these strategies can be incompetent when they are not sufficiently embedded and supported within a health system (319,320).

In the UK, secondary prevention of CVD is the most common prevention strategy used. Secondary prevention of CVDs has been included in the QOF, with an aim to promote high-quality and standardized clinical practice for secondary prevention of CVDs to gain considerable health benefits. The impact of this pay-for-performance scheme has been evaluated; early findings have shown reductions in immediate outcomes, e.g. blood pressure and lipid levels (321). There is limited evidence on the impact of CVD prevention measures within QOF on long-term outcomes of CVD. One study demonstrated that increased quality of CHD care in primary care practices reduced CHD related hospital admissions (322); however another study failed to find such a relation (323). Although early data has shown no impact of QOF on clinical outcomes due to hypertension, such as incidence of CVD or all cause mortality (324), it might be too early to assess the impact of the scheme on such long-term CVD outcomes. The evidence on the effectiveness of the pay-for-performance scheme on CVD outcomes should not be confused with the evidence behind the effectiveness of secondary prevention.

The outlined trials on the effectiveness of secondary prevention of CVD, together with the recent evidence on the effectiveness of QOF on improving CVD outcomes suggest that secondary prevention of CVD is effective in the current primary care service in the UK. The evidence of effectiveness of secondary prevention strategies does not necessarily reflect the effectiveness of primary prevention strategies, because secondary and primary prevention strategies target different population as outlined earlier in Chapter 2.2. The evidence behind the effectiveness of primary prevention strategies therefore needs to be thoroughly examined.
2.6 Evidence for clinical effectiveness of interventions involved in high-risk primary prevention strategies

Primary prevention strategies include interventions that aim to control CVD risk factors in individuals without a pre-existing CVD condition. These involve interventions to manage risk factors related with life-style change, for example physical activity, weight management and smoking cessation, and medical therapy for the management of clinical risk factors, such as statins for lowering blood lipid levels and antihypertensive agents for hypertension.

2.6.1 Interventions involved within the NHS Health Check

Processes under the NHS Health Check are outlined in Chapter 3.4.1. A number of interventions and referrals are proposed to be carried out directly in the NHS Health Check for the patients with low and medium global CVD risk and elevated individual risk factors, for example those smoking, obese and physically inactive. Although there is a national NHS smoking service, other interventions may not be delivered extensively in clinical practice. Patients with high-risk exit the programme and are registered to high-risk registers to be intervened with statins, as well as other risk management interventions for elevated risk factors. Patients diagnosed with hypertension or other chronic conditions are entered to relevant disease registers and intervened appropriately. I shall describe the evidence for effectiveness of brief lifestyle advice, smoking cessation, weight management interventions and physical activity interventions as interventions directly involved in the NHS Health Check. The effectiveness of medical therapy in primary prevention, use of statins and antihypertensive agents will follow.

2.6.1.1 Brief lifestyle advice

In the NHS Health Check programme, individuals at all levels of CVD risk are provided with a brief lifestyle intervention. The evidence behind the effectiveness of brief interventions for lifestyle change is limited, although a number of cardiovascular screening trials included brief lifestyle counselling (325,326). It is demanding to assess the individual effect of brief interventions, since they are mostly administered as part of multidisciplinary primary prevention programmes.

Evidence suggests that brief smoking cessation interventions delivered by physicians, nurses and pharmacists are effective in reducing smoking rates (327,328). However, there is also
evidence that smoking cessation interventions are not effective when carried out by practitioners not specialized in smoking cessation (327). Brief interventions for weight loss are ineffective unless combined with pharmacological interventions. However, although better than with only brief weight management interventions, the effect of combined interventions on weight loss is still low (329). Brief interventions for physical activity in primary care can be effective, but follow-up is required for sustainable effect (330).

Although evidence suggests that brief lifestyle interventions can be effective, there is no evidence on effectiveness of brief interventions carried out by non-clinicians. Therefore, it is not possible to comment if brief interventions delivered in the Health Check will be effective, especially when delivered outside of a healthcare setting by non-clinicians.

2.6.1.2 Weight loss interventions

Weight has a complex relationship with CVD risk, since excess weight acts as an individual risk factor for CVD and is also associated with other risk factors of CVD. Weight loss is therefore essential as an individual risk factor (67) and also to reduce CVD risk factors such as blood lipid levels and blood pressure in CVD risk management process (331).

In the Health Check programme, patients with a need of weight management interventions are referred to either services under standard primary care or commercially provided programmes. Evidence suggests that weight management interventions delivered by commercial providers may be more effective in reducing weight than interventions provided by standard primary care services (332–334). Commercial weight management programmes are also more cost-effective than services provided by trained primary care staff (332). There are, however, demographic and social class basis inequalities in the uptake of and compliance with commercial weight management programmes (333). Commercial programmes were also suggested as effective in reducing CVD risk factors, namely lipid and insulin levels (335). Caution should, however, be taken when considering these findings, since some of them are funded by industries delivering the commercial weight management programmes (333,334) and the findings may accordingly be in favour of their activities.

The evidence behind the impact of weight-loss interventions on CVD risk and long-term CVD outcomes is limited (336). Weight loss, nevertheless, carries a crucial importance in the efforts of reducing CVD risk and comprehensive and multi-disciplinary interventions are essential for effective reduction in weight (337).
2.6.1.3 Physical activity interventions

Physical activity has a positive impact on CVDs, with reduced risk of CVD events and mortality in both primary and secondary prevention of CVDs. This impact is correlated with the level of physical activity, with greater benefit in those with higher level of physical activity (338,339). Over and above the prevention of CVD events, physical activity is also suggested as improving total life expectancy and life years free from CVD (338). Physical activity has a complex relationship with CVDs. The impact of physical activity on CVD risk can be partly explained by reduced body weight, lipid levels, blood pressure and inflammatory factors with greater physical activity (340). Physical activity and physical fitness also act as independent risk factors for CVD risk; improved physical fitness has benefits for cardiovascular health irrespective of the other CVD risk factors (70,341).

A recent systematic review and a meta-analysis of randomised controlled trials on the effectiveness of promoting physical activity interventions in primary care have reported improved level of physical activity at one year (342). There is limited and conflicting evidence demonstrating if more intensive interventions are more effective than brief interventions (342,343). Further studies examining the effect of brief interventions on physical activity are therefore essential (342). Despite this evidence of positive effect of physical activity interventions delivered in primary care, there are uncertainties over the effectiveness of interventions delivered by third parties upon referral from primary care (exercise referral) (344). For example, a recently published systematic review found limited benefit derived from ‘exercise on referral’ programmes (345).

Interventions for promoting physical activity are cost-effective and suggested as having similar cost-utility as pharmacological interventions. Physical activity interventions delivered without direct coaching from a professional; such as exercise groups or interventions delivered by phone or mail, are more cost-effective than programmes delivered by an instructor (346). A nurse-led physical activity promoting intervention, with regular follow-up by telephone can be cost-effective (347).

Although evidence suggests that physical activity interventions reduce CVD mortality in secondary prevention (306), there is lack of evidence on their effectiveness in primary prevention strategies. Depending on the area, physical activity interventions are provided either in the primary care services by brief interventions, exercise referral schemes or
community based programmes in the NHS Health Check (348). There are still uncertainties and conflicting evidence over the effectiveness of interventions involved in the Health Check programme, it is therefore not possible to comment exactly on if physical activity interventions provided as part of the programme will be effective.

2.6.1.4 Smoking cessation

Smoking is one of the major risk factors of CVDs and smoking cessation has a crucial role in reducing vascular risk (349). Smoking cessation is mostly delivered as part of multi-faceted interventions and only few data have isolated the effect of smoking cessation on CVD risk in primary prevention (350). Although not significant, these interventions produced reductions in prevalence of smoking (odds ratio (OR) for smoking prevalence reduction was 0.87 [95% CI: 0.75-1.00]) (350). With the strong evidence on the positive effect of smoking cessation on CVD outcomes (351), it is possible to comment that significant and effective smoking cessation interventions need to be involved in primary prevention strategies.

Services that are solely dedicated for smoking cessation have been shown to be effective in reducing smoking (352). In the UK, a national smoking cessation service has been established (353) and the evidence suggests that the “NHS stop smoking service” is effective in reducing smoking rates at both short-term and long-term (354). Smokers involved in the NHS Health Check programme are referred to the “NHS stop smoking service”, therefore it is possible to argue that this programme would be effective in reducing smoking, which would in turn provide benefits in terms of CVD outcomes as discussed earlier.

2.6.2 Medical therapy in primary prevention

As outlined earlier and in Chapter 3.4.1, patients identified with high CVD risk and those diagnosed with hypertension or another chronic disease exit the Health Check pathway and provided with medical interventions for managing their risk and preventing future CVD events.

2.6.2.1 Statins

Blood lipid levels are strongly associated with CVD risk, with raised cholesterol levels increasing the risk of CVDs, particularly CHD (55). Even if an individual has normal cholesterol levels, they may be at risk of having high lipids levels in long term, which may in
turn increase their CVD risk (355). Although there were concerns about the impact of lowering lipid levels on the CVD primary prevention initially (356), more recent evidence suggests a positive impact of blood lipid levels on lowering vascular disease risk (357). Cholesterol levels in the blood can be effectively reduced by a group of drugs called statins; statins act to prevent cholesterol production and also remove bad cholesterol from blood (358). This group of medications has ability to reduce risk of CVDs in high-risk patients, regardless the baseline levels of cholesterol. Statins are, therefore, useful in the primary prevention strategies using high-risk approach (56).

Evidence supports that statins are effective in reducing the risk of fatal and non-fatal CHD events in patients with pre-existing CVD (secondary prevention) (359). There is also evidence on the effectiveness of statins in other high-risk patients groups, such as those with diabetes (360), hypertension (361) and hyperlipidaemia (362). Statins were effective in reducing the risk of CVD morbidity and mortality in individuals without a previously diagnosed CVD event but at high CVD risk (363,364). The recently updated Cochrane review on the effectiveness of statins in primary prevention of CVDs suggested that the use of statins have positive impacts on CVD outcomes in both high-risk and low-risk patients and they do not produce substantial harm (365). However, there are still questions around the effectiveness of statins in low-risk individuals, although the evidence on the effectiveness of statins in high-risk based primary prevention is better established. While majority of evidence supports the limited impact of statins in low-risk individuals (168,363,366), a recent meta-analysis directed the evidence in favour of use of statins in low-risk populations. This study suggested that statins are effective in reducing CVD events and mortality in low-risk individuals. It was also suggested that these benefits of statins overweigh their harms (367). Despite this recent evidence on positive clinical effect of statins in low-risk healthy individuals, the existing evidence on cost-effectiveness of them is arguable. Cost-effectiveness analyses have largely shown that statins are less cost-effective (168,366) and provide small life expectancy gains in low-risk individuals compared to high-risk populations (298). There is therefore need for further analysis and consideration on the cost-effectiveness of statins in low-risk individuals to bring clarity before approving their use for CVD prevention in low-risk, general populations (365). Recently, the use of low-cost statins is becoming generic and the evidence suggests these statins may be cost-effective when used for primary prevention of CVD in low-risk populations (368,369). In addition to cost-effectiveness of statins, there are other factors that need to be considered before involving
statins in the actions for reducing CVD risk in general low-risk populations: these factors include the feasibility of treating a large proportion of the population with statins; the acceptance of use of drugs in healthy individuals for the rest of their life-time; the possibility of reducing attention from activities to enhance uptake of statins in high-risk individuals; and the non-therapeutic population level strategies to manage lipids (e.g. legislations to reduce fat intake) (365). The current evidence largely supports that providing statins to individuals at high-risk is the most effective and cost-effective approach in preventing CVD and the adoption of this approach should be continued until the proposition of any strong evidence in favour of use of statins in general population.

2.6.2.2 Anti-hypertensive agents

There is a directly proportional association between levels of blood pressure and vascular mortality risk; the increase in vascular risk can start from as low as 115 mm Hg systolic blood pressure and 75 mm Hg diastolic blood pressure. In patients aged 40 to 69 years, the risk of CVD mortality increases by two folds or more with each 20 mm Hg increase in systolic blood pressure and about 10 mm Hg increase in diastolic blood pressure (52). Blood pressure is more strongly associated with the risk of stroke compared to CHD, which is more associated with high blood lipid levels. However, blood pressure has strong relationship with both stroke and CHD (370,371). Management of blood pressure therefore reduces the risk of CVD events and mortality (372,373). There are a variety of anti-hypertensive agents for appropriate and effective control of hypertension (299). Evidence supports that majority of these agents are effective in managing levels of blood pressure and reducing CVD risk in individuals with and without pre-existing CVDs (374,375). The NHS Health Check aims to identify patients with hypertension. The patients diagnosed with hypertension as a result of a Health Check are transferred to hypertension registers for effective control of their conditions. Those diagnosed with hypertension become ineligible for the Health Check and are managed separately in primary care (Chapter 3.4.1).

2.6.2.3 Evidence for prescription patterns and adherence to therapy in primary prevention

Instead of the clinical effectiveness of therapeutic agents, it is essential to maintain a good prescription pattern and continuous use of medications to achieve effective reductions in CVD outcomes. In preventive medicine prescription, both practitioners and patients play a
role, but practitioners may play the greater role in achieving high and equal prescription levels across the population (376,377). In central and Eastern European countries, an average of 86.4% physicians reported regular use of statins in primary prevention of CVDs; this was slightly higher for secondary prevention with 89.9% of physicians reporting regular use of statins (378). However, there is also evidence suggesting a very low statin prescription in primary prevention, with 18.5% statins prescribed in a population with diabetes in Germany. The prescription for secondary prevention of CVD was significantly higher, with 38.1% of diabetic patients prescribed with statins (379). In the UK, there has been an increase in the prescription of statins especially after the introduction of QOF (380–382). Statin prescription varies with a number of factors, with largely lower prescription in communities with greater need for preventive measures (383). Statin prescription is lower in older patients (>75 years) (383) and greater in men than women in individuals younger than 65 years (but equal in older individuals) (384). Although the statin prescribing was lower in deprived communities at earlier times (383,385), after the introduction of QOF, the more deprived areas started to show greater statin prescribing levels (386). Ethnicity is also associated with statin prescribing, with for example lower prescribing in South Asian patients who are in the most need for CVD prevention because of their greater risk of developing CVDs (383,387). Although there is limited evidence on the prescription patterns in individuals without a pre-existing CVD condition, the evidence on overall statin prescribing patterns has shown that statin prescription is greater with higher prevalence of CVDs, suggesting that statin prescribing in primary prevention is lower than secondary prevention (386).

Besides high levels of prescriptions by physicians (388), a high adherence to medications by patients is needed to manage risk factors and in turn achieve effective disease prevention (115,389,390). Adherence to medications is important to control the condition of an individual and improve their clinical outcomes (389). Enhanced adherence to preventive medications is, therefore, crucial in high-risk based prevention programmes to achieve population-level benefit (391,392).

Evidence surrounding the adherence to therapeutic agents for prevention of CVD in patients with existing CVD conditions has suggested that adherence to risk factor management drugs is low in secondary prevention of CVDs. In US, a study assessed the adherence to aspirin, beta-blockers and statins among patients discharged from hospital after an MI between 2003 and 2004. One month after the prescription of drugs, the adherence to all three medications
was 66.3%, with 12.1% discontinued the use of all three medications and 17.9% discontinued the use of one medication. The mortality rates after one year was greater in patients who failed to adhere to all three medications one month after the prescription compared to those who continued the use of one or more medications (393). In another study in US using data collected between 1998 and 2002, the long-term adherence to aspirin was 71% among the patients with a diagnosed CHD, while the adherence to lipid lowering medications and antihypertensive agents (β-blockers) was lower, with less than 50% consistent use of these agents. Adherence to combination of therapeutic agents was even lower, with only 21% of patients using three agents consistently (394). Again in US, 38.9% of patients who had stroke discontinued the use of statins within one year after discharge from hospital (395). In the UK, although only 7.7% of all patients who had the first MI between 1990 and 1995 used statins, the adherence to statins was high, with 73.5% adherence in males and 80.7% in females (396). In an observational study including data from a number of countries, the adherence to therapeutic agents, including beta-blockers, ACE inhibitors, aspirin and statins, at 6-months follow-up was ranged from 80 to 92% in patients who were hospitalised from CHD, with 87% adherence to statins and 88% adherence to beta-blockers (397). Although the above evidence suggests that the adherence to drug therapy for prevention of CVD can be limited in patients with already diagnosed disease, it is more limited in populations without a pre-existing condition. A meta-analysis on the adherence of seven different types of drugs used in prevention of CVDs suggested that adherence to drug therapy is significantly larger in secondary prevention than primary prevention, with 66% adherence in secondary prevention and 50% in primary prevention over a median time period of one year (398). Evidence also supports the suggestion that long-term adherence is greater in patients with higher CVD risk (more CVD risk factors) compared to patients with lower CVD risk (399). Broad evidence has shown poor adherence to drug therapy in primary prevention of CVDs. In US, at 5-years follow-up the adherence to statin therapy was only 26% (400). In Italy, the adherence to statin treatment was less than half, with only 46% of patients without a pre-existing CVD condition adhered to medications after 1 year (401). In Canada, the adherence to statins in a primary prevention cohort was reported as 35% after three years in a cohort (114), while in another cohort the adherence was 25.4% after two years (402). In another Canadian cohort, the long-term adherence to different types of drugs was similar, with adherence ranging from 25% to 39% (403).
As well as overall poor adherence to preventative medications, there are also inequalities in the medication adherence across the populations. Evidence suggests that adherence to medications can be poorer in females (401,404), younger (401) or very old individuals (400), smokers (405), and those with non-white ethnicity (400) and lower SES (400,406). This therefore shows that a high-risk prevention approach involving prescription of therapeutic agents for lowering CVD risk can lead to further inequalities (407).

Apart from demographic characteristics, there are a number of patient and practitioner level factors associated with non-adherence to therapeutic interventions. The first considerable factor can be concerns about side effects, this can be due to a previous experience, not preferring to use drugs for lifetime or willing to manage their risk by alternative methods, such as lifestyle changes (377,408). Other reason for not continuing to drug therapy can be poor perception of risk in patients (409). Relatively, patients might be lack of knowledge about the prescribed medicine, such as statins and their potential benefit on the risk management. These can be caused by practitioners’ failure to provide essential information about the risk of patients and the benefits of the prescribed medicine (408,410). Inconvenience about taking medicines is another factor for non-adherence, forgetting to take drugs or thinking to wait for collecting medications in pharmacy is inconvenient are some of the stated reason for not adhering to preventive medications (408,411). Prescription costs is also a factor that can impair adherence to medications (412). For example, it was shown that increasing prescription costs was associated with reduction in medication adherence (413).

These patient level factors for non-adherence are apparently associated with practitioner level problems; for example, poor ability of practitioners to perceive patients’ non-adherence to medications (411), inappropriate or insufficient communication of information on CVD risk of patients and the importance of taking medications for reducing their risk can limit the adherence to medications (376,377). The perception of risk by physicians, patients and communication of risk play important role in prescription of medications and drug adherence, these will be discussed in details in Chapter 4.4.

Evidence suggests there has been a poor adherence to medications in primary prevention, which may reduce the cost-effectiveness of statin treatment in primary prevention (168). Poor drug adherence has even been observed in secondary prevention, where the target population has apparent diseases with live symptoms and are expected to have good adherence to risk managing medications. This therefore suggests that there is substantial need for interventions
to improve drug adherence. There are a variety of interventions that can be used to improve adherence to medications; these include educational interventions; behavioural interventions, for example reminding patients on taking medications via mail or telephone; interventions to improve communication between practitioners and patients; and technical interventions, for example simplification of medication dosage by practitioners. These are mostly complex interventions, requiring large resources (411,414).

Under the NHS Health Check, which is a primary prevention programme using a high-risk approach, the only therapeutic agent used for the primary prevention of CVD are lipid lowering agents, statins, in patients identified with high-risk. Technically, the patients determined with high-risk as a result of screening are managed separately in routine primary care. The statin prescription patterns and the effect of statins in these patients are very important to reflect the success of the programme, since the main aim of the programme is to identify high-risk patients and manage their risk with intensive interventions as if they have a chronic condition. The patients diagnosed with chronic conditions, such as hypertension and diabetes, are managed separately in the relevant disease registers with appropriate therapeutic agents for primary prevention of CVD (348). Therefore, in order for the Health Check programme to be successful in its goal to reduce CVD rates across the nation and reduce associated health inequalities, it is crucial to achieve high and equal prescription of statins and also maintain the drug adherence across the populations.

The early local studies on evaluating effect of NHS Health Check have shown that in the first year of the programme in a local area at North-West London, less than half (44.8%) of the determined high-risk patients who received a Health Check were prescribed statins. The study group included patients with previous statin prescribing and patients with hypertension; this proportion might, therefore, be lower if only those prescribed with statins after the attending the programme were considered. Female, South Asian patients and those with the highest risk levels saw greater increase in statin prescribing than other patient groups (415). In another local study in Stoke on Trent, again in the first year of the Health Check among the patients with estimated high-risk, the statin prescribing was similar, with 43.6% of patients who had a health check and were confirmed as at high risk were prescribed statins (416). The Department of Health anticipated an uptake of 85% of high-risk patients prescribed statins (417); the statin uptake figures observed in the first year of the study in two local areas among patients with an estimated high risk before recruitment to the programme
are well below this. However, these figures may not reflect the findings in other areas and may have improved in the following years of the programme. There is still no literature on the adherence to statin prescription as a result of cardiovascular risk assessment. The Health Check programme targets those at high risk, but not with a vascular condition like hypertension or diabetes. This population is therefore not either a general population or a population with high risk due to a symptomatic vascular condition. The statin adherence in the target group of the Health Check programme cannot therefore be precisely estimated based on the existing evidence. One might hypothesise that adherence may be low, because the adherence to drugs may only be strongly associated with the knowledge of clinical diagnosis. The statin uptake in the NHS Health Check can be limited by inappropriate communication of CVD risk information to patients (418). Additional resources might be needed to enhance the adherence to statins (419) and also other risk management interventions through, for example, training for improving the ability of practitioners to communicate risk information effectively to patients (271).

2.7 Evidence for the effectiveness of high-risk primary prevention strategies

2.7.1 International evidence

International evidence about the effectiveness of high-risk based CVD primary prevention strategies is limited due to difficulties of implementing large trials, for example, those including screening and multiple interventions for managing risk profiles. The most important problem faced with large trials is the large workload and cost required for their implementation (420). Despite these difficulties, there have still been a number of international trials on primary prevention of CVDs.

The studies on CVD primary prevention from the USA can be considered as a major group of international evidence, although there have been a small number of trial carried out on this particular field. The multiple risk factor intervention trial (MRFIT), implemented from 1973, was one of the randomized trials on primary prevention of CVD in the USA. The trial, targeting men aged 35 to 57 years, aimed to examine the effect of CVD risk management interventions on CVD mortality. Participants in the intervention group were provided with intensive therapeutic or lifestyle interventions for improving CVD risk factors, for example for reducing blood serum cholesterol and diastolic blood pressure and stopping smoking. Participants receiving interventions were followed up with four-monthly visits to monitor the change in risk factors and ensure meeting the previously set aims for risk factor reduction.
The intervention phase of the trial lasted for 7 years. After 7 years follow-up, the trial produced greater reduction in level of risk factors in the intervention group; however, these reductions did not translate into a decline in CHD mortality (422). Despite these unfavourable findings on the long-term CVD outcomes, a recent study, using post hoc analysis generating new outcomes for nonfatal CVD events observed during the 7 years (over the trial), suggested that combined fatal and nonfatal CVD rates were lower in intervention group over the 7-year follow-up period (423). There was 8.3% lower CVD mortality rate in the intervention group after 10.5 years, a mean of 3.8 years following the end of the intervention phase (424). The advantage of the intervention group, in terms of CVD mortality, sustained over years, with 7.9% lower CVD mortality rate in the intervention group after 16 years (425). The MRFIT trial is one of the important trials providing significant knowledge to public health policy in the primary prevention field (426), despite the limitations in its methodology, with exclusion of men at the lowest risk and extremely resource consuming nature.

The international evidence on the effectiveness of primary prevention strategies has mainly originated from studies held in Scandinavian countries. The Malmo study (427), held in Sweden, was a primary prevention programme with an aim to protect population from a wide range of health outcomes. Thus, the trial was not solely on preventing CVDs, but other health outcomes like alcohol abuse and breast cancer in women. The trial included screening to identify patients with high-risk and providing interventions to lower their risk; women patients had mammography in addition to CVD screening and were referred to specialist clinics if necessary. Interventions addressing CVD risk included management of blood pressure, blood lipid levels and blood glucose levels. The trial included birth cohorts aged 32 to 51 years and people attending a screening were compared with those not. After about 20-years follow-up, there was no difference in CVD morbidity and mortality between intervention and control groups (427,428). There were population-level reductions in CVD risk factors since 1980s that largely explain the decline in CHD mortality rates in Sweden (429), similar to other Scandinavian regions (430). Since the long follow-up period in Malmo study was long, these population-level changes in CVD risk factors, but not the potential benefit of the interventions, are more likely to explain the similar reductions in CVD rates between control and intervention groups. This therefore has lead to arguments over if the existing prevention approaches are able to produce population-level benefits or other
approaches with a greater potential to overcome usual trends in risk reduction are needed (428).

Another multifactorial CVD primary prevention programme was carried out again in 1970s in Goteborg, Sweden. The study population included men aged 47 to 55 years at the start of the programme and they were allocated randomly to one intervention and two control groups (each with similar size). The intervention group participants were screened at baseline and those with high risk factors, identified using previously set thresholds for each risk factor, were provided with interventions: participant with high blood pressure had pharmacological treatment, those with high blood lipid levels were given dietary advice and smokers were referred to smoking cessation interventions. Similar to the findings of the Malmo study, at the end of the 10-year follow-up period, there were declines in levels of all risk factors, smoking prevalence, blood pressure and lipid levels, in both intervention and control groups (431).

The Oslo diet and antismoking study was a randomised trial to examine the effect of change in dietary habits and smoking cessation on prevention of CHD. The study included 1,232 men aged 40-49 years without a pre-existing CVD, diabetes and hypertension, but with high-risk of having CVD (those with cholesterol levels between 7.5 an 9.8 mmol/L and with a high global CHD risk score). Smoking prevalence among these participants was 80% (432,433). The participants were recruited to the programme in 1972 and were followed up for 5 years. All participants were screened and then randomized at baseline into control and intervention groups. When the control group attended clinics annually after the randomization and was not provided with dietary advice, the intervention group were followed up every six months for five years. The intervention group was provided with individually tailored advice for dietary intake and their risk factor levels were assessed. Smokers were additionally intervened for smoking cessation (432).

After 5-year observation period, there was a significant reduction in cholesterol concentration in the intervention group, with 13% lower mean total cholesterol in the intervention group compared to the control group. The difference in smoking cessation in the intervention group compared to control group was smaller, with 17% decrease in the smoking in the control group and 24% in the intervention group. At the end of the trial period, these reductions in risk factors, particularly cholesterol, were translated into reduction in the incidence of CVD (MI and stroke) and sudden death; there was 47% lower MI and sudden death incidence in the intervention group than the control group (433). Risk factor reductions were equal across
the social groups. However the CHD incidence was surprisingly lower in men with lower SES; this may be due to greater benefits of interventions in the smokers from lower socio-economic classes (434). At a mean 8.5 years follow-up after the initiation of the programme, the reduced cholesterol levels were maintained in the intervention group, while the control group saw decline in cholesterol levels. However, smoking increased in the intervention group, while it remained the same in the control group. Despite the reduced difference in risk factors between intervention and control groups, the significant difference in the incidence of MI and sudden deaths between the two groups was maintained after three years from the end of the trial; but the difference in the total mortality rates between the groups significantly increased (434). Although the difference in the incidence of MI between intervention and control groups was apparent for 10 years after the end of the trial, the difference was lost at eleventh year (432). After 20 years from the end of the trial, there was no difference in the prevalence of smoking and lipid concentrations between intervention and control groups, but the benefits of intervention on lifestyle were still evident, with lower fat intake and healthier lifestyle in the intervention group (435). The Oslo diet and antismoking study provided important implications on the primary prevention of CVD using a high-risk approach. The study produced substantial reductions in risk, particularly in lipid levels, and CVD events; it is important to note that these improvements were obtained with only lifestyle advice without using therapeutic interventions. The loss in relative benefits of the interventions, after a long period of time, might be explained by improving trends in risk factors and CVD rates in the whole population. Nevertheless, the trial showed that lifestyle interventions in high-risk patients are effective in producing sustainable lifestyle change in the population.

In Ebeltoft district of Denmark, a randomised controlled trial was launched in 1991 in nine general practices. This study, called “the Ebeltoft Health Promotion Study”, aimed to assess the effect of two methods of CVD prevention, differing based on the used resources: general practitioner (GP) delivered health checks and health checks plus health discussions were compared. The study recruited 30 to 50 year old men and women and the participants were randomly allocated into three groups: one control and two intervention groups. All three study groups received a questionnaire for a detailed health assessment. While one intervention group received only health check, the other intervention group had health discussion with a general practitioner, in addition to the health check (436). Health checks involved assessment of CVD risk, followed by feedback from GPs. In the feedback, GPs advised participants to change their lifestyle and to visit their GP, if their CVD risk is high.
Health discussions were 45 minute long consultations with GPs on CVD risk tailored based on the questionnaires completed by participants before the consultations. Follow-up was carried out at first and fifth years, including questionnaires and health checks depending on the intervention group. The intervention group receiving both health check and discussion were also encouraged to have annual consultations for five years (437,438).

Five years after the initial screening, intervention group had lower CVD risk, BMI and lipid levels compared to the control group. Reduction in risk was greater in patients at high risk at baseline (437); reduction in lipid levels was higher in those at the greatest baseline global CVD risk (438). The number of patients with high CVD risk in the control group was twice the number of high-risk patients in the intervention groups at the end of the 5-year follow-up (437).

The intervention group had greater life expectancy compared to the control group over 5 years. After six years, the costs to the health system in the intervention group were not different compared to the control group. There was an increase in the GP consultation rates among the patients invited for the programme in the early years of the programme, but this rate then declined (439).

When two intervention groups were compared, the outcomes did not differ between the group having only the health check and the group having combined health check and health discussion. This implies that the additional health discussion with GP and follow-up consultations did not produce benefits over and above those of the health check alone. This may be explained by a number of practical factors. Those at high risk were recommended to see their GP for risk management and if they chose this, they had GP consultation, although not intensive as the health discussion offered to health check plus health discussion group. This might led to a dilution effect, confounding the variation in the intensity of interventions between the two groups. Another reason could be very low follow-up after the first health discussion in the intervention group with additional health discussion; only about half had 2 or more and only 18.1% had 3 or more health discussion sessions (437).

2.7.2 Evidence from the United Kingdom; before the NHS Health Check

The NHS Health Check, a national vascular risk assessment and management programme, is a high-risk prevention strategy, since it aims to identify patients with a high likelihood of developing CVD and to manage their risk. The UK has never implemented a primary
prevention of CVD at national level before the NHS Health Check and therefore the clinical and epidemiological trials have been the sources of the majority of evidence on the effectiveness of high-risk based strategies in the UK. There have been a number of local and trial based high-risk primary prevention programmes in the UK. However, because of their size and subsequent influence, the Oxford and Collaborators Health Checks (OXCHECK) trial and the British Family Heart Study (BHFS) are the leading studies in this area.

The BFHS (326) was the major randomized controlled trial of primary prevention of CVD run by nurses in 13 towns in the UK. A total of 26 practices, one pair of control and intervention practices from each town, participated in the study, with additional control group in each intervention practice. All men aged 40 to 59 years in each practice were eligible and those in the intervention group were invited to health checks with their whole immediate family. Although in intervention groups, all family members attending an appointment were screened, only couples, men with their partners, were followed up. The health checks involved CVD risk assessment and lifestyle interventions based on the risk level of participants. Based on the individual risk factors and overall CHD risk, a strategy for follow-up was agreed between nurse and participants. Control groups in intervention and control practices were only screened one year after the start of the programme (326).

After one-year follow-up, there were reductions in weight, cholesterol level and blood pressure in the intervention group, with reduction in overall CHD risk score at similar levels in both sexes. All these reductions in risk were more likely to be significantly greater in patients with greater risk at baseline (326). In this family oriented intervention, the improvements in CVD risk profile were clustered between couples, with similar changes in CVD risk between couples (440). Although there was an improvement in the number of clinical diagnosis in the intervention group, there was no associated increase in the levels of drug prescription. The intervention had a limited effect on smoking rates, with very a small reduction in smoking prevalence after one year; those who dropped-out were more likely to smoke; therefore, the reduction in smoking might not reflect the true change (326).

The OXCHECK study, the second largest health check trial in the UK, was carried out in five practices in Bedfordshire (325,441). The intervention was again a nurse-led health check programme, targeting patients aged 35 to 64 years registered with the practices. The intervention involved measurement of CVD risk factors and counselling of patients for changing lifestyles to manage their risk. 17 695 were invited to participate in the study,
80.3% of which responded to invitation and returned questionnaires for collecting information on the baseline characteristics; such as smoking habits. These participating individuals were randomly allocated to four groups to be screened in four years (between 1989 and 1992) (441). The study employed internal controls to minimize the dilution effect between intervention and control groups. In clinical trials, participants in control groups can adopt behaviours of intervention groups and this may therefore dilute the results of the trial (442). Therefore, the control group for an intervention group receiving health checks in a given year was the population who received the intervention in one of the subsequent years; for example populations with a health check in year one had the population screened in any of the years two to four as control. Control groups received the same intervention as the intervention groups, but at a later time period (441), therefore avoiding the adoption of the behaviours of the intervention group by control group.

Before the OXCHECK, a pilot study was carried out to assess the effect of training of primary care practice teams by facilitators to set up preventive services. Facilitators’ roles included assisting primary care teams to set up disease prevention programmes; providing help to develop registers of patients eligible for the primary prevention programme being set up; training nurses on prevention techniques, e.g. blood pressure measurement and lifestyle advice; and establishing techniques to evaluate the progress of the prevention programmes (443). The assistance given by the facilitators to primary care teams improved recording of risk factors, including blood pressure, smoking and BMI, after the health checks (444), however after three years of implementation of the health checks, there were small and non-significant changes in risk factors levels of patients (445).

Considering the main OXCHECK health check trial again, at baseline, the health check eligible population had a high prevalence of CVD risk factors and a substantial proportion of the population was in need of follow-up and interventions for managing risk (446). There were reductions in level of cholesterol, blood pressure and improvements in dietary habits, such as lower intake of butter, at one year after the initial health checks. However, the health checks failed to produce significant reduction in smoking prevalence (441). Four years after the initial health check, there were significant reductions in cholesterol, blood pressure and BMI levels, with additional improvements in dietary habits (e.g. intervention group having less fatty diet) and exercise. The health checks were again shown as not beneficial to levels of smoking after four years, consistent with the findings after one year. It was also shown that
repeating health checks annually have no effect on changing levels of risk factors, with similar risk change in those having annual checks and those having a single check (325).

**Relative effectiveness and cost-effectiveness of OXCHECK and BFHS Trials:** The BFHS trial was proposed to produce an estimated 12% reduction (13% in men and 10% in women) in overall CVD risk, if the reductions in risk factor levels are maintained for long-time (326). In the OXCHECK study, the estimated MI risk reduction was comparable with that reported for BFHS: if the cholesterol reduction obtained after four years was maintained for long term, the study was likely to produce an estimated 6% reduction in MI risk in men and 13% in women and with a specific amount of reduction in blood pressure, a further 7% estimated risk reduction would be obtained (325). Although the OXCHECK seems to be slightly more effective than the BFHS, when the impact of two programmes on change in life expectancy is considered, the OXCHECK can be suggested as slightly less effective than the BFHS. This is because, while a greater reduction in risk was proposed in women who tend to have lower absolute risk than men in the OXCHECK study, a higher risk reduction was estimated in men in BFHS (447).

In terms of cost, the short-term improvements in CVD risk profile in BFHS were achieved at a cost. The substantial part of the cost spending of the intervention was allocated to nurse time. Although this resulted in cost savings from health services by GPs due to reduction in visits to GPs in the intervention group, there was an increase in the costs of outpatient services (448). The OXCHECK study was also costly, with a large cost for nurse time spent on carrying out the health checks and additional work for follow-up, tests and others; therefore, it was projected by authors that reducing the time spent on the health checks was unlikely to reduce the overall cost of intervention (449). The cost to be spent for achieving one percent reduction in CVD risk per person was estimated as £2.25 for the OXCHECK study (449) and £4.30 for BFHS (448). Therefore, although BFHS, a more intensive intervention, was clinically more effective than the OXCHECK study when life years gained is considered, it was less cost-effective. Nevertheless, implementation of both trials producing similar results, with reductions in CVD risk factors in the immediate time frame, was costly. Both trials were largely dependent on nurse time and produced large workload in the broader health system. In order for a programme to be cost-effective, the reduction in risk should be maintained for at least five years. Longer follow-up with larger populations than
used in both trials is, therefore, required for assessing the overall effectiveness and cost effectiveness of the CVD prevention programmes (447).

The prevention programmes cannot only be cost-effective, but also cost saving that means an intervention provide health benefits at the same time it reduces the costs. Basic preventive strategies requiring low cost can reduce the CVD events and therefore expensive medical interventions needed for cure (450). OXCHECK and BFHS trials failed to prove evidence on the cost-saving effect of cardiovascular prevention strategies. The trials assessed complex CVD outcomes, such as mortality, which can be largely affected by a number of factors (447); therefore diluting effect of other factors makes it difficult to determine the effect of an intervention on outcomes. Therefore, instead of trials, modelling studies can act as better sources of evidence on the economic impact of CVD prevention strategies (451).

Besides OXCHECK and BFHS trials, there have been a number of trials carried out in the UK to examine the effect of high-risk based primary prevention strategies. The first major trial implemented in the UK on the primary prevention of CVD was the South East London Screening Study (SELSS) (452). The trial was started in 1967 in two large general practices in South London. Patients aged 40 to 64 years registered in the practices were targeted and randomly allocated into two groups of screening or control. The study was carried out in four years: after the initial screening, the intervention groups were followed-up every 2 years, therefore, patients were followed-up twice after the initial screening in four years. Nurses carried out CVD risk assessment, followed by lifestyle interventions, including smoking cessation advice, and referrals to GPs for diagnosis and interventions when appropriate. The study examined a limited number of outcomes, which were mostly long-term outcomes. Nine years after the first implementation of the programme, there was no difference in GP consultation rates, hospital admissions and CVD mortality between control and screening groups (452).

In 1989, another trial on CVD screening for primary prevention was introduced in North West England, Stockport. This population-based screening programme targeted all population aged 35 to 60 years who were registered with general practices. Trained nurses were responsible from delivering the CVD risk screening. The programme included measurement and recording of CVD risk factors, followed by health advice provided to all participants for reducing modifiable risk factors. Those identified with blood pressure and/or
cholesterol higher than the previously defined thresholds for determining high risk were referred to GPs (453,454).

Over a ten-year period, there was a decline in cholesterol levels, blood pressure, smoking, and alcohol consumption, but an increase in BMI (454). There was a greater decline in cholesterol, but lower decline in smoking in more deprived patients (455). The baseline risk of participants was a significant predictor of the effect of screening in reducing risk; the decline in the risk was greater in patients with higher baseline risk (454). Although there was greater reduction in blood pressure in patients at the highest risk, there was an overall increase in blood pressure in the population at lowest risk. Reductions in smoking, cholesterol levels and alcohol consumption were greater in patients with higher baseline risk (454). The greater risk reduction in the higher risk population is a generally reported finding in CVD primary prevention programmes including multiple risk factor interventions to modify risk (350).

Another community-based CVD primary prevention programme, the Healthy Hearts Study, was implemented more recently in Wales (456). The study was carried out in three general practices, targeting patients aged 45 to 64 years without pre-existing CVD. The eligible population was invited to have CVD risk screening. The CVD risk assessment was carried out by nurses, followed by referral to appropriate intervention programmes (e.g. smoking cessation services), dieticians or to GPs (for disease diagnosis and treatment), where necessary. After one year, there were reductions in lipid levels, pulse rate, blood pressure and blood glucose in attending individuals: These improvements in risk factor profile were reflected as reduction in CVD risk, with a 6.7% relative risk reduction (RRR) (mean risk reduced from 13.1% to 12.3%). Consistent with the Stockport trial findings, there was an increase in mean BMI over one year (456).

There was also improvement in single risk factors being managed in the referral services, such as reduction in smoking and alcohol intake, and improvement in regular exercise, suggesting elevated individual risk factors generating referral to interventions at baseline act as predictors of risk reduction. Again, the participants with the highest risk at baseline had the greatest overall CVD risk reduction. The improvements in the CVD risk in attending individuals in this small trial in a short period of time is promising; however, a crucial limitation to the favourable findings of the study was the low uptake levels achieved, with only 29% of the initially invited population attending to screening (456). The lack of
assessment on the determinants of the study uptake, the cost-effectiveness and the impact of the programme on long-term CVD outcomes impede commenting on the universal effectiveness of this primary prevention programme.

2.7.3 Summary of evidence on the effectiveness of high-risk based primary prevention

Evidence from the UK and elsewhere shows that high-risk based prevention of CVDs may reduce risk factors and overall CVD risk in the short term (325,326,431). However, evidence on the impact of CVD risk assessment and management programmes such as the Health Checks on longer-term outcomes, such as CVD mortality and morbidity, is scarce (427). This is not to suggest that such programmes are not effective, but rather there is an absence of supporting evidence, due to flaws in study design and the need for longer-term follow-up. Because there is long period between the interventions and outcomes (e.g. CVD mortality), a number of other factors, for example, changing trends in risk factors and other interventions, may influence the outcome. The effect of an intervention on outcomes in study populations may, therefore, be diluted (442). Another reason for limited evidence may be that CVD events are rare in trial settings, which makes achievement of adequate statistical power difficult. Because of these limitations, Lindholm and Rošen (442) recommended the use of intermediate outcomes, such as cholesterol and blood pressure levels, which are strongly associated with long-term outcomes (e.g. mortality), as measures of effectiveness of CVD prevention (442).

The NHS Health Check programme (Chapter 3.4) in the UK aims to assess CVD risk in the entire English population aged 40-74 years. However, in practice the programme uses a high-risk based approach. Evidence shows that although high-risk primary prevention strategies reduce risk factors and overall risk in eligible populations, the reduction in risk is commonly in those at high risk (326,431,454). Emberson et al. (350) suggested that although there was evidence that multiple risk factor interventions for primary prevention were effective in producing benefits in the high-risk group, there was no evidence of their effectiveness in the general population. It is therefore questionable whether the Health Check will be effective in producing benefit in the general population.

There are also concerns over other aspects of the high-risk based prevention programmes, including the risk assessment and interventions offered to reduce risk. For example, low uptake of risk assessment (456) and low uptake and adherence to interventions (e.g. statins
and weight management interventions) (Chapter 2.6) may limit the effectiveness of such programmes. Considering the NHS Health Check, achieving high uptake of screening and interventions and adherence to interventions is important for the success of the programme.

A recent Cochrane review concluded that the general health checks are not effective in reducing morbidity and mortality of CVD and cancer (457). However there are many limitations to this study and there are questions over the relevance of its findings to the NHS Health Check programme (Chapter 3.4) (458,459). First, they defined general health checks differently; their general health checks aim to screen populations to identify existent disease conditions (e.g. cancer) or increased risk of diseases (CVDs), which were previously unknown. Secondly, the review included a limited number of trials, which were out-of-date. Lastly, interventions that the included trials offered were also different, with only brief lifestyle interventions offered to manage risk. This was because, interventions used today, such as risk prediction tools allowing identification of target groups and low-cost statins to be offered to those at increased risk, were not available at the time of the included old studies (457–459).

Potential cost-effectiveness of high-risk based strategies for prevention of CVD, in six countries, including the UK, France, Poland, Germany, Denmark and Italy, was estimated in a modelling study, since there have been no data from clinical trials or empirical settings to assess cost-effectiveness of these strategies. The study used a well-validated model to estimate cost-effectiveness of a variety of strategies using different methods (460). Schuetz et al. (460), overall, suggested that a Health Check like programme has potential for being cost-effective at 30 years in all six countries and even cost saving depending on the strategy and country (e.g. in Poland, but not in the UK). One of the key messages of this study was that targeted strategies (pre-screening to select target group for health checks) can provide more cost-effective prevention of CVDs, with considerable public health impacts. Targeted health check strategies, for example, screening those with high estimated CVD risk, were estimated to be cost saving in the UK (460).

There was, therefore, scarce evidence on both clinical effectiveness and cost-effectiveness of CVD risk assessment prior to the decision of implementing the NHS Health Check, in England. There is crucial need for evaluation of the effectiveness and cost-effectiveness of disease prevention programmes, particularly using empirical data (458).
2.8 Effectiveness of population level primary prevention strategies

Population level strategies aim to control CVD risk factors in the entire population. A number of studies have assessed the effect of these population-based interventions implemented in a range of countries. I shall here present evidence from these studies on the effectiveness and cost-effectiveness of population-based interventions, including interventions for controlling smoking, salt-intake and trans-fat intake, and Polypill interventions.

2.8.1 Smoking cessation interventions

Controlling smoking prevalence and consequently preventing second-hand smoking carries crucial importance to reduce deaths attributable to smoking (461). Population-level measures to reduce the smoking prevalence include increasing prices of and taxes on tobacco products for reducing the demand, implementing smoking bans in indoor places (e.g. workplaces) to prevent exposure to second-hand smoke, health warnings on the packaging of tobacco products and increasing awareness on dangers of smoking through mass media campaigns (462,463).

A recent systematic review demonstrated that there is strong evidence on the effectiveness of increasing prices (taxes) of tobacco in reducing prevalence of smoking, however less strong evidence on the effectiveness of smoking bans in indoor places, bans for advertisement of smoking products, warning labels and mass media campaigns (462). Although the evidence on the effectiveness of health warnings labels on smoking prevalence has not been fully established yet, it has been shown that health warnings are effective in increasing the knowledge of health risks of smoking (464).

Bans for smoking in a number of settings, including public places and workplaces, have been increasingly implemented in many countries. These smoking bans, often called smoke-free legislations, primarily aim to prevent exposure of non-smokers to second-hand smoke. These legislations also anticipate encouraging smoking cessation and reducing active smoking prevalence. Evidence suggests smoking bans have been effective in reducing passive smoking and also improved CVD outcomes (465). Smoking bans have been associated with significant reductions in CVD events, with 17% reduction in the incidence of MI (466,467) and 10% reduction in the incidence of acute coronary events (468). There has been a consistent decline in CVD outcomes, suggesting the benefits of smoking legislations have
been growing over time (466,467). The evidence on the impact of smoking legislations on active smoking is however limited (465).

Considering the smoke-free legislations specifically in the UK, in Scotland, the exposure to second-hand smoke in non-smokers reduced significantly within 10 months following the introduction of legislation compared with the exposure within 10 months prior to the legislation. There was also a 17% reduction in hospital admissions due to acute coronary syndrome within 10 months after the legislation compared with only 4% reduction in admissions in England, where there was not such legislation in place at that time. An estimated 67% of the decline in hospital admissions was attributable to reductions in inhalation of second-hand smoke (469). In England, there was a good compliance with the legislation for smoke-free public places and workplaces after eight months from the introduction of bans, with a significant decrease in population smoking in indoor places (470). This was translated into a substantial decline in exposure to second-hand smoke in non-smokers after the introduction of the smoke-free legislation (471). The smoking ban in indoor places was also associated with health benefits; there was 2.4% reduction in hospital admissions due to MI (equals to 1200 less MI admissions) at short-term, 15 months after the introduction of legislation (472). There was a significant, but not sustainable increase in the attempts to stop smoking after the implementation of smoking legislations in Ireland (473).

Smoking is the major independent risk factor leading to health inequalities and is responsible from most of the inequalities in disease mortality (474). An extensive reduction in smoking may reduce health inequalities (475–477). However, there are opposing views that population-level interventions would further widen inequalities, concentrating benefits of interventions more on the affluent populations (478). The preliminary and provisional evidence suggests that population-level interventions (e.g. smoking restrictions in workplaces and schools) to reduce smoking may be effective in reducing health inequalities (475,479). There are however opposing findings; (475) for example, it was shown that exposure to second-hand smoke is greater in public houses in deprived areas compared to affluent areas (480). Studies concerning childhood exposure to second-hand smoke in the UK largely suggest that the smoke-free legislation has not been effective in reducing the socio-economic inequalities in exposure to second hand smoke in children (481–483). Evidence surrounding the effectiveness of population-based smoking strategies on health inequalities is not clear and further research is therefore warranted to assess their impact on health inequalities.
2.8.2 Interventions for reducing salt intake

Strategies to reduce salt-intake at population level can prevent a great number of CVD events in the entire population regardless of their disease status (both normotensive and hypertensive individuals), in contrast to high-risk based prevention strategies that are only able to produce benefit in a limited proportion of population (only in hypertensive individuals). Population-level approaches for reducing salt intake, therefore, have large potential to reduce risk of CVD outcomes (484). Modelling studies have suggested that reductions in daily salt intake can produce substantial declines in CVD and health care cost savings (485–488). In the US population, 3 g per day salt intake reduction would reduce the annual incidence of CHD by up to 120,000, stroke by up to 66,000, MI by up to 99,000 and reduce the annual all cause mortality by 92,000. This 3 g per salt reduction was also suggested as having potential to save up to 392,000 QALYs and $10 to 24 billion healthcare costs annually. Even a smaller reduction with only a 1 g per day reduction in salt intake would be cost saving and more cost-effective than medical treatment of hypertensive patients (486). Another modelling from the US supported the benefits of reducing salt intake at population level. A 9.5% reduction in dietary salt intake would save an estimated $32.1 billion in healthcare costs. This is a very favourable effect considering that potential reduction in salt intake would be achieved through cooperation with food industry (487). In the UK, population level reduction in the intake of salt by 1 g per day using policy-based strategies estimated to annually decrease about 3,186 CVD deaths (488). Another modelling study proposed that reducing salt intake by 15% at population level would produce an 8.5 million CVD death reduction in low and middle-income countries within ten years; this could be achieved at only an estimated annual expense of between $0.04 and $0.32 per person (489).

A number of countries have already established population-based strategies to reduce salt intake at population level; these strategies have included community education to enhance the awareness on the harms of consuming high levels of salt, collaborating with food industry to reduce salt content of processed food and to appropriately labelling food to present the salt content of food to customers. Finland and England are important examples for countries that already established strategies for reducing salt intake at population level and successfully achieved population-level reduction in salt intake (490).

Finland is the first country that produced a population-based programme for preventing CVD: The North Karelia Project was initiated in 1979 as a pilot project for developing
population level strategies to tackle main CVD risk factors. Three years after the implementation of this project the strategy was applied to the whole country (491,492). Finland is among the first countries that have implemented population level strategies to reduce salt intake. The actions to reduce salt intake at population level included media campaigns to enhance awareness of population on the harms of salt and the importance of reducing its intake; collaboration with food industry to control the salt content of processed food; and government legislations to appropriately label salt content of food (492–494). Actions to control the intake of salt through industry have great potential and important especially in developed countries, because a large proportion of salt intake is from processed food or restaurant food (492,493). For example, an estimated 75% of consumed salt is from processed food in the UK (495), while this number is about 70% in Finland (496). After the introduction of the population-based strategies for reducing salt intake, there was significant decrease in salt intake in Finland, with one-third reduction in salt intake within 30 years. This reduction in salt intake was reflected as a 10 mmHg reduction in the population mean blood pressure. In the same period, Finland experienced approximately a 80% reduction in CVD mortality (497). The majority of blood pressure reduction in Finland is largely attributable to reduction in salt intake, since the country has experienced an increase in the obesity prevalence and alcohol intake. The reduction in salt intake has therefore played a significant role in the decline in CVD events: Besides salt intake reduction, decrease in fat consumption (decrease in blood cholesterol), improved consumption of vegetables and fruits, reduction in smoking prevalence and enhanced intake of potassium and magnesium (Sodium enriched salt replaced with potassium and magnesium-enriched salts – “Pansalt”) have also contributed to the decline in CVD events (492,493,497).

The UK has also taken actions to control the salt intake at population level. In 2003, an initiative to reduce salt intake in the UK population was introduced by the Department of Health and Food Standards Agency (FSA). The FSA has set the target for reducing salt intake from individual intake of 9.5 g per day to 6 g per day (498); with the latest revision of salt reduction targets in 2009, this reduction aimed to be achieved by 2012 (499). The FSA targets for salt intake reduction requires 40% reduction in the use of salt at table or while cooking and 40% reduction in salt content of foods by food industry. The reduction in use of salt by individuals aimed to be encouraged through media campaigns to improve awareness on the importance of salt reduction (490). However, this seems constituting a small part of the strategy. Meeting the salt reduction targets in the UK has been largely through
collaboration with food industries; however the involvement of industries in the actions to reduce salt intake is voluntary and it is not through legislations as in Finland (500).

The UK salt reduction strategy has resulted in some success. In 2008, five years after the introduction of initiative, there was a fall in estimated salt intake from 9.5 g to 8.6 g per day (501); this was further reduced to 8.1 g per day in 2011 (500). Although there have been significant reduction in the salt intake and also use of salt at the table following the salt-reduction initiative, the inequalities in the excess salt-intake and salt use at table have not been faded in some population groups; for example, men, younger, socio-economically deprived and ethnic minorities still had higher salt intake (502,503). The reduction in the use of salt added in the table may show the success of campaigns aiming to enhance public awareness on salt intake (503).

Although the salt intake reduction strategy in the UK has succeeded to produce significant salt intake reduction, the reduction is becoming slower (only 0.5 g per day reduction between 2008 and 2011) (500). It seems that the strategy have not meet its target of reducing salt intake to 6 g per day by 2012; it has been suggested that because of slowing decline in salt intake, the target is likely to be achieved later than 2012 in 2015 (504). This slow reduction in salt-intake seems to be due to lack of strict legislations to reduce salt intake in food industry. As outlined earlier, Finland experienced substantial salt-intake reductions (497,505). These successes suggest that legislations and direct government involvement in population strategies have great potential to provide additional benefits compared with non-formal collaboration with industry (504). A modelling study compared the effectiveness of different strategies for reducing dietary salt intake. The comparison included four studies; two were high-risk based prevention strategy aiming to reduce salt intake through dietary advice to high-risk individuals and two were population-based prevention strategies, of which one was using legislation to enhance the reduction in salt intake in food industry and the other one was an incentive programme for food industry to voluntarily reduce the salt content of food. Although both population-based strategies were cost-effective, high-risk based salt reduction strategies were not. However, the government legislation to reduce salt-intake in the processed food was much more cost-effective, with 20-times greater cost saving, than the voluntary approach (506). Cappuccio et al. (507) suggested that lowering salt content in processed food at some extent is acceptable by food industries; however, they may oppose to reduce salt levels further with a worry that this would decrease the profitability of foods.
Although food industry, in the UK, has been cooperative with the government in the actions to reduce salt content (508) and has succeeded to lower the salt content of food by about 15%, further reduction in salt content of food may therefore not be possible without stricter legislation strategies (83). Nevertheless, the UK has shown success in reduction of salt intake levels through promoting public awareness on the importance of salt reduction and food industry collaboration in reducing the salt content of food. The UK is the leading developed country with the lowest level of salt intake. Many international governments have followed the UK salt intake reduction strategies in their actions to implement similar approaches in their countries (161,490,509).

2.8.3 Interventions to reduce trans-fat consumption

Trans fatty acids (trans-fat) are one of the significant nutritional risk factors that need to be tackled through population strategies to fight against CVDs (83). Denmark is the first nation in the world that brought a legislative action against trans-fats (510). It is asserted that about 1 g trans-fat intake is associated with minimal health problems. In 2001, in Denmark, although the average trans-fat intake in the population was 1 g per day, it was possible to consume up to 30 g trans-fat in a meal containing two or three products with high trans-fat content, e.g. French fries, biscuits. Denmark introduced legislation in 2004 to ban the consumption of industrial trans fats, restricting trans fats to 2% of the total dietary fat in a food product (511). Trans fat legislation has been shown to be highly effective: by 2005, there were substantial reductions in trans-fat content of food, which contained high levels of trans-fat before the ban (e.g. French fries and bakery goods) (512). In 2005, the trans-fat content of particular traditionally trans-fat rich foods was 30 fold lower than the amount in 2001. The reduction in trans-fat content of foods did not adversely affect the cost, availability and taste of foods (511). Denmark, consequently, has one of the lowest levels of trans-fat content in foods compared to other countries (511,513).

The trans-fat legislation in Denmark was followed by similar actions to eliminate the trans-fat content of foods in a number of other countries (83). In US, New York City was the first to implement legislative strategy on trans-fat elimination after Denmark. In this city, a legislation to restrict the trans-fat content of foods in restaurant chains was introduced in 2006, following the unsuccessful voluntary actions to reduce trans-fat content in restaurant foods (514). Two years after this legislation, by 2008, there was a reduction from 50% to less than 2% in trans-fat content of restaurant food (515). There was significant decrease in trans
fat content of fast food between 2007 and 2009 (516), with an average of 2.7 g trans fat reduction per 1000 kcal fast food (516). A number of other regions in US and other countries, including Switzerland, Canada and Austria have also introduced legislations to restrict trans-fat use (83,515).

There were concerns if the trans-fats would be replaced by only saturated fatty acids, therefore if the trans-fat legislation would increase the saturated fatty acid content of foods. However, the assessments after the introduction of legislations in different countries have shown that in contrast to the concerns, trans-fatty acids have been replaced with a mixture of saturated fatty acids and healthier fats, namely monounsaturated and polyunsaturated fatty acids. With the replacement of trans fatty acids with healthier fatty acids, the legislations would provide greater benefits than expected (517). Again as opposed to the concerns, legislations on restricting trans-fats did not increase the price of foods and did not affect the taste of foods (511,512). Trans fat banning legislations do not therefore have adverse implications, but provide substantial benefits.

It was asserted that if trans-fat content of foods is reduced by 1% of total energy consumption, an estimated 11 000 heart attacks and 7000 total deaths would be prevented in the England, in one year (518). This and the evidence outlined earlier, therefore, support the need for strict regulations to control the trans-fat content of food in the UK. Although, in 2010, NICE supported the use of legislative actions to restrict trans-fats in food (160), previously the FSA (519) and now the Department of Health (520) has not espoused a legislative approach to ban industrial trans-fats. Both organizations have supported that voluntary actions of food industry would be effective in reducing trans-fat content of food products (520,521). A number of food industries have already removed trans-fats from the food products and others have declared that they are putting effort to reduce trans-fats from foods (510,520). However, it has been contended that stricter legislative approaches may have more potential to produce greater benefits than voluntary actions; these approaches may also help to prevent inequalities in disadvantaged populations (e.g. socio-economically deprived and children) and also reduce the pressure on food industries (83,518). Despite these, in the today’s political and economic environment, it is improbable that the UK government would introduce legislative approaches against trans-fat use (510).
2.8.4 Polypill intervention

A combination of pharmacological agents, each addressing CVD risk factors, including LDL cholesterol, blood pressure, serum homocysteine and platelet function, was proposed as a population-based strategy for effective prevention of CVD. The formulation of this drug combination, called the Polypill, contains statins, aspirin, three anti-hypertensive agents and folic acid (522).

Wald and Law, founders of the Polypill strategy, suggested that rather than using pharmaceutical agents at high doses in those with elevated individual risk factors, small amounts of pharmaceutical agents addressing major CVD risk factors in entire high-risk populations, regardless the level of their risk factors and therefore, without a need for screening, would be more effective in population-level reduction of CVD risk (173,522). The Polypill can shift the population distribution of CVD risk factors due to its components and these risk factor reductions along the entire distribution can therefore produce effective reductions in CVD-risk at population level (109,145,173,522). It was estimated that the use of the Polypill in individuals with a pre-existing CVD (secondary prevention) and all those aged 55 years and older (primary prevention) can produce 88% and 80% reduction in CHD and stroke risk respectively (522).

Despite strong interest to the Polypill (523), limited progress has been made on the use of the strategy due to criticisms surrounding the concept and practical difficulties in testing drug formulations (524). However, there are a number of on-going Polypill trials (525). The first considerable concern is over the effectiveness of the Polypill in those with no elevated risk. Although the effectiveness of use of the components of the Polypill in secondary prevention is well established (526), evidence on the effectiveness and safety of use of the Polypill in primary prevention among those at lower risk levels is scarce (524). There is evidence surrounding the effectiveness and safety of use of statins and blood pressure lowering agents in primary prevention, even in those at lower risk levels (183,375). However there have been concerns over the effectiveness and safety of using folic acid and aspirin in primary prevention. Aspirin can create a risk of gastrointestinal bleeding and its harms may outweigh the benefits (527). Although it does not have an evident harm, folic acid is suggested as not effective in reducing CVD risk (528). Because of these reasons aspirin and folic acid were excluded from the formulation of the Polypill. Wald et al. (529) showed that on the Polypill excluding aspirin and folic acid components is effective in reducing blood pressure and
cholesterol levels in those aged 50 years and over without a pre-existing CVD. It was suggested that if this effect is sustained in long term, the Polypill can be effective in prevention of CVDs (529).

Another concern regarding the Polypill is that it combines a number of agents and this could limit the effectiveness of each individual agent. The PolyCap trial, carried out in India, first showed that the Polypill has lower effectiveness compared with its individual ingredients. For example, simvastatin in combination with other agents has lower effectiveness compared to simvastatin alone (530). However, the PolyCap trial later showed no evidence of interactions between drugs (531).

The potential side effects of the Polypill are another concern. Aspirin, a component of the Polypill, for example, was shown to have limited impact in primary prevention and can expose patients to increased risk of gastrointestinal bleeding (527). This is further associated with adherence to the Polypill, which is highly important for the effectiveness of the strategy. The effectiveness of the strategy at population level reduces, if adherence decreases. Wald and Law suggested that the Polypill would lead to minimal adverse effects and assumed that the adherence would be high based on the evidence from short-term trials (522). This assumption has, however, been criticized, since adverse outcomes may be greater and adherence may be lower in long term (524). Trials evaluating adherence have reported reasonably good adherence. Pill Collaborative Group (532) reported that 23% of the group using the Polypill did not complete the treatment over a 12-month period, with 18% due to side effects. In PolyCap trial (530), 16% of participants discontinued the treatment within 12 weeks and 3.4% of discontinuation was because of side effects. In another trial examining the adherence in longer term, it was shown that 17% of participants discontinued the treatment within 4 years (533). The evidence from trials is nevertheless scarce and in real settings, drug uptake and adherence can be lower, particularly in those without a pre-existing condition (401,409).

One of the most crucial concerns on the use of the Polypill strategy is over its cost-effectiveness. The cost of the Polypill must be low, in order for the strategy to be cost-effective (534). The economic analysis of a multidrug regimen, including statins, ACE inhibitor, a blood pressure lowering agent (e.g. a calcium channel blocker or a β-blocker) and aspirin, initially suggested that this regimen is cost-effective both in high-risk based primary prevention and secondary prevention, conforming to WHO recommendations (535). Cost of
the Polypill may, however, be lower than this multidrug and the strategy using the Polypill may be more cost-effective. However, the cost of the Polypill depends on the cost of a number of processes, for example, formulation, research on its adverse effects, marketing, distribution, as well as the cost of its pharmaceutical components (524). The work modelling the cost-effectiveness of different combinations of the Polypill suggested that the Polypill strategy can be more cost-effective than usual care and treatment with a drug targeting a single risk factor, if delivered using a high-risk approach. It was suggested that the most effective reduction in CVD events can be obtained if the Polypill including two doses of statins and no aspirin is provided to those at and greater than 7.5% CVD risk within next 10 years (536). Another recent study also proposed that a Polypill strategy including women at high-risk and all men aged 55 years and over can provide effective and cost-effective reduction in CVDs. This study in Latin America also suggests that even countries with minimal income can obtain cost-effective prevention of CVD using the Polypill strategy (537). Further evaluations are essential for assessing the cost-effectiveness of the Polypill strategy, particularly when delivered in fully population-based manner not employing risk stratification, compared with other primary prevention strategies.

Another concern regarding the population-wide use of the Polypill is that it can over-medicalize healthy populations and may cause populations to not adopt healthy lifestyles and even take risky behaviours, leaving responsibility of protection to the drugs (159,524). Medicalizing healthy populations may also not be acceptable to individuals and physicians, which can further reduce the uptake of the strategy and therefore its effectiveness and cost-effectiveness (538). Another significant concern is that the Polypill may lead physicians to not adequately address those at high-risk, by reducing the attention on these patients (539). When the Polypill strategy is delivered population-wide, it does not require resources for risk stratification, which is important for its cost-effectiveness. However, since the Polypill produces equal and small CVD risk reduction in all those at different risk levels (522), it may disregard high-risk populations, who require immediate management of risk. Physicians may prefer to choose the Polypill as a straightforward approach and this may therefore impair physicians’ role in preventive care of high-risk patients (539).

There are a number of concerns over the use of the Polypill as a population-based strategy, particularly surrounding its acceptance, uptake, adherence and cost-effectiveness in routine settings. Although the Polypill concept was first developed for potential use in the general
population, the existing evidence is mainly on its use in high-risk populations. There is, thus, no established evidence on its effectiveness and cost-effectiveness, if delivered as a population-based approach. There has also been no work comparing the Polypill to other population-based interventions described above, which have greater evidence of effectiveness. Further evaluations are, therefore, highly warranted to clarify a number of concerns regarding the population-wide use of the Polypill as a primary prevention strategy for CVD.

2.9 Comparative effectiveness of population and high-risk based prevention strategies

The choice of preventive strategies for CVD carries crucial importance in terms of both effectively and cost-effectively reducing the CVD burden. Modelling studies evaluating the effectiveness of population level and high-risk based strategies are important to comment on the relative effectiveness of these strategies. As well as hypothetical support for the effectiveness of high-risk based strategies, particularly after the advancements in the identification of high-risk patients (development of CVD risk scores) and therapeutic management of risk factors (Chapter 2.2.2.4), there is supportive evidence from modelling studies. Murray et al. (540), focusing on the reduction of cholesterol and blood pressure to manage associated CVD risk, suggested that high-risk strategies, particularly a combination of treatments for reducing multiple risk factors based on global CVD risk are more effective in reducing CVD risk than population based approaches, including legislations to reduce salt-intake at population level. They showed that high-risk based strategies could save 63 million more DALYs annually worldwide compared with population-level strategies, which were modelled as having potential to save more than 21 million DALYs annually worldwide. They, however, also suggested that the benefits of population-level interventions might be greater than those modelled. Despite greater effectiveness of high-risk based strategies, population level strategies were presented as more cost effective. They further admitted that population-based interventions are more effective, if limited resources are available (540).

Manuel et al. (149) more strongly supported the effectiveness of high-risk based strategies over population-level approaches. They suggested that high-risk based strategies, including screening for stratification of high-risk patients and risk management interventions, produce greater benefits than population-based strategies. Whilst high-risk based strategy using CVD risk scores was modelled as preventing 35 800 CHD deaths annually in Canada, population
level approaches prevent only 5160 deaths. This study was, however, criticised for underestimating the benefits of the population-level strategies (541). This was due to a number of limitations to methods used in the study. They assumed that compliance to risk management interventions (e.g. statins) in high-risk approach is complete, which is practically not possible (149). Accounting for poor adherence to risk management interventions is important when estimating the impact of high-risk based strategies. When comparing the effectiveness of high-risk based and population based strategies, they used an outcome of ‘number of deaths avoided’, which has important limitations. Presenting the reduction in risk would provide a more real time comparison between strategies (542). They included patients with already diagnosed CHD, which can substantially underestimate the impact of population-based strategies. In their analysis, they assumed that population-level approaches produce a modest reduction in risk, with only 2% reduction in lipid levels. As well as the effect size, they underestimated the scope of the population strategies; because these strategies can also have effect on risk factors other than cholesterol (541). The study, also, did not examine costs and cost-effectiveness of the population and high-risk based approaches (149).

In another modelling study by Zulman et al. (543), effectiveness of different CVD prevention strategies were assessed and compared. Two population based strategies, which differ by the intensity of interventions and resources used, and two types of targeted strategies, one of which targeted those with elevated single risk factor (LDL levels) and the other targeted those with high overall CVD risk (high-risk approach), were examined in the study. They suggested that more intense population level strategy provided greater benefits in terms of preventing CVD events than high-risk approach, which had greater benefits than less intense population strategy. However, considering gains in QALYs and numbers needed to treat to prevent an event, high-risk approach using advanced risk prediction tools was suggested to be more efficient than both population-based approaches, even compared to less intense strategy that has minimal adverse effects (543). This may, however, because they used greater estimates for adverse effects of population strategies. Capewell and Graham (407) criticised assumptions used in this study for overestimating the effectiveness of high-risk based strategies.

Although these outlined studies provided evidence more supportive of high-risk based strategies, they do not totally discount benefits of population level approaches. Murray et al.
(540) and Manuel et al. (149) suggested that combining population level approaches with high-risk based strategies may be the most effective and cost-effective approach in preventing CVDs (149,540). There is also strong evidence from modelling studies that population level strategies have greater potential of providing benefit compared with high-risk based strategies (544–546). For example, Cooney et al. (545) showed that 10% population-level reduction in risk factors, including blood cholesterol, blood pressure and smoking prevalence, could provide greater benefits, with 9125 lives saved per million over 10 years, compared with high-risk based approach, which could prevent 7452 CVD deaths per million if uptake of pharmaceutical intervention among high-risk patients is 80% and the compliance to the intervention is complete, which is realistically not achievable (545). Another modelling suggests that 5% population-level reduction in systolic blood pressure (7 mmHg reduction) and cholesterol levels (0.3 mmol/L reduction) could reduce the risk of first CVD within next 10 years by 26%. However using high-risk approach, similar risk reduction can be achieved by treating all patients at or greater than 20% 10-year risk of CHD with statins, aspirin and anti-hypertensive drugs. High-risk strategies need to be used widely to provide greater benefits in the population; managing risk in larger populations using pharmaceutical agents, however, requires greater resources (544). Population strategies to reduce risk factors are highly cost-effective (540,547) and they are important for producing considerable benefits population-wide (544).

The potential impacts of population level strategies in the UK have been modelled and the comparison of these with the NHS Health Check, a high-risk based universal CVD screening programme (Chapter 4) (195), are illustrated in Table 1. The NHS Health Check is projected to generate less benefit at population level compared with the population approaches.
Table 1: The projected impacts of the CVD prevention strategies; high-risk and population-based approaches, in the UK.

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Explanation</th>
<th>Impact (Annual reduction in CVD burden)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NHS Health Check</td>
<td>Universal programme using high-risk approach. Anticipated impact modelled with 75% uptake</td>
<td>1600 heart attack and stroke 650 CVD deaths (417)</td>
</tr>
<tr>
<td>Salt-intake reduction</td>
<td>3 g reduction in daily salt intake (to achieve 6 g daily salt intake target proposed by FSA)</td>
<td>14,000–20,000 CVD deaths (160)</td>
</tr>
<tr>
<td>Trans-fat ban</td>
<td>Reducing industrial trans-fat consumption by 1% of total energy intake</td>
<td>11,000 heart attacks 7000 deaths (86,518)</td>
</tr>
<tr>
<td>Smoke-free legislation</td>
<td>Smoking ban in all enclosed spaces to prevent second-hand smoke</td>
<td>10,000 CVD deaths (461)</td>
</tr>
</tbody>
</table>

The impact of population-level and high-risk strategies on health inequalities, as well as their overall effectiveness and cost-effectiveness, is important when selecting CVD prevention strategies to manage CVD burden in a population. There are inequalities in the accessibility and use of health care (Chapter 4), in addition to the inequalities in CVD burden and its risk factors (Chapter 1). There are arguments that high-risk based CVD prevention strategies can increase health inequalities (407). Julian Tudor-Hart (548) suggested that access to health care is inversely associated with the need of a population. This statement was called as "inverse care law". Acheson (549) subsequently proposed that this inverse association is particularly present in the access to preventive services, for example, cancer screening and immunisation programmes, and defined this as "inverse prevention law". Capewell and Graham (407) suggested that the effectiveness of high-risk prevention programmes can be poorer in populations in greater need, consequently, increasing health inequalities. The inequalities can appear at every stage within the prevention process, including attendance at screening, and uptake of and compliance to interventions (407). For example, attendance at screening can be lower in those with lower SES (550) and ethnic minority populations (551,552). The uptake and compliance to interventions for managing risk (e.g. statins) can also be poorer in disadvantaged populations, such as those living in socio-economically deprived areas (385,386).
The reason for these inequalities may be that high-risk prevention strategies are highly dependent on patient-level factors, since they aim to change patient behaviours when addressing CVD risk (407,553). Those in greatest need generally have poorer health behaviours (554,555), which, for example, can be predictors of low attendance at screening or compliance to interventions in these populations (556). This therefore reduces the potential of the strategies on producing benefits in those in greatest need and increase inequalities. Population strategies, however, are generally not dependent on health behaviours. They do not aim to modify patients’ behaviours directly, but change the whole environment, where poor behaviours occur. They target change in behaviours by modifying the underlying factors of poor behaviours (553). Population strategies can, therefore, reduce risk factor levels equally in the whole population, which can help reducing health inequalities. Because changes in mean levels of CVD risk factors in a population are directly associated with changes in CVD burden (557). Population-level interventions, therefore, have greater potential of targeting whole populations more equally and reducing health inequalities (160).

A modelling study compared the impacts of a population strategy and a high-risk approach on socio-economic health inequalities. The study delivered both approaches in a large cohort of men in the UK. For high-risk based prevention strategies, they assumed very good compliance to interventions and reduction in risk. Population based strategy was found more effective in reducing overall risk and socio-economic inequalities compared with high-risk based approach (558).

Frohlich and Potvin (478), however, criticized population strategies and suggested that these strategies, in opposition, have potential of increasing health inequalities. They argue that those in greatest need gain less from population interventions (inverse care law) (548), as it is in the access to healthcare and also in high-risk based prevention, increasing health inequalities. Their other concern was that in population based strategies suggested by Rose, interventions focus on only a single risk factor and do not address multiple risk factors. However, vulnerable populations are more likely to be exposed to more than one risk factor and Frohlich and Potvin (478) suggest that population interventions are ineffective in adequately addressing risk in these populations. They also argue that population approaches do not address “fundamental causes” of diseases. Their final argument was that although life-course exposure to risk factors is associated with CVD risk, population-level strategies can
only change distribution of risk factors at population level, however not change the life-course trajectories of exposure to risk factors (478).

Frochlich and Potvin (478) proposed a method of prevention called “vulnerable population approach” to be delivered combined with population approaches to effectively reduce health inequalities. Vulnerable population approach focuses on populations who are more likely to have high risk due to their social status (e.g. those living in a socially deprived area who have greater mean risk level than other populations), but not individuals at high risk. In this approach, interventions are applied in the vulnerable populations to reduce the “fundamental causes” of risk, e.g. CVD risk in CVD prevention, therefore, reducing exposure to high risk (478). This approach, however, received criticism (553), since it has a number of limitations. Although it uses a different approach in defining a target population, vulnerable population approach is not actually different from a high-risk approach and therefore most of the limitations to high-risk based strategies also apply to this approach (Chapter 2.2.2.1). For example, poorer uptake of interventions in disadvantaged populations can influence the success of the approach.

Mclaren et al. (553) argued that Frohlich and Potvin did not fully comprehend the principles of Rose’s population approach. They discussed that there are different types of population strategies and not all have potential of increasing health inequalities. They defined a continuum from structural to agentic, where structural population approaches aim to change the environment in which behaviour occurs and agentic approaches aim to change behaviours of individuals. The impact of a population strategy on health inequalities depends on where it is in this continuum. Poor health behaviours can influence the inequalities in care, given that a strategy is provisioned equally. If a population strategy is more structural, the intervention is therefore less likely to increase health inequalities; however, if a strategy is more agentic, the intervention has more potential of increasing health inequalities (553). Rose defined his population approach as radical (135), which is parallel to structural approach described by McLaren et al. (553) and therefore is likely to reduce health inequalities. Although Frohlich and Potvin (478) suggested that not all population level interventions can reduce health inequalities, some population interventions have potential to address them.

Evidence, overall, suggests that high-risk and population based approaches are not mutually exclusive, but they are complementary (545). Most effective prevention of CVDs can be achieved if they are employed in combination (540,544,545). High-risk strategies are
important to reduce CVD risk in susceptible populations; however, to achieve sustainable and equitable reductions in CVD burden, population interventions are essential (135). It is, therefore, not appropriate to argue on which strategy is the most effective approach, but a good balance between high-risk and population approaches when employing them in a population is crucial (135).

2.10 Key points from Chapter 2

Primary prevention of CVD aims to prevent occurrence of diseases by managing CVD risk factors in those with no pre-existing conditions, where secondary prevention manages risk factors in those with an already existing CVD and aims to prevent reoccurrence of conditions. Primary prevention of CVDs, as well as secondary prevention, is important to effectively and cost-effectively manage the large burden of CVDs (Chapter 1). A primary prevention can use a high-risk or population approach. Strategies using a high-risk approach target populations at the greatest CVD risk, where those using population approach aim to reduce CVD risk factors in entire populations and shift the entire distribution of risk factors. There have been arguments over the relative effectiveness of high-risk and population approaches in primary prevention in order to determine the best prevention strategies to effectively and cost-effectively manage CVD burden in entire populations. There have been efforts to improve the effectiveness of primary prevention strategies. Development of CVD risk prediction tools to identify those at high risk is an important advancement for the high-risk based prevention of CVD. This advancement has influenced the arguments on the relative effectiveness of population and high-risk approaches in primary prevention of CVD and lead to suggestions conflicting with Rose, who suggested that population approaches have greater potential than high-risk approaches.

Although empirical evidence over the effectiveness of both high-risk and population strategies is scarce, evidence from modelling studies using realistic assumptions suggest that population strategies have greater potential in producing population-level benefit than high-risk strategies. More structural interventions, such as interventions to reduce salt intake, trans-fat and second hand smoke at population level, can effectively target health inequalities. However, more agentic interventions, those aiming to manage risk factors by modifying patient behaviours, can be less likely to reduce inequalities in risk factors. Evidence strongly supports the adoption of both high-risk and population strategies to effectively and cost-
effectively prevent CVD in the entire population (135,540,545), but caution should be taken to achieve a good balance between approaches (135).
Chapter 3: Policy for Prevention of Cardiovascular Disease

The high prevalence, death rates and enormous burden of CVD has led policy makers to position actions to address this growing burden. As well as countries taking individual actions, health organisations have also generated regulations for reducing the CVDs worldwide. Individualized country actions led by US, Australia and the UK, and strategic efforts of World Health Organization (WHO) include preventative measures for both improved treatment of already developed CVDs to reduce the risk of death (secondary prevention) and also for avoiding the establishment of diseases (primary prevention). In recent history, there has been greater emphasis on the primary prevention (559,560).

3.1 Global and international policy for cardiovascular disease prevention

3.1.1 Global policies on cardiovascular disease prevention

NCDs, including CVDs, are the most common diseases that lead to an enormous economic burden and health inequalities worldwide (Chapter 1.2). The WHO has sought to address the significance of preventing NCDs by approving a global strategy for the prevention and control of NCDs in 2000. The strategy clearly defined the roles of WHO, Member States and international partners in the fight against NCDs (561). This strategy proposed that policies and intervention programmes to prevent and improve the care of NCDs at national or other applicable levels need to be implemented. Following this strategy, in 2005, WHO recommended a national policy and planning framework to be followed by policy makers of nations to organize their resources efficiently for taking actions against NCDs (562).

The executive board of WHO requested the development of an action plan for preventing and controlling NCDs at global and national levels between 2008-2013 in 2007 (563). The action plan mainly focused on the prevention of four main NCDs; namely, CVDs, diabetes, cancer and chronic respiratory disease, and their shared risk factors of tobacco use, unhealthy diet, excess alcohol and physical inactivity. Since the majority of NCD deaths occur in low- and middle-income countries, this action plan had a particular focus on the prevention and control of NCDs in these settings. The plan set six objectives to be implemented, each explained in details for actions at all levels; domestic, national and international (564). The progress of this action plan has been evaluated (565) and the action plan for the period of 2013 – 2020
has being drafted; this action plan again focuses mainly on four NCDs and their shared risk factors outlined above (566).

As well as general prevention strategies, WHO have also adopted strategies for managing individual risk factors of NCDs. The World Health Report, 2002, highlighted the importance of controlling main risk factors of NCDs, mainly unhealthy diet, obesity, physical activity and tobacco use (567). In 2004, the WHO Global Strategy on Diet, Physical Activity and Health (DPAS) was endorsed. This is an important public health initiative focusing on the two important risk factors, namely diet and physical activity, for CVDs and other NCDs (568). DPAS informs and guides all related stakeholders, including WHO, Member States, non-governmental organizations, international partners and the private sector, about effective intervention strategies on promotion of healthy diet and physical activity, with an aim to reduce the risk of NCDs. Recommendations addressed to these bodies include actions to be taken for effective implementation of dietary and physical activity interventions; approaches to be taken for achieving the aims and objectives of the strategy; and the ways of monitoring and evaluation of intervention programmes.

As recommended in DPAS, WHO set up a framework in 2008 to monitor and evaluate the implementation of interventions on the promotion of healthy diet and physical activity. This framework provides guidance to Member states on monitoring and evaluation of policies and plans that are related to diet and physical activity and also help them determine indicators for assessing the implementation of these policies and plans (569).

Tobacco smoking is another crucial risk factor for chronic diseases and it is the top cause of preventable death. There is an epidemic of tobacco smoking worldwide. Although the disease burden associated with smoking is still higher in high-income countries, its prevalence is significantly increasing in developing nations (567). WHO developed a framework called “The WHO Framework Convention on Tobacco Control (WHO FCTC)” to take an action against the global tobacco epidemic. WHO FCTC is an evidence-based treaty aiming to protect the rights of people to have high standard of health. The treaty articles underlines the measures for controlling tobacco smoke; for example, Article 6 defines the price and tax measures to be taken for reducing the demand for tobacco and Article 8 outlines the measures to be taken for protecting people from exposure to tobacco smoke (e.g. smoke-free environment policy) (463). WHO have evaluated the progress of controlling Tobacco smoke after the WHO FCTC treaty. Although some Member States had approved WHO FCTC and
made progress in controlling for tobacco smoke, many member states had not still implemented national smoke-free environment policy. They emphasized the need for more efforts on controlling tobacco smoke worldwide (570).

WHO recommends implementation of high-risk strategies, as well as population based approaches for effective management of CVD burden. Guidelines underlying the methods of targeting high-risk populations were provided by WHO to guide nations in their actions of implementing high-risk strategies (186,571). Individuals at high-risk are recommended to be identified based on overall CVD risk, which is determined following a screening for cardiovascular risk factors. WHO also provided guidance on the use of the risk prediction tool called World Health Organization/International Society of Hypertension (WHO/ISH) risk prediction chart, which can be preferably used for determining high-risk individuals. The WHO guidelines provided details on the management of risk factors in individuals at different risk levels, for example to provide lifestyle advice on managing risk factors, such as physical activity, to all screened individuals and to offer statins to those aged 40 years and over with high lipid levels or with a CVD risk of 30% and over regardless their lipid levels (186).

The United Nations (UN) General Assembly held the High-level Meeting on the prevention and control of NCDs in September 2011. The assembly emphasized the importance of taking actions to control NCDs, which threaten many states in terms of development and economy, especially the developing nations. The assembly acknowledged the considerable burden of NCDs and the actions to be taken by all Member State and related stakeholders to prevent NCDs (572). The meeting outcomes outlined the actions to control risk factors for NCDs, for example through policies to develop environments to promote healthy lifestyles. Another important issues highlighted in the meeting was improving the national health systems, and promote and support policies for effective prevention and control of NCDs; for instance, including NCD prevention and control activities within programmes such as on sexual and reproductive health, particularly in primary care services. The actions to be taken for effectively researching on NCDs and evaluating the progress of prevention programmes were also highlighted (573).
3.1.2 National risk assessment and management programmes elsewhere

Global strategies for the effective reduction of CVD burden are outlined earlier in Chapter 3.1.1. I shall now focus on the initiatives by individual states targeting the prevention of specifically CVDs and associated diseases.

In US, “Healthy People 2020” initiative launched in 2010 set new national targets to promote better health for the nation. One of the targets of the initiative is to reduce chronic disease, including CVDs and diabetes, whose risk factors are largely preventable (574). National Quality Strategy and National Prevention Strategy emphasized the importance of implementing effective prevention and treatment interventions for common causes of deaths. Both strategies prioritized actions for preventing CVDs, the leading cause of mortality in US (575,576). The Department of Health and Human Services launched an initiative called “Million Hearts” in September 2011, as an action to meet the aims of the above strategies and also further formalise CVD prevention in US (559).

Million Hearts aims to prevent CVD across US with the collective efforts of federal and local organisations, private-sector providers and other non-profit organisations. The initiative has set a real target of preventing one million CVD events within 5 years (559). This target is to be achieved by implementation of proven, effective and cost-effective interventions to improve clinical management of high-risk patients and manage CVD risk factors at population level. The clinical component of the prevention strategy involves management of risk factors by promoting “ABCS”: aspirin prescription, blood pressure and cholesterol control, and smoking cessation for reducing risk of developing CVDs and mortality in high-risk patients. The initiative aims to standardise CVD prevention practice; incorporate CVD prevention by ABCS into physician performance metrics; mandate preventative checks in Medicare; and promote preventative health checks in all private insurers. Regarding the community based local and national prevention strategies, the initiative aims to promote policy and programmes for reducing smoking, and policies for controlling salt and trans-fat intake (e.g. menu labelling policy).

Million Hearts is a significant act in US, aiming to achieve a common target of preventing CVDs by gathering all health service organizations together (577). The initiative does not offer a systematic population level screening as the NHS Health Check in the UK and is less
bold. However, it fits well into the current health system in US and has different strengths: it may, therefore, be effective in organizing activities to promote CVD prevention.

In Canada, the health system offers its population universal access to mainly publicly funded health care. In 2006, following the federal elections in Canada, the provision of “the Canadian Heart Health Strategy and Action Plan (CHHS-AP)” was initiated with the declaration from Ministry of Health, with an aim to control the large burden of CVDs in Canada (560). The strategy committee launched the final strategy document, called “Building a Heart Health Canada” in 2009. CHHS-AP set a number of targets to be met by 2020 around CVD care and prevention.

The strategy emphasized the importance for population level strategies, as well as clinical management of risk factors, to establish heart healthy environments using approaches including policies, legislation, regulations and education for enhancing physical activity, health diet, reducing smoking and eliminating other social disparities. The strategy provided recommendations on both CVD care and prevention. These recommendations included reforming the health service to allow integrated CVD care and prevention, building heart healthy environment, and establishing health services competent to deliver effective preventative care.

CHHS-AP proposed the development of a systematic and universal screening programme covering the population aged 45 years and over, and set a target of achieving 90% programme coverage by 2020. The Canadian health system does not have an established information system for chronic disease prevention and management; there is a lack of an information system essential for carrying out global screening for CVDs. The primary approach in establishing a prevention strategy will therefore be developing a national CVD information system (578).

The Australian government developed a National Chronic Disease Strategy to promote prevention of chronic diseases in 2006 (579). CVD was one of the disease areas that the strategy prioritised and “the National Service Improvement Framework for Heart, Stroke and Vascular Disease” was developed. The Framework set a number of intervention models for reducing risk of developing CVDs, early diagnosis, care and management of CVD patients; the framework also emphasized the actions to be prioritised for prevention and management of CVDs (580). The Council of Australian Governments introduced “the Australian Better
Health Initiative” in 2006 to support actions to improve health of the population and reduce the chronic disease burden (581). The Australian government, to meet the aims of this initiative, has consequently implemented a number of Medicare funded schemes, similar to the NHS Health Check, which are collectively called “the Medicare Benefits Schedule Health Assessments”(582).

The first considerable Medicare health assessment programme that involves CVD prevention activities is the “the Medicare 45 Year Old Health Check” programme (583). This targets 45 to 49 (inclusive) years old population with high chronic disease risk identified based on clinical judgement. These identified patients must have at least one risk factor of chronic disease, i.e. lifestyle risk factor (e.g. smoking), clinical factors (e.g. high cholesterol) and family history of chronic diseases. The health check includes risk assessment for CVD, as well as other chronic conditions. In addition to assessments, the programme includes lifestyle advice on healthy behaviour change, clinical interventions for managing risk factors and referrals to other services for risk management. The government have provided guidance to support GPs in primary prevention of diseases (584).

The Australian health check programmes, described above, do not have a universal coverage. However, Australia has on-going initiatives for managing risk factors at population level; for example regulations on food labelling, exemption of fresh food from good and service taxes, smoking cessation policies and public awareness campaigns surrounding the risk factors of CVD (585).

New Zealand has shown substantial improvement in the primary prevention of CVDs. Enhancing the proportion of population having complete CVD risk assessment is one of the targets set by New Zealand Ministry of Health to improve the performance of CVD and diabetes services in the nation (586): the target is to have 90% of the eligible population assessed for CVD risk within five years (July 2014) and to achieve coverage of 75% by 2013 (587). The Ministry of Health supported primary care organisation in their CVD prevention and diabetes screening activities with detailed evidence based guidance (588).

The Primary Health Organisation Performance Management Programme, a pay-for-performance programme was launched in 2006 to improve population health and address health inequalities. The programme provides financial incentives to primary care organisation for their performance in a range of activities, including breast cancer and cervical cancer
screening coverage. CVD risk assessment has recently been embedded as a performance indicator in the programme (589). Despite having an aim to reduce health inequalities, the programme is voluntary for primary health organisations. This therefore impedes the universal coverage of the services, including CVD risk assessment and diabetes screening.

3.2 Policy for cardiovascular disease prevention in the United Kingdom

The UK governments have not given priority to the structured CVD prevention in the early history of the NHS, but have begun to accept its importance over the last two decades. ‘The Health of a Nation” white paper, which was launched by the Department of Health in 1992, set targets to improve the health of the nation. These targets focused on five key disease-areas; CHD and stroke, the main types of CVD, were one of these prioritized areas (590). The guidance of the white paper specifically on CHD and stoke emphasized the significance of health promotion in improving CVD outcomes (591).

Although CVD prevention was first emphasized in the 1992 white paper, it was not followed by a national prevention strategy. This was because, there was no obligation for health care professionals to act upon the guidance, but the government directed professionals to develop local CVD prevention services. In 1999, the next white paper “Saving Lives: Our Healthier Nation” was published (592). This paper introduced the first comprehensive plan of the government that focused on CHD and stroke, as one of the four common killers, and set a target of reducing 40% of CVD mortality rate in those aged less than 75 years by 2010. Population-wide management of risk factors, such as smoking, unhealthy diet and physical inactivity, rather than treatment of established diseases, was highlighted as the key strategy for attaining this goal (593).

The initiative called “New NHS” was introduced in 1998 to improve the health care provided by NHS. This was aimed to be achieved by modernizing care and treatment through a ten-year period (594). Guidance was provided by the Department of Health for health service providers and commissioners to describe priorities and actions to be taken to accomplish the targets of modernizing health care through a ten-year programme of transforming NHS. This guidance provided details for enhancing the speed of services, increasing preventive services and improving primary, community and acute services (595).

The report by the Acheson group (1998) (549), as “the Black Report” (596), supported that inequalities in health are due to social inequalities, not because of inequalities in access to
health care (597). The Acheson report suggested that there is an inverse relationship between social inequalities and access to preventive services. Populations at the greatest risk of diseases, thus those at the greatest need, are less likely to access to preventive services (inverse prevention law). The Acheson group provided policy recommendations with an aim to address health inequalities by reducing social inequalities and in turn access to health care and preventive health services. The majority of the recommendations (36 out of 39) were targeting social inequalities; only three policy recommendations were regarding improving health care (549, 597). A strategy, introduced in correspondence to the Acheson report, aimed to reduce inequalities in infant mortality and life expectancy at birth by 2010 and to achieve sustainable reduction in health inequalities (598). The Marmot review (599), published in 2010, reported the social determinants of health and provided implications for policy actions to reduce social inequalities. As the Acheson report, one of the key suggestions of the Marmot review was that access to preventive services is inversely related with need and effective strategies should be employed to address social inequalities in order to reduce inequalities in access to preventive health services and in turn, inequalities in health outcomes (599).

The National Service Framework – CHD (NSF-CHD) (600) was launched in 2000 with an aim to improve the quality and equity of health care provided by NHS. This documentation defined health service models and set 12 national standards for prevention, diagnosis and treatment of CHDs. One of these standards emphasized the prevention of CHDs in individuals without pre-existing condition. This standard was specified as: ‘General practitioners and primary health care teams should identify all people at significant risk of cardiovascular disease but who have not developed symptoms and offer them appropriate advice and treatment to reduce their risks’ (p.4) (600). This framework was, however, criticized for not placing enough emphasis on prevention.

Another white paper called “Choosing Health” was introduced in 2004 defining a number of public health goals. Many of these targets had implications for CVD prevention. These targets strongly focused on primary prevention of CVD, for example, through improving smoking cessation services and managing obesity by, for example, enhancing exercise opportunities and reducing salt, sugar and fat intake in cooperation with food industry. The significance of this paper is that it emphasized the Department of Health’s goal of smoke-free environments. The documentation outlined the aim for making all government departments
and NHS smoke-free by 2006, and also for introducing the legislation for smoke-free enclosed public places and workplaces by late 2008 (601).

The importance of CVD primary prevention was highlighted in Public Service Agreement (PSA) in 2007. This also included an explicit target to reduce CVD inequalities (602). With the inclusion of primary prevention of CVDs in the Public Service Agreement 18, it became strongly entrenched within the framework of the NHS. This was followed by a momentous attempt of Department of Health to enhance NHS’s focus on primary prevention of CVDs and other vascular disease, namely hypertension, diabetes and CKD. NHS Health Check was first introduced in England in 2008 as a nationwide systematic CVD risk assessment and management programme. It is first of its kind implemented on such a large scale in the world (195). As mentioned earlier, this thesis focuses on the evaluation of the Health Check and the details of this programme will be outlined further in Chapter 3.4.

### 3.3 Financial incentives for cardiovascular disease prevention in the UK

Provision of a high quality primary care is crucial in establishing an effective and equitable health system that consequently would improve the health of the entire population (603). According to this, many countries have initiated strategies to improve quality of primary care. These initiatives include financial incentives to deliver effective health services, therefore, to improve performance (pay for performance schemes), as well as enhancing use of electronic medical records, clinical audits and performance monitoring (604–606).

Financial incentives have been embedded in the UK health system to improve the performance of primary care providers since 1990s (607). In 2004, the general practice contracts and payment structure within the NHS was changed with the introduction of the New General Medical Services (nGMS) Contract (608). The nGMS contract maintained a total payment called “Global Sum” to each general practice based on list size, as well as practice weighting for need. This payment is to manage a general practice and to provide fundamental services, such as costs of staff and others. In the case of a change in additional services provided by practices, this is reflected in the global sum (608).

#### 3.3.1 Pay-for-performance schemes – Quality Outcomes Framework

In 2004, QOF (609), the largest pay-for-performance scheme in the world, was introduced as part of the nGMS contract. QOF provides payment to practices in addition to the global sum
and consists of indicators to improve the care provided by practices. The achievement of the QOF indicators are translated into number of points based on the degree of the achievement and these points are annually translated into payments for each practice (610).

The QOF set a number of quality standards for reducing risk in patients with already established diseases; therefore, it mainly focuses on the secondary prevention of diseases. CHD and stroke/TIA are two major CVD groups targeted within the clinical domain of the scheme. Indicators set for these disease groups provide financial incentives to general practices for the activities to improve and standardize the care of patients already diagnosed with these CVDs and registered to appropriate disease registers. QOF largely aims to promote good clinical practice by controlling risk factor levels in patients with known conditions; for example through regular measurement of blood lipid levels and blood pressure (609).

Although QOF, initially, mainly focused on the investment of secondary prevention of diseases, there was a little attempt to reach the target of NHS-CHD, which was to identify high-risk individuals without pre-existing clinical diseases. There are four QOF indicators referring to the patients without existing diseases. Three of these indicators are in the organizational domain: One is to promote the smoking status recording in the population aged 16 years and over (Record 22) and rest are to promote the recording of blood pressure in population aged 45 years and over (Record 11 and 17). Another indicator targeting individuals without existing diseases is in the clinical domain and it is to promote recording of population aged 16 and over with a BMI of 30 or greater (Record OB1) (611). All these four indicators are components of primary prevention, but they do not represent a comprehensive cardiovascular risk assessment. The number of points awarded for these indicators are small, thus the payment allocated for investment of these primary prevention activities is lower compared with the secondary prevention.

In the financial year of 2009/10, the revision of the QOF added two indicators for primary prevention of CVDs (612). These indicators require face-to-face assessment of CVD risk using an assessment tool in newly diagnosed hypertensive patients and management of risk factors by giving lifestyle advice on, for example, diet and physical activity. It is however arguable if these indicators address primary prevention, since they involve patients with already diagnosed hypertension.
3.3.1.1 Local Quality Outcomes Frameworks

The NHS review “High Quality Care For All”, introduced in 2008, emphasized the importance of prevention of disease, as well as the need for resources of PCTs to deliver locally tailored services based on needs of populations (604). In 2009, the consultation on developing the QOF introduced the proposal for implementing local QOFs that would meet the needs of the local populations of PCTs (613). There were inconsistencies in the responses of different groups regarding this proposal. Whilst NHS organizations responsible from management supported the introduction of local QOFs, GPs and patient organizations were opposed to this suggestion. Organizations supporting the local QOF proposed that in the first instance, no more than 5% of the annual budget of QOF would be allocated to local QOF indicators (614).

Although there have been a few attempts to establish local QOF schemes (615), these schemes have considerable potential to meet the health needs of local populations. QOF Plus (QOF+) has been the largest local QOF programme that was established. In September 2008, the QOF+ was launched in NHS Hammersmith and Fulham, PCT of a west London borough; this scheme will be thoroughly defined in Chapter 6. About £2.2 million was allocated to this scheme by the PCT. This was in addition to the £4.4 million available to local GPs through the national QOF programme. Hence, the programme was a significant boost to the funds available nationally for meeting quality targets (615). CVD primary prevention programme, locally tailored NHS Health Check outlined below, was embedded in the QOF+ to enhance the coverage of the programme and effectively manage CVD risk in the local population (616).

3.3.2 Enhanced Services

Other components of the nGMS contract are enhanced services; these are to provide additional services beside the routine services in practices, specialist skills may be required to provide these services. There are three types of enhanced services, namely Directed Enhanced Services (DES), National Enhanced Services (NES) and Local Enhanced Services (LES) (617). DES is the financial incentive scheme that is used to enhance the access of patients to additional, but universally essential services, such as child immunisations and influenza immunisations. Although it is mandatory for PCTs to provide these services to their populations, individual practices have the right to not deliver these services (618). NES are
optional to be implemented by PCTs. PCTs can choose to provide these services based on the needs of their local population, but also based on the national standards and prices. These services include minor injury treatment services. LES are again services incentivized to provide services based on the local needs, but the difference of LES from NES is that PCTs are allowed to set up and commission these services. Services to provide care to people with learning difficulties or asylum seekers are examples of LES (617). These enhanced services are mostly paid on fee-for-service basis.

The majority of local CVD primary prevention programmes are incentivized through LES, aiming to enhance the coverage of the programme (619,620). PCTs have set criteria for the completion of the Health Check, as discussed in Chapter 3.4. Although the minimum standards are same, some components differ according to the local needs. Practices need to follow the rules of their PCTs when screening their patients and they only receive payment based on the number of patients who have had complete screening (those having all the Health Check components completed).

### 3.4 The NHS Health Check programme

The idea of delivering a systematic vascular risk assessment and management programme was primarily put forward by Sir Muir Gray in the NSC in 2006 (621). Two years following (early 2008), the UK Prime Minister, Gordon Brown announced the plans of establishing a national programme to control vascular diseases in England (622). Although NSC has not approved this national screening programme for vascular diseases; they support a systematic approach for identifying individuals with high vascular diseases risk and evidence-based management of their risk. NSC introduced a handbook in March 2008 for supporting the structured activities of assessing and managing vascular disease risk (194), which was updated in 2012 (196). The Department of Health introduced the proposals of the programme with the publication called “Putting prevention first. Vascular Checks: risk assessment and management” (195).

The programme was primarily titled as “Vascular Checks”, which was then changed to “NHS Health Check”. The implementation of the programme has been supported with further guidelines, which defined the scope of the programme, best practice and programme commissioning (348,417,623,624). The programme aims to offer a vascular risk assessment to English population aged 40 to 74 years, who do not have a pre-existing vascular disease.
Patients with a diagnosis of CVD (including CHD, stroke or TIA), peripheral vascular disease, heart failure, diabetes, hypertension, and hypercholesterolemia were excluded from having the assessment (625). The programme assumes that the vascular risk of these excluded patients, most of who are registered on QOF disease registers, are already managed by appropriate interventions.

The NHS Health Check national rollout was initiated in April 2009, with an expectation to reach complete rollout by 2012/2013 financial year. The programme is a five-year rolling programme; patients once screened need to be invited for the next Health Check after five years, if they have not been diagnosed with a vascular disease in the meantime. Since the programme is a five-year rolling programme, 20% of all eligible population must be invited for having a Health Check to meet the aim of reaching a full complete rollout by 2012/2013. The Department of Health proposed an uptake of 75%, meaning that 75% of those offered will attend to have a health check (417). The NHS Health Check programme consists of two main processes of assessment of vascular risk and management of risk factors using appropriate interventions. The programme was estimated to generate an annual cost of between £180 and £243 million based on costs in 2008. The economic modelling of the programme suggests that the programme will be highly effective and also cost-effective, with an estimated cost of less than £3,000 per QALY gained, in reducing CVD burden (624).

Primary care trusts (PCTs) were initially responsible from commissioning the NHS Health Check delivered by primary care providers (623). PCTs were NHS organizations that were responsible for commissioning and delivering primary care and community health services, and commissioning secondary care. Planning, funding and coordinating health services at local level were the main responsibilities of these NHS organizations (626). From April 2013, the commissioning system of the NHS health services changed. A single organization called the NHS Commissioning Board is responsible for commissioning health services provided under the GP contract. The development of health of local communities, including health promotion and public health services, is under the responsibility of local authorities (627). From then, commissioning of the NHS Health Check, CVD risk assessment and lifestyle interventions, has therefore been by local authorities. Treatment provided by NHS after the Health Check assessment and risk management has been transferred to related clinical commissioning groups. Care of patients diagnosed with a chronic condition in the Health Check has been commissioned by related NHS Commissioning Board (628).
The Department of Health provided substantial autonomy to commissioning bodies (PCTs at the time of the first implementation) when delivering the Health Check based on the needs of their local population (417); setting of screening, screening approach, risk assessment tools and payment rates paid to providers for delivering the programme can vary between areas (629). This is, however, valid as long as commissioners meet minimum standards of the programme (417).

The setting of the risk assessment is one of the key areas that the Health Check guidance provides flexibility to commissioners (623). The programme aims to assess all eligible population and reduce health inequalities; the programme is designed as appropriate for implementation in various venues to reach to a larger target population. Although the majority of the Health Check workload has been in general practices, pharmacies (630) and community setting (e.g. mosques, community centres) support the activity to enable hard-to-reach groups, those with less access to general practices, to benefit from the programme (417,623). Although the programme implementation model is similar in most areas, mainly health care assistants and nurses are employed to carry out risk assessment in general practices (631), some commissioners offer the Health Checks opportunistically in pharmacies and community places, such as faith centres, workplaces and shopping centres (629).

The Department of Health minimum data requirements for collecting core components of the Health Check are outlined in Figure 6. From April 2013, when commissioning of the programme was transferred to local authorities, two new elements were included in the programme. All participants must now be assessed for alcohol consumption and those aged 65 to 74 must be provided with information on signs and symptoms of dementia to increase their awareness of dementia (632,633). The components of the Health Check are also subject to vary between areas based on the local population needs, as long as the minimum requirements (Figure 6) are met. Local providers can incorporate additional tests and clinical measurements where appropriate. For example, there are real examples for commissioners, which have involved alcohol-screening test into the Health Check process and pulse check to screen attendants for atrial fibrillation (629).

Before the proposed initial rollout, commissioners were provided with guidance that defined the components of the programme. However, the dataset defining the minimum standards was published late, more than two years after the initial rollout (634). This caused considerable difficulties for local commissioners (PCTs) and service providers; many PCTs
designed a local Health Check programme and have done modifications over the years to meet the minimum standards set by the Department of Health.

<table>
<thead>
<tr>
<th>NHS Health Check Information</th>
<th>Demographics</th>
<th>Observation for Risk Assessment</th>
<th>Information and Advice Provided</th>
<th>Referral to Risk Factor Management Services</th>
<th>Further Assessment</th>
<th>Prescriptions</th>
<th>Disease Diagnosis</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Commissioner organization</td>
<td>• Lower Layer Super Output Area</td>
<td>• NHS Health Check location</td>
<td>• General lifestyle advice</td>
<td>• Referral acceptance to Stop Smoking Service</td>
<td>• Assessment for diabetes</td>
<td>• Statins prescribed</td>
<td>• Diagnosis of chronic kidney disease (Stage 3-5)</td>
</tr>
<tr>
<td>• NHS Health Check provider</td>
<td>• Age at assessment</td>
<td>• Body mass index</td>
<td>• Stop smoking advice for smokers</td>
<td>• Referral acceptance to Physical Activity Service</td>
<td>• Assessment for impaired fasting glycaemia/impaired glucose tolerance/lifestyle management</td>
<td>• Anti-hypertensive medication prescribed</td>
<td>• Diagnosis of type 2 diabetes</td>
</tr>
<tr>
<td>• Health Check eligible population</td>
<td>• Gender</td>
<td>• Blood pressure while sitting</td>
<td>• Weight management advice</td>
<td>• Referral acceptance to Weight Management Service</td>
<td>• Assessment for serum creatinine</td>
<td></td>
<td>• Diagnosis of hypertension</td>
</tr>
<tr>
<td>• Invitation offer sent</td>
<td>• Ethnic category</td>
<td>• Total cholesterol</td>
<td>• Brief intervention on physical activity</td>
<td></td>
<td>• Assessment for fasting cholesterol</td>
<td></td>
<td>• Diagnosis of non-diabetic hyperglycaemia</td>
</tr>
</tbody>
</table>

* Elements included in the NHS Health Check from April 2013, when Local Authorities took over the commissioning of the programme.

Figure 6: Minimum dataset with core components of the NHS Health Check (Adapted from: The NHS Information Centre for Health and Social Care, 2011) (634)

There is a strong political support of the NHS Health Check programme. The NHS Operating Framework for England 2012/2013 targeted the programme as a national performance measure (635). The Department of Health asked PCTs to report the measures, including the number of Health Check eligible individuals who were offered a Health Check and the number of those who have received a Health Check, to monitor the performance of commissioners in promoting the programme (636,637). The Health Check was also included as an indicator for health improvement outcome in “Public health outcomes framework for England 2013-2016” (638). This indicator is to be used to evaluate the performance of the Health Check commissioning bodies in improving public health. The Health Check was also
included as a priority for preventing deaths in the Public Health England priorities for 2013/2014 (639).

3.4.1 The NHS Health Check process

The NHS Health Check programme consists two main components of vascular risk assessment and management of risk factors (195). The process undertaken in each Health Check is illustrated in Figure 7. Recording and measurement of risk factors is the primary process during the Health Check. All the minimum data required for risk assessment outlined in the Figure 6 must be recorded. Health Check providers are expected to record all risk factor data at one clinical encounter. Further testing in addition to minimum dataset must be carried out for patients with increased risk of diabetes, hypertension and CKD (348).

Patients at risk of diabetes to be referred to further assessment with blood glucose testing are determined using a diabetes filter. This sets a criterion of having blood pressure of 140/90 mmHg or over, or BMI of 30 or greater in all ethnic groups, except those from any Asian ethnic group, who are considered as at risk with a BMI of 27.5 or over. Having blood pressure at or over 140/90 mmHg is the only indicator for patients at risk of CKD and they must be further assessed with serum creatinine test. Patients with a blood pressure of 140/90 mmHg or over must be considered as at risk of hypertension and further assessed by GPs (348).
Figure 7: A diagrammatic presentation of the NHS Health Check programme, a vascular risk assessment and management programme (348)

“This image has been reproduced with the permission of the rights holder, Department of Health.”

Recorded risk factor data are used to predict global CVD risk using risk prediction tools outlined in Chapter 2.4. The type of risk prediction tool to be used depends on the decision of PCTs; the Department of Health provided guidance on collecting data for and predicting risk using Framingham or QRISK2 (348).

Patients having a health check go through three possible routes. (Figure 7) The first possibility is that patients are diagnosed with a vascular condition, e.g. hypertension, diabetes or CKD, as a result of tests done in a Health Check. If patients are observed as having signs of a disease during a Health Check in a setting outside the general practice, they are referred to general practice to see a GP to receive formal diagnosis procedure. Once patients are diagnosed with a vascular disease, they become ineligible for having a Health Check and leave the programme. These patients are placed on the appropriate disease register and their
conditions are managed with appropriate interventions, e.g. anti-hypertensive agent prescription to those diagnosed with hypertension (348).

The second possible outcome of the Health Check procedure is to be determined as having a high risk of CVD. Patients with 20% or over risk of developing CVD within next 10 years determined by either JBS2 or QRISK2 (Chapter 2.4) are considered as having high CVD risk. These patients are also referred to general practices to join practices’ high-risk registers and they become eligible for having annual follow-up to control their risk. These patients on the high-risk registers are also not eligible for having a Health Check anymore and leave the programme pathway (348). This high-risk population becomes eligible for having a statin prescribed by their GP based on the clinical guidance (190). These high-risk patients are also offered appropriate interventions for managing their risk factors (e.g. smoking cessation service) (348).

The final possible result of the Health Check is remaining in the programme pathway and having their risk managed directly within the programme. This group consists those with a designated low to moderate CVD risk (<20%). The primary step after the risk assessment is communicating level of risk, together with a brief lifestyle intervention on risk factors that is tailored based on the level of risk. It worth noting that this is a routine procedure provided at the time of the Health Check to all participants regardless the risk level. Appropriate training must be provided to Health Check providers on the communication of results, level of risk and risk management, to providers based on the clinical guidance (640). Population with single risk factors higher than normal in the low to moderate risk groups are signposted and referred to more intensive risk factor management intervention (Figures 6 and 7). These interventions include smoking cessation service, weight management and physical activity programmes and impaired glucose tolerance (IGT) lifestyle interventions; interventions, except smoking cessation services are often underdeveloped in local areas. This cohort of low to moderate risk population, still eligible for the Health Check, enter the five-year rolling recall (348).

### 3.4.2 Summary of possible impacts of the NHS Health Check

Two main goals set by the Department of Health with the implementation of the NHS Health Check are to reduce overall CVD burden and narrow health inequalities in England. Reduction in CVD burden is aimed to be achieved through both prevention of development
of future CVDs by reducing their risk and early detection of vascular diseases, including hypertension, CKD, diabetes and CVDs among those who are not currently diagnosed with a vascular disease. The Department of Health anticipated that the five-year rolling programme targeting 40 to 74 year old population will prevent development of approximately 1,600 heart attacks and stroke, and more than 4000 diabetes; reduce CVD deaths by 650 every year; and identify over 20,000 undiagnosed diabetes and CKD cases annually (417). These will not only improve the health of the nation, but will also have economic benefits, reducing the economic burden of vascular diseases on the health system (417,451,624).

The first contested issue about the effectiveness of the NHS Health Check is the fact that it focuses on global CVD risk rather than raised individual risk factors, following the recent trend in basing CVD prevention programmes on global risk. Patients having a Health Check are provided with brief lifestyle interventions, risk management interventions, and statin prescriptions, tailored according to their predicted global risk. The first concern is that there are still questions on which tool to use. Primary trusts have been given autonomy to decide which tool to use, either QRISK2 or JBS2, leading to variation in detection of real high-risk patients (629,631), therefore, inequalities in access to risk factor management interventions across the nation. The other concern related to global risk scores is that only specific risk factors are managed based on the global risk; provision of only brief lifestyle intervention for diet or physical activity management and statin prescription are defined by level of global risk. Other CVD risk factors are treated based on the level of single risk factor. For example, only those diagnosed with hypertension are provided with interventions for blood pressure management. Evidence, however, suggests that all risk factors, including blood pressure, need to be managed in high-risk populations based on the global risk, regardless the level of individual risk factors (175).

The NHS Health Check is obviously a primary prevention programme; however, it is arguable if it uses a population or high-risk approach. This argument is important in terms of exploring its potential to produce health benefit and its impact on health inequalities. The Health Check is a universal programme and whole population meeting the programme criteria is eligible, but in practice the focus is on high-risk individuals. It is also regarded as a “screening and treatment” initiative (641), providing support for the programme being a high-risk strategy. In contrast, there are opposite thoughts suggesting that the programme is a population strategy, since individuals with low CVD risk may also receive lifestyle advice
around, for example, diet, physical activity and smoking. It is also asserted that by providing extra management to those with high risk, the programme involves targeted approach, as well as whole population approach. It is, therefore, suggested that the programme has potential to change risk universally (642).

Although the programme involves interventions to all attendees, most of the intense interventions are targeted to high-risk populations. The interventions available to entire population are limited in scope. Brief lifestyle interventions are suggested as effective in modifying risk factors (328,643); however, their effectiveness is questionable if delivered by non-clinical staff (644). Evidence suggests that practitioners with less experience in giving lifestyle interventions are less motivated, which can limit the effectiveness of the interventions, e.g. brief interventions for smoking cessation (328,448). There is need for further research to assess the universal effectiveness of all brief interventions provided under the Health Check.

Risk communication is another concern that would limit the potential success of the Health Check (Chapter 4.4.2). The effectiveness of risk communication in modifying risk reduction behaviours, beliefs and knowledge about diseases may have been restricted; this could reduce the scope of the programme as a population-wide intervention (645). Limited effectiveness of risk communication would therefore reduce attendance and adherence to interventions. Consequently, the Health Check can be accepted as an expanded version of high-risk prevention approach that reaches to entire population, in contrast to customary high-risk strategies.

As well as reducing the future risk of developing a vascular disease, another important aim of the NHS Health Check is to promote early detection of vascular diseases, including, hypertension, CKD, diabetes and CVDs, in those who have not already been diagnosed with a vascular disease. The programme is expected to facilitate early detection of especially type 2 diabetes and CKD cases. Early detection of these cases will allow the initiation of the management of these diseases earlier, which can in turn minimize morbidity and also mortality (195). The Department of Health projected that the programme could enable the early identification of at least an estimated 20,000 persons with diabetes or CKD annually (417). However, a recent study by Khunti et al. (638) showed that this number is likely to be much greater, with for example at least 84,038 persons with diabetes and 181,320 persons with CKD newly detected, if an uptake of about 75%, as projected by the Department of
Health, is achieved. They also suggested that these new diagnosis rates would still be higher, even if the uptake achievement is very low, with, for example, 20% annual uptake (638). The Department of Health and NSC have provided guidance to Health Check providers on the detection of vascular diseases, which have not been identified to date, in Health Check eligible population (Chapter 3.4.1). Filters with specified thresholds for risk factors were recommended for use to identify those with high risk of having an undiagnosed vascular disease, who need to be referred to further assessment for diagnosis (196,348). The effectiveness of recommended tools to filter those at risk of having a vascular disease in all population groups is, however, arguable (646). Further research is therefore necessary to determine effective and cost effective measures for identification of undiagnosed vascular diseases. The Health Check may have potential to enhance the identification of undiagnosed vascular diseases, if effective measures are used to detect those at increased risk of undiagnosed vascular diseases.

It is proposed that the Health Check has potential to reduce CVD inequalities. The programme is designed in the way that is accessible for all societal groups; therefore, aims to achieve a universal risk reduction across all societal groups. If this could be achieved, since CVD burden is greater in disadvantaged groups, they will benefit from the greatest global risk reduction (56). The potential impact of the Health Check on lessening health inequalities is, however, debatable (159,647). The “inverse care law”, as outlined earlier in Chapter 2.9, refers to the benefit to be received from a health service is lower, if the need for it is greater (548). In order for the Health Check to reduce inequalities, uptake of the programme and interventions, adherence to risk management interventions and thus clinical effectiveness of the programme must be high in all societal groups to meet their needs; this may entail more interventions in disadvantaged populations (407). If the programme fails to address the needs of all population groups, the relationship explained by the “inverse care law” will be sustained; therefore, as Capewell and Graham (407) suggest, the programme will increase health inequalities, failing to achieve its goal. This could be overcome by employing more resources for promoting high uptake of the programme and interventions across all population groups.
3.4.3 Effectiveness of the NHS Health Check; findings from early evaluations of local NHS Health Check programmes

The NHS Health Check, a high-risk based CVD primary prevention programme, has been in the national rollout phase and there have therefore been a limited number of studies on the evaluation of effectiveness of the NHS Health Check program. Current literature on the NHS Health Checks is based on local studies and these limited number of studies have examined short term outcomes, such as attendance to the programme; change in uptake of prescriptions and other risk management interventions (415,416); change in risk factors and global risk (648); and the effect of the programme on diagnosis of vascular disease, such as diabetes (646). The evidence on the uptake of the Health Check will be discussed thoroughly in Chapter 4.3.2, leaving only one randomized trial assessing the effect of NHS Health Checks in general practices on CVD risk factors and global risk, and one retrospective study assessing the effect of the programme on the identification of patients with unknown diabetes to be discussed in this section. The change in statin prescription after the NHS Health Check programme was explained and discussed earlier in Chapter 2.6.2.

A randomized trial, carried out in Stoke on Trent, central England, aimed to compare the effectiveness of the routine primary prevention care, the NHS Health Check, with the primary prevention care involving additional risk management intervention, lifestyle support (NHS Health Check plus lifestyle support) (648). The routine care provided under the NHS Health Check is explained in-detail in Chapter 3.4.1: in practice, the Health Check includes the assessment of CVD risk followed by medications and referral to risk management interventions (e.g. smoking cessation services) based on the level of risk of patients, but it does not include additional lifestyle support. The additional lifestyle support studied in this trial included a number of intensive interventions, such as one to one discussions on health and lifestyle improvement with lifestyle coaches and referrals to supporting interventions for weight management, physical activity and healthy cooking based on the preference of participants (649).

The trial involved 38 general practices and 601 patients aged 35 to 74 years with an estimated high-risk of CVD at baseline. Between September 2009 and February 2010, the eligible patients were recruited and randomized to receive the NHS Health Check or the NHS Health Check plus lifestyle support, by a researcher blinded to information on patients and practices. The changes in global CVD risk (10-year CVD risk calculated by JBS2), individual CVD risk
factors (i.e. blood pressure, lipid levels, smoking) and lifestyle related factors (i.e. BMI, weight, diet and physical activity) over one year (first year of the trial) were compared between the NHS Health Check group and the NHS Health Check plus lifestyle support group (648,649).

After one-year follow-up, participants in both intervention groups experienced significant decline in overall CVD risk and individual risk factors, including blood pressure, lipid levels and smoking, and the changes in CVD risk did not differ significantly between the two groups. Considering the reduction in overall CVD and individual CVD risk factors, it is possible to argue that additional lifestyle support did not have additional benefit. In terms of lifestyle related risk factors, both groups show similar improvements in diet and physical activity, but while the NHS Health Check plus lifestyle support group showed significant reduction in central obesity, the NHS Health Check only group did not. The findings of this study, therefore, suggests that the NHS Health Check programme is effective in reducing CVD risk, however this favourable finding is limited by the low uptake of the programme. This low uptake may suggest that the population was not motivated enough to make the expected change, although the targeted population was including those who had high risk at baseline. Since CVD prevention programmes are voluntary, the low attendance will considerably limit their population-wide health benefits; therefore (648), the scope of the NHS Health Check in providing public health benefits is arguable.

The Health Check programme, as explained in Chapter 3.4.1, also aims to enhance the detection of patients with unknown vascular disease, including diabetes, hypertension and CKD, and therefore, improve the diagnosis of these diseases (348). An observational study carried out in a local area in Birmingham aimed to assess the ability of the NHS Health Check in identification of people at high risk of type 2 diabetes (646). The study included patients aged 40 to 74 years, who had a Health Check and were identified as having high diabetes risk using the diabetes filter.

This study demonstrated that the NHS Health Check was able to identify two thirds of patients with an actual high risk of diabetes. Among those identified as at high risk using the filter, less than half of the patients (41%) actually had high risk. Two thirds of all patients identified as having high risk using the diabetes filter were actually at low-risk, meaning that two thirds of those who had blood glucose test did not actually require further diagnostic testing. The study also assessed the impact of using different threshold for BMI (based on
WHO recommendations – 23.0 kg/m\(^2\) instead of 27.5 kg/m\(^2\)) on identifying diabetes cases among Asian population, who have high prevalence of diabetes). The study showed that when this lower threshold is used, the sensitivity of the filter increases substantially to 94.4%, suggesting that the filter could not identify only about 5% of Asians at actual high-risk of diabetes. However, this reduction in threshold reduced the specificity of the tool and therefore increased the number of patients, who were exposed to unnecessary testing. These findings may not be applicable for populations with different prevalence of diabetes. This study’s population had large diabetes prevalence; the programme performance using the current filter in identification of high-risk patients may be poorer in populations with lower diabetes prevalence. Although this study suggests that the diabetes filter recommended for use in the NHS Health Check programme provides reasonable benefits in terms of identification of diabetes patients, the programme may be more effective in detection of undiagnosed diabetes patients, if other tools authorized for the UK population are used (646).

Although the findings of these two local studies provide important implications about the implementation of the NHS Health Check, there is a need for further studies evaluating routine practice of the programme, especially in real world settings at both local and national levels. It is also important to assess the effectiveness and cost-effectiveness of the programme in different settings, e.g. general practices and pharmacies. This is extremely important for commenting on the programme’s ability to provide population level benefits and for deciding on the future of the programme.

### 3.5 Key points from Chapter 3

Global and international organisations have launched a number of initiatives to control the burden of CVDs. In the UK, there has been an increased emphasis on CVD care and secondary prevention for decades; but towards the end of the last decade, the Department of Health launched a national, systematic CVD risk assessment and management programme, named the NHS Health Check. The NHS Health Check is the first CVD prevention programme nationwide delivered on such a large scale. The NHS Health Check aims to reduce the burden of CVDs and other vascular diseases, and associated health inequalities by identifying those at high CVD risk and improving the detection of undiagnosed vascular disease cases. PCTs had been responsible for the commissioning of the programme since the first implementation; however, the commissioning of the programme was transferred to local authorities, with the recent changes to NHS structure. The early evidence from the
development stages of the programme suggests the programme may be effective in reducing CVD risk, but high uptake of the programme must be ensured for the programme being beneficial population-wide.
Chapter 4: Lessons from Existing Screening Programmes

4.1 Uptake of screening programmes

NHS Health Check is a screening programme offered to adults aged 40-74 years in England. There are a number other national screening programmes available for the adult population in England: these include diabetic retinopathy, breast cancer, colon cancer, cervical cancer, abdominal Aortic Aneurysm and prostate cancer screening programmes. All these programmes, excluding abdominal Aortic Aneurysm screening programme, are also delivered in other countries within the UK (650). While diabetic retinopathy, breast cancer, colon cancer, cervical cancer, abdominal Aortic Aneurysm are authorised by and managed under the NSC, the NHS Health Check and prostate cancer screening are not authorised by the NSC. The NHS Health Check is delivered by the Department of Health (651). The NHS Breast Cancer Screening, the first screening programme of its kind worldwide, was introduced in 1988 (652). Although the cervical screening has been undertaken since 1964 in England, the screening was not well organised to enable widespread coverage and follow-up. NHS Cervical Screening was rationalized with a national computerised call-recall system in 1988 (653). NHS Bowel Cancer Screening programme was introduced more recently in 2006, with a complete rollout by 2009. It is the first screening programme in the UK, targeting both sexes (652).

As outlined earlier, for a screening programme to be feasible it is essential that the programme is equally accessible to entire populations. There is broad evidence behind the screening programmes undertaken in the UK, even on the more recently introduced NHS Bowel Cancer Screening programme. There are general patterns in the access to preventive services (654–656) and other aspects of health care (657). It is, therefore, possible to derive lessons from wide literature for the uptake of the NHS Health Check programme. While reviewing the literature on screening programmes, it is important to consider that screening programmes have unique characteristics and therefore different uptake patterns are inevitable. For example, response of patients to more invasive procedures, such as flexible sigmoidoscopy, may be different from response to less invasive procedures (658). I shall review the existing literature around the uptake of different screening programmes and provide implications applicable to the NHS Health Check. There will also be a review on the uptake of CVD prevention programmes, including the evidence on the immediate uptake findings of the NHS Health Check programme.
4.1.1 Determinants of screening uptake

A number of determinants of uptake of different screening procedures have been studied for years and many determinants have been shown as correlated with the uptake of screening. Figure 8 illustrates examples of categorised determinants of uptake of screening programmes. While some predictors are more strongly associated with uptake of specific screening procedures, the association of uptake with some predictors has not been well established (656).

Although there are many common determinants of uptake of different screening procedures, differences in the uptake patterns of different screening procedures is inevitable. This is because each screening procedure has unique characteristics, which lead patients to show different responses to procedures (551,656,659). For example, in a study comparing the uptake of cervical screening and breast cancer screening programme in the same British population, there were difference in determinants of uptake between screening programmes. While ethnicity and education were significant predictors of the uptake of cervical screening, economic factors (e.g. owning a car or house) were important in breast cancer screening (551). There is no exact explanation for these differences in predictors of uptake between breast and cervical cancer screening programmes; however practical barriers may explain some of the variation. The reason for difference in uptake by car ownership in breast cancer screening, but not in cervical screening, may be because cervical screening is delivered in more local settings and owning a car does not act as a barrier. However, mammography procedures in breast cancer screening are usually not available locally and require long travel (551). Damiani et al. (659) also compared uptake in breast and cervical cancer screening programmes in the same Italian population. While education level and occupational class of women were influential in uptake of both screening programmes, education level was more strongly associated with cervical cancer screening: there was an increasing gradient in uptake of cervical screening with level of education, but uptake of breast cancer screening was significantly associated with the highest level of education. Cervical cancer screening programme uptake was more strongly associated with marital status than breast cancer programme. This can be explained by the fact that Pap test in cervical screening is involved in the pre or post natal services offered to married women (659). The association between age and uptake of breast cancer and cervical cancer screening programmes was contrasting, with greater uptake of breast cancer screening with older age and lower uptake of cervical cancer
screening with younger age. The less importance given to preventive activities by younger people may explain this finding (659).

Besides demographic and practical barriers to participation in screening programmes, there are more complex factors that can influence the attendance to screening. These include knowledge about the condition being screened for and the screening test, perception of disease risk, seriousness of the condition being screened and barriers to receive screening test (660–662). The influence of these factors may differ between social groups; for example, perceptions of colorectal cancer and flexible sigmoidoscopy test used in colorectal cancer screening, which act as barriers to attendance to screening, differ between ethnic groups (658). As well as the condition screened for, the method of screening for a specific condition influences the attendance to preventive health programmes. For example, predictors of attendance to two different prostate cancer-screening methods, namely digital rectal examination (DRE) and prostate-specific antigen (PSA) test, differ significantly in Australian men. While psychological factors, such as perception of prostate cancer risk, affect the attendance to DRE, external influences such as involvement of partner’s decisions are important for the attendance to PSA test (663).

The only systematic review available on the determinants of uptake of screening programmes is the one by Jepson et al. (656), which was published in 2000. There is therefore strong need for up to date systematic reviews assessing the factors associated with screening uptake. For the purpose of this thesis, I shall review the evidence on the most commonly studied determinants of screening uptake, focussing mainly on those that will be addressed throughout the data analysis sections of the thesis.
Figure 8: Examples of determinants of screening (Adapted from: Jepson et al, 2000) (656)

<table>
<thead>
<tr>
<th>Socio-demographic Factors</th>
<th>Knowledge, attitudes, beliefs and behaviours</th>
<th>Health Status</th>
<th>Barriers</th>
<th>Structural factors of screening</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Perception of risk of condition, for which being screened</td>
<td>Previous experience of condition</td>
<td>Inconvenience</td>
<td>Distance to screening venue / lack of transport</td>
</tr>
<tr>
<td>Sex</td>
<td>Intention to attend screening test</td>
<td>Previous visits to practice / doctor</td>
<td>Embarrassment of attending and having procedure</td>
<td>Characteristics of practitioner performing the screening procedure</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>Poor health behaviors, including unhealthy diet, tobacco use</td>
<td>Self-reported health status</td>
<td>Fear of pain or discomfort</td>
<td>Organization type of screening programme (systematic or opportunistic screening)</td>
</tr>
<tr>
<td>Socio-economic Position</td>
<td>Previous attendance to preventive health programmes</td>
<td>Family history of the disease</td>
<td>Fear of getting positive test results</td>
<td></td>
</tr>
<tr>
<td>Summary measure of SES</td>
<td>Intention to attend screening</td>
<td>Ability to perform daily living activities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Income</td>
<td>Family history of diseases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material SES</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Marriage</td>
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<tr>
<td>Sexual Orientation</td>
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<tr>
<td>Transience</td>
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</tr>
</tbody>
</table>

(Adapted from: Jepson et al, 2000) (656)
4.1.2 Socio-demographic characteristics and screening uptake

4.1.2.1 Socio-economic status

SES has been widely used to study the determinants of health care usage, including preventive services. SES can be defined as ‘an individual’s place in the social hierarchies built around education, occupation and income’ (p.3) (664). Deprivation refers to low level of SES and Townsend (665) defined deprivation as ‘a state of observable and demonstrable disadvantage relative to the local community or the wider society or nation to which an individual, family or group belongs’ (p.125). It has been, traditionally, supported that there is strong association between SES and health outcomes, with better outcomes in more affluent groups compared to deprived groups. Inequalities in uptake of preventive health services may explain these socioeconomic inequalities in health outcomes (Inverse care law, Chapter 2.9) (548,664).

Sabates & Feinstein suggests that there are a number of limitations to findings supporting the lower usage of preventive services in those with lower SES and two most crucial points to be considered when assessing the association between screening uptake and SES are: First, SES is not a single factor that determine the health behaviour, but it constitutes components that influence behaviours. SES is a complex determinant, which has many components interacting with each other. Second, the apparent influencing SES factor may not be actual; there may be an alternative determinant that plays role in health behaviour. The time between SES and health behaviour is important, since there must be a plausible process through development of health behaviour with the impact of SES (666). These points are generally not considered and the findings are therefore misapprehended. However, for example, considering the first point, it is practically not possible to determine all components of SES and also to determine SES as an individual measure. Substitute measures therefore need to be determined, but caution should be taken when more than one measure is included because of the possible co-linearity between components of SES measures. The components of SES are extremely inter-correlated and therefore making it difficult to determine a causal relationship between outcomes and specific SES components.

A number of different indicators have been used to assess the association between SES and attendance to preventive health programmes. The commonly used measures include education, employment, income, car ownership and housing. In addition to individual
components of SES, area-based measures of SES have been developed using many SES components (667) and are often used in health research.

**Area-based measures of socio-economic status**

The area-based measures of deprivation are commonly used in health research, because other single measures of SES are not generally reported in medical records and therefore not available for researchers’ use. The most commonly used area-based measures of SES in the UK are the Indices of Multiple Deprivation (IMD) (668) and the Townsend Deprivation score (667). These indices demonstrate mean level of SES in a small geographical area at a single time point. Using area-based measures of SES, nevertheless, lead to limitations in the analysis. These measures are at area-level and not all people in an area have same socio-economic characteristics. Another issue is that these measures are developed at a single time point; therefore do not represent SES levels throughout the life course (667). The area-based measures are also unable to capture absolute SES, which has a complex nature (666). It is therefore essential to consider these limitations, when interpreting the findings on the impact of area-based measures of SES on uptake of screening programmes.

Evidence suggests that area-based measures of SES are strongly correlated with uptake of screening. Uptake of breast screening (669–671), colorectal screening (550,672–674), diabetic retinopathy screening (675–677) and cervical screening (678,679) are poorer in areas with greater deprivation, when defined by area-based measures. Baker & Middleton examined the inequalities in access to cervical screening programme, using the Townsend Deprivation Index, in England over time (678). They presented that coverage of the cervical screening programme being nationalized in 1988 improved in the next decade, particularly in deprived areas. In the early 1990s, there was very high socio-economic inequality in cervical screening coverage, with much higher coverage in affluent areas than deprived areas. Since coverage in affluent areas was reaching to maximum in the same period, affluent areas showed slower increase in coverage than deprived areas, which showed very high increases. This increase continued in the coming years, when coverage in affluent areas was close to maximum (~98%). In the late 1990s, the difference in coverage between areas was lower, with narrower inequality between affluent and deprived areas (678). These findings support “inverse equity hypothesis” asserted by Victora et al. (680) to explain changes in equity between those at higher and lower SES after the introduction of public-health programmes. This hypothesis suggests that although interventions first address those with greater SES,
worsening inequities in programme coverage and health outcomes at early stages, coverage and outcomes improve later in those at lower SES, closing equity gaps between poor and rich, with slower improvements in those at higher SES who have reached maximum achievements in coverage and outcomes (680). The findings surrounding the access to national cervical screening, a prevention programme delivered in general practices unlike other cancer screening (e.g. mammography), provide important implications for the Health Check. The impacts of the preventive health programmes delivered in general practices on health inequalities may become apparent over a time period and the trends in coverage of the programme must, therefore, be monitored for many years to determine the public health impacts of the programme.

In health research, when examining health outcomes or health behaviours, two aspects of population are considered: its context and composition. Context is characteristics of areas in which populations live and composition is about characteristics of populations (composition covers individual components of SES, such as income and education). Consequently, while “contextual effects” are about the influences in the environment of populations that affect their health and health behaviours, “compositional effects” are the features of individuals that affect their health and health behaviours (681,682). Contextual measures when combined with compositional measures may present different associations. The findings with only area-level SES measures must therefore not be confused with those produced using area-level measures as well as individual SES measures. Evidence suggests that contextual factors have significant influences on poor health, when controlled for compositional factors. For example, areas with greater deprivation have higher CVD prevalence (683) and CVD mortality (684). Stafford and Marmot suggested that people with greater individual deprivation may be influenced from the impacts of living in a deprived context more than less deprived (685).

Regarding the uptake of preventive services, a small number of studies combined both compositional and contextual factors when assessing their impacts on uptake. When controlled for individual SES measures, individuals living in deprived areas had lower uptake of breast screening (686) and health screening - for prevention of a number of conditions, including hypertension, diabetes mellitus, hyperlipidaemia and colorectal screening (687). In a systematic review, there was no significant association between area level deprivation and uptake of cancer (breast, cervical and colorectal cancer) screening, when controlled for
individual level factors. This finding could, however, be because of limited number of studies included and methodological weaknesses (688).

A study in South England assessed the determinants of colorectal cancer screening uptake considering both compositional and contextual factors. Since individual level SES variables were not available, the contextual factors included geodemographic segmentation as well as area-level deprivation (IMD Score). Geodemographic segmentation, an area level measure, can be used to explain health related outcomes that are not captured by summary measures of deprivation (IMD score). Geodemographic segmentation can include components, such as unemployment rates, council tax bands and house prices. The study showed that patient level factors, gender and age, are responsible for much of the variation in uptake of colorectal cancer screening, while contextual factors had smaller, but significant influences on the variation in uptake. Within contextual factors, geodemographic segmentation had a larger impact on variation in screening uptake compared to IMD score (674). Although the evidence on the impact of area-level deprivation on uptake is limited, it cannot be disregarded. Interventions that address both compositional and contextual measures of SES, including area level deprivation are required to enhance the uptake of screening programmes.

**Employment**

Employment is also a commonly studied component of SES in health research. Although there is considerable literature on the impact of employment on the uptake of screening procedures, the evidence surrounding the impact of employment on the attendance to screening is not clear (656). The employment status of patients is defined as binary variable, e.g. employed or unemployed, and classified occupation, e.g. manual, non-manual, self-employed, other and not employed. Considering uptake of breast cancer screening, there is evidence that unemployed individuals are less likely to attend to mammography than employed (659,689–692). There is also evidence that those with greater class of employment (e.g. skilled workers) are less likely to attend to have mammography compared to those with lower employment status (e.g. unskilled workers) (693). However, there are also some contrasting evidence suggesting that there is no association between employment status and uptake of breast cancer screening (551,694). Uptake of cervical cancer screening (551,659,695) and colorectal cancer screening (696) is also associated with employment status, with again lower attendance in unemployed (659,695,696). In contrast to the evidence on uptake of cancer screening programmes, the evidence from Denmark suggests that the
uptake of type 2 diabetes screening programme is likely to be greater in unemployed than employed (697).

**Education**

Education is another most commonly studied component of SES to examine factors influencing health outcomes and uptake of health services. Evidence suggests that attendance to screening is strongly associated with level of education, with particularly greater likelihood of highly educated individuals to participate in a screening programme compared with less educated individuals. Individuals with higher levels of education are more likely to have colorectal cancer screening than those less educated (698); this is applicable to uptake of the faecal occult blood test (FOBT), flexible sigmoidoscopy (699) and colonoscopy (700). Being more educated is associated with greater interest to attend to a colorectal screening test (701) and higher attendance to screening upon invitation (661).

**Material socio-economic status**

Material SES can be directly measured by income or wealth, and alternatively by car or home ownership. Jepson et al. (656), in their systematic review in 2000, demonstrated that there was no definite evidence on the impact of income on screening uptake. Evidence from the UK, demonstrated that there is no significant association between income of patients and uptake of breast cancer (702,703) and cervical cancer screening (702). There is evidence that individuals with higher income levels are more likely to attend to prostate screening (704) and abdominal aortic aneurysm screening (705). In the USA, the evidence suggests that greater income is associated with higher uptake of breast cancer, cervical cancer, colorectal cancer and prostate cancer screening (700,706,707). In Denmark, there was again evidence for greater uptake of colorectal cancer screening in those with higher income levels (696). The difference in the impact of income on screening uptake between countries may be explained by different health care systems in these countries. In countries with free health care, such as in the UK, level of income of populations may not attribute to inequalities in screening uptake, but in countries without a free health care system like in the USA, income levels of populations are important, since people have to pay for screening expenditure, if not covered by health insurance (703). Health insurance status may, therefore, act as an extra factor influencing screening uptake in specific countries (708).
The evidence from the UK suggests ownership of car or house can be a determinant of the uptake of screening. Moser et al. (551) demonstrated that greater number of car or house ownership is associated with higher uptake of breast cancer screening; however they failed to show an association between car or house ownership and cervical screening uptake. Owning a car or house was also shown to increase the interest in (701) and attendance to colorectal screening (661,709).

4.1.2.2 Ethnicity

Ethnicity is another most commonly studied factor in relation to the uptake of screening programmes. There are difficulties in defining ethnicity in health research and it is frequently confused with race (710). Ethnicity and race are, however, different concepts. Whilst ethnicity is defined as “the sharing of a common culture, including shared origin, shared psychological characteristics and attitudes, shared language, religion, and cultural traditions” (711), race is a biological concept that classifies individuals based on their genetic characteristics (712).

There is considerable literature suggesting variations in uptake of preventive health programmes with ethnicity. Evidence suggests uptake of screening is lower in ethnic minority groups (552,713,714). Ethnic minorities also have lower perceptions of colorectal cancer and the screening procedures (715). Studies in the UK have shown that south Asian patients have lower uptake of colorectal, cervical and breast screening (666,713,716,717). There is even evidence for further differences in uptake of colorectal screening within south Asian population, with lower attendance in the Muslim population compared with other south Asian populations (717). Patients living in more ethnically diverse areas are less likely to have colorectal screening (673). Uptake of breast, cervical and colorectal cancer screening programmes is lower in ethnic minority groups in the USA (718).

There are, however, concerns regarding the lower uptake in ethnic minority groups, since there are methodological difficulties that limit the assessment of health inequalities between ethnic minority groups. The first considerable problem is that SES may be confounding with ethnicity (719). Although ethnic variation is demonstrated in univariate analysis, this association may be lost after adjusting for SES (696,715,720). It is, however, important to note that there is evidence suggesting that the ethnic variation is consistent after adjusting for SES (713,717). The other difficulty in assessing the heath inequalities among ethnic
minorities is problems in splitting ethnic minority populations into study groups. These groupings can be too broad including diverse ethnic populations in one group; this may, thus, disguise variations between groups (719). For instance using south Asian ethnic grouping may mask the variations in the fundamental ethnic groups such as Indian, Pakistani and Bangladeshi. It was demonstrated in an English study that south Asians had greater access to cervical screening in practices with a larger proportion of south Asian population. When more than half of the total practice population was south Asian, the uptake was significantly greater in this ethnic group (721).

A number of factors may explain lower uptake of screening in ethnic minorities. Poor health literacy is an important factor that may influence the uptake rates in ethnic minorities. Since an understanding of health materials is crucial in decisions to attend screening or to carry out the test as in FOBT, those with low literacy are likely to fail attending screening (713,717,722,723). Patients from same ethnic background and same sex as their physician may be more likely to attend to screening; for instance, cervical screening uptake was greater in south Asian women who were registered with south Asian GPs (724). Cultural differences between ethnic minorities may, therefore, be another factor explaining variations in screening uptake (666).

Ethnicity may not affect the uptake of screening itself, but other associated factors may. Language is one of these factors; non-English speakers are more likely to have lower awareness of screening programmes (725) and also poorer attendance at screening programmes (725). The place of birth has also been shown to influence the uptake of screening; overseas birth was shown as a better predictor of variation in uptake than ethnicity (721). Variation in uptake by place of birth may be again attributable to language and cultural factors.

4.1.2.3 Sex

The majority of evidence available is on the determinants of uptake of cervical and breast cancer screening programmes, which have been implemented for many years both in the UK and other parts of the world. There is, therefore, limited evidence on the association between sex of patients and uptake of screening programmes. The literature on the uptake of colorectal screening, which is offered to both sexes, acts as a source for the evidence on the sex differences in uptake of screening. There is strong evidence that uptake of FOBT is
greater in women than men (672,696,726–728); however, the evidence on association between gender and the uptake of endoscopic colorectal cancer screening procedures is less clear. Although the majority of evidence supports higher uptake of endoscopic tests (e.g. colonoscopy, flexible sigmoidoscopy) in men compared to women (699,709,729), there is also contrasting evidence (730,731). The greater FOBT uptake in women may be explained by the greater willing of women to ask for help regarding health and consequently to use health services (672). The reason for greater uptake of endoscopic procedures in men can be because they are less concerned about discomfort of procedures than women (709).

4.1.2.4 Age

Although evidence has suggested an association between age and uptake of screening, the relationship between them is not well defined (656). This is because there is not a linear correlation between age and uptake of screening and also this relationship depends on the type of screening procedure. The uptake of colorectal screening increases with increasing age, but evidence also supports that the uptake decreases in the oldest age groups. Decrease in the uptake of invasive endoscopic procedures of colorectal screening (e.g. flexible sigmoidoscopy) in the older patients may be greater than that of FOBT (672,726–729,732). This can be because of the fear from discomfort and the procedures require fitness (550). The lower uptake in older patients can be also explained by lower perception of cancer risk in older patients (733). The patterns of attendance at breast cancer screening and cervical cancer screening programmes in different age groups is similar to that of colorectal cancer screening, with increasing attendance up to a certain age (734,735) and decreasing uptake in the older populations (671,734–736).

4.1.2.5 Marriage

Marital status is one of the important determinants of uptake to the screening programmes. Married patients or those living as married are more interested in having (701) and more likely to attend colorectal cancer screening (709,729,737). There is also strong evidence that married people have greater uptake of cervical cancer screening (659,662) and breast cancer screening (659,660,738). Men living with a partner had greater uptake of PSA testing; however, there was no association between having a partner and uptake of DRE (663). Nijs et al. also reported that those who attended prostate cancer screening were more likely to be married than those who refused attending to a screening (739). Marriage increases the uptake
of screening in both women and men and invitation of both couples to screening together has potential to further increase the uptake (740).

There is no clear explanation if the association between marriage and attendance to screening is due to a causal effect or selection effect. The possible reasons for the association are therefore: being married motivates individuals to attain healthier behaviour or individuals with greater consciousness about health are those who choose to be married and to be screened (740). Health behaviours can be influenced by marriage through a number of possible mechanisms: marriage can enhance individuals’ health behaviours due to increased responsibility to their partners. The other reason could be because marriage increases the social control of health of partners. This can be either active control or passive control. In active control, the direct interaction of partners can influence the health behaviours, e.g. attendance at screening programmes, and in passive control, more structured lives of married individuals may indirectly influence health behaviours (740,741).

4.1.2.6 Population mobility

Although practical evidence surrounding the impact of population mobility on the screening uptake is limited, hypothetical evidence suggests that population mobility is an important determinant of poor screening uptake (742). Population mobility can influence uptake largely from the organisation side of screening (742,743). However, patient level factors may also be important; for example, population mobility can lead to social exclusion and reduce social cohesion of the population. This can, therefore, cause the mobile population to be less informed of screening programmes and less likely to attend screening (744).

Considering organisation level factors, accuracy of medical records is important for screening uptake (743). Inaccuracies with records can be due to under-recording (less patients than actual registered population) or inflation (more patients than actual population) of records. Under-recording occurs if patients living in the practice area do not register with a general practice, whilst inflation occurs if patients have double records, or deceased or patients who left practice (ghost patients) are not deregistered. These inaccuracies are highly associated with population mobility, which causes a high patient turnover. This therefore can lead to either under-recording or list inflation. Population mobility commonly cause list inflation in the UK practices, particularly in young mobile populations (742,743,745). London, particularly inner London, has the largest population mobility in the UK and turnover
between boroughs is greater in London than other areas. High mobility and therefore frequently changing practice registers in London makes updating practice lists difficult, causing large list inflation and therefore reducing accuracy of registers (743). This in turn reduces the accuracy of invitations to screening programmes (743,746). Therefore, in theory, list inflation reduces screening coverage, although this impact is not on the actual coverage, but on the evident coverage level calculated based on the list-size. For example, the cervical screening coverage in a London borough was 73% based on the apparent register size, but the actual coverage based on the registered population was 88%, which suggest that 12% of the registered population are ghost patients and therefore, coverage can never be greater than 88% in the area. The government target of 80% cervical screening coverage is also very difficult to achieve, since 89% of all invited women need to be screened to reach this target (743).

Practical evidence surrounding the impact of list inflation, a consequence of population mobility, and different measures of population mobility on the uptake of screening also largely support that population mobility reduces screening uptake. The uptake of cervical (745,747) and breast cancer (748) screening reduces with higher list inflation. There are limitations of measures used to study population mobility (749), however studies using good mobility measures, such as change of address (695) showed that population mobility reduces cervical screening uptake. Population mobility, in summary, is an important factor influencing screening uptake. The impacts of population mobility on practice registers and consequently screening uptake can be partly managed by improved activities of organizations, for example by updating practice lists frequently (745).

4.1.3 Health behaviours and screening uptake

Poor health behaviours, including smoking, unhealthy diet, physical inactivity, low use of seat belt and alcohol and drug use, are prevalent in populations and they are associated with increased risk of mortality (554,555,750–752). Poor health behaviours are associated with SES of populations (554,555,753). Poor health behaviours can be strong predictors of screening uptake (556,656), however they cannot be a causal factor of poor uptake. This may be because mechanisms limiting the attendance at screening and causing poor health behaviours can be common; they may originate from same patient characteristics.
Evidence demonstrates that smoking (661,754), and infrequent visit to physician (699), including dentistry (661) and general practice (701), are associated with poor attendance to colorectal cancer screening. Evidence largely suggests lower attendance at breast cancer and cervical cancer screening programmes in smoker women (714,755–757), although there are evidence suggesting no association between smoking and attendance at cancer screening programmes in women (659,758). Smoking has also been shown as a predictor of non-attendance at diabetic retinopathy screening (676). Women with higher physical activity and who have greater use of health care are likely to have higher uptake of cervical cancer screening (758,759). A number of health behaviours are associated with poor breast cancer screening attendance; infrequent doctor visits, no regular physical activity and not drinking alcohol are examples of these (692,736,760). There is a large association between the uptake of breast cancer and cervical cancer screening, with greater likelihood of attending breast cancer screening in those who attended a previous cervical cancer screening (692,736,738). Previous attendance at mammography is also directly associated with greater uptake of breast cancer screening, with lower likelihood of having mammography in those who did not previously attended screening (693,738). It was shown that there is a “dose-response” relationship between health behaviours and attendance at preventive health programmes including cancer screening programmes; an additional favourable health behaviour increases the odds of attending to screening (761).

4.1.4 Health status and uptake of screening

Health status of individuals is also associated with the uptake of screening programmes. Individuals at high risk of developing colorectal cancer, for example, due to previous self-history of bowel disease or family history of colorectal cancer, are more likely to attend colorectal screening (701,762). However, those with other risk factors such as obesity and diabetes were shown to be less likely to attend colorectal screening (659,762). Obesity was also a predictor of poor attendance at cervical screening (659,759). Although limited, there is evidence suggesting that family history of diseases increases the likelihood of attendance at colorectal cancer (701), breast cancer (763) and ovarian cancer screenings (734). High perception of risk may increase screening attendance (660,764). Since family history of diseases is associated with perception of risk, the increased screening uptake by family history of diseases may be due to increased perception of risk (701,733). Another factor associated with perception of risk is subjective health (765). From this relationship, it is
therefore expected that subjective health is associated with screening attendance. However, the evidence surrounding the influences of subjective health on screening attendance is mixed (660,701,705,709,736).

4.1.5 Structural factors and uptake of screening

A number of structural features of screening programmes may affect the attendance at screening. In a population, screening can be delivered under organised programmes or opportunistically; a combination of both organised and opportunistic methods can also be used. Organised programmes involve well-defined eligibility criteria, enhanced follow-up and recall system, improved quality assurance and better evaluation; these characteristics potentially help programmes to provide better and standardized care (766). The main difference between organised and opportunistic screening programmes is that whilst in organised programmes, eligible populations are invited to screening by formal invitation based on centralised registers and offered fixed appointments, invitation is made either during consultation with health care providers or upon request from patients in opportunistic screening (766). Evidence suggests that fixed appointments are important for improved screening uptake (767). Patients invited opportunistically tend to be less informed regarding the screening procedure than those formally invited (755,768). In the UK, coverage of the cervical screening improved substantially after being organised and nationalized in 1988 (678,769,770). In Belgium, it was also presented that an organised breast cancer screening programme improved the screening coverage (771). It is suggested that organised programmes can play a role in improving inequalities (755). Although the national cervical screening programme in the UK was effective in reducing social inequalities in coverage (678), the breast screening programme in Belgium failed to produce reduction in inequalities after it become organised (771).

Distance to screening venue can be a determinant of screening uptake; increased distance to screening venue may reduce attendance, since travel requires extra effort, costs and time (705). Evidence on the association between distance travelled and screening uptake is, however, mixed. A number of studies have presented that there is no significant association between distance travelled to screening venue and uptake of breast cancer,(660) diabetic retinopathy (676) and abdominal aortic aneurysm (705) screening programmes. Sutton et al. (660), in contrast, showed that uptake of breast cancer screening uptake decreases slightly as the distance travelled increases, with no difference in uptake of screening between fixed and
mobile screening units. An earlier study also showed that increased distance travelled is associated with significantly lower uptake of breast screening in mobile units. 

Remoteness is also a determinant of poorer cervical screening uptake, with lower attendance to screening as distance increases.

The uptake of screening programmes delivered in general practices, such as cervical cancer screening, can be influenced by practice list-size. Cervical screening uptake was shown to be greater in larger practices, when practice size was determined based on the number of GPs in practices. Webb et al. (724), in contrast, showed that uptake is greater in practices with smaller patient list-size; this association might however be because the study did not account for the number of GPs per practice. This evidence therefore suggests that larger practices can have improved screening uptake, because they have greater staff capacity that can be deployed to enhance organisation of screening, for example, to improve call and recall system.

Another factor influencing the screening uptake can be the characteristics of practitioners (e.g. GP, nurse) carrying out the screening procedures. Gender of practitioners is particularly important for the uptake of screening procedures targeting women; for example, women registered with a female GP are more likely to have breast (669) and cervical cancer screening (695). Evidence suggests that the uptake of breast screening would be lower, if male mammographers are involved in screening programmes (775). Ethnicity of practitioners may be also important; cervical screening uptake is lower in practices with south Asian male GPs (724). Majority of screening procedures are not carried out directly by GPs, but they may still affect the uptake. During consultations, GPs with a greater perception of disease risk can encourage their patients to attend screening (776).

4.2 General practice attendance rates

The NHS Health Check is generally carried out in general practices across England and the general practice attendance rates are thus expected to be a crucial determinant of the attendance to the Health Checks, especially in the areas, where the programme is delivered at an opportunistic basis. A number of factors are associated with usage of general practices. There are gender inequalities in general practice attendance rates, with greater attendance rates in women compared to men (777,778). This gender difference in consultation rates is suggested as due to consultations for reproductive care in women. Women, particularly
young, visit general practice frequently for contraception, maternity care and other reproductive care (779). However, when controlling for reproductive needs, women still have greater attendance rates than men (778). Other alternative reasons for the difference in attendance rates can be that women suffer from disease symptoms more frequently and have greater morbidity than men, although men develop more life-threatening conditions and have greater mortality (778,780). Women are more inclined to perceive their health as poor and are more likely to seek health care than men (778,781).

General practice consultation rates are also associated with age. There is a U-shaped association between age and attendance rates, with the greater rates in children and older patients (779). This difference is generally regarded as “legitimate” and because of this reason rates are usually standardized for age; therefore there is very little work on the impacts of age on attendance rates (782).

Evidence, using a number of SES measures, suggests that deprived patients are more likely to attend general practices than affluent populations (779,782,783). This difference is largely due to increased demand for care in socio-economically deprived populations (779). Despite increased consultation rates in those with low SES, the quality of consultations in these patients is questionable. Those socio-economically deprived are more likely to seek care immediately after a health problem (784). However, it was suggested that referral rates from primary care to secondary care are lower in deprived patients than those with higher SES (785,786). Patients with lower SES are traditionally known as having greater morbidity and mortality, therefore they are more likely to be in need for specialist care. This, therefore, may suggest deprived groups cannot make the best use of the GP consultations.

General practice attendance rates in the UK are greater among ethnic minority groups, particularly in Indian, Pakistani, Bangladeshi and Caribbean, than white populations. Although ethnic differences in general practice consultations reduced when controlled for perceived health care need, differences were still significant, particularly in south Asian populations (782,787). Earlier evidence suggested that other ethnic groups, such as Chinese, African and young Pakistani women have lower attendance rates (782,788), although more recent evidence showed similar attendance between Chinese and white populations (787). Lower attendance rates in young Pakistani women can be due to a number of barriers, including refusing examination by male GPs and language barriers (789).
Ethnic differences in general practice attendance rates may partly be explained by quality of service received (787,788). Evidence showed that although ethnic minority populations have greater consultation rates, they are less likely to be referred for further care, including follow-up appointment and prescriptions (790). Consultation quality can be dependent on fluency in language and understanding of patients, such that language problems and poor mutual understanding can influence the GP and patient relationship and consequently reduce quality of consultations (791). These may, for example, suggest ethnic minority groups may seek care more frequently than other ethnic groups, because they cannot obtain the anticipated outcome from poor quality consultations, as well as their greater health needs (790).

Inequalities in general practice attendance by age, gender, ethnic and SES inequalities may reflect the uptake of the NHS Health Check, which is largely offered in general practices. Delivering the programme also in a community setting may be helpful in addressing those with lower general practice attendance. It is, however, important to note that these interventions also have limitations (630,792).

4.3 Uptake of Health Check programmes

High uptake is essential for the CVD prevention strategies to achieve effective reduction of population burden of CVDs (326,407). For a programme to meet its aim of reducing health inequalities, the uptake must also be high in the vulnerable populations (793). While examining the impact of the CVD primary prevention strategies on populations, it is, therefore, important to consider the level of programme uptake and the share of different populations benefiting from the programme. In this section, I shall discuss the levels of attendance to CVD screening programmes and the patterns of attendance in different populations.

4.3.1 Uptake of high-risk based cardiovascular prevention programmes

A number of trials examining the effectiveness of the CVD primary prevention programmes in primary care have been carried out in England before the implementation of the NHS Health Check. Most of these trials used a systematic CVD risk assessment and management approach that is also currently used in the today’s NHS Health Check (Chapter 2.7.2). BFHS was the largest trial that has been employed in the UK for examining the effectiveness of health check interventions. Although the patterns of uptake of the trial have not been examined, the level of attended eligible population was reported. After excluding the ghost
patients, 73% of all invited health checks eligible population in the study area attended the initial screening (326). Attendance to the first screening in another major trial, the SELSS, was again about 73% (452). Populations that could be followed-up after a particular time period were even lower (326,452). In more recent trials, examining the effect of high-risk based CVD risk assessment programme, the uptake of health checks was much lower. Richardson et al. (456) demonstrated an attendance rate of 29% among those invited. Attendance to CVD risk assessment in another trial held in both general practices and pharmacies was only 24.3% (794).

The OXCHECK study, another major health checks trial held in the UK, provided evidence on the uptake patterns of health checks. The OXCHECK study achieved quite good attendance rate, with about 82% of invited patients attending a health check. Women, married individuals, those from higher social classes and individuals who owned car were more likely to attend a health check (795). Greater likelihood of attending health checks in women compared with men was also reported in other studies (796,797). Jones et al. (796), assessing a systematic CVD screening programme, suggested that attendance to health checks is lower in those with lower social class and less educated. In an opportunistic health check programme, attendance was again greater in women, married and those with higher social class (798). Uptake of health checks for new patient registration in general practice was again greater in those with lower SES, with lower attendance in unemployed individuals and in those with lower social class (799).

Literature on the impact of age on the uptake of health checks is limited, but compliant with the evidence for the uptake of cancer screening, Lambert et al. (794) suggested that attendance rates increased up to a certain age (75 years) and the oldest age group has the lowest attendance rates. Considering the impact of ethnicity on the uptake of health checks, the recent trial on the CVD risk assessment in general practices and pharmacies demonstrated that uptake is greater in south Asians and black patients compared with whites (794). However, in an earlier trial studying the uptake of new registration health checks, the attendance was significantly lower in black patients (799).

The health check studies have also shown association between attendance and health behaviours. Smoking has been shown to be a predictor of poor attendance in a number of studies (794,795,797–799). Evidence also suggests that those with less frequent GP
attendance (795), poorer diet (795,798) and greater alcohol intake (795,796) are also less likely to attend to a health check.

Internationally, there is no broad evidence on the uptake patterns of major CVD prevention trials, such as Oslo study, MRFIT and others. Only Malmo study reported the difference between those attended and non-attended the screening. The attendance was associated with social and demographic characteristics, with for example, greater attendance in cohabiting partners (427). Outside health check trials; a population based health survey called the Oslo Health Study was carried out in Oslo. This study screened the health survey participants and determined those with high CVD risk for further assessment and management in hospital. The study, examining the differences between participants and non-participants, demonstrated significant associations between attendance and demographic and social characteristics. Males, younger, unmarried and those with lower levels of education and income were less likely to attend to the health survey (800).

4.3.2 Uptake of the NHS Health Check

The NHS Health Check programme has been delivered nationally for four years (from April 2009) (Chapter 3.4). There have been, therefore, limited studies evaluating the delivery and impact of the programme (Chapter 3.4.3). A couple of studies have evaluated the uptake of the programme in local areas but there has not been an academic work evaluating the attendance to the programme at national level. I shall explain the current local-level evidence surrounding the attendance to the Health Checks and then discuss the figures surrounding the attendance to the Health Checks programme provided by the Department of Health.

Dalton et al. (415) evaluated the uptake of the NHS Health Checks programme offered locally in general practices in Ealing (North West London) in the first year of the programme; the local programme was implemented before the national rollout from 1st September 2008. Unlike the national NHS Health Check, because of the needs of the local population, patients aged 35 to 74 years and those with hypertension were included in the programme. In the first year of the programme, the Ealing PCT targeted only those with high estimated CVD risk (≥20% 10-year CVD risk), identified based on the incomplete and already recorded medical data. The total uptake of the Health Checks was 44.8% among those invited in one year. The uptake of the Health Checks was significantly associated with patient and practice characteristics: women, south Asian, those with mixed ethnicity and individuals registered
with smaller practices were more likely to attend a Health Check. The study also examined the change in statin levels, which is discussed in detail in *Chapter 2.6.2.3* (415).

The second study on the uptake of the NHS Health Checks assessed the response and attendance to the local programme in Stoke on Trent (416). This study again reported the attendance levels in the first year of the local programme, but within 6 months from August 2009. This local Health Checks programme, again, included a younger age population, patients aged 32 to 74 years, compared to the national target population; however compliant to the national NHS Health Checks, all those with known vascular disease were excluded. As in Ealing, the first year of the programme targeted those with estimated high CVD risk. Of those invited, 63.3% responded to the invitations and 43.7% attended a health check. Older individuals and those living in more affluent areas were more likely to respond to invitations. In contrast to Ealing, the attendance rates were greater in males than females in Stoke on Trent. Again as in responses, the uptake of invitations was greater in older people and those from more affluent areas. The study also assessed uptake of treatment, including lifestyle advice, fibrates, usual care and statins, following the Health Checks. The uptake of statins is discussed in *Chapter 2.6.2.3*. In total, 29.8% of invited patients took up treatment; uptake of treatment was lower in females, younger patients and those registered in larger practices (416).

Ealing and Stoke on Trent used similar approaches in the implementation of the Health Checks in the first year of the programme in their areas. The attendance rates among those invited to the Health Checks in two areas were similar (44.8% and 43.7%) (415,416) and lower than the Department of Health anticipated uptake of 75% (417).

The patterns of attendance to NHS Health Checks have not been examined at a national-level yet. However, there have been studies examining the variations in delivery of the programme in commissioner organisations, PCTs and discussions on attendance rates and their consequences based on the PCT level data published by the Department of Health. As outlined earlier (*Chapter 3.4*), 20% of all eligible population should be offered a health check each year for the programme to complete a 5-year rollout. For this reason, PCTs need to aim inviting 20% of their eligible population to Health Checks annually. Because of available budget in the financial year of 2011/2012, the Department of Health expected PCTs to aim offering Health Checks to 90% of the annually targeted population, which is equivalent to 18% of all eligible population (636). HEART UK Freedom of Information survey showed
that a large proportion of PCTs that participated in the study (118 PCTs out of 151 UK PCTs) were shown to not set the expected target of 18% for 2011/2012 (793,801,802). Only 36 of the responding PCTs targeted to offer the Health Checks to 18% of their eligible population (793).

The national data for the population eligible, offered and attended a health check in 2011/2012 were made available by the Department of Health (803). More information on the data and the analysis for examining the determinants of attendance to the Health Check attendance can be found in Chapter 9.2.

### 4.4 Practitioner and patient level barriers to primary prevention strategies

In high-risk based primary prevention strategies, effective communication of risk to patients by practitioners and accurate perception of the communicated risk by patients carries crucial importance in achieving effective management of risk (804). Practitioner and patient level barriers can, therefore, limit the effectiveness of high-risk based primary prevention programmes and in order for these programmes, such as the NHS Health Check, to be successful in improving population health outcomes, these barriers needs to be carefully considered.

#### 4.4.1 Patient level perception of vascular risk

High-risk primary prevention strategies involve risk stratification and effective communication of the predicted risk is important for the strategies to be successful. Effective communication of risk is essential for improving the perception of risk in patients and to motivate the change in behaviours to reduce risk (805). Accuracy of perception of CVD risk by patients, as well as practitioners, is important in terms of achieving better clinical outcomes (806). Evidence suggests that increasing the understanding of CVD risk estimates of patients improves the prescriptions of preventative therapy (e.g. lipid lowering drugs) by clinicians (297) and consequently reduce lipid levels (807).

There is discrepancy between the actual and perceived risk of CVD in patients. Populations have a poor understanding of CVD risk and they generally underestimate the risk of CVD, while majority of people tend to perceive cancer as a greater risk to health (808). For example, 80% of patients with high CVD risk perceive their risk as low and 20% of low-risk patients perceiving their risk as high (804). Evidence suggests that perception of risk varies
between populations; accuracy of perception of risk tends to be poor particularly among men, those with diabetes (804) and smokers (809).

The inaccurate perception of risk in patients may be partly explained by poor health literacy, which is defined as ‘a constellation of skills, including the ability to perform basic reading and numerical tasks required to function in the health care environment’ (p.553) (810). Poor health literacy in patients limits the usage of health care services and health improving actions, for example behaviour change and use of medications, which in turn lead to poor health outcomes (811). Health literacy can be considered in three levels of functional health literacy, which refers to the ability of individuals to read and write health related concepts; interactive health literacy, the ability to be actively involved in health related decisions and benefit from health communication; and critical health literacy, the ability to critically evaluate and use health related information (812–814).

A systematic review suggests that limited health literacy is common in populations, with a prevalence ranging from 34 and 59%. Since the thresholds for determining limited health literacy varied between the included studies, it is however not possible to determine a true estimate for limited health literacy (815). Health literacy is strongly correlated with a number of factors, including SES, education level, language, occupation, demographic factors and cultural factors (813). Differences in health literacy between populations can lead to health inequalities (816). For example, populations with low SES are more likely to have limited health literacy, however, SES also has a co-linear relationship with health literacy (810).

A high level of health literacy, specifically ability to assimilate and use numerical information, is essential for patients to effectively perceive the communicated health information. Considering the CVD risk assessment procedures, a good level of health literacy is important for attaining better perception of risk, vascular risk communication by practitioners, access and adherence to interventions. These all in turn helps to obtain greater benefits, better outcomes from the CVD screening strategies (806,817). The method of communication of risk information is associated with the effects of health literacy on perception of risk; therefore, effective risk communication addressing the negative impacts of health literacy is essential to improve the perception of risk. It is crucial to address the stages of health literacy, discussed earlier, when communicating risk information to patients. Although it is not possible to change the interactive ability of patients, the ability to read and understand risk information can be improved by effective communication of CVD risk
information using appropriate methods for clear and perceivable presentation of CVD risk (806).

4.4.2 Effective vascular risk communication

Effective communication of risk and treatment options to patients is crucial for the success of CVD primary prevention strategies. Practitioners have an important role in maintaining accurate perception of risk by patients and compliance to risk management interventions. Practitioners should be able to accurately judge patients’ ability to understand health information (health literacy) to tailor the effective communication of risk information and possible treatment strategies for risk management (818). For effective communication of risk to patients, practitioners must have a good relationship with their patients that patients can be more confident in the practitioner (819). Besides risk communication, practitioners should collaborate with patients during the CVD risk management process. For example, if practitioners involve patients in decision-making, better understanding of importance of the treatment, adherence to interventions and more benefits in terms of health outcomes can be achieved (820–822).

Considering the methods of effective communication of risk information to patients, it is primarily important to provide simple information that can be easily comprehended by patients. Only most necessary information must be communicated to patients. For example, patients generally need to know what is the best solution for their problem, rather than background information on the mechanism of their condition (810). Patients mostly prefer the risk information to be presented in numeric and/or visual formats (821,823), since numeric or visual information are more understandable than risk information presented in verbal format, explanation of numerical results (824).

RR is the more preferred numeric method by patients compared to the absolute risk and the numbers needed to treat (823). Presentation of RRR is also suggested as the most effective method when explaining the benefits of interventions for encouraging patients to have treatment (825); RRR is also the most preferred method by practitioners when they decide on treatment options (826). A weakness of RR is that it can lead to overestimation of risk; however presenting baseline absolute risk combined with RR can invalidate this problem (824,827). In the numerical presentation of the information, caution should be taken to present them appropriately and effectively. For example, it is important to use round numbers
instead of decimals and same numeric format when comparing numbers (e.g. odds ratio must not be compared with percentages) (824).

Presentation of risk in visual format provides more effective risk communication and in turn better understanding of risk than numerical methods and others. Visual information can be in the form of tables, pictures or graphs; but tables are the most preferred format of visual information (821,828) and guidelines recommend the use of risk tables for effective communication and management of risk of patients without a pre-existing CVD. There are, however, a number of barriers that may hinder the effective risk communication using risk tables. These can be risk table (guideline) related, patient related (e.g. poor perception of risk), GP related (e.g. poor risk perception and communication skills) and environment related (e.g. organisational factors - risk communication might be delivered by practitioners other than GPs, health care assistants, who may not be effective in risk communication) (829). Patient and practitioner level barriers to risk communication can be tackled by education (830); for example, patients can be educated to improve their health literacy (831) and practitioners can be educated to improve their risk communication skills (821).

Risk communication is one of the major components of the NHS Health Check programme. Risk communication and brief lifestyle interventions are mostly the only interventions provided to the majority of the population attending the programme. The perception of vascular risk in the Health Check eligible population is therefore one of the predictors for the success of the programme. Risk communication, a complex and important process in the primary prevention strategies, must possess high quality to be effective in producing benefits and avoid unfavourable outcomes. There are a number of developments in relation to risk communication; using lifetime risk scores and heart age may potentially improve effectiveness of risk communication. However, the effectiveness of these methods in practice have not still been validated (177,269). Health care assistants are responsible for delivering majority of CVD risk communication under the NHS Health Check. The risk communication may be too complex for these practitioners, hindering effective communication of risk (829). It is therefore crucial for commissioning organizations (local authorities) to monitor the vascular risk communication delivered by these practitioners.
4.4.3 Harm associated with primary prevention

All prevention strategies cause harm; a prevention programme can be effective, if there is a balance between benefits and harms of the programme. The first step in the high-risk based prevention programmes is screening the population to identify the target population. The balance between benefits and harms of a primary prevention programme is generally considered by patients when deciding on attendance at screening and practitioners when referring a patient to prevention programmes (832). It is important that the benefits of a primary prevention programme exceed its benefits (833).

The harms of the primary prevention programme can be observed at one of the three levels of the process; at the initial screening, during the further investigation of the screening results, or during the interventions for managing detected abnormalities. The potential harm for a patient increases as he goes through all three levels of the process; the potential harms at level two and three are greater than level one. During the prevention process, people may be exposed to physical, psychological or social harms (832).

Each screening or prevention programme uses different procedures to estimate risk or identify the presence of a disease, the physical harm that each strategy causes, therefore, depends on the procedures used. In high-risk based CVD primary prevention strategies, the initial risk assessment with questionnaires, simple measurements and blood tests for lipid levels, and further investigations have minimal potential to harm patients. The only invasive procedure in CVD risk assessment is venepuncture and therefore the only harm can be adverse reaction to venepuncture; this may be minimised by increasingly used less invasive technique of point of care testing (POCT) (834). Although the screening process in CVD primary prevention is minimally invasive, the interventions for management of risk factors in those with raised risk factors or global risk lead to potential harms. Among the interventions provided under the NHS Health Check programme, weight loss interventions have potential harm implications. These may cause eating disorders, reduction in bone density, increased risk of fractures and increased mortality risk (832,835). Statins, lipid lowering medications offered to those identified as at high-risk, also cause a number of potential adverse effects, including acute renal failure, liver dysfunction, cataract and myopathy (155). The NHS Health Check does not have a large potential for physical harm, however it is still important to consider its possible adverse effects when assessing participation in the programme and uptake of interventions.
Prevention programmes are associated with a number of psychological harms. At the primary stage of the process, patients might perceive discomfort from the screening procedure: for example, anxiety regarding venepuncture. While waiting for the test results after screening, a patient may develop increased anxiety about possible positive results (high risk in the case of CVD assessment) of the test (832). Positive results of screening test may lead to anxiety, depression or distress. This may also lead to reduction in social functioning of patients; e.g. absenteeism from work (832,836). The screening results may lead to change in perception of risk; although this may have positive effect of promoting healthy behaviours (e.g. healthier diet for cholesterol management), it can also lead to excessive anxiety (832). A study using patients participated in BFHS (Chapter 2.7.2) suggested that the programme including CVD risk assessment and management interventions do not increase concerns about general health and CVD risk, and lead to psychological problems. It instead increased perception of lowered risk associated with changes in risk factors; those with greater risk reductions as a consequence of the interventions became more positive about their health. A significant negative impact of the programme was that it reduced patients’ perception of ability to manage their future CVD risk (837).

As well as causing adverse psychological outcomes such as anxiety in patients determined with high risk, screening programmes can lead to reassurance in those at low or moderate risk (with negative result). Screening tests are not faultless and in the case of CVD risk assessment; individuals may be classified as having low or moderate risk wrongly (false negative) and this may lead to false reassurance (832,838,839). Reassurance can therefore lead these people to ignore preventive measures and even attain or continue risky behaviours (832). In BFHS, the perception MI risk was lower in the intervention group than the control group. This may suggest that the CVD risk assessment and management programmes are reassuring, instead of threatening. This also negatively affects the potential benefits of a prevention strategy (837). There are limited qualitative studies surrounding reassurance; there is also no evidence on false-reassurance. A qualitative study examined the perceived benefits of a CVD risk assessment programme in patients determined to be at low CVD risk. The study showed that patients with confirmed low risk feel confident about the result of the comprehensive assessment and therefore reassurance is high. These participants, therefore, no longer think that there is need to change their lifestyle to manage their risk; this was even valid for those who already had risk factors (e.g. smoking) (840).
A limited number of studies have examined the psychological harms caused by risk assessment, particularly CVD risk assessment. A meta-analysis assessing the psychological effects of estimating risk of a range of diseases, including CVD, demonstrated that anxiety and depression increased in the short term in patients who received positive test results. However, this impact was not maintained in the long term and the adverse psychological effects were not permanent in patients confirmed with high risk (836). Another meta-analysis assessing the adverse emotional effects of screening strategies (including one study on CHD risk assessment) again suggested that no screening programmes cause adverse emotional effects at longer term (more than four weeks) (841). Another review assessed the psychological effects of specifically knowledge of CVD risk levels. The study, including limited number of studies (only four), showed no evidence of psychological harm from knowledge of CVD risk in high-risk patients, but in those classified as having intermediate levels of risk. Additional counselling and scheduled or optional follow-up in high-risk patients may reduce any potential harm. This therefore explicates poorer outcomes in patients at intermediate level of risk who are not generally followed-up (261). A qualitative study suggested that patients generally leave CVD risk assessment with favourable experiences, including improved understanding of CVD, willingness to make lifestyle changes and improved perception of CVD risk. These benefits were, however, reliant on the relationship between patient and doctor, quality of consultations (e.g. good timing and content of consultations), effectiveness of risk communication and accessibility of follow-up sessions (842). A recent review examining the positive and negative effects of general health checks, including screening for health outcomes or disease risk, suggested that there is a shortage of studies on the effects of health checks on adverse psychological outcomes and depending on the available literature, there is no evidence on the adverse psychological effects of general health checks (457).

In the case of the NHS Health Check, psychological harms may represent greater threat than the physical harms. CVD risk assessment and communication of the risk information are the processes that may cause most of the patient harm in the NHS Health Check. If a screening tool, CVD risk score in the case of the CVD risk assessment, has low sensitivity; many patients would be predicted as having positive result (high risk), although actually they are not (false-positive result). Since positive results may lead to increased anxiety, patients inaccurately stratified as having high risk may, therefore, be exposed to unnecessary anxiety (838). Labelling patients as at high risk may have consequences other than psychological
effects; for example, it may cause problems with receiving health insurance (159,457). Low sensitivity of the risk prediction tool may also result in classification of a number of patients as at lower risk than their actual risk (false negative), which may lead to false reassurance (832,837,839). The accuracy of prediction tools used in screening therefore carries crucial importance in reducing possible harm from a prevention strategy.

One of the main concerns regarding the NHS Health Check is the fact that it medicalizes healthy people. Individuals without an existing health condition who are labelled as with high risk as a consequence of CVD risk assessment are offered medications to manage their risk (159). Medicalization can cause harm, such as iatrogenic illness, poor decisions on treatment in patients, wasting economic resources, an unnecessary focus on therapeutic and individualized interventions in healthy patients (292), reduction in self-efficacy to improve health and urging patients to adopt risk increasing behaviours (159). Over-medicalization is more concerning if the prevention is carried out in general practices (843). This, therefore, suggests NHS Health Check has significant implications regarding over-medicalization. If high risk is regarded as medical condition and prevention is carried out from a medical perspective, over-medicalization is likely to be concerning. High-risk prevention strategies, therefore, have potential to cause unnecessary harm (140). A novel approach called quaternary prevention (Chapter 2.1) is suggested as an alternative to these strategies to avoid side effects of over-medicalization (140,843).

Prevention strategies are associated with a number of harms other than psychological and physical harms. For example, the opportunity cost of the screening may not balance the loss of time spent for screening and any consequent loss of financial earning (i.e. due to time lost from work) (832). Although there are a number of other potential harms associated with CVD risk assessment and management programmes, there is still scarce literature surrounding these harms (457). There is, however, need for strong evidence surrounding the harms of CVD prevention to justify the routine and widespread implementation of CVD primary prevention programmes (458,838).

Based on the existing evidence outlined earlier, there is no prediction of great harm potential from a health check, CVD risk assessment and management programmes. Mills et al. (766) suggested that organised programmes, like the NHS Health Check, have greater potential to reduce harm than opportunistic screening programmes; this can be because organised programmes use standardised procedures, such as inclusion of patients based on a specified
eligibility criteria, follow-up, and quality assurance (766). High quality screening and risk management procedures (for example, if effective communication of risk and sufficient follow-up can be maintained) in the NHS Health Check may prevent potential adverse psychological impacts (e.g. anxiety) that can result from being classified as at high risk (261,842). The benefits of a screening programme can be mitigated by enhanced reassurance as a result of screening; false reassurance is concerning. There is limited evidence surrounding this issue, but a recent qualitative study on the patient experiences of the NHS Health Check programme in general practice showed that many patients, even some of those with mixed results, were reassured following a Health Check (844). This may suggest the programme has potential of causing excess reassurance, such that the harms overweigh its benefits.

No prevention strategy is without harm, but it is important to keep harm at minimum. For this reason, it is important to evaluate prevention programmes routinely. There is need for further evidence on the adverse effects of the NHS Health Check programme to confirm if it produces substantial benefits to population; this is especially important in the current financial environment when there are strict restrictions on the NHS spending, prioritising greater benefit and less costly programmes (458).

4.5 Key points from Chapter 4

Evidence on the inequalities in the uptake of CVD risk assessment and management programmes is scarce. Existing broader evidence surrounding the inequalities in the uptake of screening and other preventative health programmes, therefore, carries crucial importance in terms of deriving implications for the implementation of CVD screening programmes, for example, the NHS Health Check. Although the determinants of uptake of screening programmes change based on the type of screening, there are also some common determinants. Among the widely studied SES factors, area-level measure of SES and education are strongly associated with the uptake of screening, with greater uptake in those with greater SES. Ethnicity may not be the determinant for the poorer screening uptake in ethnic minorities itself, but other factors, particularly language may be important. Transience is also an important factor influencing the screening uptake. Transience can reduce the accuracy of practice registers, affecting the accuracy of invitations and therefore, restricting the screening uptake that can be attained. Poor health behaviours can be strong predictors, but
not a causal factor of poor uptake. Individuals with poorer health behaviours, therefore those with greater need, are less likely to attend screening.

The NHS Health Check is commonly delivered in general practices; therefore the inequalities in general practice attendance can be an important determinant of the programme uptake, particularly when the programme is delivered opportunistically. There are inequalities by age, sex, SES and ethnicity of patients in general practice attendance. Early evaluations of local NHS Health Check programmes also showed inequalities in the programme uptake by patient and practice characteristics. These inequalities can be tackled by tailored interventions and screening in community settings.

The success of preventive health programmes can be influenced by a number of practitioner and patient level barriers. Effective communication of screening results, CVD risk in the case of the NHS Health Check, and good level of perception of risk in patients are essential for the programme being effective. It is important for the programme commissioners and providers to ensure predicted risks are communicated effectively to screened individuals. This is important in terms of obtaining improved understanding and involvement in the interventions in all patient groups.
Chapter 5: Aims and Objectives of the Study

5.1 Summary of the literature review findings

1- CVDs are the leading cause of morbidity and mortality worldwide, although they can be prevented by modifying CVD risk factors, mainly tobacco smoking, obesity, high blood pressure, diabetes, unhealthy diet and physical inactivity.

2- CVDs remain the commonest cause of mortality, mortality and health care expenditure in high-income countries, despite considerable reductions in CVD burden during the last five decades.

3- There are large socio-demographic inequalities in CVD burden and CVDs are the major cause of health inequalities in high-income countries.

4- Due to the increasing aging population in high-income countries, an increase in CVD prevalence is anticipated, which would lead the countries to face dramatic CVD care costs. These countries may not be able to cope with these expenditures, if primary prevention actions are not taken to reduce CVD incidence.

5- Despite the limited evidence on the effectiveness of high-risk approaches in primary prevention of CVDs and growing evidence surrounding the effectiveness of more cost-effective population-based prevention approaches, high-risk prevention remains the most commonly used prevention strategy in practice.

6- A number of CVD risk scores that are effective in stratifying the CVD risk of populations have been developed. CVD risk scores can be useful in targeted primary prevention strategies.

7- The NHS Health Check programme, a systematic high-risk based CVD prevention programme, is the first of its kind implemented on such a large scale worldwide. The programme is anticipated to reduce the CVD burden and CVD related health inequalities in the UK.

8- The NHS Health Check programme would inevitably have large cost implications and there are a number of concerns regarding the deployed prevention strategy and the way of its implementation.
9- There are considerable socio-demographic inequalities in the uptake of preventive health programmes, which may limit the public health impact of prevention strategies.

5.2 Hypothesis

The introduction of the NHS Health Check programme, a high-risk based CVD primary prevention, will be effective in reducing the CVD risk and will reduce health inequalities.

5.3 Main research questions

1- Is the NHS Health Check highly accessible to all population groups?

2- What is the impact of the NHS Health Check on CVD risk? Will it be able to reduce inequalities in cardiovascular health?

3- Is the prevention approach (high-risk based primary prevention) employed by the NHS Health Check effective in improving English public health?

5.4 Aim

To examine the early impacts of the NHS Health Check programme.

5.4.1 Objectives

- To determine the recording of CVD risk factors in the electronic medical records before the implementation of the NHS Health Check programme and to examine variation in risk factor recording by patient and practice characteristics. (Local study using general practice data from Hammersmith and Fulham QOF+ Health Checks)

- To assess the levels of the patient uptake of the NHS Health Check programme in the early years and to examine the variation in uptake by patient and practice characteristics. (Local study using general practice data from Hammersmith and Fulham QOF+ Health Checks)

- To assess the nationwide coverage of the NHS Health Check programme and to examine the variation in coverage by population and primary care provider (PCT) characteristics. (National study using PCT-level data from Department of Health NHS Health Check Dataset)
- To evaluate the impact of the NHS Health Check on CVD risk and prescription of lipid lowering drugs after the introduction of the programme and to examine the variation by patient characteristics. (Local study using general practice data from Hammersmith and Fulham QOF+ Health Checks)
Chapter 6: The NHS Health Check Programme in Hammersmith and Fulham

6.1 Hammersmith and Fulham Borough

Hammersmith and Fulham is a borough in West London, with an estimated population of 182,500 in mid-2011 (845). Prior to changes in NHS structure in April 2013, NHS Hammersmith and Fulham was the PCT that was responsible for delivering the health care needs of the borough’s population. NHS Hammersmith and Fulham was responsible for providing primary care through 31 general practices, as well as commissioning secondary care and specialist services. A greater number of people were registered with the general practices in the borough compared to the resident population of the borough, with 191,000 registered people compared to 182,500 resident population in 2011 (846). The reason of this difference is mainly patients who left the area without notifying their practices to deregister (ghost patients). The PCT has made effort to improve the accuracy of practice lists, but the difference between registered population and estimate population has not shown considerable decline (difference between registered and resident populations was 5.5% in 2009, while 4.5% in 2011) (846,847).

Hammersmith and Fulham population consists of generally young population compared to the rest of England (Figure 9), with 19.7% of the population aged 19 years or lower and more than half of the population (52.8%) aged between 20 to 44 years, greater than London’s average. A low proportion of the borough population is aged 65 years or over (9%), suggesting that majority of the borough population is at working age (848).
Figure 9: Age profile for Hammersmith and Fulham (Source: 2011 Census Data from Office for National Statistics, 2012) (848)

Hammersmith and Fulham consists of pockets of deprivation and affluence (Figure 10). The borough, using index of multiple deprivation 2010, is classified as the 59th most deprived local authority in England and 13th within 32 PCTs in London (846). Compared to national deprivation outline, 26.4% of Hammersmith and Fulham population belongs to the most deprived national quintile, slightly lower than the central London average, and lower than 1% of the population fits into the least deprived quintile (849).
Figure 10: Deprivation levels (Index of Multiple Deprivation 2010) in the borough of Hammersmith and Fulham (*Source: Department of Health, 2012*) *(850)*

“This image has been reproduced with the permission of the rights holder, Department of Health.”

According to the latest census in 2011, 45% of the Hammersmith and Fulham residents are white British, with 3% white Irish and 20% other white (*Figure 11*). South Asians (Indian, Pakistani and Bangladeshi) constitute 4% of all local resident population, while 12% of entire population is Black and 5% from mixed ethnic backgrounds *(851)*.
Figure 11: Ethnic composition of Hammersmith and Fulham in 2011 (Source: Census 2011 Data from Office for National Statistics, 2012) (851)

Considering the health profile of the Hammersmith and Fulham, the life expectancy of both sexes in the borough is greater than the England average, with higher life-expectancy in the least deprived areas compared to the most deprived areas (difference is 7.5 years in men and 4.6 years in women). The overall death rates have reduced over the last 10 years in the borough (850). Although there have also been reductions in CVD mortality rates in the borough, e.g. 66.0% decrease in CHD deaths in males and 59.3% in females between 1996 and 2012, CVDs are still the leading cause of all deaths. CVD mortality rate in the 2008-10 period was 147.3 per 100,000, which was lower than the England and London average. In the population aged 75 years and lower, 22.6% of all deaths were attributable to CVDs, while this was 35.2% for population aged 75 years and over. CHD is the major single cause of total deaths in the borough, with 14% in men and 11.2% in women. Stroke, the second commonest cause of CVD deaths, leads to 4.2% of all deaths in males and 9% in females. There are also inequalities in CVD mortality rates; for example, greater CVD mortality in the most deprived population group compared to the least deprived (849).
6.2 Implementation of the NHS Health Check in Hammersmith and Fulham

In Hammersmith and Fulham, the implementation of a CVD prevention programme was initiated ten months before the national schedule in July 2008. The programme was initially administered under a LES in the borough before the introduction of local QOF incentive scheme, called QOF+, in December 2008 (852). The Health Check administered under QOF+ (QOF+ Health Checks) was run for two financial years: Year 1 from 1st July 2008 to 30th November 2009 and Year 2 from 1st December 2009 to 31st March 2011 (853). The scheme was halted as initially scheduled in 2011 and it was therefore not continued after Year 2 (854). The implementation of the QOF+ Health Check programme showed differences between the two financial years (Figure 12), which will be detailed below. Following the QOF+, the NHS Health Check has been administered in GPs under LES. It is also worth to note that the programme has been delivered in pharmacies as well as GPs in the area from the second year of the programme (855,856).

![Figure 12: Differences between the target populations in the first two years of the NHS Health Check in Hammersmith and Fulham (Source: NHS Hammersmith and Fulham, 2009 and NHS Hammersmith and Fulham, 2010) (853,857)
This thesis will mainly present findings using QOF+ Health Check data and I now, therefore, would like to present details about the target populations, cardiovascular screening and management of CVD risk in Year 1 and Year 2 of the QOF+ Health Check programme. In Year 1, the programme targeted patients aged 32 to 74 years, who are not already diagnosed with diabetes and CVD, but included hypertension and CKD patients as opposed to the national programme for better management of these patients. The QOF+ Health Check target population in Year 1 included younger patients (32-74 years) than the national programme recommended age-range (40-74 years); the reason for this is that the premature mortality rates due to CVD disease in Hammersmith and Fulham are high and the PCT aimed to target this by screening and managing CVD risk in patients younger than 40 years. In Year 1, a targeted approach was used in screening and only patients, who are more likely to have an actual high CVD risk were included in the programme: estimated CVD risk scores were used to determine patients to be screened and those with a 20% or greater estimated risk of developing CVD within next 10 years were targeted. Estimated CVD risk scores (JBS2) are calculated using existing risk factor information already recorded on EMRs, substituting missing data with population estimates (852,858,859). The patients determined with an estimated high-risk were registered on the CVD at-risk register and sent formal invitation letters for screening. NHS Hammersmith and Fulham provided guidance and assistance to general practices on how to set the CVD at-risk register and implement the CVD prevention programme (858,860).

Patients who respond to invitations need to be screened and have their risk factors recorded into EMRs appropriately, as well as provided with appropriate risk management interventions, e.g. statins. The practices received incentives under the QOF+ based on their performance. In Year 1, practices received separate incentives for each risk factor recording and risk management indicator (Figure 13) (857,860). This suggests that healthcare staff might fail to complete all components essential for a proper assessment of CVD risk and management of risk factors under the Health Check, leading to having only a partial Health Check. The PCT provided guidance on recording the Health Check components on EMRs using appropriate Read-Codes, determining the completeness of each component of the Health Check and also the criteria of excluding patients from each indicator (exception reporting). There are situations that practices are unable to meet the criteria of indicator; for this reason, exception reporting is used in QOF schemes to prevent these situations affecting
the achievement of indicators. The main criteria for exception reporting of patients from +CVD PREVENT indicators in Year 1 are outlined in Figure 13 (857).

The target population of the QOF+ Health Check changed in Year 2 (Figure 12). In this financial year, 40 to 74 year old patients were targeted instead of 32 to 74 year old population. The reason for this change was that in the Year 1, a few patients from 32 to 39 year old age group were determined as being at high-risk and the PCT recommended practices to manage these younger patients separately (616). The rest of the population not screened in Year 1 was screened under two approaches, opportunistic and targeted. For the targeted approach, a cardiovascular high-risk register was set up; this register included 40 to 74 year old patients without existing diabetes and CVD, who were on QOF+ Year 1 CVD high-risk register and those, who had a 10-year CVD risk at 20% or over since the first day of Year 2 (1st December 2009). Practices were recommended to screen those on the high-risk register in two different approaches based on their risk level. Patients with an estimated risk of 30% and over were to be invited formally to practices to receive risk assessment and lifestyle advice for risk management, while those with a CVD risk between 20% and 30% recommended to be screened either by a pre-arranged appointment or opportunistically (616,853).

The second population who were to be screened in Year 2 consisted of patients aged 40 to 74 years without a diagnosed CVD, diabetes and hypertension and those who were not registered on CVD high risk registers (not identified as having CVD risk ≥ 20%), these patients can be called as well patients. This group of patients was not invited formally to have risk assessment, since they do not have a known high-risk. Practices were recommended to perform health checks to these well patients at three instances: opportunistically during the appointments for medication review or review for a chronic condition, during new patient registration appointments, or when patients apply to have a Health Check (616).

Patients, both high-risk and well patients, attending a health check in Year 2 were required to receive face-to-face risk assessment and have all the screening components (e.g. blood pressure, smoking status, blood glucose and etc.), defined in Figure 13 for QOF+ Year 2, recorded appropriately. The recorded risk factors were used to calculate the actual risk score (JBS2) as instructed by the PCT in QOF+ guidelines. QOF+ requires healthcare staff to communicate patients’ CVD risk appropriately and provide lifestyle advice on exercise and diet to all patients regardless their level of risk; statin prescribing must be considered only for
high-risk patients (*Figure 13*). In addition to basic lifestyle advices, patients with an elevated risk factor can also be referred to appropriate risk management services; for example, referral to fit for life, a weight management programme in Hammersmith and Fulham (616).

The guidance (Financial and Business rules) on recording of Health Check components on EMRs using appropriate Read-Codes and criteria for determining the completeness of the components of the QOF+ Health Check in Year 2 was provided to practices by NHS Hammersmith and Fulham (853). In Year 2, practices were required to enter Health Check completed Read-Code, when they complete a screening as opposed to Year 1, where there was not such a Read-Code. High-risk patients were considered for +HEALTH CHECK 1 indicator; in order for practices to receive payment for the performance achievement under this indicator, all components outlined in *Figure 13* need to be completed. Practices were rewarded points if they achieved a performance at 70% or greater. The rest of the population were considered for +HEALTH CHECK 2 indicator. Since the programme is a five-year rolling programme, all of the well population needs to be screened over the remaining 4 years (Year 1 targeted only the high-risk patients). For this reason, practices were required to achieve at most 30% coverage in the first year. They were awarded full points for this achievement, although there were also extra incentives for practices achieving higher coverage of 30% to 45% (853).

Finally, the exception reporting criteria for both two Year 2 Health Check indicators were outlined by the PCT (*Figure 13*). For +HEALTH CHECK 1 and 2 indicators, patients were excluded if they declined CVD risk assessment in the reference period, did not respond to three subsequent invitations, and did not attend booked health check appointments or respond to efforts of practice staff to rebook the appointment. The practices were required to appropriately record the exception codes on the patients’ EMRs (853).

<table>
<thead>
<tr>
<th>QOF+ YEAR 1</th>
<th>QOF+ YEAR 2</th>
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<tr>
<td><strong>+CVD PREVENT 1-6</strong>&lt;br&gt;8 Points for 40-90% achievement&lt;br&gt;Percentage of 32 to 74 year old patients at high-risk* who have the following individual risk factors recorded within 17 months prior to Year 1 end date (since 1st July 2008 inclusive).&lt;br&gt;<strong>Screening Components</strong>&lt;br&gt;Blood Pressure (+CVD PREVENT 1) / BMI (+CVD PREVENT 2) / Total and HDL cholesterol (+CVD PREVENT 3) / Fasting blood glucose (+CVD PREVENT 4) / Family history of CHD in first degree relatives (+CVD PREVENT 5) / Family history of diabetes in first degree relatives (+CVD PREVENT 6)</td>
<td><strong>+HEALTHCHECK 1</strong>&lt;br&gt;40 Points for 70-95% achievement&lt;br&gt;Percentage of 40 to 74 year old patients at high-risk* who have had all the following components of the Health Check completed within 33 months prior to Year 2 end date (since 01 July 2008 inclusive).&lt;br&gt;<strong>Screening Components</strong>&lt;br&gt;- Smoking status&lt;br&gt;- Ethnicity&lt;br&gt;- Blood pressure&lt;br&gt;- BMI&lt;br&gt;- Random total and HDL cholesterol&lt;br&gt;- Blood glucose&lt;br&gt;- Family history of diabetes and premature CHD in a first degree relative&lt;br&gt;- Actual cardiovascular score predicted by JBS 2&lt;br&gt;<strong>Risk Management Components</strong>&lt;br&gt;- Lifestyle advice on exercise&lt;br&gt;- Lifestyle advice on appropriate dietary changes&lt;br&gt;- Offer of Statin prescription if clinically appropriate</td>
</tr>
<tr>
<td><strong>+CVD PREVENT 7,8</strong>&lt;br&gt;10 Points for 40-90% achievement&lt;br&gt;Percentage of 32 to 74 year old at high-risk* who have the following individual risk factors recorded within 17 months prior to Year 1 end date (since 1st July 2008 inclusive).&lt;br&gt;<strong>Risk Management Components</strong>&lt;br&gt;Lifestyle advice on exercise and appropriate dietary changes (+CVD PREVENT 7) / Offer of Statin prescription if clinically appropriate (+CVD PREVENT 8)</td>
<td><strong>+HEALTHCHECK 2</strong>&lt;br&gt;63 Points for 5-30% achievement / 23 Extra Points for 30-45% achievement&lt;br&gt;Percentage of population aged 40 to 74 years without high risk who have had all the following components of the Health Check completed within 16 months prior to Year 2 end date (since 1 December 2009 inclusive).&lt;br&gt;<strong>Screening Components</strong>&lt;br&gt;- Smoking status&lt;br&gt;- Ethnicity&lt;br&gt;- Blood pressure&lt;br&gt;- BMI&lt;br&gt;- Random total and HDL cholesterol&lt;br&gt;- Blood glucose&lt;br&gt;- Family history of diabetes and premature CHD in a first degree relative&lt;br&gt;- Actual cardiovascular score predicted by JBS 2&lt;br&gt;<strong>Risk Management Components</strong>&lt;br&gt;- Lifestyle advice on exercise&lt;br&gt;- Lifestyle advice on appropriate dietary changes&lt;br&gt;- Offer of Statin prescription if clinically appropriate</td>
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**Exception Reporting**:<br>1- Patients who had recording of CVD risk score at or greater than 20% within last three months prior to the end date of Year 1. (Applicable to only +CVD PREVENT indicators)<br>2- Patients who declined the Health Check offer during the reference period.<br>3- Patients who do not respond to serial invitations for a Health Check.<br>4- Patients who fail to attend a Health Check appointment and do not respond to attempts to rebook the appointment.

* Patients on CVD At-Risk Register who have a 10-year cardiovascular risk equal to and greater than 20%<br>** Applicable to both QOF+ Year 1 and Year 2, unless stated
Chapter 7: Assessment of Recording and Level of Cardiovascular Risk Factors Prior to the NHS Health Checks in an Urban Setting: Cross-sectional Study

7.1 Introduction

The completeness of CVD risk factor recording in general practice records has considerable implications for the Health Check programme. Some PCTs might prioritize screening for patients with higher estimated CVD risk based on the existing medical records (861). For instance, in Hammersmith and Fulham, patients with an estimated CVD risk score of $\geq 20\%$ were targeted in the first year of the programme (862). Although CVD risk can be estimated with incomplete risk factor data, more complete data give better sensitivity and specificity of estimation (258). More complete risk factor data leads to more accurate prioritisation of high-risk patients. As well as for better quality patient care, complete primary care data is essential for secondary analysis, when combined and for public health surveillance, when associated with other health datasets (863).

Completeness of CVD risk factor recording is also important for the potential workload implications of the programme for general practice. The Department of Health expects from NHS Health Check providers to carry out and record all fundamental components of the programme in one encounter (195); CVD risk factor data recorded before the Health Check date would be counted as invalid (864). Even if a CVD risk factor is already on records, it should be re-measured and re-recorded when appropriate (e.g. if smoking status is not different from the already recorded, there is no need to re-record it). However, in practice, previously recorded information is used to assess cardiovascular risk. If this is adopted by Health Check providers, the workload of the Health Check would be dependent on the completeness of medical records existing before the programme.

Since the implementation of the QOF in general practice in 2004, there has been an improvement in CVD risk factor recording in areas covered by QOF indicators. Recording of CVD risk factors improved in patients with established CVD in the early stages of the QOF (321,865). In diabetes patients, recording of blood pressure, cholesterol, HbA1c, weight (866,867) and smoking status (868) also improved following the introduction of the QOF. There might however be improving patterns in risk factor recording prior to the implementation of the QOF in 2004. For example, in Wandsworth, south London, the
improvement in blood pressure recording was continuous from 1997 onwards till 2007 in CVD patients; recording increased from 40.3% to 91.7% between 1997 and 2007 (869). There was improvement also in recording of lipid levels (from 31.6% to 93.1%) in the same region over a similar time period, from 1998 to 2007 (870). There were increases in the measurement and recording of blood pressure, HbA1c and lipid levels from 1997 to 2005 in patients with established diabetes (both type I and II) (871). Whatever the source of the improvement in medical recording, evidence demonstrates obvious enhancements in the completeness of medical records, with many close to complete, in patients with chronic diseases.

Risk factor recording in patients without existing CVD is poorer, except for risk factors covered by the QOF indicators for primary prevention (smoking status and blood pressure recording). A cross-sectional study covering all general practices in England reported that in 2007, 3 years after the introduction of the QOF, 88.3% of all registered patients aged over 45 years had a blood pressure recording within last five years (872). Blood pressure recording, the achievement in the indicator covering blood pressure recording for primary prevention (609), improved since the introduction of QOF (872). In Wandsworth, south London, as well as the patients with established CVD, patients aged 45 years and over without existing CVD experienced an increase in the recording of blood pressure measured within last 12 months between 1998 and 2007, with an increase in recording from 13.0% to 36.6% (869). As in patients with a chronic condition, improvement in blood pressure recording might start from prior to the introduction of the QOF. Evidence demonstrated high recording of blood pressure in two general practices in West Midlands before the QOF, in 2002 and 2003, although recording of lipid levels was poor (257).

A study using data extracted from EMRs of general practices in North West London, Ealing, between 2008 and 2009 showed that among the patients aged 35 to 74 years without established CVD and diabetes, the blood pressure recording in the past 5 years was greater (85.6%) compared to recording of other clinical risk factors like BMI (72.8%) and lipid levels (59.9%), which are not covered by QOF indicators. In the same population, 95.9% of all patients had smoking status recorded (873); this might be due to the QOF indicator covering the recording of smoking status in all general population over the age of 15 years (609).
Although the evidence is scarce, there are patient and practice level inequalities in the recording of CVD risk factors. In a nationwide study (872), there was lower blood pressure recording in more deprived areas just after the introduction of the QOF (82.8% recording in the least deprived areas compared with 81.1% in the most deprived areas in 2004-2005), but this small difference further reduced after three years (87.9% recording in the least deprived areas compared with 87.7% in the most deprived areas in 2006-2007), possibly with the impact of the QOF payments (872). However, in a local study (873), the opposite relation was observed, with greater blood pressure and lipid level recordings in patients living in the most deprived areas compared to those in more affluent areas. These data were from 2008 (four years after the QOF implementation) and the QOF possibly have played a role in closing the disparity gap between deprived and affluent groups, even leading deprived groups to be more advantageous. Another patient level disparity was between genders, with lower blood pressure, cholesterol, BMI and smoking recording in men than women. In the same local study, Dalton et al. reported better blood pressure and cholesterol recording in South Asian patients without existing CVD and diabetes (873). An earlier study, however, showed that recording of risk factors, including smoking, blood pressure and alcohol consumption, was similar between white and Bangladeshi, as well as other different ethnic groups (white, black, and Chinese or Vietnamese) (552). Variation in risk factor recording due to practice level characteristics was also reported in the literature: Ashworth et al. (872) observed lower blood pressure recording in practices with larger proportion of black patients, located in less deprived areas, with greater number of GPs and with larger list size per GP.

There is very little up to date information on the completeness of CVD risk factor recording in the UK general practice. The aim of this study was to examine the recording and level of risk factors before the implementation of the Health Check in NHS Hammersmith and Fulham, and to examine how recording varies with patient and practice characteristics.

7.2 Methods

7.2.1 The NHS Health Check in NHS Hammersmith and Fulham

The details on the implementation of the NHS Health Check in NHS Hammersmith and Fulham under the local QOF+ scheme are described in Chapter 6.2. NHS Hammersmith and Fulham targeted to offer the Health Checks to patients with an estimated high-risk (≥ 20% risk of a CVD event within next 10 years) in the first year of the programme (858). Although
the national guidance for the NHS Health Check programme requires *de novo* recording of all components of programme (including CVD risk factors), in NHS Hammersmith and Fulham, it was not compulsory to record all CVD risk factors and other components of the Health Check in order to receive financial incentives under the QOF+. The recording of every single component of the programme within the first financial year (within last 17 months - between 1st July 2008 and 30th November 2009) was incentivised separately (857). However, for receiving incentives under QOF+, in the second year of the Health Checks in the area, all Health Check components were required to be complete and recorded within the second financial year (within last 16 months - between 1st December 2009 and 31st March 2011) for patients with estimated low- and medium-risk and since the start of the first financial year (within last 33 months – between 1st July 2009 and 31st March 2011) for those with estimated high risk (*Figure 13*) (853).

### 7.2.2 Study sample and data

I obtained baseline data for the Health Check programme that were extracted automatically from EMRs of patients registered in 28 of the 31 general practices in Hammersmith and Fulham using the Oberoi Clinical Observations software. These included Read-Coded data of patients aged 40 to 74 years, registered in practices on 31st June 2008 and not already on CVD (CHD, stroke/TIA and atrial fibrillation) or diabetes registers. Although the national programme excludes hypertensive and CKD patients, they were included in the first year of the QOF+ Health Checks, to improve disease management in these patients. Extracted data included demographic information (e.g. age, sex, ethnicity); clinical information (e.g. BMI, blood pressure, disease status); prescribing data; and date of recording of each element. I extracted the data on the most recent recording of each CVD risk factor from the dataset. In this study, I was interested in assessing the proportion of patients with recording of five most significant risk factors for CVDs, namely blood pressure, BMI, blood glucose, lipid ratio and smoking. NHS Health Check requires up to date measurement of these risk factors; therefore, I reported the proportion of patients with a CVD risk factor recorded within last 5 years.

### 7.2.3 Outcome measures

The outcome measures of the study were the recording and level of CVD risk factors: blood pressure, cholesterol, glucose, BMI and smoking status.
7.2.4 Predictor variables

I divided age into four groups of 40-44, 45-54, 55-64 and 65-74 years, with reasonable number of patients in each group. I used the 2001 UK Census for ethnicity classification, but condensed 17 categories, 16 ethnicity categories and one category for “not stated”, into ten categories due to small numbers (Appendix 1 - Table 28). I included patients with missing ethnicity in the category of those who did not want to state their ethnicity. I obtained disease status for hypertension and CKD, as well as family history for CHD. I also obtained data on asthma, mental health, depression, hypothyroidism, chronic obstructive pulmonary disease (COPD) status and classified patients with one or more of these comorbidities as having non-CVD co-morbidity. I assumed variables as null, if data, for example smoking status, BMI (to determine overweight group), non-CVD disease groups, were missing. Each patient was assigned a deprivation score (IMD 2007) that is an English composite, area level measure of deprivation based on postcode of residency. I divided patients into local thirds of deprivation (where 1 is the most deprived). As well as patient level predictor variables, I included a number of practice level factors into my analysis. I obtained postcodes for each practice and worked out IMD 2007 scores for each practice; I split practices into local thirds of deprivation (where 1 is the most deprived) to produce categories with similar number of individuals. I obtained practice list size, number of full-time equivalent (FTE) GPs in each practice and QOF performance indicators for each practice; one indicator from each of the clinical, patient experience and additional services domains.

7.2.5 Statistical analysis

I assessed characteristics of the study population and levels of CVD risk factors, blood pressure, cholesterol, glucose and BMI, and smoking status, with univariable analysis. I calculated age-standardised risk factor levels by direct-standardisation to examine risk factor levels between gender groups. I, again, used univariable methods to examine overall recording of CVD risk factors and variation in risk factor recording between practices and patients.

I, also, examined the recording of CVD risk factors using multilevel logistic regression analysis. I tested each variable individually for the best fitting model structure; no level 2 structure, random effects or random slope model, using Akaike Information Criterion (AIC) (875) to compare. Random effects models provided the best fit for all variables. I used
random effects models with patient variables at level 1 and practice at level 2 in the final model. Recent evidence has suggested that model selection methods produce poorly performing models, which are unstable and not reproducible (876–878). I, therefore, used regression models including all variables eligible for selection.

For each CVD risk factor, I built three sets of models; one with only patient level variables, one with only practice level variables, and one with both patient and practice level variables to examine the relative impact of practice and patient level variables on CVD risk factor recording. I determined an estimate of variance at level 1 ($\sigma_\mu$), the Median Odds Ratio (MOR) (879) and Intra-class Correlation Coefficient (ICC) (880) to quantify the variance in risk factor recording at practice or patient level. MOR is suggested as a good measure of level 2 variance compared to $\sigma_\mu$ (879), it shows the odds ratio of risk factor recording between two randomly selected practices.

Analyses were carried out using Stata version 11.1. Ethical approval for the study was granted from National Research Ethics Service Committee.

7.3 Results

7.3.1 General characteristics of the study population

Characteristics of the patient population are presented in Table 2. In 28 practices, 42 306 patients (19 561 male and 22 745 female) were aged 40 to 74 years and eligible for a Health Check. The mean age of the study population was 52.2 years. 77.7% had a valid ethnicity record and 35.9% of these patients were white British, 2.5% South Asian (Indian, Pakistani and Bangladeshi) and 8.6% black African and Caribbean. The percentage of patients with hypertension was 15.4% and CKD was 3.0%.

7.3.2 Variation in risk factor recording between practices and patients

There was a considerable variation in risk factor recording by patient and practice characteristics (Table 2 and Figure 14). A high proportion of patients (86.1%) had smoking status recorded within the last 5 years, but there was a high variation in recording between practices (range = 67.4–98.1%) (Figure 14). Blood pressure recording was also high with 82.5% of all patients having a record and the inter-practice variation in blood pressure recording was more moderate (range = 70.7–93.9%). A lower proportion (59.5%) of patients
had BMI recording, with large variation between practices (range = 29.4–91.5%). Cholesterol and glucose were also less well recorded, with 47.5% of patients having a cholesterol measurement and 47.2% having a glucose measurement.
Table 2: Characteristics of the study population and the recording of blood pressure, cholesterol, glucose, BMI and smoking status within last 5 years

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Number of Patients (%)</th>
<th>Blood Pressure (% recorded)</th>
<th>Cholesterol (% recorded)</th>
<th>Glucose (% recorded)</th>
<th>BMI (% recorded)</th>
<th>Smoking (% recorded)</th>
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<td></td>
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<td>19 561 (46.2)</td>
<td>78.3</td>
<td>44.4</td>
<td>42.0</td>
<td>57.9</td>
<td>84.8</td>
</tr>
<tr>
<td>Female</td>
<td>22 745 (53.8)</td>
<td>85.9</td>
<td>49.5</td>
<td>51.1</td>
<td>60.7</td>
<td>87.5</td>
</tr>
<tr>
<td><strong>Age</strong></td>
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<td></td>
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<tr>
<td>40-44</td>
<td>11 271 (26.4)</td>
<td>73.1</td>
<td>31.2</td>
<td>34.5</td>
<td>58.9</td>
<td>84.7</td>
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<tr>
<td>45-54</td>
<td>15 473 (36.2)</td>
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<td>42.8</td>
<td>43.1</td>
<td>57.3</td>
<td>84.3</td>
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<tr>
<td>55-64</td>
<td>10 313 (24.1)</td>
<td>87.4</td>
<td>59.1</td>
<td>55.7</td>
<td>59.8</td>
<td>87.9</td>
</tr>
<tr>
<td>65-74</td>
<td>5 649 (13.2)</td>
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<td>70.2</td>
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<td>92.0</td>
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<td>91.1</td>
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<td>65.4</td>
<td>91.0</td>
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<td>52.0</td>
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<td>92.1</td>
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<td>Practice register size</td>
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<td>6000&gt;PS&gt;3500</td>
<td>12 377 (29.3)</td>
<td>86.3</td>
<td>53.9</td>
<td>52.7</td>
<td>72.3</td>
<td>89.7</td>
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<td>10 000&gt;PS&gt;6000</td>
<td>15 346 (36.3)</td>
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<td>41.1</td>
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<td>52.0</td>
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<td>69.9</td>
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<tr>
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<td>3&lt;FTEGP≤7</td>
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<td>40.4</td>
<td>54.9</td>
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<tr>
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<td>51.1</td>
<td>81.0</td>
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<td>63.9</td>
<td>89.6</td>
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<tr>
<td></td>
<td>2</td>
<td>15 005 (35.5)</td>
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<td>46.0</td>
<td>49.0</td>
<td>54.3</td>
<td>81.5</td>
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<td>3</td>
<td>8701 (20.6)</td>
<td>82.5</td>
<td>41.5</td>
<td>36.8</td>
<td>58.6</td>
<td>87.2</td>
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<tr>
<td>Total</td>
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<td>42 306</td>
<td>82.5</td>
<td>47.5</td>
<td>47.2</td>
<td>59.5</td>
<td>86.1</td>
</tr>
</tbody>
</table>

a Indices of Multiple Deprivation 2007 - local third (1 most deprived)
b Non-CVD comorbidities – asthma, chronic obstructive pulmonary disease, depression, mental health, hypothyroidism
c Patients with either no ethnicity recording or patients who did not want to state their ethnicity
Figure 14: The practice level variation in recording of cardiovascular disease risk factors within last 5 years

Risk factor recording showed variation across patients with different characteristics (Table 2 and Table 3). A significantly higher proportion of women had blood pressure, cholesterol, BMI, glucose and smoking status recording than men (for blood pressure, AOR = 1.70; [95% Confidence Interval (CI), 1.61–1.80]). There was significantly higher risk factor recording, except BMI and smoking status, in older patients than younger (65–74 years compared to 40–44 years). BMI recording was significantly lower in older individuals than younger (AOR = 0.91; [95% CI, 0.84–0.98] in 65 to 74 years old patients compared to 40 to 44 years). Patients from black Caribbean and black African ethnic backgrounds had higher risk factor recording than white British patients (for blood pressure, AOR = 1.22; [95% CI, 1.02–1.47] in black Caribbean compared with white British). Patients from other white and mixed ethnic backgrounds had all risk factors, except blood pressure, recorded better than white British. Bangladeshi patients had higher cholesterol, glucose and BMI recording than white British (for cholesterol, AOR = 2.21; [95% CI, 1.36–3.59]). Indian and Pakistani patients had higher cholesterol and glucose recording than white British. Patients without a valid ethnicity record had lower recording of all risk factors than white British. All risk factors were less well recorded in the least deprived patient group compared with the most deprived (for blood
pressure, AOR = 0.79; [95% CI, 0.73–0.85]). Hypertension and CKD were strongly and positively associated with risk factor recording (for cholesterol recording, AOR = 7.24; [95% CI, 6.67–7.86] in hypertensive patients and AOR = 6.19; [95% CI, 4.95–7.75] in CKD patients). Patients with non-CVD comorbidities had higher risk factor recording than patients without (for BMI, AOR = 1.53; [95% CI, 1.45–1.61]).

Practices with a practice size between 3500 and 6000 had higher glucose, BMI and smoking status recording than smaller practices (<3500) (for BMI, AOR = 2.40; [95% CI, 1.04-5.52]) (Table 3). There was no significant association between risk factor recording and practice level deprivation scores or practice scores on the QOF.
Table 3: Multivariable logistic regression analysis results of blood pressure, cholesterol, glucose, BMI and smoking status recording with practice level clustering

<table>
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<tr>
<th>Patient Characteristics</th>
<th>Blood Pressure</th>
<th>Cholesterol</th>
<th>Glucose</th>
<th>BMI</th>
<th>Smoking Status</th>
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<tr>
<td></td>
<td>AOR (95% CI)</td>
<td>AOR (95% CI)</td>
<td>AOR (95% CI)</td>
<td>AOR (95% CI)</td>
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</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
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<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
</tr>
<tr>
<td>Female</td>
<td>1.70 (1.61–1.80)</td>
<td>1.20 (1.15–1.25)</td>
<td>1.45 (1.39–1.52)</td>
<td>1.09 (1.05–1.14)</td>
<td>1.16 (1.09–1.23)</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-44</td>
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<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
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<tr>
<td>45-54</td>
<td>1.75 (1.65–1.87)</td>
<td>1.53 (1.44–1.61)</td>
<td>1.35 (1.28–1.43)</td>
<td>0.85 (0.81–0.90)</td>
<td>0.87 (0.81–0.94)</td>
</tr>
<tr>
<td>55-64</td>
<td>2.16 (2.00–2.33)</td>
<td>2.55 (2.40–2.71)</td>
<td>1.98 (1.86–2.10)</td>
<td>0.85 (0.80–0.90)</td>
<td>0.95 (0.88–1.04)</td>
</tr>
<tr>
<td>65-74</td>
<td>2.66 (2.37–2.98)</td>
<td>3.11 (2.87–3.36)</td>
<td>2.42 (2.24–2.61)</td>
<td>0.91 (0.84–0.98)</td>
<td>1.06 (0.94–1.19)</td>
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<td>Ethnicity</td>
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<td>1.00</td>
<td>1.00</td>
<td>1.00</td>
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<tr>
<td>Other White</td>
<td>0.90 (0.83–0.98)</td>
<td>1.08 (1.02–1.15)</td>
<td>1.12 (1.05–1.19)</td>
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<tr>
<td>Mixed</td>
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<td>1.25 (1.09–1.43)</td>
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<td>1.65 (1.41–1.93)</td>
<td>1.44 (1.10–1.89)</td>
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<td>2.14 (1.78–2.57)</td>
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<td>1.02 (0.75–1.39)</td>
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<td>1.61 (1.26–2.06)</td>
<td>1.15 (0.87–1.51)</td>
<td>0.72 (0.51–1.04)</td>
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<td>Bangladeshi</td>
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<td>2.21 (1.36–3.59)</td>
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<td>2.62 (1.34–5.12)</td>
<td>2.04 (0.63–6.57)</td>
</tr>
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<td>Black Caribbean</td>
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<td>1.32 (1.17–1.48)</td>
<td>1.51 (1.35–1.70)</td>
<td>1.40 (1.23–1.59)</td>
<td>1.41 (1.13–1.76)</td>
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<td>1.65 (1.48–1.85)</td>
<td>1.82 (1.61–2.06)</td>
<td>1.29 (1.07–1.56)</td>
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<td>Other ethnic group</td>
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<td>0.56 (0.53–0.60)</td>
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<td>1.00</td>
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<tr>
<td>No</td>
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</tr>
<tr>
<td>Yes</td>
<td>5.50 (4.67–6.46)</td>
<td>7.24 (6.67–7.86)</td>
<td>4.93 (4.58–5.30)</td>
<td>2.22 (2.06–2.38)</td>
<td>7.48 (6.16–9.09)</td>
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<td>Chronic Kidney</td>
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<td>Yes</td>
<td>3.37 (2.38–4.77)</td>
<td>6.19 (4.95–7.75)</td>
<td>5.08 (4.14–6.24)</td>
<td>1.38 (1.19–1.59)</td>
<td>1.49 (1.15–1.92)</td>
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<td>1.00</td>
<td>1.00</td>
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</tr>
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</tr>
<tr>
<td>comorbidities(^b)</td>
<td>No</td>
<td>2.06 (1.91–2.22)</td>
<td>1.71 (1.63–1.80)</td>
<td>1.82 (1.73–1.92)</td>
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</tr>
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<td>Yes</td>
<td>1.65 (1.49–1.83)</td>
<td>1.66 (1.55–1.78)</td>
<td>1.34 (1.30–1.49)</td>
<td>1.73 (1.61–1.86)</td>
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### Practice Characteristics

<table>
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<tr>
<th>Practice register size</th>
<th>&lt;3500</th>
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<tr>
<td>Practice IMD(^a)</td>
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<tr>
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<tr>
<td>2</td>
<td>0.78 (0.57–1.07)</td>
<td>0.91 (0.69–1.18)</td>
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<td>0.67 (0.38–1.20)</td>
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<tr>
<td>3</td>
<td>1.19 (0.79–1.79)</td>
<td>0.82 (0.59–1.15)</td>
<td>0.89 (0.57–1.39)</td>
<td>1.55 (0.74–3.25)</td>
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<td>QOF Indicators</td>
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<td>CHD8(^c)</td>
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<td>1.00 (0.99–1.02)</td>
<td>1.00 (0.98–1.01)</td>
<td>0.99 (0.96–1.02)</td>
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<td>PE07(^d)</td>
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<td>1.00 (0.98–1.01)</td>
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<td>CS1(^e)</td>
<td>0.99 (0.98–1.00)</td>
<td>1.00 (0.99–1.02)</td>
<td>0.99 (0.98–1.01)</td>
<td>0.98 (0.96–1.01)</td>
</tr>
</tbody>
</table>

\(^a\) Indices of Multiple Deprivation 2007 - local third (1 most deprived)

\(^b\) Discordant comorbidities – asthma, chronic obstructive pulmonary disease, depression, mental health, hypothyroidism

\(^c\) CHD08 - The percentage of patients with coronary heart disease, whose last measured total cholesterol (measured in the previous 15 months) is 5 mmol/l or less

\(^d\) PE07 - the percentage of surveyed patients who said they could get an appointment with their practice within 48 hours of requesting one

\(^e\) CS01 - The percentage of patients aged from 25 to 64 (in Scotland from 21 to 60) whose notes record that a cervical smear has been performed in the last five years

Note: Odd ratios are adjusted for all variables in the table
7.3.3 Is the variation in risk factor recording predominantly attributable to practice or patient level factors?

Measures of heterogeneity in risk factor recording due to practice and patient level characteristics are shown in Table 4. MOR, ICC and $\sigma_\mu$ were greater in regression models with only patient level characteristics compared to those in models with only practice level characteristics, and both practice and patient level characteristics. The variation in risk factor recording is more strongly associated with patient level characteristics than practice level characteristics.

Table 4: The heterogeneity in the cardiovascular disease risk factor recording when adjusted for patient level, practice level, and both patient and practice level characteristics

<table>
<thead>
<tr>
<th></th>
<th>Patient level model</th>
<th>Practice level model</th>
<th>Practice and patient level model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Blood pressure</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\sigma_\mu$ (95% CI)</td>
<td>0.41 (0.31–0.54)</td>
<td>0.38 (0.29–0.50)</td>
<td>0.34 (0.26–0.46)</td>
</tr>
<tr>
<td>ICC</td>
<td>0.111</td>
<td>0.104</td>
<td>0.094</td>
</tr>
<tr>
<td>MOR</td>
<td>1.87</td>
<td>1.82</td>
<td>1.77</td>
</tr>
<tr>
<td><strong>Cholesterol</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\sigma_\mu$(95% CI)</td>
<td>0.37 (0.28–0.49)</td>
<td>0.28 (0.21–0.37)</td>
<td>0.29 (0.22–1.39)</td>
</tr>
<tr>
<td>ICC</td>
<td>0.101</td>
<td>0.078</td>
<td>0.081</td>
</tr>
<tr>
<td>MOR</td>
<td>1.81</td>
<td>1.67</td>
<td>1.69</td>
</tr>
<tr>
<td><strong>Glucose</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\sigma_\mu$ (95% CI)</td>
<td>0.46 (0.35–0.60)</td>
<td>0.37 (0.28–0.49)</td>
<td>0.38 (0.29–0.51)</td>
</tr>
<tr>
<td>ICC</td>
<td>0.123</td>
<td>0.101</td>
<td>0.104</td>
</tr>
<tr>
<td>MOR</td>
<td>1.94</td>
<td>1.81</td>
<td>1.82</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>$\sigma_\mu$ (95% CI)</td>
<td>0.83 (0.64–1.09)</td>
<td>0.63 (0.48–0.82)</td>
<td>0.65 (0.49–0.84)</td>
</tr>
<tr>
<td>ICC</td>
<td>0.201</td>
<td>0.161</td>
<td>0.165</td>
</tr>
<tr>
<td>MOR</td>
<td>2.43</td>
<td>2.17</td>
<td>2.19</td>
</tr>
<tr>
<td><strong>Smoking Status</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>$\sigma_\mu$ (95% CI)</td>
<td>0.56 (0.42–0.74)</td>
<td>0.45 (0.34–0.60)</td>
<td>0.45 (0.33–0.59)</td>
</tr>
<tr>
<td>ICC</td>
<td>0.145</td>
<td>0.120</td>
<td>0.120</td>
</tr>
<tr>
<td>MOR</td>
<td>2.07</td>
<td>1.92</td>
<td>1.92</td>
</tr>
</tbody>
</table>

$\sigma_\mu$ – Estimated Variance
ICC – Intra-class Correlation Coefficient
MOR – Median Odd Ratio
95% CI – 95% Confidence Interval
7.3.4 Level of cardiovascular risk factors

Mean levels of CVD risk factors are presented in Table 5. Mean levels of systolic and diastolic blood pressure were significantly higher in men. Significantly more men had high blood pressure (≥140/90 mmHg) compared with women (29.7%; [95% CI, 29.1–30.4] compared to 19.8%; [95% CI, 19.3–20.3]). Age-adjusted mean cholesterol and BMI levels were not significantly different between men and women (for BMI 26.6 kg/m²; [95% CI, 25.5–26.7] compared to 26.7 kg/m²; [95% CI, 26.6–26.8]), but a higher proportion of men had high glucose levels (≥6.0 mmol/l) and more men were overweight or obese (BMI ≥25kg/m²) compared with women. Proportion of women (32.6%; [95% CI, 32.0–33.2]) with raised total cholesterol was higher than in men (27.2%; [95% CI, 26.6–27.9]). Smoking prevalence was higher in men than women (26.1%; [95% CI, 25.5–26.7] compared to 18.8%; [95% CI, 18.3–19.3]).

<table>
<thead>
<tr>
<th>Table 5: Age standardised mean levels of cardiovascular disease risk factors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Risk Factor</strong></td>
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<tr>
<td><strong>Blood pressure</strong></td>
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<tr>
<td></td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>Cholesterol</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Glucose</strong></td>
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<tr>
<td></td>
</tr>
<tr>
<td><strong>BMI</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>Smoking</strong></td>
</tr>
</tbody>
</table>
7.4 Discussion

7.4.1 Main findings

Smoking status and blood pressure were well recorded in patients eligible for the NHS Health Check in Hammersmith and Fulham, a culturally and socio-economically diverse area in London. The variation in risk factor recording between practices was large. Variation in risk factor recording was more strongly associated with characteristics of the study population than practice level factors. Recording of risk factors varied in patients with different characteristics. Women had better risk factor recording than men, older individuals had higher blood pressure, cholesterol and glucose recording than the younger. Patients living in more deprived areas were more likely to have a risk factor recording. Black patients had higher risk factor recording than white patients; likewise South Asian (Indian, Pakistani and Bangladeshi) patients had more complete cholesterol and glucose recording. Having co-morbid diseases (e.g. hypertension, CKD, asthma) was also a strong determinant of risk factor recording.

7.4.2 Comparison with existing literature and explanation of findings

The high blood pressure recording in my study was consistent with the findings of the previous work, which reported very high blood pressure recording in individuals older than 45 years without chronic disease and an improvement in blood pressure recording after the introduction of the QOF (872). Poorer BMI and cholesterol recording confirms the previous evidence, which showed less complete BMI and cholesterol recording in individuals aged 32 to 74 years without CVD and diabetes (873). Although the size of the financial incentives for the QOF indicators covering blood pressure and smoking recording in those without existing diseases is modest, I showed that the recording of these risk factors was better than other risk factors; cholesterol, glucose and BMI. The QOF may, therefore, play a role in the better recording of blood pressure and smoking.

Dalton et al. (873) found better cardiovascular risk factor recording in women and that variation in recording is largely due to the differences in patient characteristics, consistent with my study. The better risk factor recording in women than men, despite greater CVD risk in men than women (286), might be due to the higher consultation rates in women than men, especially those at reproductive ages (777). The greater risk factor recording in older individuals than younger may also be attributable to the higher GP consultation rates in older
individuals (881) and the QOF incentives for risk factor recording in older individuals (609). Although evidence of better risk factor recording in deprived patients is limited, Lyratzopoulos et al. (455) reported that deprived patients had better BMI and smoking status recording. GPs working in deprived areas perceive patients to be at greater risk of CVD (882), therefore may be more likely to record CVD risk factors. Increasing emphasis on policies to reduce inequalities in CVDs may also be another factor that promoted the improved recording of risk factors in deprived areas (598,883,884).

Unlike previous studies, my study presents variation in cardiovascular risk factor recording in a wide range of ethnic groups. I illustrated that Black Caribbean and African patients have better recording of all risk factors than white British patients, while Dalton et al. (873) reported only cholesterol recording was better in Black patients. Whilst I showed that south Asian patients have better recording of cholesterol and glucose, Dalton et al. (873) suggested that south Asians have better cholesterol and blood pressure recording. The higher GP consultation rates of Black and South Asian people (782) and GPs’ perception of greater CVD risk in Black and South Asian people (885) may have a role in the greater risk factor recording in these populations.

I illustrated that patients with non-CVD comorbidities are more likely to have CVD risk factors recorded. This may be due to more frequent attendance to general practice for regular review of co-morbid conditions. My findings support previous work, which suggests that hypertensive patients are more likely to have CVD risk factor recording (873). In hypertensive patients, GPs’ perception of higher CVD risk in these patients and larger size of the QOF incentives for recording of risk factors (609) may also play a role in the better risk factor recording.

7.4.3 Implications for policy and clinical practice, and future research

My findings show incomplete recording of risk factors particularly glucose, cholesterol and BMI, suggesting that the recording of risk factors for cardiovascular disease risk assessment will generate a large workload for primary care teams. This is particularly the case, if we assume that de novo recording of all data is required. However, this was not a requirement in the first year of the Health Check in Hammersmith and Fulham under the terms of a local financial incentive programme (QOF+).
Attention to the prevention of CVD has grown worldwide. A number of prevention initiatives have recently been introduced; for example the “Million Hearts” initiative in US (886) and the Canadian Heart Health Strategy and Action Plan (560), but none have had the scope of the UK’s NHS Health Check. The latter involves primary care teams offering health checks to specific patient groups, but not the entire population (887). Work presented here suggests that considerable efforts will be required and that additional support to primary care teams may be required to facilitate improved risk factor recording.

A high proportion of the study population is overweight and obese, have raised blood pressure and cholesterol levels. Efforts must be made by primary care teams to manage CVD risk factors effectively. Early findings suggest that the uptake of statins, in eligible patients, after the Health Check was low (415). The strong uptake and adherence to interventions is vital for the management of the large burden of CVD risk factors found here and in turn for the success of the programme. The uptake of both the initial Health Check and subsequent interventions must be further monitored across different settings, and as the programme progresses.

I have shown that a higher proportion of men are overweight and obese, and have raised blood pressure and higher glucose levels than women. Although men have higher levels of CVD risk factors compared to women, they have lower attendance at general practice (881) and lower usage of preventative health care (888). Primary care teams must promote the Health Check attendance in male patients and ensure the appropriate management of their CVD risk. The management of this risk will generate a large workload for the Health Check programme, in addition to the workload of screening.

There are inequalities in CVD morbidity and mortality between ethnic and socio-economic groups. I found that the risk factor recording was the highest in ethnic groups at the greatest risk of CVD. However, the ethnicity recording was incomplete in general practices participating in our study. Hammersmith and Fulham is an ethnically diverse borough, accommodating small ethnic minorities and the recording must, therefore, be improved to enable commissioners to monitor the equality in delivery of the programme (846).

7.4.4 Strengths and limitations

The size of the study population was large, and the study covered most of the population eligible for the Health Check in one English PCT. I used the most recent data from patient
medical records and examined associations between risk factor recording and a number of patient and practice characteristics.

Patients from three practices could not be included due to low data returns, but the patients of these practices did not differ in their characteristics to our study population. Since all patients have universal access to primary care services, no patient group was excluded from the study. This study was based on a primary care population of a diverse area both in terms of deprivation and ethnicity, where CVD is common. The findings of this study cannot be generalised to the UK, but they may be similar to those in other urban areas with similar patterns of deprivation, ethnic diversity and a high burden of vascular disease. Another limitation concerning generalisation of the findings is that the Health Check programme delivered locally was modified to meet the needs of the local population (e.g. included hypertension and CKD patients in the first year of the programme for better management, although national programme excludes them). The findings may therefore not be generalizable to other areas that follow national minimum standards. Another weakness of this study is that I did not have complete ethnicity recording for the study population. An area deprivation score based on postcodes was used as a measure of SES for patients and practices. Other individual level measures of SES of patients, such as household income and education, might have better measured SES; however, these are not present in routine medical data. A practice level characteristic, number of FTE GP may be a potentially important covariate, but could not be included in multivariable analysis because of mathematical reasons. I however present its univariable associations. Other practice level characteristics, such as age, ethnicity and place of training of GPs, could be included in models to examine their association with risk factor recording, but were again unavailable.

7.5 Key points from Chapter 7

Patients without existing CVD and diabetes have low CVD risk factor recording in electronic medical records, although risk factor recording in individuals with chronic conditions has been increasing in the UK. Risk factor recording varies between practices and patients with different characteristics, but this variation is mostly associated with patient characteristics. CVD risk factors are elevated in a large proportion of patients without CVD and diabetes. The Health Check will generate a considerable workload for general practices through the management of patients with high CVD risk, as well as in the initial screening of patients.
Chapter 8: Uptake of the NHS Health Check Programme in an Urban Setting: a Cross-sectional Study

8.1 Introduction

The NHS Health Check, a national population based cardiovascular risk assessment and management programme, aims to address the huge burden of CVDs and reduce socio-economic, ethnic and gender inequalities in health (*Chapter 3.4*) (195,417). A high uptake of the NHS Health Check is essential for the programme to be successful in meeting its aim of reducing CVD burden. The cost-effectiveness modelling of the programme projected an annual uptake of 75% (417).

The Department of Health suggested that the Health Check will produce greater benefit in most vulnerable populations, who tend to have greater CVD risk (417). It has, however, been argued that strategies using a high-risk approach like the NHS Health Checks widen inequalities, benefiting less to those in greater need (159,407). Inequalities between population groups can appear at attendance to screening, uptake of and compliance to interventions and at any other stage during the prevention process (407). An equal uptake of screening is important for a prevention programme to not *worsen* inequalities in health. However, although an equal uptake of screening between groups is achieved, it is not possible to say that this will *reduce* inequalities in health outcomes. This is because reducing risk also depends on other factors related to the proceeding processes of CVD prevention programmes, including uptake and compliance to interventions (e.g. prescriptions) (*Chapter 2.9*) (407). The Department of Health guided commissioners to effectively address and reduce inequalities, when delivering the Health Check. Commissioners were recommended to ensure all population groups have access to the programme and to take further actions tailored to reduce health inequalities (623). While assessing the success of the NHS Health Check on health inequalities, it is therefore important to examine all aspects that would influence the success of the programme on reducing inequalities, including uptake of screening and interventions, and impact on CVD risk and other outcomes (*Chapter 10*).

Early local evaluations of the NHS Health Check programme reported an uptake ranging from 24.3% to 45% (415,416,794), which are well below the Department of Health anticipated uptake of 75%. Evidence from established preventive health services in the UK suggests that there may be variations in uptake with gender, age, SES and ethnicity (*Chapter
4.1). For instance, uptake may be lower in deprived groups compared with affluent, especially in the early development stages of the programmes (678). The early assessments of the Health Check uptake produced mixed results. Cochrane et al. (416) suggested lower uptake in those from affluent areas, consistent with the evidence from previous preventive health programmes. As oppose to the evidence suggesting lower screening uptake in ethnic minorities (Chapter 4.1.2.2), Dalton et al. (415) presented greater uptake in south Asian population and those with mixed ethnicity.

Financial incentives are increasingly employed to promote preventative interventions, such as smoking cessation, in primary care (889). General practices are commonly paid to screen and manage patients under the Health Check programme. Often simple payments, based on fee-for-service, are structured within a local enhanced service (LES). A small number of areas include the Health Check within a local quality outcomes framework (QOF), a more complex pay-for-performance framework (615). In NHS Hammersmith and Fulham, the Health Check programme was delivered under the local QOF+ for two financial years (from 2008 to 2011) (Chapter 6.2).

I aimed to assess the Health Check uptake, exclusions of patients from the programme (exception reporting) and statin prescriptions in the first two years of the programme in Hammersmith and Fulham, particularly examining the impact of the local QOF+ financial incentive scheme. I also examined whether uptake, exception reporting and statin prescriptions within the programme differed between socio-demographic groups.

8.2 Methods

8.2.1 The NHS Health Check in NHS Hammersmith and Fulham

The details of the implementation of the Health Checks in NHS Hammersmith and Fulham under the local QOF+ scheme are outlined in Chapter 6.2. In summary, Year 1 (1 July 2008 – 30 November 2009) focused on those patients at estimated high-risk (≥ 20% JBS2 CVD risk within next 10-years) on the basis of existing data and Year 2 (1 December 2009 – 31 March 2011) focused on the remaining eligible population. The eligible patients in two years differed by age-range for eligible patients and disease groups excluded (Figure 12). To make my Year 1 data comparable to Year 2 and national data, I included patients aged 40 to 74 years without diabetes, CVD, hypertension and CKD, as per national guidance. In Year 1, practices were incentivised to complete each component of the Health Check individually for
90% of the population with estimated high-risk. In Year 2, practices were incentivised to provide a Health Check to 30% of the remaining population (Figure 13) (616,853).

8.2.2 Study sample and data

Data were extracted from EMRs in 27 of the 31 practices on all patients registered on 30\textsuperscript{th} November 2009 for Year 1 and in 29 practices on all patients registered on 31\textsuperscript{st} March 2011 in Year 2 using the Oberoi Clinical Observations software. Patients that were determined as eligible for the Health Check were included in the dataset (Chapter 7.2.2). In Year 1, patients aged 40 to 74 years, without an existing CVD, hypertension, diabetes and CKD, and with estimated high CVD risk were determined as eligible. In Year 2, the rest of the eligible population (40 to 74 year old population excluding those with diabetes, CVD, hypertension and CKD) with non-high estimated risk constituted the dataset.

For both years, data on demographic characteristics (e.g. age, sex, ethnicity), clinical characteristics (e.g. BMI, blood pressure, disease status), prescribing and exclusions from the Health Check that determine payments to general practices (exception reporting) (Chapter 6.2) (Figure 13) were extracted automatically from EMRs. Newly registered patients i.e. those registered with general practices in the last 3 months of the reference periods, were excluded, because there was insufficient time to complete a Health Check. The most recent record of each CVD risk factor was extracted.

8.2.3 Outcome measures

Uptake of a complete Health Check was the primary outcome, with exception reporting and prescription of statins in eligible patients (180) as secondary measures. The business rules of the local financial incentive scheme were applied to determine completeness of all the Health Check components and exception reporting (853).

In Year 1, the NHS Hammersmith and Fulham did not employ a Read-Code for the practices to indicate the attendance and completeness of the Health Checks. QOF+ scheme incentivised each component of the Health Checks separately in Year 1, not as a bundle as in Year 2 (857,862). For this reason, I determined the completeness of the Health Check based on the national guidance, in both Year 1 and Year 2 to make the data comparable; patients with all components of the Health Check were counted as having a complete Health Check. The
national criteria for determining Health Check uptake are outlined in Table 6 and three valid criteria for exception reporting of patients in Figure 13.

The Department of Health recommended Health Check providers to offer statins to patients with actual high risk, in line with the NICE guidance (180,348). NHS Hammersmith and Fulham incentivised statin prescription offers to high-risk patients, when it is appropriate (857). Although the PCT nominated Read-Codes to use if statin eligible patients were offered a prescription, it is questionable if prescription offers were appropriately reported. For the estimated high-risk group in Year 1, whose Health Check completeness is more likely to be influenced by statin offers, I performed a sensitivity analysis by including offers for statin prescription when determining the completeness of Health Checks (complete Health Check – Criterion 2).

Table 6: Criteria for completeness of the Health Check according to national criterion

<table>
<thead>
<tr>
<th>Completeness of recording of all:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Blood pressure</td>
</tr>
<tr>
<td>- Total and HDL cholesterol</td>
</tr>
<tr>
<td>- BMI</td>
</tr>
<tr>
<td>- Family history of CHD</td>
</tr>
<tr>
<td>- Ethnicity</td>
</tr>
<tr>
<td>- Smoking status</td>
</tr>
<tr>
<td>- Lifestyle advice on exercise and dietary change</td>
</tr>
<tr>
<td>- Statin prescribing (if appropriate) – included in sensitivity analysis for Year 1</td>
</tr>
</tbody>
</table>

8.2.4 Predictor variables

Age, sex, ethnicity, deprivation (IMD 2007 based on postcode of residency), family history of CHD, non-CVD comorbidities (asthma, mental health, depression, hypothyroidism and COPD), smoking status and practice list size were predictor variables.

I divided age into three groups (40-54, 55-64 and 65-74 years). I used the 2001 UK Census for ethnicity classification, but condensed 16 ethnicity categories plus one category for “not stated” into five due to small numbers (Appendix 1 - Table 28). I combined those with missing ethnicity with those who did not state their ethnicity and included them in the same
category. I divided patients into local thirds of deprivation using IMD 2007 scores (where 1 is the most deprived). Patients with one or more of non-CVD comorbidities were classified as having non-CVD co-morbidity.

8.2.5 Statistical analysis

I assessed characteristics of the study populations, the Health Check eligible patients in Year 1 and Year 2, and examined risk factor recording and level of risk factors in the eligible patients and those with a complete Health Check. I assessed factors predicting Health Check uptake, exception reporting and statin prescription in patient and practice subgroups. I firstly compared the unadjusted differences in the prevalence of outcomes using two-tailed t-test for proportions. Multi-level logistic regression was then used to examine the predictors of uptake, with adjustment for covariates. I built mixed models, with patient variables at level 1 and practice at level 2, including predictor variables described above. I tested each variable individually for the best fitting model structure; no level 2 structure, random effects or random slope model, using AIC to compare. Random effects models provided the best fit for all variables. I included all variables, using random effects, into the final model, not employing model selection (Chapter 7.2.5) (876,878). The amount of unexplained variance, a proxy for the differences between practices not attributable to their characteristics, in uptake and statin prescribing at the practice level was assessed by calculating MOR and variance partitioning coefficient (VPC); a large coefficient suggests marked practice level variation (890).

All analyses were conducted using Stata version 11.2 SE. Ethical approval was granted from National Research Ethics Service Committee, London – Queen Square.

8.3 Results

8.3.1 General characteristics of the study population

In the first year of the Health Check, 4748 patients aged 40 to 74 years with an estimated risk greater than 20% were targeted and the remaining 35 364 patients not at high estimated risk were eligible for the Health Check in Year 2 (Figure 15). Table 7 shows the characteristics of the eligible populations. In Year 1, the mean age of the eligible population was 60.9 years and more men (78.4%) than women were eligible for the programme. The mean age of the eligible population was 50.0 years and a higher proportion of women (54.8%) were eligible
in Year 2. A larger proportion of high-risk patients eligible for the Health Check in Year 1 were older and smokers compared to the non-high risk Health Check eligible group in Year 2 (e.g. about half (50.7%) of eligible population were smokers in Year 1, whilst only 21.1% of the eligible patients were smokers in Year 2).

Figure 15: Study participants who were eligible for and received a Health Check in Year 1 and Year 2
Table 7: Patient and practice characteristics of the study populations eligible for the NHS Health Check in the first two financial years of the programme (Year 1: July 2008 – November 2009 and Year 2: December 2009 – 31 March 2011)

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Year 1 - High risk</th>
<th>Year 2 - Others</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>3721</td>
<td>78.4</td>
</tr>
<tr>
<td>Female</td>
<td>1027</td>
<td>21.6</td>
</tr>
<tr>
<td>Age Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40–54</td>
<td>1035</td>
<td>21.8</td>
</tr>
<tr>
<td>55–64</td>
<td>2087</td>
<td>44.0</td>
</tr>
<tr>
<td>65–74</td>
<td>1626</td>
<td>34.2</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>3389</td>
<td>71.4</td>
</tr>
<tr>
<td>Black</td>
<td>277</td>
<td>5.83</td>
</tr>
<tr>
<td>South Asian</td>
<td>137</td>
<td>2.89</td>
</tr>
<tr>
<td>Other</td>
<td>482</td>
<td>10.2</td>
</tr>
<tr>
<td>Missing*</td>
<td>463</td>
<td>9.75</td>
</tr>
<tr>
<td>Local deprivation third*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1422</td>
<td>30.0</td>
</tr>
<tr>
<td>2</td>
<td>1669</td>
<td>35.1</td>
</tr>
<tr>
<td>3</td>
<td>1657</td>
<td>34.9</td>
</tr>
<tr>
<td>Non-CVD comorbidities**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>3658</td>
<td>77.0</td>
</tr>
<tr>
<td>Yes</td>
<td>1090</td>
<td>23.0</td>
</tr>
<tr>
<td>Family history of CHD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>3395</td>
<td>71.5</td>
</tr>
<tr>
<td>Yes</td>
<td>1353</td>
<td>28.5</td>
</tr>
<tr>
<td>Smoking Status</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2340</td>
<td>49.3</td>
</tr>
<tr>
<td>Yes</td>
<td>2408</td>
<td>50.7</td>
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<table>
<thead>
<tr>
<th>Practice Characteristics</th>
<th>Year 1 - High risk</th>
<th>Year 2 - Others</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Practice list size</td>
<td></td>
<td>&lt;6000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6000–10000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;10000</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>4748</td>
</tr>
</tbody>
</table>

*a* Patients with either no ethnicity recording or patients who did not want to state their ethnicity  
*b* Index of Multiple Deprivation 2007 (1 = most deprived, 3 = least deprived)  
*c* Non-CVD comorbidities – asthma, mental health, depression, hypothyroidism and chronic obstructive pulmonary disease
8.3.2 Recording and level of risk factors

CVD risk factor recording and level of risk factors are shown in Table 8. In Year 1, there was a high recording of smoking status and ethnicity recording in all eligible patients. Recording of blood pressure, cholesterol and family history of CHD were 67.0%, 55.9% and 69.1% respectively in Health Check eligible high-risk patients. Mean blood pressure was 134.7/80.6 mm Hg in all eligible patients and 133.7/80.4 mm Hg in patients with a complete Health Check. Smoking prevalence was 45.7% in all eligible patients and 44.4% in patients who had a complete Health Check. Mean total and HDL cholesterol were 5.37 mmol/L and 1.28 mmol/L respectively in all eligible patients, and 5.29 mmol/L and 1.27 mmol/L in those with a complete Health Check. The levels of risk factors in complete Health Check group determined using alternative criterion (including additional statin prescription offers) were similar to the risk factor levels in the standard complete health check group.

In Year 2, recording of smoking status and ethnicity were again high, at 85.5% and 84.7% respectively, in Health Check eligible patients (Table 8). Blood pressure, cholesterol and family history of CVD recording were 57.7%, 36.2% and 42.9% respectively. Mean blood pressure was 125.5/78.0 mm Hg in all eligible patients and 125.6/78.2 mm Hg in patients who had a complete Health Check in Year 2. Smoking prevalence was 16.2% in all Health Check eligible patients and 19.7% in those with a complete Health Check in Year 2. Mean total and HDL cholesterol were 5.29 mmol/L and 1.45 mmol/L respectively in all eligible patients, and 5.31 mmol/L and 1.45 mmol/L in those with a complete Health Check.
Table 8: Recording of cardiovascular risk factors in the Health Check eligible populations and levels of risk factors in the eligible patients and those with a complete Health Check

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>All eligible Patients</th>
<th>Year 1</th>
<th>Year 2</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% Recorded</td>
<td>Mean</td>
<td>Mean</td>
<td>Mean</td>
<td>Mean</td>
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<td>------------------------------</td>
<td>------------</td>
<td>-----------------------</td>
<td>-------------</td>
<td>-----------------</td>
<td>-----------------</td>
</tr>
<tr>
<td></td>
<td>N = 4748</td>
<td>N = 1886</td>
<td>N = 1551</td>
<td>N = 35 364</td>
<td>N = 7076</td>
</tr>
<tr>
<td>Smoking Status (%)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>83.1</td>
<td>45.7 (44.1-47.3)</td>
<td>44.4 (42.2-46.7)</td>
<td>44.3 (41.8-46.8)</td>
<td>85.5 (15.8-16.6)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td>89.3</td>
<td>-</td>
<td>-</td>
<td>84.7</td>
<td>-</td>
</tr>
<tr>
<td>Systolic Blood Pressure (mmHg)</td>
<td>67.0</td>
<td>134.7 (134.2-135.3)</td>
<td>133.7 (133.2-134.4)</td>
<td>133.7 (133.0-134.5)</td>
<td>57.7 (125.5 (125.3-125.7)</td>
</tr>
<tr>
<td>Diastolic Blood Pressure (mmHg)</td>
<td>67.0</td>
<td>80.6 (80.3-81.0)</td>
<td>80.4 (80.0-80.8)</td>
<td>78.0 (77.8-78.1)</td>
<td>78.2 (78.0-78.4)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>58.1</td>
<td>26.7 (26.5-26.9)</td>
<td>26.9 (26.7-27.1)</td>
<td>26.4 (26.3-26.5)</td>
<td>26.5 (26.4-26.7)</td>
</tr>
<tr>
<td>Total Cholesterol (mmol/L)</td>
<td>55.9</td>
<td>5.37 (5.32-5.41)</td>
<td>5.29 (5.23-5.34)</td>
<td>5.29 (5.28-5.31)</td>
<td>5.31 (5.29-5.33)</td>
</tr>
<tr>
<td>HDL (mmol/L)</td>
<td>55.9</td>
<td>1.28 (1.63-1.29)</td>
<td>1.27 (1.25-1.29)</td>
<td>1.45 (1.44-1.46)</td>
<td>1.45 (1.44-1.46)</td>
</tr>
<tr>
<td>Family history of CHD (%)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>69.1</td>
<td>41.3 (39.6-42.9)</td>
<td>40.0 (37.6-42.5)</td>
<td>39.9 (39.2-40.7)</td>
<td>27.1 (26.0-28.1)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Mean percentage of patients who smoke.

<sup>b</sup> Mean percentage of patients with a family history of CHD.
8.3.3 Uptake of complete Health Check

Variations in uptake of complete Health Check by patient and practice characteristics are illustrated in Table 9. In Year 1, 39.2% of high-risk patients had a complete Health Check (Table 9 and Figure 15). Although there was no variation in the uptake of the Health Checks between genders in the univariable analysis, the uptake was significantly lower in females than males when accounting for other patient and practice level factors (AOR = 0.80; [95% CI, 0.68–0.94] in females compared with males). Older patients were more likely to have had a complete Health Check (AOR = 1.98; [95% CI, 1.63–2.42] in 65 to 74 year old compared with 40 to 54 year old patients). Patients with non-CVD comorbidities (AOR = 1.47; [95% CI, 1.27–1.71]) and family history of CHD (AOR = 2.60; [95% CI, 2.25–3.01]) were more likely to have a complete Health Check. Smokers were significantly less likely to have a Health Check compared to non-smokers (AOR = 0.67; [95% CI, 0.58–0.77]). The overall Health Check uptake was 32.7% when uptake was determined using the alternative criterion (including statin prescription). Variations in uptake by patient and practice characteristics were similar when the completeness of Health Checks was determined using both criteria (Table 9).

In Year 2, the overall uptake of complete Health Check was 20.0% (Table 9 and Figure 15). The uptake was greater in women (AOR = 1.27; [95% CI, 1.20–1.35]), in older patients, in ethnic minorities (Black, South Asian and other) compared with white patients, and in patients living in deprived areas (least deprived third AOR = 0.80; [95% CI, 0.73–0.87] compared with the most). Patients with non-CVD comorbidities (AOR = 1.75; [95% CI, 1.64–1.87]) and family history of CHD (AOR = 2.01; [95% CI, 1.87–2.16]) were again more likely to have a complete check. Smokers were less likely than non-smokers to have a Health Check (AOR =0.83; [95% CI, 0.77–0.90]).

High MOR and VPC in both Year 1 and Year 2 demonstrated large unexplained variance in uptake between practices. The MOR was large with 2.17; [95% CI, 1.94–2.47] in Year 1 and 3.91; [95% CI, 3.23–4.89] in Year 2, suggesting that there was a large odds of change in Health Check uptake, when patients move between practices. 16.1%; [95% CI, 12.3–4.74%] of the total variance in Year 1 and 37.3%; [95% CI, 30.6–44.6%] in Year 2 were attributable to unexplained practice level factors.
Table 9: Variation in the Health Check uptake by patient and practice characteristics; univariable and multivariable analysis

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Year 1 – High risk</th>
<th>Year 1 – High risk (Criterion 2)</th>
<th>Year 2 – Others</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>AOR</td>
<td>%</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>39.2</td>
<td>1.00</td>
<td>32.6</td>
</tr>
<tr>
<td>Female</td>
<td>41.4</td>
<td>0.80 (0.68–0.94)</td>
<td>33.0</td>
</tr>
<tr>
<td>Age Group</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40–54</td>
<td>33.1</td>
<td>1.00</td>
<td>26.9</td>
</tr>
<tr>
<td>55–64</td>
<td>37.4*</td>
<td>1.34 (1.12–1.59)</td>
<td>30.5*</td>
</tr>
<tr>
<td>65–74</td>
<td>46.9**</td>
<td>1.98 (1.63–2.42)</td>
<td>39.2**</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>43.9</td>
<td>1.00</td>
<td>35.7</td>
</tr>
<tr>
<td>Black</td>
<td>37.5*</td>
<td>1.00 (0.76–1.32)</td>
<td>31.8</td>
</tr>
<tr>
<td>South Asian</td>
<td>53.3*</td>
<td>1.23 (0.84–1.80)</td>
<td>47.4**</td>
</tr>
<tr>
<td>Other</td>
<td>41.1</td>
<td>0.98 (0.80–1.22)</td>
<td>34.2</td>
</tr>
<tr>
<td>Missing</td>
<td>4.39**</td>
<td>0.10 (0.06–0.15)</td>
<td>4.75**</td>
</tr>
<tr>
<td>Local deprivation thirdc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>38.4</td>
<td>1.00</td>
<td>32.5</td>
</tr>
<tr>
<td>2</td>
<td>40.2</td>
<td>0.97 (0.81–1.15)</td>
<td>32.8</td>
</tr>
<tr>
<td>3</td>
<td>40.4</td>
<td>0.88 (0.73–1.06)</td>
<td>32.7</td>
</tr>
<tr>
<td>Non-CVD comorbiditiesd</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>37.2</td>
<td>1.00</td>
<td>30.2</td>
</tr>
<tr>
<td>Yes</td>
<td>48.3**</td>
<td>1.47 (1.27–1.71)</td>
<td>40.8**</td>
</tr>
<tr>
<td>Family history of CHD</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>33.5</td>
<td>1.00</td>
<td>27.4</td>
</tr>
<tr>
<td>Yes</td>
<td>55.2**</td>
<td>2.60 (2.25–3.01)</td>
<td>45.9**</td>
</tr>
<tr>
<td>Smoking Status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>44.8</td>
<td>1.00</td>
<td>36.9</td>
</tr>
<tr>
<td>Yes</td>
<td>34.8**</td>
<td>0.67 (0.58–0.77)</td>
<td>28.5**</td>
</tr>
<tr>
<td>Practice Characteristics</td>
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<td></td>
</tr>
<tr>
<td>Practice list size</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6000</td>
<td>38.1</td>
<td>1.00</td>
<td>32.6</td>
</tr>
<tr>
<td>6000–10000</td>
<td>40.0</td>
<td>0.96 (0.54–1.70)</td>
<td>30.3</td>
</tr>
<tr>
<td>&gt;10000</td>
<td>41.8*</td>
<td>1.04 (0.53–2.05)</td>
<td>36.1</td>
</tr>
<tr>
<td>Total</td>
<td>39.7</td>
<td>32.7</td>
<td>20.0</td>
</tr>
<tr>
<td>-----------</td>
<td>------</td>
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</tr>
<tr>
<td><strong>Random effects</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median odds ratio</td>
<td>2.17 (1.94–2.47)</td>
<td>2.38 (2.11–2.73)</td>
<td>3.91 (3.23–4.89)</td>
</tr>
<tr>
<td>Variance partitioning coefficient (%)</td>
<td>16.1 (12.3–20.7)</td>
<td>19.4 (15.2–24.4)</td>
<td>37.3 (30.6–44.6)</td>
</tr>
</tbody>
</table>

*a* Reference group in z-test, ** *P* < 0.01 & *P* < 0.05 for z-test  
*b* Patients with either no ethnicity recording or patients who did not want to state their ethnicity  
*c* Index of Multiple Deprivation 2007 (1 = most deprived, 3 = least deprived)  
*d* Non-CVD comorbidities - asthma, mental health, depression, hypothyroidism and chronic obstructive pulmonary disease  

*Note:* Odds ratios are adjusted for all variables in the table.
8.3.4 Exception reporting

Table 10 demonstrates the variation in exception reporting with patient and practice characteristics. In Year 1, 46.4% of eligible patients were exception reported. Older patients, patients with non-CVD comorbidities (AOR = 0.66; [95% CI, 0.56–0.77]) and a family history of CHD (AOR = 0.41; [95% CI, 0.35–0.48]) were all less likely to be exception reported. Smokers (AOR = 1.37; [95% CI, 1.19–1.59]) and patients with missing or not stated ethnicity record (AOR = 5.23; [95% CI, 3.92–6.99] compared with white) were more likely to be exception reported. Those living in the least deprived areas were significantly more likely to be exception reported when controlling for other patient and practice level factors (AOR = 1.23; [95% CI, 1.02–1.48] in the least deprived areas compared to the most).

In Year 2, an overall 5.72% of all eligible patients were exception reported. Women (AOR = 0.78; [95% CI, 0.69–0.88]), older patients, black patients (AOR = 0.63; [95% CI, 0.50–0.79] compared with white), and patients with non-CVD comorbidities and a family history of CHD were all less likely to be exception reported. Patients with missing or not stated ethnicity record (AOR = 3.00; [95% CI, 2.50–3.60] compared with white), smokers, those living in less deprived areas (least deprived third AOR = 1.21; [95% CI, 1.03–1.43] compared with the most) and patients registered with larger practices were more likely to be exception reported.

There was very high variation in exception reporting between practices in both years, demonstrated by MOR and VPC values. The odds of change in exception reporting, if moving between practices was large with a MOR of 3.10; [95% CI, 2.65–3.72] in Year 1 and 5.06; [95% CI, 3.85–7.06] in Year 2. 29.1%; [95% CI, 23.3–35.6] of total variance in exception reporting in Year 1 and 45.7%; [95% CI, 36.7–55.0] in Year 2 were due to unexplained practice level factors.
Table 10: Exception reporting by patient and practice characteristics in the first two years of the NHS Health Check; univariable and multivariable analysis.

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Year 1 - High risk</th>
<th>Year 2 – Others</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%</td>
<td>AOR</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>47.5</td>
<td>1.00</td>
</tr>
<tr>
<td>Female</td>
<td>42.3**</td>
<td>1.13 (0.96–1.34)</td>
</tr>
<tr>
<td>Age Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-54</td>
<td>54.8</td>
<td>1.00</td>
</tr>
<tr>
<td>55-64</td>
<td>49.8**</td>
<td>0.69 (0.58–0.83)</td>
</tr>
<tr>
<td>65-74</td>
<td>36.6**</td>
<td>0.37 (0.30–0.45)</td>
</tr>
<tr>
<td>Ethnicity</td>
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<td></td>
</tr>
<tr>
<td>White</td>
<td>41.9</td>
<td>1.00</td>
</tr>
<tr>
<td>Black</td>
<td>44.8</td>
<td>1.15 (0.86–1.54)</td>
</tr>
<tr>
<td>South Asian</td>
<td>33.6</td>
<td>0.92 (0.61–1.39)</td>
</tr>
<tr>
<td>Other</td>
<td>47.7*</td>
<td>1.08 (0.87–1.34)</td>
</tr>
<tr>
<td>Missing</td>
<td>82.7**</td>
<td>5.23 (3.92–6.99)</td>
</tr>
<tr>
<td>Local deprivation</td>
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<td></td>
</tr>
<tr>
<td>1a</td>
<td>46.8</td>
<td>1.00</td>
</tr>
<tr>
<td>2</td>
<td>43.7</td>
<td>1.03 (0.86–1.23)</td>
</tr>
<tr>
<td>3</td>
<td>48.7</td>
<td>1.23 (1.02–1.48)</td>
</tr>
<tr>
<td>Non-CVD comorbidities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>49.2</td>
<td>1.00</td>
</tr>
<tr>
<td>Yes</td>
<td>36.9**</td>
<td>0.66 (0.56–0.77)</td>
</tr>
<tr>
<td>Family history of CHD</td>
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<tr>
<td>No</td>
<td>51.6</td>
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</tr>
<tr>
<td>Yes</td>
<td>33.2**</td>
<td>0.41 (0.35–0.48)</td>
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<td>Smoking Status</td>
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<td></td>
</tr>
<tr>
<td>No</td>
<td>42.2</td>
<td>1.00</td>
</tr>
<tr>
<td>Yes</td>
<td>50.4**</td>
<td>1.37 (1.19–1.59)</td>
</tr>
<tr>
<td>Practice Characteristics</td>
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<td>Practice list size</td>
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<td></td>
</tr>
<tr>
<td>&lt;6000</td>
<td>45.1</td>
<td>1.00</td>
</tr>
<tr>
<td>6000-10 000</td>
<td>45.9</td>
<td>1.30 (0.39–4.34)</td>
</tr>
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<td></td>
<td>&gt;10 000</td>
<td></td>
</tr>
<tr>
<td>------------------</td>
<td>---------</td>
<td>----------</td>
</tr>
<tr>
<td></td>
<td>48.8*</td>
<td>1.80 (0.44–7.34)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>46.4</td>
<td></td>
</tr>
</tbody>
</table>

**Random effects**

| Median odds ratio | 3.10 (2.65–3.72) | 5.06 (3.85–7.06) |
| Variance partitioning coefficient (%) | 29.1 (23.3–35.6) | 45.7 (36.7–55.0) |

*Reference group in z-test, ** $P < 0.01$ & * $P < 0.05$ for z-test

b Patients with either no ethnicity recording or patients who did not want to state their ethnicity
c Index of Multiple Deprivation 2007 (1 = most deprived, 3 = least deprived)
d Non-CVD comorbidities - asthma, mental health, depression, hypothyroidism and chronic obstructive pulmonary disease

*Note: Odds ratios are adjusted for all variables in the table*
8.3.5 Prescription of statins

Table 11 shows statin prescription in patients who had a Health Check in Year 1 and were confirmed as at high-risk (≥20%); statin prescriptions were assessed in both populations who were identified as having a complete Health Check using two criteria. When the standard criterion to determine the completeness of Health Check is used, 14.0%; [95% CI, 12.1–15.9] of 1321 high-risk individuals were prescribed statins before the Health Check, whilst 47.8%; [95% CI, 45.1–50.5] of the patients were prescribed statins after. Statin prescriptions before and after Health Checks were 16.8%; [95% CI, 14.5–19.0] and 57.7%; [95% CI, 54.8–60.6] respectively in 1092 high-risk patients when the completeness of Health Check was determined using the alternative criterion.

Older patients had greater statin prescription before having a Health Check (AOR = 2.81; [95% CI, 1.50–5.28] in 65 to 74 years age group compared with 40 to 54 year old patients); however there was no significant difference in prescribing by age after the Health Check. Patients with non-CVD comorbidities were also more likely to be prescribed a statin before the Health Check, but statin prescriptions were not significantly different between patients with and without non-CVD comorbidities after the Health Check. Post-Health Check statin prescription was higher amongst Black patients (AOR = 1.74; [95% CI, 1.02–2.97]) compared with white. Although not highly significant, statin prescription after the Health Check was also higher in smokers (AOR = 1.37; [95% CI, 1.07–1.76]) compared with non-smokers. Variations in statin prescriptions were similar both before and after the Health Check in patients determined as having a complete Health Check with the alternative criterion, including completeness of offers for statin prescription.

Unexplained variation in statin prescription between practices reduced over time (from 12.5%; [95% CI, 7.06–21.3] prior to the Health Check to 5.19%; [95% CI, 2.08–12.3] after the Health Check). In the Health Check group identified using the alternative criterion including the statin prescription offers, the unexplained variation in statin prescriptions between practices was greater, with 19.6%; [95% CI, 13.4–27.7] before the Health Check and 12.0%; [95% CI, 7.58–18.8] after the Health Check.
Table 11: Statin prescriptions before and after the Health Check in patients who had a complete Health Check in Year 1 and were eligible for treatment; univariable and multivariable analysis

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Year 1 (N= 1321)</th>
<th>Year 1 - Criterion 2 (N= 1092)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-HC</td>
<td>Post-HC</td>
</tr>
<tr>
<td>%</td>
<td>AOR</td>
<td>%</td>
</tr>
<tr>
<td>---</td>
<td>-----</td>
<td>---</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>13.4</td>
<td>1.00</td>
</tr>
<tr>
<td>Female</td>
<td>17.2</td>
<td>1.02 (0.66–1.57)</td>
</tr>
<tr>
<td><strong>Age Group</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40–54</td>
<td>7.73</td>
<td>1.00</td>
</tr>
<tr>
<td>55–64</td>
<td>13.4*</td>
<td>2.04 (1.11–3.75)</td>
</tr>
<tr>
<td>65–74</td>
<td>16.5**</td>
<td>2.81 (1.50–5.28)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>14.6</td>
<td>1.00</td>
</tr>
<tr>
<td>Black</td>
<td>10.6</td>
<td>0.66 (0.29–1.52)</td>
</tr>
<tr>
<td>South Asian</td>
<td>13.8</td>
<td>1.00 (0.45–2.26)</td>
</tr>
<tr>
<td>Other</td>
<td>11.9</td>
<td>0.83 (0.46–1.51)</td>
</tr>
<tr>
<td>Missing</td>
<td>5.26</td>
<td>0.44 (0.05–3.59)</td>
</tr>
<tr>
<td><strong>Local deprivation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a</td>
<td>14.8</td>
<td>1.00</td>
</tr>
<tr>
<td>2</td>
<td>13.0</td>
<td>0.97 (0.63–1.48)</td>
</tr>
<tr>
<td>3</td>
<td>14.4</td>
<td>1.15 (0.74–1.79)</td>
</tr>
<tr>
<td><strong>Non-CVD comorbidities</strong></td>
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<tr>
<td>Noa</td>
<td>12.0</td>
<td>1.00</td>
</tr>
<tr>
<td>Yes</td>
<td>19.3**</td>
<td>1.87 (1.32–2.64)</td>
</tr>
<tr>
<td><strong>Family history of CHD</strong></td>
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<td></td>
</tr>
<tr>
<td>Noa</td>
<td>13.4</td>
<td>1.00</td>
</tr>
<tr>
<td>Yes</td>
<td>14.7</td>
<td>1.21 (0.86–1.70)</td>
</tr>
<tr>
<td><strong>Smoking Status</strong></td>
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<tr>
<td>Noa</td>
<td>14.2</td>
<td>1.00</td>
</tr>
<tr>
<td>Yes</td>
<td>13.8</td>
<td>1.12 (0.78–1.61)</td>
</tr>
<tr>
<td><strong>Practice Characteristics</strong></td>
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<td></td>
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<tr>
<td>Practice list size</td>
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</tr>
<tr>
<td>&lt;6000a</td>
<td>17.7</td>
<td>1.00</td>
</tr>
<tr>
<td>6000–10 000</td>
<td>11.9*</td>
<td>0.54 (0.30–0.95)</td>
</tr>
<tr>
<td>&gt;10 000</td>
<td>12.1*</td>
<td>0.63 (0.33–1.23)</td>
</tr>
<tr>
<td>Total</td>
<td>14.0</td>
<td>47.8</td>
</tr>
<tr>
<td>-------------</td>
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</tr>
<tr>
<td><strong>Random effects</strong></td>
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<td></td>
</tr>
<tr>
<td>Median odds ratio</td>
<td>1.95 (1.63–2.51)</td>
<td>1.51 (1.29–1.94)</td>
</tr>
<tr>
<td>Variance partitioning coefficient (%)</td>
<td>12.5 (7.06–21.3)</td>
<td>5.19 (2.08–12.3)</td>
</tr>
</tbody>
</table>

a Reference group in z-test, ** P < 0.01 & * P < 0.05 for z-test
b Patients with either no ethnicity recording or patients who did not want to state their ethnicity
c Index of Multiple Deprivation 2007 (1 = most deprived, 3 = least deprived)
d Non-CVD comorbidities - asthma, mental health, depression, hypothyroidism and chronic obstructive pulmonary disease

*Note: Odds ratios are adjusted for all variables in the table.*
Table 12 demonstrates variation in statin prescription in patients who had a Health Check in Year 2 and were identified as eligible for statin prescriptions (population confirmed as at high-risk). Statin prescription increased from 19.4%; [95% CI, 16.0–22.8] to 43.1%; [95% CI: 38.8–47.4] over the Health Check. Older patients had significantly greater statin prescription before the Health Check (AOR= 4.97; [95% CI, 2.15–11.5] in 65 to 74 year old patients compared to 40 to 54 years; the significance was maintained for only 65 to 74 year old age group after the Health Check (AOR= 2.21; [95% CI, 1.22–3.99]). South Asian patients were significantly more likely to be prescribed a statin before the Health Check (AOR = 3.17; [95% CI, 1.32–7.59]) compared with whites, but there was no difference in prescriptions by ethnicity after the Health Check.

There was a reduction in unexplained variation in prescription of statins between practices over the Health Check. For example, for patients who had a complete Health Check in Year 1, whilst 12.5%; [95% CI, 7.06–21.3] of total variance in statin prescriptions was attributable to unexplained practice level factors prior to the Health Check, this was 5.19%; [95% CI, 2.08–12.3] after the Health Check.
Table 12: Statin prescriptions before and after the Health Check in patients who had a complete Health Check in Year 2 and were eligible for treatment; univariable and multivariable analysis

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<th>Post-HC</th>
<th>AOR</th>
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<tbody>
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<td></td>
<td></td>
<td>%</td>
<td></td>
<td>%</td>
<td></td>
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<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td>19.0</td>
<td>1.00</td>
<td>44.8</td>
<td>1.00</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td>20.9</td>
<td>0.85(0.45–1.60)</td>
<td>37.4</td>
<td>0.60(0.37–1.00)</td>
</tr>
<tr>
<td>Age Group</td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td>40–54</td>
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<td>9.42</td>
<td>1.00</td>
<td>38.4</td>
<td>1.00</td>
</tr>
<tr>
<td>55–64</td>
<td></td>
<td>19.9**</td>
<td>2.67(1.25–5.70)</td>
<td>42.7</td>
<td>1.50(0.90–2.51)</td>
</tr>
<tr>
<td>65–74</td>
<td></td>
<td>26.9**</td>
<td>4.97(2.15–11.5)</td>
<td>47.4</td>
<td>2.21(1.22–3.99)</td>
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<td>Ethnicity</td>
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<td>17.8</td>
<td>1.00</td>
<td>40.4</td>
<td>1.00</td>
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<td>Black</td>
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<td>1.50(0.69–3.25)</td>
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<td>1.56(0.78–3.13)</td>
<td>50.0</td>
<td>1.44(0.84–2.48)</td>
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<tr>
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<td>1.20(0.13–11.2)</td>
<td>36.4</td>
<td>1.24(0.31–4.92)</td>
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<td>Local deprivation third^c</td>
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<td></td>
<td></td>
</tr>
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<td>1a</td>
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<td>22.2</td>
<td>1.00</td>
<td>48.0</td>
<td>1.00</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>16.0</td>
<td>0.66(0.36–1.21)</td>
<td>41.1</td>
<td>0.83(0.52–1.31)</td>
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<tr>
<td>3</td>
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<td>19.70</td>
<td>0.88(0.46–1.66)</td>
<td>38.7</td>
<td>0.71(0.42–1.18)</td>
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<td>Non-CVD comorbidities^d</td>
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</tr>
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<td>20.7</td>
<td>1.00</td>
<td>46.8</td>
<td>1.00</td>
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<tr>
<td>Yes</td>
<td></td>
<td>16.8</td>
<td>0.91(0.53–1.57)</td>
<td>35.3*</td>
<td>0.66(0.44–1.00)</td>
</tr>
<tr>
<td>Family history of CHD</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No^a</td>
<td></td>
<td>18.3</td>
<td>1.00</td>
<td>41.5</td>
<td>1.00</td>
</tr>
<tr>
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<td></td>
<td>23.5</td>
<td>1.47(0.82–2.64)</td>
<td>48.7</td>
<td>1.46(0.92–2.34)</td>
</tr>
<tr>
<td>Smoking Status</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>No^a</td>
<td></td>
<td>22.3</td>
<td>1.00</td>
<td>42.4</td>
<td>1.00</td>
</tr>
<tr>
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<td>16.3</td>
<td>1.20(0.69–2.09)</td>
<td>43.8</td>
<td>1.54(0.99–2.40)</td>
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<td>Practice Characteristics</td>
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<tr>
<td>Practice list size</td>
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<td></td>
</tr>
<tr>
<td>&lt;6000^a</td>
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<td>23.3</td>
<td>1.00</td>
<td>50.3</td>
<td>1.00</td>
</tr>
<tr>
<td>6000–10 000</td>
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<td>21.5</td>
<td>1.15(0.43–3.13)</td>
<td>38.5*</td>
<td>0.78(0.36–1.67)</td>
</tr>
<tr>
<td>&gt;10 000</td>
<td></td>
<td>15.5</td>
<td>0.60(0.23–1.61)</td>
<td>40.7</td>
<td>0.67(0.32–1.39)</td>
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<tr>
<td><strong>Random effects</strong></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Median odds ratio</td>
<td>2.30 (1.87–3.05)</td>
<td>2.03 (1.67–2.62)</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Variance partitioning coefficient (%)</td>
<td>18.2 (11.1–28.5)</td>
<td>13.9 (7.84–23.0)</td>
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<td></td>
</tr>
</tbody>
</table>

* Reference group in z-test, ** * < 0.01 & * * < 0.05 for z-test

*b* Patients with either no ethnicity recording or patients who did not want to state their ethnicity

*c* Index of Multiple Deprivation 2007 (1 = most deprived, 3 = least deprived)

*d* Non-CVD comorbidities – asthma, mental health, depression, hypothyroidism and chronic obstructive pulmonary disease

**Note:** Odds ratios are adjusted for all variables in the table.
8.4 Discussion

8.4.1 Main findings

Uptake of a Health Check was low at 39.7% among estimated high-risk patients in the first year, with even lower uptake at 32.7% when completeness was determined including the offers for statin prescription. There was a 20% Health Check uptake in rest of the non-high risk eligible population in the second year. In both years, uptake was lower in younger patients, smokers and patients with no ethnicity record. In the second year, uptake was higher amongst patients of South Asian and Black ethnic backgrounds. Exclusions from the Health Check that determine general practice payments in QOF+ were high in the first year, with 46.4% exception reporting among all eligible patients and low in the second year, with 5.72%. Statin prescription increased from 14% to 47.8% in patients confirmed with high-risk after a Health Check in the first year and from 19.4% to 43.1% among patients confirmed as at high-risk after a Health Check in the second year. There was high practice variation in Health Check uptake, exception reporting and statin prescribing.

8.4.2 Comparison with existing literature and explanation of findings

Evidence on the uptake of cardiovascular screening in routine settings is limited. In a deprived and culturally diverse area, 44.8% of high-risk patients attended the Health Check (415). The present study showed lower uptake among patients assessed as at estimated high risk, but unlike this previous study excluded patients with hypertension and CKD, whose reviews in general practice may improve uptake. The uptake reported in this study was, however, also lower than that in another deprived area, where the uptake was 43.7% among those without an established vascular disease, but again with estimated high-risk (416). The low uptake among eligible individuals may suggest that despite being at estimated high risk, the population has poor motivation to make change for reducing their risk or is unclear about the purpose of the Health Check programme and how they might personally benefit (844).

Dalton et al. (415) and Cochrane et al. (416) reported poorer uptake of Health Checks in younger patients, consistent with my findings from both years. My findings produced mixed results for the association between gender and uptake of the Health Check. Men were more likely to have a complete Health Check in the first year, supporting the findings of Cochrane et al. (416). However, the OXCHECK study (795) and Dalton et al. (415) showed that men
were less likely to attend a cardiovascular screening, consistent with my findings from Year 2. The lower Health Check attendance in men probably reflects their lower attendance levels at general practice (777,779). The Health Check uptake may be strongly dependent on consultation rates in the second year, when it was delivered opportunistically. Another explanation for lower uptake in men can be lower use of preventative services more generally (888). The findings from Year 2 support previous work, which suggests that patients from south Asian and Black groups may be more likely to attend a CVD screening (415,794). This is contrasting with the evidence suggesting that ethnic minorities, particularly south Asians are less likely to attend preventive care (Chapter 4.1.2.2). The greater uptake in south Asian and Black patients may be again attributable to higher consultation rates in these patient groups (782). Another explanation for greater uptake in these patients can be GP’s perception of higher CVD risk in black and south Asian populations (127,885,891). Previous studies examining uptake of Health Checks by SES have produced mixed results (415,416,794,795). I identified higher uptake in patient groups living in deprived areas, but this was only apparent in Year 2. Improved prevention in deprived groups may be due to general practitioners’ perception of greater CVD risk (882).

I showed that about half (47.8%) of the patients confirmed to be at high CVD risk had statin prescription in the first year and 43.1% of patients confirmed with a high risk had statin prescription in the second year. These are similar levels to those found in previous studies (415,416) and considerably lower than that anticipated in the Department of Health impact modelling, which assumed that the uptake of statins would be 85% (417). Limited statin prescription for primary prevention may be because of patients’ and practitioners’ attitudes to cardiovascular risk and beliefs about the benefits of statins prescriptions in patients without established disease (892,893).

This is the first study to examine exception reporting of patients from the Health Check programme in England. Previous UK evidence suggests that patient exclusions from the QOF, a pay for performance scheme incentivising secondary prevention interventions are low (894–896). My study shows that exception reporting was low in the second year, however approximately half of patients were excluded in the first year. In the first year, the programme was delivered systematically and patients were formally invited to have a Health Check; if patients declined or did not respond to invitation, they were exception reported. This may, therefore, explain the high exception reporting in the first year. In the second year,
opportunistic screening was employed with no formal invitations, resulting in a lower number of patients exception reported.

8.4.3 Implications for policy and clinical practice, and future research

The present study has shown that men without previous CVD and other vascular disease are less likely to attend and more likely to be excluded from the Health Check. This is a concern given that they are at greater CVD risk than women and may suggest that the Health Check will widen gender inequalities in CVD outcomes. One key implication of the study is the need for primary care teams to promote Health Check attendance in men.

Previous work suggests that the NHS Health Check have considerable workload implications for primary care (873) and there have been concerns over the cost-effectiveness of the programme (159,647). The Department of Health cost-effectiveness modelling assumes 75% of invited patients attend a Health Check, with 85% uptake of statins (417). First year attendance amongst high-risk patients was low, with only about 40% uptake in all eligible patients targeted to be screened. NHS Hammersmith and Fulham aimed to screen the remaining non-high risk population in the following four years. This corresponds to 25% of all non-high risk population screened in each of the four years. Hence, in contrast to the uptake in the first year of the programme, 20% uptake (of the entire eligible population) in the second year is in keeping with the local target (30%) and programme’s goal to screen all persons aged 40 to 74 years over a five-year period. Strictly speaking, the uptake figure in the second year is surely coverage, but I called it uptake to keep wording consistent. This is because in the second year of the programme, the Health Check was not delivered in a systematic manner, as in the first year, but using an opportunistic approach. Patients were, therefore, not invited to the programme by formal invitation to allow determination of number of patients who were offered a health check and in turn uptake of the programme (number of patients attended/number of patients offered a health check). The high attendance achieved in the second year may decrease in subsequent years, since highly motivated individuals might attend for screening in the first two years. It is therefore important that uptake of the Health Check programme be monitored over time. Qualitative assessment of patients’ experiences of the Health Check may also be necessary to derive lesson for improving programme performance. Achieving high uptake in hard-to-reach groups may require dedicated strategies and greater resources (897).
There are questions over the effectiveness of the Health Check in improving health outcomes (159,457). Although a recent systematic review suggested that Health Checks are not effective in improving health outcomes (457), there was a lack of recent studies in the review and the findings of the review may not be relevant to the NHS Health Check (458). The Health Check programme will not achieve its aims of reducing the CVD burden and health inequalities with a low uptake observed in the first year of the programme.

The high exception reporting of patients during the first year of the programme is concerning and needs to be monitored in future programmes with a pay for performance element. The impact of pay-for-performance schemes on the quality of health care is questionable. In the UK, pay-for-performance schemes mainly incentivise secondary prevention (898), but in US often incorporate primary prevention (899). The effect of pay-for-performance programmes depends on their design and context. Evidence suggests that the QOF may not improve the quality of hypertension management (900) or effectively address inequalities in the management of chronic conditions (901). A US study on the impact of pay-for-performance schemes on preventive services indicated that they have little impact on the quality of services (902). Whilst the study design did not permit me to isolate the impact of the financial incentives on the performance of the Health Check, uptake in the study area was lower than that in a similar urban setting, where no such financial incentive scheme was in place (415). Examining the effect of different implementation and payment approaches may help identify other incentives, financial and organisational methods linked to greater uptake of the Health Check programme.

8.4.4 Strengths and limitations of the study

This study covers almost all the population eligible for the NHS Health Check in one PCT. Patients from four practices in Year 1 and two practices in Year 2 could not be included due to technical errors in data extraction, but patients from these practices were similar in their characteristics to the study population. Although the study population is not representative of the whole UK, findings may be representative of other urban areas with similar patterns of deprivation, ethnic diversity and burden of CVD. National evaluation of the Health Check has been initiated in 2012; however, given variation in approaches between areas, local programme assessment remains vital.
I defined eligibility and uptake based on the national guidance, however many eligible patients had some risk factors recorded, which may be a partial Health Check. The findings of this study are therefore comparable with those from other areas. Nationally, the Health Check can be carried out outside of general practice, for example in pharmacies (630,794). However, the findings do not provide evidence on the uptake of the programme in such settings.

I could only assess statin prescription in eligible patients, with no data concerning adherence. For primary prevention, adherence may be low (892). I was unable to examine the uptake and adherence to other interventions, such as weight and exercise management, and smoking cessation. Patient and practice deprivation were determined using postcode based scores. Individual measures of SES might better predict health outcomes, but these are not included in routine medical data. I was also unable to account for population mobility, which is strongly associated with the uptake of screening (Chapter 4.1.2.6); because data on mobility measures, e.g. practice registration and deregistration dates, and list-inflation, were not available.

### 8.5 Key points from Chapter 8

Uptake of the Health Check programme was low in the first year in patients with estimated high risk, despite financial incentives to general practices. However uptake among non-high risk eligible patients matched the national required rate in the second year. The level of statin prescription in eligible patients improved significantly, albeit not reaching levels estimated by the Department of Health. Further evaluation of cost and clinical effectiveness is needed, as programme resources may be better deployed in whole population strategies, to increase physical activity, reduce smoking and encourage healthy eating (903), for reducing cardiovascular risk. This is particularly important in the context of a financial environment in which NHS spending will be increasingly scrutinised to reduce spending on lower benefit and more costly programmes (133).
9.1 Introduction

NHS Health Check, a 5-year rolling programme, aims to offer CVD screening to all eligible patients over a five-year period, requiring a 20% coverage per year (417). In the financial year of 2011/2012, the Department of Health anticipated that PCTs plan to target 90% of this complete rollout, which is equivalent to 18% coverage per year. This reduction in expected coverage was because of the shortage in the available funding in PCTs in the financial year (636).

When pursuing a high-risk approach to CVD prevention, like the NHS Health Check, high coverage of those eligible is vital to significantly reduce the disease burden across the whole population (545). When estimating the likely impact of the programme, the Department of Health initially used an assumption of 75% uptake to model the costs and benefits of the programme (417). Early local pilot studies, however, place uptake in the invited groups well below this estimate – ranging from 24.3 to 45% (415,416,456,794). Equal uptake is also important across patient groups – inequalities in this first contact with a prevention programme can worsen inequalities in health (Chapters 2.9 and 8.1) (407). Previous studies have suggested that patient-level differences impact on the uptake of CVD prevention programmes (415,794). In addition to patient differences, coverage of screening programmes varies between primary care organizations (679). Structural or organizational differences in both primary care centres and commissioning organizations may be also important (Chapter 4.1.5) (724).

I aimed to assess coverage of the NHS Health Check programme at national level and examine whether these differ by patient socio-demographic characteristics; primary care provider characteristics, such as staffing and budget; and markers of need for CVD prevention.
9.2 Methods

9.2.1 Study sample and data

I collected data from the integrated performance measures monitoring website of the Department of Health. Data represented the number of people who were eligible for, offered and received a Health Check in one financial year (April 2011 – March 2012) (803). PCTs collect these data through their performance monitoring schemes (e.g. Local Enhanced Services) or contracts with Health Check providers. Strategic Health Authorities collected these performance data through the collation of mandatory PCT data returns. The Department of Health specified requirements for the collection of the data; therefore, PCTs are expected to provide data conforming to these (636). The data were available for all 151 PCTs in England.

9.2.2 Outcome measures

Coverage of the Health Check programme was the primary outcome measure. I estimated the coverage of the programme in each PCT as the number of individuals who received a Health Check divided by the number eligible (i.e. not the number offered, which would indicate uptake). Three PCTs reported no patients invited or receiving a Health Check, however all PCTs were included when assessing the coverage. Although uptake is an important measure, and may better reflect an individual’s contact with a screening programme, coverage is the better measure for assessing public health impact.

I used poor coverage as a secondary measure; defined as PCTs with coverage of less than 5%. I determined the cut-off point of 5% coverage based on the nationwide distribution of coverage (Appendix 1 – Figure 17). I aimed to assess whether different factors impact on the very poorest coverage, compared with the coverage across its entire distribution.

9.2.3 Explanatory variables

I obtained explanatory variables at PCT level. I examined socio-demographic factors – deprivation, the proportion of the population from ethnic minority groups, the proportion of the total population aged 40 to 74 years (those eligible for a Health Check) and total population size; service related factors – patient experience, coronary heart disease (CHD) care performance measures, annual PCT budget, number of practices, FTE GP and other staff
in each PCT; and variables related to cardiovascular prevention need – the estimated proportion of the population at high-risk and estimated CVD prevalence (Table 13).
Table 13: Data sources and references for explanatory variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Source</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation (IMD Score)</td>
<td>The Department for Communities and Local Government website</td>
<td>The Network of Public Health Observatories, 2011 (904)</td>
</tr>
<tr>
<td>Ethnic minority proportion (%)</td>
<td>Count me in Census</td>
<td>Care Quality Commission, 2013 (905)</td>
</tr>
<tr>
<td>Proportion of population in 40–74 age range (%)</td>
<td>Office for National Statistics</td>
<td>Office for National Statistics, 2011 (906)</td>
</tr>
<tr>
<td>Population size</td>
<td>General Practice Quality Outcomes Framework</td>
<td>The Information Centre for Health and Social Care, 2013 (907)</td>
</tr>
<tr>
<td><strong>Primary care factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QOF CHD</td>
<td>General Practice Quality Outcomes Framework</td>
<td>The Information Centre for Health and Social Care, 2013 (907)</td>
</tr>
<tr>
<td>Patient experience (total patient survey points)</td>
<td>GP Patient Survey</td>
<td>GP Patient Survey, 2011 (908)</td>
</tr>
<tr>
<td>Annual budget</td>
<td>Department of Health</td>
<td>Department of Health, 2012 (909)</td>
</tr>
<tr>
<td>Full-time equivalent GPs</td>
<td>General Practice Census</td>
<td>The Information Centre for Health and Social Care, 2012 (910)</td>
</tr>
<tr>
<td>Full-time equivalent other practice staff</td>
<td>General Practice Census</td>
<td>The Information Centre for Health and Social Care, 2012 (910)</td>
</tr>
<tr>
<td>Number of practices</td>
<td>General Practice Quality Outcomes Framework</td>
<td>The Information Centre for Health and Social Care, 2013 (907)</td>
</tr>
<tr>
<td><strong>Cardiovascular prevention need factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated high risk proportion (QRISK) (%)</td>
<td>Health Survey for England</td>
<td>Dalton et al., 2011 (232)</td>
</tr>
</tbody>
</table>

223
<table>
<thead>
<tr>
<th>Estimated CVD prevalence (%)</th>
<th>The Network of Public Health Observatories</th>
<th>The Network of Public Health Observatories, 2011 (911)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Imperial College London</td>
<td>Walford et al., 2011 (912)</td>
</tr>
</tbody>
</table>
I used the 2010 IMD score to measure SES, taking the median IMD score from across every lower super output area within a PCT (904). I obtained ethnicity data for each PCT from the Care Quality Commission (905). These data estimate ethnic makeup based on the proportions admitted to hospitals in an area’s resident population (913). The percentage of the PCT population made up of ethnic minority groups was calculated by combining percentages from south Asian, Black, and Mixed ethnic backgrounds. I calculated the proportion of patients aged 40 to 74 years from the 2010 mid-year population estimates from the Office for National Statistics (ONS) (906) and total registered population from the 2010/2011 General Practice Quality and Outcome Framework (QOF) (907).

I included QOF performance data (2010/2011) (907). I used the total points gained for CHD secondary prevention as a measure of CHD care quality (609). I also included the total points gained from the patient satisfaction survey (908), since patient experience has been associated with the quality of care received (914). The total annual budget for 2010/2011 was collected for each PCT from the Department of Health (909). I collected information on the total number of FTE GPs and other practice staff (healthcare assistants and practice nurses) for 2011 (910). Staffing levels may impact on the quality of care (911), with Health Checks often conducted by healthcare assistants and nurses. I also collected information on the number of practices from the 2010/2011 General Practice QOF (907).

The estimated prevalence of CVD and the proportion of high-risk individuals may be an important indicator of the population need for CVD prevention. I obtained the proportion of individuals estimated at high risk (≥20% risk of a cardiovascular event within next 10 years – using the QRISK2 score) in each PCT from previous modelling (232) and estimated CVD prevalence from the Association of Public Health Observatories (December 2011) and Imperial College London (912,915).

9.2.4 Statistical analysis

I summarised the characteristics of the outcome and explanatory variables in the study sample at PCT level. I assessed the univariable correlations between the Health Check coverage and explanatory variables at PCT-level using Spearman’s rank correlation coefficient; a non-parametric test, since variables were not normally distributed. For subsequent analysis, I generated categorical variables by splitting all explanatory variables
into equal thirds. I measured median levels of Health Check coverage in each category for all explanatory variables, using Wilcoxon rank-sum test to assess differences.

I assessed associations between absolute levels of coverage and explanatory variables by multivariable linear regression models, adjusting for primary care and population level factors. I used a square-root transformation of Health Check coverage before analysis to create a normally distributed variable for linear regression; results presented were transformed back to their original form. I used multivariable logistic regression analysis to assess the association between the poorest performing PCTs and explanatory variables. I included all explanatory variables in the final models, not employing model selection (*Chapter 7.2.5*) (876,878). I examined co-linearity between explanatory variables using the variance inflation factor (VIF). Due to high co-linearity, I omitted annual PCT budget, number of staff other than GPs and number of practices into the final regression models. All analyses were conducted using Stata version 11.2 SE.

9.3 Results

9.3.1 Characteristics of outcome and explanatory variables

A summary of coverage and explanatory variables is shown in Table 14. Median PCT level coverage of the Health Check programme was 8.2% in 2011/12, ranging from 0% to 29.8%. There were wide variations in most explanatory variables at PCT level. For example, the percentage of PCT population from ethnic minority groups ranged from 2.1% to 58.7% and the number of FTE GPs in PCTs ranged from 56 to 717.
Table 14: NHS Health Check coverage and PCT level predictor variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>SD</th>
<th>Min-Max</th>
<th>Median</th>
<th>IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage (%)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>8.1</td>
<td>5.4</td>
<td>0–29.8</td>
<td>8.2</td>
<td>8.0</td>
</tr>
<tr>
<td><strong>Population factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation (IMD Score)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>23.6</td>
<td>8.4</td>
<td>8.8–45.3</td>
<td>23.3</td>
<td>12.9</td>
</tr>
<tr>
<td>Ethnic minority proportion (%)</td>
<td>12.1</td>
<td>10.8</td>
<td>2.1–58.7</td>
<td>7.9</td>
<td>14.2</td>
</tr>
<tr>
<td>Proportion of population in 40–74 age range (%)</td>
<td>40.8</td>
<td>5.1</td>
<td>24.8–48.6</td>
<td>42.4</td>
<td>7.08</td>
</tr>
<tr>
<td>Population size</td>
<td>359 725</td>
<td>197 277</td>
<td>94 556–1 325 050</td>
<td>298 190</td>
<td>193 890</td>
</tr>
<tr>
<td><strong>Primary care factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QOF CHD</td>
<td>4707</td>
<td>2236</td>
<td>1022–12 658</td>
<td>4298</td>
<td>2819</td>
</tr>
<tr>
<td>Patient experience (total patient survey points)</td>
<td>1847</td>
<td>987.5</td>
<td>0–5543</td>
<td>1626</td>
<td>1229</td>
</tr>
<tr>
<td>Annual budget</td>
<td>578 548</td>
<td>295 969</td>
<td>177 109–1 848 102</td>
<td>513 963</td>
<td>292 631</td>
</tr>
<tr>
<td>Full-time equivalent GPs</td>
<td>207.7</td>
<td>122.8</td>
<td>56.0–717</td>
<td>168</td>
<td>109</td>
</tr>
<tr>
<td>Full-time equivalent other practice staff&lt;sup&gt;c&lt;/sup&gt;</td>
<td>485.5</td>
<td>286.4</td>
<td>132.3–1887</td>
<td>404.5</td>
<td>235.5</td>
</tr>
<tr>
<td>Number of practices</td>
<td>55.1</td>
<td>26.0</td>
<td>12–146</td>
<td>51.0</td>
<td>33.0</td>
</tr>
<tr>
<td><strong>Cardiovascular prevention need factors</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated high risk proportion (QRISK) (%)</td>
<td>10.6</td>
<td>1.66</td>
<td>6.4–13.7</td>
<td>10.7</td>
<td>2.8</td>
</tr>
<tr>
<td>Estimated CVD prevalence (%)</td>
<td>11.6</td>
<td>1.49</td>
<td>7.9–15.2</td>
<td>11.8</td>
<td>2.0</td>
</tr>
</tbody>
</table>

<sup>a</sup>Coverage = Number received / Number eligible  
<sup>b</sup>Index of Multiple Deprivation 2010
9.3.2 Association between Health Check coverage, and primary care and population level factors

*Table 15* presents univariable correlations between Health Check coverage and explanatory variables. There was a significant positive correlation between deprivation and coverage (Spearman’s Rank Correlation Coefficient (rho) = 0.35, P = <0.001); hence, Health Check coverage was significantly higher in more deprived PCTs. A higher proportion of population aged 40 to 74 years (rho = -0.23, P = <0.005), a larger population size (rho = -0.21, P = 0.011), and more FTE GPs (rho = -0.23, P = 0.005) and other practice staff (rho = -0.16, P = 0.048) were negatively associated with coverage. Health Check coverage was, therefore, significantly lower in areas with greater proportion of population aged 40 to 74 years, a larger population size, and higher number of FTE GPs and other practice staff.

### Table 15: Correlation between Health Check coverage and predictor variables (Spearman Rank Correlation Coefficient)

<table>
<thead>
<tr>
<th>Predictor Variable</th>
<th>Coefficient (rho)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation (IMD Score)*</td>
<td>0.35</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ethnic minority proportion (%)</td>
<td>0.12</td>
<td>0.132</td>
</tr>
<tr>
<td>Proportion of population in 40–74 age range (%)</td>
<td>-0.23</td>
<td>0.005</td>
</tr>
<tr>
<td>Population size</td>
<td>-0.21</td>
<td>0.011</td>
</tr>
<tr>
<td><strong>Primary care factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QOF CHD</td>
<td>-0.11</td>
<td>0.167</td>
</tr>
<tr>
<td>Patient experience (total patient survey points)</td>
<td>-0.10</td>
<td>0.238</td>
</tr>
<tr>
<td>Annual budget</td>
<td>-0.14</td>
<td>0.082</td>
</tr>
<tr>
<td>Full-time equivalent GPs</td>
<td>-0.23</td>
<td>0.005</td>
</tr>
<tr>
<td>Full-time equivalent other practice staff</td>
<td>-0.16</td>
<td>0.048</td>
</tr>
<tr>
<td>Number of practices</td>
<td>-0.12</td>
<td>0.154</td>
</tr>
<tr>
<td><strong>Cardiovascular prevention need factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated high risk proportion (QRISK) (%)</td>
<td>0.13</td>
<td>0.108</td>
</tr>
<tr>
<td>Estimated CVD prevalence (%)</td>
<td>-0.11</td>
<td>0.179</td>
</tr>
</tbody>
</table>

*Index of Multiple Deprivation 2010*
Median Health Check coverage and differences in coverage between grouped explanatory variables are shown in Table 16. PCTs in more deprived areas had higher coverage than less deprived PCTs (median coverage = 5.39% in the least deprived areas compared with 10.6% in the most deprived areas, P<0.001). PCTs with larger population size (median coverage = 4.80% in PCTs with the largest population size compared with 9.46% in PCTs with the smallest population size, P = 0.008), and more FTE GPs had significantly lower coverage (median coverage = 4.96% in PCTs with the highest numbers of FTE GPs compared with 9.34% in PCTs with the lowest numbers of FTE GPs, P = 0.024).

Table 17 presents associations between Health Check coverage, and primary care and population level factors, when examined using multivariable linear regression models. Coverage was significantly higher in areas with greater deprivation (coefficient = -0.51; [95% CI, -1.88–0.00] in the least deprived PCTs compared with the most, P = 0.035). Other explanatory variables, which were significant in our univariable analysis, did not remain significant in our adjusted analyses, although PCTs with a moderate proportion of individuals at high CVD risk were significantly more likely to have lower coverage than those with the lowest proportion (coefficient = -0.31; [95% CI, -1.15–0.00] in the PCTs with a moderate proportion of high-risk individuals compared with the PCTs with the lowest, P = 0.033).
Table 16: Association between Health Check coverage and categorized PCT level predictors: univariable analysis using Wilcoxon Rank Sum Test

<table>
<thead>
<tr>
<th>Predictor Variable</th>
<th>Median Health Check Coverage</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation (IMD Score)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (most deprived)</td>
<td>10.6</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>8.41</td>
<td>0.025</td>
</tr>
<tr>
<td>3 (least deprived)</td>
<td>5.39</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Ethnic minority proportion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>7.37</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>7.77</td>
<td>0.285</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>8.97</td>
<td>0.095</td>
</tr>
<tr>
<td>Proportion of population in 40–74 age range</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>8.59</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>8.87</td>
<td>0.937</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>5.82</td>
<td>0.100</td>
</tr>
<tr>
<td>Population size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest numbers)</td>
<td>9.46</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9.20</td>
<td>0.957</td>
</tr>
<tr>
<td>3 (highest numbers)</td>
<td>4.80</td>
<td>0.008</td>
</tr>
<tr>
<td><strong>Primary care factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QOF CHD points</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>9.08</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>7.97</td>
<td>0.918</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>6.77</td>
<td>0.328</td>
</tr>
<tr>
<td>Patient experience (total patient survey points)</td>
<td></td>
<td></td>
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<tr>
<td>1 (lowest satisfaction)</td>
<td>9.23</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>7.98</td>
<td>0.855</td>
</tr>
<tr>
<td>3 (highest satisfaction)</td>
<td>6.77</td>
<td>0.279</td>
</tr>
<tr>
<td>Annual Budget</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>8.97</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9.04</td>
<td>0.247</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>6.10</td>
<td>0.202</td>
</tr>
<tr>
<td>Full-time equivalent GPs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest numbers)</td>
<td>9.34</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9.24</td>
<td>0.397</td>
</tr>
<tr>
<td>3 (highest numbers)</td>
<td>4.96</td>
<td>0.024</td>
</tr>
<tr>
<td>Full-time equivalent other practice staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest numbers)</td>
<td>8.78</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>9.52</td>
<td>0.306</td>
</tr>
<tr>
<td>3 (highest numbers)</td>
<td>5.82</td>
<td>0.347</td>
</tr>
<tr>
<td>Number of practices</td>
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<tr>
<td>1 (lowest)</td>
<td>9.18</td>
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</tr>
<tr>
<td>2</td>
<td>7.76</td>
<td>0.874</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>6.29</td>
<td>0.278</td>
</tr>
<tr>
<td><strong>Cardiovascular prevention need</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated high risk proportion (QRISK)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>7.98</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>5.71</td>
<td>0.085</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>9.92</td>
<td>0.232</td>
</tr>
<tr>
<td>Estimated CVD prevalence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>7.76</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>8.87</td>
<td>0.649</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>7.37</td>
<td>0.750</td>
</tr>
</tbody>
</table>

* Index of Multiple Deprivation 2010
Table 17: Association between Health Check coverage (%) and PCT level factors: multivariable analysis

<table>
<thead>
<tr>
<th>Predictor Variable</th>
<th>Coefficient</th>
<th>Confidence interval</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Socio-demographic factors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation (IMD Score)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (most deprived)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>-0.06</td>
<td>-0.49</td>
<td>0.05</td>
</tr>
<tr>
<td>3 (least deprived)</td>
<td>-0.51</td>
<td>-1.88</td>
<td>0.00</td>
</tr>
<tr>
<td>Ethnic minority Proportion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.15</td>
<td>-0.01</td>
<td>0.81</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>0.08</td>
<td>-0.17</td>
<td>0.95</td>
</tr>
<tr>
<td>Proportion of population in 40-74 age range</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>-0.02</td>
<td>-0.58</td>
<td>0.22</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>-0.03</td>
<td>-0.87</td>
<td>0.36</td>
</tr>
<tr>
<td>Population size</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest numbers)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>-0.12</td>
<td>-0.95</td>
<td>0.08</td>
</tr>
<tr>
<td>3 (highest numbers)</td>
<td>-0.57</td>
<td>-2.93</td>
<td>0.04</td>
</tr>
<tr>
<td><strong>Service factors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QOF CHD points</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.04</td>
<td>-0.34</td>
<td>1.01</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>0.01</td>
<td>-0.72</td>
<td>1.08</td>
</tr>
<tr>
<td>Patient experience (total patient survey points)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest satisfaction)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>-0.04</td>
<td>-0.77</td>
<td>0.25</td>
</tr>
<tr>
<td>3 (highest satisfaction)</td>
<td>0.08</td>
<td>-0.36</td>
<td>1.33</td>
</tr>
<tr>
<td>Full-time equivalent GPs</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest numbers)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.10</td>
<td>-0.11</td>
<td>0.94</td>
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<td>3 (highest numbers)</td>
<td>0.02</td>
<td>-0.62</td>
<td>1.16</td>
</tr>
<tr>
<td><strong>Cardiovascular prevention need</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated high risk proportion (QRISK)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>-0.31</td>
<td>-1.15</td>
<td>0.00</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>-0.04</td>
<td>-0.9</td>
<td>0.31</td>
</tr>
<tr>
<td>Estimated CVD prevalence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>Ref.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.30</td>
<td>-0.01</td>
<td>1.42</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>0.10</td>
<td>-0.17</td>
<td>1.06</td>
</tr>
</tbody>
</table>

* Index of Multiple Deprivation 2010
Ref. = Reference
The associations between explanatory variables and binary outcome, poor coverage are demonstrated in Table 14. PCTs in the least deprived areas were significantly more likely to have the poorest Health Check coverage compared with those in the most deprived areas (AOR = 4.81 [95% CI, 1.05–22.2] in the least deprived compared with the most, P=0.044). There was no association between poor Health Check coverage and other primary care or population level factors.
Table 18: Association between poor Health Check coverage and PCT level factors; multivariable analysis

<table>
<thead>
<tr>
<th>Predictor Variable</th>
<th>AOR</th>
<th>Confidence interval</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population factors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Deprivation (IMD Score)&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (most deprived)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>2.21</td>
<td>0.73</td>
<td>6.73</td>
</tr>
<tr>
<td>3 (least deprived)</td>
<td>4.81</td>
<td>1.05</td>
<td>22.2</td>
</tr>
<tr>
<td>Ethnic minority proportion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.76</td>
<td>0.22</td>
<td>2.67</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>0.63</td>
<td>0.11</td>
<td>3.50</td>
</tr>
<tr>
<td>Proportion of population in 40-74 age range</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.47</td>
<td>0.11</td>
<td>1.90</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>0.59</td>
<td>0.10</td>
<td>3.56</td>
</tr>
<tr>
<td>Population size</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest numbers)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1.49</td>
<td>0.31</td>
<td>7.23</td>
</tr>
<tr>
<td>3 (highest numbers)</td>
<td>5.45</td>
<td>0.53</td>
<td>55.9</td>
</tr>
<tr>
<td><strong>Primary care factors</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>QOF CHD points</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1.48</td>
<td>0.22</td>
<td>9.73</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>2.36</td>
<td>0.25</td>
<td>22.3</td>
</tr>
<tr>
<td>Patient experience (total patient survey points)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest satisfaction)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.96</td>
<td>0.18</td>
<td>5.09</td>
</tr>
<tr>
<td>3 (highest satisfaction)</td>
<td>0.27</td>
<td>0.03</td>
<td>2.50</td>
</tr>
<tr>
<td>Full-time equivalent GPs</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest numbers)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.33</td>
<td>0.07</td>
<td>1.66</td>
</tr>
<tr>
<td>3 (highest numbers)</td>
<td>0.46</td>
<td>0.05</td>
<td>4.02</td>
</tr>
<tr>
<td><strong>Cardiovascular prevention need</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estimated high risk proportion (QRISK)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1.88</td>
<td>0.58</td>
<td>6.06</td>
</tr>
<tr>
<td>Estimated CVD prevalence</td>
<td>3 (highest)</td>
<td>0.96</td>
<td>0.15</td>
</tr>
<tr>
<td>--------------------------</td>
<td>------------</td>
<td>------</td>
<td>------</td>
</tr>
<tr>
<td>1 (lowest)</td>
<td>1.00</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>0.57</td>
<td>0.14</td>
<td>2.31</td>
</tr>
<tr>
<td>3 (highest)</td>
<td>1.33</td>
<td>0.25</td>
<td>7.05</td>
</tr>
</tbody>
</table>

\(^a\) Index of Multiple Deprivation 2010

*Note: Poor Health Check coverage = Health Check Coverage of less than 5%*
9.4 Discussion

9.4.1 Main findings of this study

The NHS Health Check had a lower median coverage of 8.2% in 2011/12 compared to the anticipated (18% coverage), with considerable variation (0–29.8%) between PCTs. Health Check coverage was significantly higher in PCTs in more deprived areas in adjusted and unadjusted analyses. Health Check coverage was significantly lower in PCTs with larger population size, higher proportion of population aged 40 to 74 years and with more primary care staff in unadjusted analyses.

9.4.2 Comparison with existing literature

There are limited national studies evaluating the performance of the NHS Health Check. A small number of studies examined the performance of local programmes: Health Check uptake has been previously reported at lower than 50% in North West London (415) and Stoke-on-Trent (416). Direct comparisons with the findings of this study are not possible, as I examined coverage rather than uptake.

There are mixed evidence surrounding the association between uptake of the Health Check and SES (415,416,794,795). I reported a higher coverage in populations living in deprived areas, which is consistent with the second year findings of the study on Health Check uptake in Hammersmith and Fulham (Chapter 8). Uptake was also higher in south Asian patients (415,794) and in patients attending small practices (415), the latter being consistent with the univariable findings of this study. The findings of this study differ from those in studies examining predictors of coverage of cervical screening, which have identified proportion of population eligible for screening; QOF performance; area level deprivation and proportion of ethnic minority groups as significant predictors of coverage (679).

9.4.3 Implications for policy and clinical practice, and future research

This is the first study reporting the national Health Check coverage and assessing the association between primary care and population factors with the programme coverage. I found lower median national coverage than the Department of Health anticipated. The Health Check is a five-year rolling programme, with 20% of the eligible population invited per year with uptake estimated to be 75% (540); the Department of Health expects PCTs to reach a
coverage of 18% in 2011/2012 (636). Coverage reported here is well below this and indicates the programme will not meet the target of screening the eligible population over a 5-year period unless the coverage improves in future years.

Lower coverage of the Health Check programme might be explained by a number of factors. The budget allocated for the Health Check varies between PCTs (629) and is not ring-fenced. PCTs may allocate the budget for other public health interventions and under-invest in the Health Checks, resulting in low coverage. Another reason limiting the coverage of the programme could be the uncertainties when the programme was first implemented. The minimum standards for what constitutes a NHS Health Check were published two years after initial rollout (634). Absence of essential support and training to Health Check providers in PCTs, and the lack of consistent central risk management interventions (631) may be other reasons for low Health Check coverage reported in this study. Finally changes to the NHS’s structure and future changes in the commissioning body of the programme (with local authorities commissioning the programme from April 2013) may have begun to affect the programme in 2011/2012 (916).

The study findings also highlight marked variation in coverage between PCTs with many seemingly well behind in achieving the target of complete rollout by 2013. This may indicate considerable geographic inequality in the programme delivery, which may partly reflect differing patient preferences to attend to a Health Check in different parts of the country (631).

In contrast to previous evidence (795,798), and indeed wider beliefs about preventive medicine, I have shown better Health Check coverage in more deprived areas. A number of public health initiatives have been introduced to reduce health inequalities, notably the prioritisation of ‘Spearhead PCTs’ to receive funding for preventive health services (883,884). The findings of this study might suggest PCTs benefiting from these initiatives are successfully addressing the needs of deprived communities. Alternately deprived areas may see greater need for CVD prevention, and therefore more vigorously support the programme. The impact of the programme on different socio-economic groups needs to be carefully monitored, but early indications from this and the study in Chapter 8 suggest concerns that the programme may widen health inequalities (407) may not be realised, and it may in fact reduce them.
I showed univariable associations between lower coverage and areas with a higher proportion of population aged 40 to 74 years, larger population size, and more primary care staff. Lower coverage in PCTs with a higher proportion of 40 to 74 year old population might suggest PCTs with older populations do not prioritise the programme, possibly spending more on other resources for their aging population. Associations between coverage and population size were, however, not significant in multivariable analysis – possibly confounded by staffing levels. It may nonetheless be valuable to promote the programme in larger PCTs, with older populations – both characteristics of areas outside of major cities.

There have been concerns over the effectiveness and cost-effectiveness of the Health Check programme from its outset (159,647). Findings from the recent systematic review of Krogsbøll et al. (457) have again raised the concern about whether the programme will improve health outcomes, although it showed there was a dearth of recent studies and there are questions on the relevance of its findings to the NHS Health Check (458). Key to the programme being effective is a high level of participation, yet my findings indicate low coverage suggesting that the programme may have limited public health impact.

Improving the Health Check coverage towards the Department of Health targets will require a concerted and multi-disciplinary approach. Strong collaboration is needed between policy makers, commissioners and health care professionals, with the programme receiving a guaranteed budget from local authorities after the commission transition in April 2013. Ongoing and timely monitoring of attendance to the Health Check is needed. It might also be important to employ qualitative approaches, to explore patients’ and health care workers’ experiences of the Health Check to derive lessons for improving performance of the programme (844). With the large spending commitment of the programme, combined with the evidence of limited effectiveness (457), the programme costs might be better deployed to lower cost and more effective population approaches, including policies to promote smoking cessation, healthy eating and regular physical activity (917). Further research is, therefore, needed to evaluate the clinical and cost-effectiveness of the programme.
9.4.4 Strengths and limitations of this study

This is the first study to assess coverage of the NHS Health Check programme nationally. Data were available for all PCTs, including those not currently running a Health Check programme. I used data returns from PCTs to examine the Health Check coverage, which may limit the accuracy of the findings. The data were collected at a national level from all 151 English PCTs, but the sample size may limit the precision of the findings. Potentially important covariates (e.g. number of staff other than GPs) were dropped from multivariable analysis because of mathematical reasons; however, I present their univariable associations.

Some PCTs administer the programme in settings other than general practices, for example pharmacies or community settings (630). This study was not able to investigate the impact of setting on programme coverage. The study had a cross-sectional, ecological design and I, therefore, could not determine the direct cause-effect relationship between the coverage and explanatory PCT-level variables (918). I did not include data from previous years of the programme. This provided a single, clear study outcome measure, but I was unable to examine cumulative coverage. Examining data returns, however, from the first two years of the programme, showed no evidence of PCTs ‘front-loading’ rollout, i.e. carrying out the bulk of activity in the start of a five-year cycle.

9.5 Key points from the Chapter 9

Coverage of the NHS Health Check was lower than predicted during 2011/12, three years into this national programme. Coverage was higher in areas with greater deprivation. Coverage needs to be increased for the potential health benefits of the programme to be realised. Greater investment in the programme may be required to increase coverage in future years. Policy makers need to decide whether any additional resource might be better invested in more cost-effective population-wide strategies, such as accelerating reductions in salt consumption and elimination of trans fats (83).
Chapter 10: Effectiveness of a Cardiovascular Disease Risk Assessment Programme, the NHS Health Check: Results After One Year

10.1 Introduction

The NHS Health Check programme (Chapter 3.4) is the largest systematic CVD risk assessment and management programme ever undertaken worldwide (647). There is limited information on the effectiveness of CVD risk assessment programmes in real world settings (Chapter 2.7). CVD risk assessment programmes primarily seek to identify and manage high-risk patients; therefore, questions remain as to whether greater benefit could be derived from investment in population-wide prevention strategies (544). One randomised controlled trial has shown that the NHS Health Check in a local English setting (in Stoke on Trent) reduced CVD risk one year after the initiation of the programme (648). A recent systematic review on the effectiveness of general health checks in adults (defined as any activity to identify signs, symptoms, or risk factors for disease (including CVD and cancer) that were previously unrecognised) indicated limited impact in reducing morbidity or mortality (457). However, there was a lack of recent studies in this review and the relevance of its findings to the NHS Health Check and other contemporary CVD risk assessment programmes is questionable (458,459). As CVD risk assessment programs are voluntary, low attendance will substantially curtail any population health benefits (Chapters 8 and 9) (456,648).

In this study, I aimed to assess whether the NHS Health Check was associated with a reduction in estimated CVD risk in NHS Hammersmith and Fulham, a deprived and culturally diverse setting in England, after one year.

10.2 Methods

10.2.1 The NHS Health Check in Hammersmith and Fulham

The Health Check programme delivered in NHS Hammersmith and Fulham is outlined in Chapter 6.2. The programme was delivered under the QOF+ scheme in the first two financial years and the characteristics of patients eligible for the Health Check in these years are explained in Figure 12. In Year 1 of the programme (baseline period: 1 July 2008 – 30 November 2009), patients with an estimated high CVD risk (≥20% 10-year CVD risk estimated by JBS2) were targeted. Patients were ineligible, and therefore excluded if
diagnosed with diabetes and CVD; hypertensive and chronic kidney disease (CKD) patients were not excluded from the programme - as per national guidance - but were excluded from my analyses (858).

10.2.2 Study sample and data

I obtained baseline data on patients aged 40 to 74 years estimated to be at high risk of CVD and targeted for a Health Check in Year 1. This was extracted from the EMRs of 27 of the 31 general practices in the PCT on 30th November 2009 using Oberoi Clinical Observations software. I excluded patients registered within 3 months of this date, as there would be insufficient time after registration to complete a Health Check. Follow-up data (Year 2) on these patients was extracted on 31st March 2011. Data for two of the 27 practices involved in Year 1 data set were not available at follow-up, because of data extraction problems. I was, thus, unable to follow-up some of the patients screened at baseline as well as those who were lost to follow-up due to death or leaving practice (Figure 16).

I extracted demographic characteristics (e.g. age, sex, ethnicity), clinical data (e.g. BMI, blood pressure, disease status) and prescription data, taking the most recent record of each CVD risk factor in both years. To assess pre-Health Check levels in statin prescription, I extracted prescription data for all included patients prior to Year 1.

10.2.3 Outcome measures

Primary outcomes were changes in the global CVD risk score (JBS2) and individual CVD risk factors (smoking status, blood pressure, total cholesterol, high density lipoprotein (HDL) cholesterol, lipid ratio (total cholesterol divided by HDL cholesterol) and BMI). The secondary outcome of the study was the prescription of a statin in eligible patients (180).

10.2.4 Predictor variables

I used age, sex, ethnicity, deprivation (the 2007 IMD scores), family history of CHD, non-CVD comorbidities (asthma, mental health, depression, hypothyroidism and COPD), smoking status and practice list size as predictor variables.

I divided age into three groups (40-54, 55-64 and 65-74 years). I used the 2001 UK Census for ethnicity classification, but condensed 16 ethnicity categories plus category for “not stated” into four due to small numbers (Appendix 1 - Table 28). Those with missing ethnicity
and those who did not want to state their ethnicity were included in the same category as those with other ethnic background. Patients with one or more of non-CVD comorbidities were classified as having non-CVD co-morbidity.

10.2.5 Statistical analysis

I determined Health Check status of patients based on the national guidance: those patients with all components (blood pressure, total and HDL cholesterol, BMI, family history of CHD, ethnicity and smoking status recorded and who had been provided with lifestyle advice on exercise and dietary changes) were counted as having a complete Health Check (348). I present CVD risk factor recording in the study population, comparing patients who had a complete Health Check and partial Health Check (one or more Health Check component complete). Global CVD risk score at baseline and follow-up was calculated using baseline age of the patients to isolate the effect of the program on change in CVD risk. I examined changes in the levels of risk factors and global CVD risk score, restricting analysis to those who had the individual risk factor and for the latter, all risk factors (blood pressure, lipid measurements and smoking status) were re-recorded at follow-up. I carried out a sensitivity analysis examining changes in risk factors only in patients with complete data recorded at follow-up. Since the study population was a high-risk sample, the findings might be influenced by regression to the mean. This is especially true for blood pressure and blood lipid levels, which could be randomly elevated at the time of the measurement. To control for regression to the mean, I adjusted follow-up CVD risk factors and global risk score for baseline measurements using analysis of covariance (ANCOVA) test (919). I examined proportion of patients who had their CVD risk score reduced at follow-up and assessed mean changes in CVD risk score at follow-up by baseline risk level within those who had a complete Health Check at baseline and complete data recorded at follow-up, and those who had their CVD risk scores reduced at follow-up. I further assessed changes in global CVD risk score between baseline and follow-up in patients with a complete Health Check at baseline and complete data recorded at follow-up between subgroups defined by sex, age, ethnicity and deprivation using t-tests.

I examined changes in statin prescription, from pre-Health Check, through the study baseline to the follow-up, comparing levels between population subgroups. I used multi-level logistic regression, building mixed-effects models, with patient variables at level 1 and practice at level 2, and including predictor variables outlined above. I tested each variable individually.
for the best fitting model structure; no level 2 structure, random effects or random slope model, using AIC for comparison (875). Random effects models provided the best fit for all variables. Because of the concerns regarding the performance of models built by model selection methods (876–878), I did not employ model selection but included all variables, using random effects, into the final model (Chapter 7.2.5).

All analyses were conducted using Stata version 11.2 SE. Ethical approval was granted from National Research Ethics Service Committee, London – Queen Square.

10.3 Results

10.3.1 Characteristics of study participants
At baseline, 4,748 patients were identified as being at high-risk of CVD based on existing medical record data and eligibility for a Health Check. Among these eligible patients, 1,886 patients (39.7%) had a complete Health Check and 2,703 patients (56.9%) had a partial Health Check in Year 1. Follow-up data were available in 1,574 patients with a complete Health Check and 2,138 with a partial Health Check (full details can be found in Figure 16). Table 7 in Chapter 8 presents the characteristics of eligible patients at baseline. Table 19 shows the characteristics of patients who had a complete and partial Health Check at baseline and had records available at follow-up.
Table 19: Patient and practice characteristics of patients who had a complete and partial Health Check at baseline (Year 1: July 2008 – November 2009) and records available at follow-up (Year 2: December 2009 – March 2011)

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Complete Health Check</th>
<th>Partial Health Check</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>1231</td>
<td>78.2</td>
</tr>
<tr>
<td>Female</td>
<td>343</td>
<td>21.8</td>
</tr>
<tr>
<td>Age Group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>40–54</td>
<td>287</td>
<td>18.2</td>
</tr>
<tr>
<td>55–64</td>
<td>687</td>
<td>43.7</td>
</tr>
<tr>
<td>65–74</td>
<td>600</td>
<td>38.1</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>1222</td>
<td>77.6</td>
</tr>
<tr>
<td>Black</td>
<td>91</td>
<td>5.9</td>
</tr>
<tr>
<td>South Asian</td>
<td>63</td>
<td>4.0</td>
</tr>
<tr>
<td>Other (^a)</td>
<td>198</td>
<td>12.6</td>
</tr>
<tr>
<td>Local deprivation third (^b)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>480</td>
<td>30.5</td>
</tr>
<tr>
<td>2</td>
<td>528</td>
<td>33.6</td>
</tr>
<tr>
<td>3</td>
<td>566</td>
<td>36.0</td>
</tr>
<tr>
<td>Non-CVD comorbidities (^c)</td>
<td>No</td>
<td>1145</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>429</td>
</tr>
<tr>
<td>Family history of CHD</td>
<td>No</td>
<td>950</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>624</td>
</tr>
<tr>
<td>Smoking Status</td>
<td>No</td>
<td>860</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>714</td>
</tr>
<tr>
<td>Practice Characteristics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Practice list size</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6000</td>
<td>557</td>
<td>35.4</td>
</tr>
<tr>
<td>6000–10 000</td>
<td>563</td>
<td>35.8</td>
</tr>
<tr>
<td>10 000+</td>
<td>454</td>
<td>28.8</td>
</tr>
<tr>
<td>Total</td>
<td>1574</td>
<td></td>
</tr>
</tbody>
</table>

\(^a\) Other ethnicity group also includes patients with missing or not stated ethnicity

\(^b\) Index of Multiple Deprivation (2007) (1 = most deprived, 3 = least deprived)

\(^c\) Non-CVD comorbidities – asthma, mental health, depression, hypothyroidism and chronic obstructive pulmonary disease
Figure 16: Flow diagram of study participants eligible for the NHS Health Check at Year 1 (July 2008–November 2009) and followed up in Year 2 (December 2009–March 2011)

- **Eligible patients**: 4748
- **Year 1**
  - **Lost follow-up with 312 patients (data not available or deceased or left practice)**
  - **Complete Health Check**: 1866 (39.7%)
    - **Completely re-screened**: 643/1574 (40.8%)
    - **Partially re-screened**: 795/1574 (50.5%)
    - **Not re-screened**: 128/1574 (8.6%)
- **Partial Health Check**: 2709 (56.9%)
- **Not Screened**: 159 (3.4%)

- **Year 2**
  - **Lost follow-up with 565 patients (data not available or deceased or left practice)**

---

a Patients with complete recording of Health Check Components; blood pressure, lipid measurements, smoking status, family history of CHD, Body Mass Index and lifestyle advice for physical activity and diet
b Patients with one or more recording of Health Check Components; blood pressure, lipid measurements, smoking status, family history of CHD, Body Mass Index and lifestyle advice for physical activity and diet
c Patients who had complete recording of blood pressure, lipid measurements and smoking status
d Patients who had one or two recording of blood pressure, lipid measurements and smoking status
10.3.2 Risk factor recording and change in cardiovascular risk

Risk factor recording at baseline and follow-up are shown in Table 20. 40.9% of patients with a complete Health Check at baseline had blood pressure, smoking status and lipid levels re-recorded at follow-up, while this figure was 23.4% in patients with a partial Health Check at baseline.

Table 20: The level of risk factor recording at baseline (Year 1: July 2008–November 2009) and follow-up (Year 2: December 2009–March 2011) in patients who had a complete or partial Health Check at baseline, and were followed up in Year 2

<table>
<thead>
<tr>
<th>Risk Factor (N=1574)</th>
<th>Complete Health Check</th>
<th>Partial Health Check</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Year 1</td>
<td>Year 2</td>
</tr>
<tr>
<td>Smoking Status (%)</td>
<td>100</td>
<td>84.6</td>
</tr>
<tr>
<td>Blood Pressure (BP) (%)</td>
<td>100</td>
<td>61.6</td>
</tr>
<tr>
<td>Body Mass Index (BMI) (%)</td>
<td>100</td>
<td>41.9</td>
</tr>
<tr>
<td>Lipid measurement (LM) (%)</td>
<td>100</td>
<td>54.7</td>
</tr>
<tr>
<td>BMI, LM, BP, smoking (%)</td>
<td>100</td>
<td>25.7</td>
</tr>
<tr>
<td>LM, BP, smoking (%)</td>
<td>100</td>
<td>40.9</td>
</tr>
</tbody>
</table>

* Lipid measurement: Both total cholesterol and HDL cholesterol measurements

Table 21 presents the changes in global risk scores and individual risk factors at follow-up. There was a significant reduction in the mean global CVD risk score in patients who had a complete Health Check at baseline (28.2%; [95% CI, 27.3–29.1] to 26.2%; [95% CI, 25.4–27.1%]). There were significant reductions in diastolic blood pressure (80.7 mmHg; [95% CI, 80.2–81.3] to 79.6 mmHg; [95% CI, 79.0–80.1]), total cholesterol levels and lipid ratios (4.44; [95% CI, 4.34–4.53] to 4.13; [95% CI, 4.05–4.23]). There was a significant reduction in total cholesterol levels in patients who had a partial Health Check at baseline (5.47 mmol/L; [95% CI, 5.34–5.59] to 5.17 mmol/L; [95% CI, 5.06–5.28]). Similar reductions were found in those patients with all risk factors re-recorded at follow-up (Appendix 1 – Table 29).
Table 22 presents changes in global risk scores and individual risk factors at follow-up after controlling for regression to the mean. The changes in CVD risk scores, total cholesterol levels and diastolic blood pressure were same or similar after adjusting follow-up measurements for baseline measurements (change in global CVD risk score was -2.00; [95% CI: -2.66 – -1.35], P<0.001 and change in total cholesterol was -0.28; [95% CI: -0.34 – -0.22], P<0.001 at follow-up). However, in contrast to unadjusted analysis, the increase in BMI at follow-up was significant after accounting for regression to the mean (change in BMI was 0.21; [95% CI, 0.05–0.36], P = 0.009).

Among patients who had a complete Health Check at baseline (Year 1) and complete rescreen at follow-up (Year 2), 73.6% had confirmed 20% and greater 10-year CVD risk at baseline; 58.8% experienced reduction in CVD risk score at follow-up; and 14.2% had a CVD risk score equal to or greater than 20% at baseline and had their risk score reduced below 20% at follow-up (Table 23).

Table 24 presents mean change in CVD risk scores after one year by baseline CVD risk level in those with a complete Health Check at baseline (Year 1) and complete rescreen at follow-up (Year 2), and those who had risk score reduction at follow-up. The mean change in CVD risk in patients at higher CVD risk was greater than the change in those with lower CVD risk. For example, among all those with a complete Health Check at baseline and complete rescreen at follow-up, the mean change in CVD risk score was -8.76%; [95% CI, -11.3 – -6.18] in the highest risk group (≥40%), -1.99%; [95% CI, -2.88 – -1.11] in those with a risk of between 20% and 40%, and 1.82%; [95% CI, 1.01–2.64] in the lowest risk group (<20%).

Changes in global CVD risk within patient sub-groups are shown in Table 25. Global CVD risk was significantly reduced at follow-up in males (from 29.7% to 27.6%; P = 0.004 compared with 23.2% to 21.4%; P = 0.143 in female), younger patients, white patients (from 28.3% to 25.9%; P = 0.001 compared with 34.9% to 35.2%; P=0.932 in south Asian) and deprived patients (29.4% to 26.4%; P = 0.010 in the most deprived compared with 27.1% to 26.5%; P = 0.561 in the least deprived).
Table 21: Levels of clinical measurements at baseline (Year 1: July 2008–November 2009) and follow-up (Year 2: December 2009–March 2011) in patients who had a complete or partial Health Check at baseline, and were followed-up in Year 2

<table>
<thead>
<tr>
<th>Risk Factor Levels</th>
<th>Complete Health Check (N=1574)</th>
<th>Partial Health Check (N=2138)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Year 1</td>
</tr>
<tr>
<td>Smoking Status&lt;sup&gt;b&lt;/sup&gt;(% - 95% CI)</td>
<td>1331</td>
<td>39.7 (37.0–42.3)</td>
</tr>
<tr>
<td>Systolic Blood Pressure (mmHg – 95% CI)</td>
<td>969</td>
<td>135.1 (134.2–136.0)</td>
</tr>
<tr>
<td>Diastolic Blood Pressure (mmHg – 95% CI)</td>
<td>969</td>
<td>80.7 (80.2–81.3)</td>
</tr>
<tr>
<td>BP &gt;= 140/90 (mmHg) (% – 95% CI)</td>
<td>969</td>
<td>10.8 (8.9–12.8)</td>
</tr>
<tr>
<td>BMI (kg/m&lt;sup&gt;2&lt;/sup&gt; – 95% CI)</td>
<td>660</td>
<td>27.5 (27.1–27.9)</td>
</tr>
<tr>
<td>BMI ≥30 kg/m&lt;sup&gt;2&lt;/sup&gt;(% – 95% CI)</td>
<td>660</td>
<td>26.7 (23.3–30.0)</td>
</tr>
<tr>
<td>BMI ≥25 kg/m&lt;sup&gt;2&lt;/sup&gt;(% – 95% CI)</td>
<td>660</td>
<td>67.3 (63.7–70.9)</td>
</tr>
<tr>
<td>Total Cholesterol (TC) (mmol/L – 95% CI)</td>
<td>870</td>
<td>5.26 (5.19–5.34)</td>
</tr>
<tr>
<td>Total Cholesterol ≥ 6 mmol/L (%- 95% CI)</td>
<td>870</td>
<td>26.7 (23.8–29.7)</td>
</tr>
<tr>
<td>Total Cholesterol ≥ 5 mmol/L (%- 95% CI)</td>
<td>870</td>
<td>58.7 (55.4–61.9)</td>
</tr>
<tr>
<td>HDL (mmol/L – 95% CI)</td>
<td>871</td>
<td>1.26 (1.23–1.28)</td>
</tr>
<tr>
<td>Lipid Ratio (TC/HDL – 95% CI)</td>
<td>861</td>
<td>4.44 (4.34–4.53)</td>
</tr>
<tr>
<td>Global Risk (JBS2 – 95% CI)&lt;sup&gt;d&lt;/sup&gt;</td>
<td>643</td>
<td>28.2 (27.3–29.1)</td>
</tr>
</tbody>
</table>

95% CI – 95% Confidence interval

<sup>a</sup> Risk factors were calculated in patients with a record of the individual risk factor at both baseline and follow-up, therefore a different sample size for each (N) – see Table 2 for the percentage with data recording.

<sup>b</sup> Proportion of patients who smoke

<sup>c</sup> HDL: High density lipoprotein

<sup>d</sup> Global risk was calculated in patients who had blood pressure, smoking status and lipid measurements completed. Baseline age was used to calculate CVD risk at two time points.
Table 22: Difference in CVD risk factors and CVD risk between baseline (Year 1) and follow-up (Year 2) when controlled for regression to mean

<table>
<thead>
<tr>
<th>Risk Factors</th>
<th>N</th>
<th>Difference between follow-up and baseline</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systolic blood pressure (mm Hg – 95% CI)</td>
<td>969</td>
<td>-0.82 (-1.63 – -0.01)</td>
<td>0.048</td>
</tr>
<tr>
<td>Diastolic blood pressure (mm Hg – 95% CI)</td>
<td>969</td>
<td>-1.12 (-1.62 – -0.61)</td>
<td>0.000</td>
</tr>
<tr>
<td>BMI (kg/m² - 95% CI)</td>
<td>660</td>
<td>0.21 (0.05 – 0.36)</td>
<td>0.009</td>
</tr>
<tr>
<td>Total Cholesterol (mmol/L – 95% CI)</td>
<td>870</td>
<td>-0.28 (-0.34 – -0.22)</td>
<td>0.000</td>
</tr>
<tr>
<td>HDL Cholesterol (mmol/L – 95%)</td>
<td>871</td>
<td>0.02 (0.00 – 0.31)</td>
<td>0.022</td>
</tr>
<tr>
<td>Global risk (JBS2 – 95% CI)</td>
<td>643</td>
<td>-2.00 (-2.66 – -1.35)</td>
<td>0.000</td>
</tr>
</tbody>
</table>

* Risk factors were calculated in patients with a record of the individual risk factor at both baseline and follow-up, therefore a different sample size for each (N).

Table 23: Proportion of patients who had their CVD risk score reduced at follow-up in Year 2*

<table>
<thead>
<tr>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>473</td>
<td>73.6</td>
</tr>
<tr>
<td>376</td>
<td>58.5</td>
</tr>
<tr>
<td>91</td>
<td>14.2</td>
</tr>
</tbody>
</table>

* Data from patients with a complete Health Check at baseline and follow-up at year 2 (N=643)
Table 24: Mean change in CVD risk scores at follow-up in those who had a complete Health Check at baseline and were followed up after one year (N = 643), and in those who had risk score reduction at follow-up (N=376)

<table>
<thead>
<tr>
<th>Proportion of patients who had a complete Health Check and follow-up (N = 643)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in CVD risk (%)</td>
<td>&lt;20% (N = 170)</td>
<td>20-40% (N = 376)</td>
<td>≥40% (N = 376)</td>
</tr>
<tr>
<td>1.82 (1.01–2.64)</td>
<td>-1.99 (-2.88 – -1.11)</td>
<td>-8.76 (-11.3 – -6.18)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Proportion of those who had risk reduction at follow-up (N = 376)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Change in CVD risk (%)</td>
<td>&lt;20% (N = 69)</td>
<td>20-40% (N = 237)</td>
<td>≥40% (N = 70)</td>
</tr>
<tr>
<td>-2.95 (-3.50 – -2.41)</td>
<td>-6.93 (-7.63 – -6.23)</td>
<td>-14.8 (-17.0 – -12.7)</td>
<td></td>
</tr>
</tbody>
</table>
Table 25: Changes in absolute cardiovascular risk (JBS2) from baseline (Year 1: July 2008- November 2009) to follow-up (Year 2: December 2009 – March 2011) in patient groups who had a complete Health Check at baseline, and complete rescreen at follow-up (N = 643)

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Absolute risk</th>
<th>N= 643</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Relative Risk Reduction</th>
<th>P-value\textsuperscript{c}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>501 (77.9)</td>
<td>29.7</td>
<td>27.6</td>
<td>0.93</td>
<td>0.004</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>142 (22.1)</td>
<td>23.2</td>
<td>21.4</td>
<td>0.92</td>
<td>0.143</td>
<td></td>
</tr>
<tr>
<td>Age Group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-54</td>
<td>60 (9.30)</td>
<td>25.9</td>
<td>21.9</td>
<td>0.85</td>
<td>0.016</td>
<td></td>
</tr>
<tr>
<td>55-64</td>
<td>274 (42.6)</td>
<td>27.0</td>
<td>24.7</td>
<td>0.91</td>
<td>0.018</td>
<td></td>
</tr>
<tr>
<td>65-74</td>
<td>309 (48.1)</td>
<td>29.8</td>
<td>28.4</td>
<td>0.95</td>
<td>0.151</td>
<td></td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>475 (73.9)</td>
<td>28.3</td>
<td>25.9</td>
<td>0.92</td>
<td>0.001</td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>50 (7.80)</td>
<td>25.1</td>
<td>25.0</td>
<td>1.00</td>
<td>0.972</td>
<td></td>
</tr>
<tr>
<td>South Asian</td>
<td>28 (4.30)</td>
<td>34.9</td>
<td>35.2</td>
<td>1.01</td>
<td>0.932</td>
<td></td>
</tr>
<tr>
<td>Other\textsuperscript{a}</td>
<td>79 (12.3)</td>
<td>27.8</td>
<td>25.9</td>
<td>0.93</td>
<td>0.253</td>
<td></td>
</tr>
<tr>
<td>Local deprivation third\textsuperscript{b}</td>
<td>1</td>
<td>226 (35.2)</td>
<td>29.4</td>
<td>26.4</td>
<td>0.90</td>
<td>0.010</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>223 (34.7)</td>
<td>28.0</td>
<td>25.9</td>
<td>0.93</td>
<td>0.035</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>194 (30.2)</td>
<td>27.1</td>
<td>26.5</td>
<td>0.98</td>
<td>0.561</td>
</tr>
</tbody>
</table>

\textsuperscript{a} Other ethnicity group includes patients with not stated ethnicity
\textsuperscript{b} Index of Multiple Deprivation 2007 (1 = most deprived, 3 = least deprived)
\textsuperscript{c} P-value: two-pairs t-test for significance of difference in CVD risk between baseline and follow-up
### 10.3.3 Statin prescribing

*Table 26* shows statin prescriptions in patients who had a complete Health Check and were confirmed as at high risk (≥20%). There was an increase in statin prescription from 14.0%; [95% CI, 11.9–16.0] in the year prior to baseline, 49.9%; [95% CI, 46.9–52.8] during the baseline year to 60.6%; [95% CI, 57.7–63.5] at follow-up in those confirmed at high risk. Prior to the Health Check, statin prescriptions were significantly greater in older (AOR = 3.47; [95% CI, 1.69–7.15] in the 65 to 74 year old group compared to 40 to 54 year old group) and those with non-CVD comorbidities. At baseline, statin prescription was significantly higher in the oldest age group, smokers and patients with non-CVD comorbidities. Statin prescription was similar between patient subgroups at follow-up, except in those with non-CVD comorbidities who had greater statin prescription (AOR = 1.67; [95% CI, 1.25–2.23] compared to those without non-CVD comorbidities).

Statin prescriptions in patients who had a partial Health Check is shown in *Table 27*. Compared with the complete Health Check group, there was no difference in prescribing before the Check (11.6%; [95% CI, 9.36–13.8] compared with 14.0%; [95% CI, 11.9–16.0] in the complete Health Check group), but lower prescribing in subsequent years (25.7%; [95% CI, 22.6–28.7] compared with 49.9%; [95% CI, 46.9–52.8] in patients with complete Health Check at baseline and 37.0%; [95% CI, 33.6–40.3] compared with 60.6%; [95% CI, 57.7–63.5] in patients with complete Health Check at follow-up). Statin prescription was similar between patient subgroups prior to the Health Check, but it was greater in older patients (AOR = 1.97%; [95% CI, 1.18–3.27] in 65 to 74 age group compared with 40 to 54 year old group at follow-up) and those with non-CVD comorbidities at baseline and follow-up.
Table 26: Statin prescription before (prior July 2008) and after Health Check (at Year 1: July 2008–November 2009 and Year 2: December 2009–March 2011) in eligible patients who had a complete Health Check at baseline (Year 1), and were followed up in Year 2.

<table>
<thead>
<tr>
<th>Patient Characteristics</th>
<th>Pre-Health Check N = 1101</th>
<th>Post-Health Check Year 1 N = 1101</th>
<th>Post-Health Check Year 2 N = 1101</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>%&lt;sup&gt;e&lt;/sup&gt;</td>
<td>AOR&lt;sup&gt;f&lt;/sup&gt;</td>
<td>%&lt;sup&gt;e&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male&lt;sup&gt;a&lt;/sup&gt;</td>
<td>13.8</td>
<td>1.00</td>
<td>51.3</td>
</tr>
<tr>
<td>Female</td>
<td>15.0</td>
<td>0.81 (0.49–1.34)</td>
<td>42.2&lt;sup&gt;+&lt;/sup&gt;</td>
</tr>
<tr>
<td><strong>Age Group</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>40-54&lt;sup&gt;a&lt;/sup&gt;</td>
<td>6.8</td>
<td>1.00</td>
<td>48.5</td>
</tr>
<tr>
<td>55-64</td>
<td>13.2&lt;sup&gt;+&lt;/sup&gt;</td>
<td>2.34 (1.17–4.70)</td>
<td>47.6</td>
</tr>
<tr>
<td>65-74</td>
<td>17.3**</td>
<td>3.47 (1.69–7.15)</td>
<td>52.7</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>White&lt;sup&gt;a&lt;/sup&gt;</td>
<td>14.8</td>
<td>1.00</td>
<td>48.8</td>
</tr>
<tr>
<td>Black</td>
<td>9.1</td>
<td>0.53 (0.20–1.42)</td>
<td>63.6&lt;sup&gt;+&lt;/sup&gt;</td>
</tr>
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</tr>
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</tr>
<tr>
<td>1&lt;sup&gt;a&lt;/sup&gt;</td>
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<td>1.00</td>
<td>53.1</td>
</tr>
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<td>2</td>
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<td>1.03 (0.65–1.64)</td>
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<td>3</td>
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<td>1.06 (0.66–1.72)</td>
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<td><strong>Non-CVD comorbidities</strong>&lt;sup&gt;d&lt;/sup&gt;</td>
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<td></td>
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<tr>
<td>No&lt;sup&gt;a&lt;/sup&gt;</td>
<td>11.7</td>
<td>1.00</td>
<td>48.2</td>
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<tr>
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<td>20.1**</td>
<td>2.09 (1.43–3.09)</td>
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<td><strong>Family history of CHD</strong></td>
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<td></td>
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<tr>
<td>No&lt;sup&gt;a&lt;/sup&gt;</td>
<td>13.5</td>
<td>1.00</td>
<td>53</td>
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<tr>
<td>Yes</td>
<td>14.6</td>
<td>1.17 (0.80–1.70)</td>
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<td><strong>Smoking Status</strong></td>
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<td></td>
</tr>
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<td>1.00</td>
<td>47.2</td>
</tr>
<tr>
<td>Yes</td>
<td>13.3</td>
<td>1.08 (0.72–1.60)</td>
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</tr>
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<td>18.7</td>
<td>1.00</td>
<td>55.2</td>
</tr>
<tr>
<td>6000-10 000</td>
<td>11.4**</td>
<td>0.44 (0.23–0.84)</td>
<td>41.2**</td>
</tr>
<tr>
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<td>11.6&lt;sup&gt;+&lt;/sup&gt;</td>
<td>0.55 (0.27–1.13)</td>
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<td></td>
</tr>
<tr>
<td></td>
<td>14.0</td>
<td>49.9</td>
<td>60.6</td>
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</table>

\(^a\) Reference group in z-test, ** \(P < 0.01\) & * \(P < 0.05\) for z-test

\(^b\) Other ethnicity group also includes patients with missing or not stated ethnicity

\(^c\) Index of Multiple Deprivation 2007 (1 = most deprived, 3 = least deprived)

\(^d\) Non-CVD comorbidities — asthma, mental health, depression, hypothyroidism and chronic obstructive pulmonary disease

\(^e\) Percentage of patients using statins in the group

\(^f\) AOR = Adjusted Odds Ratio

**Note:** Odds ratios are adjusted for all variables in the table.
Table 27: Statin prescription before (prior July 2008) and after Health Check (Year 1: July 2008-November 2009 and Year 2: December 2009 – March 2011) in eligible patients who had a partial Health Check at baseline (Year 1) and were followed up in Year 2

<table>
<thead>
<tr>
<th>Partial Health Check</th>
<th>Pre-Health Check N = 803</th>
<th>Post-Health Check Year 1 N = 803</th>
<th>Post-Health Check Year 2 N = 803</th>
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<td></td>
<td>%e</td>
<td>AORf</td>
<td>%e</td>
</tr>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malea</td>
<td>11.2</td>
<td>1.00</td>
<td>25.8</td>
</tr>
<tr>
<td>Female</td>
<td>13.5</td>
<td>1.06 (0.57–1.97)</td>
<td>24.8</td>
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<tr>
<td><strong>Age Group</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>40-54a</td>
<td>10.3</td>
<td>1.00</td>
<td>22.4</td>
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<tr>
<td>55-64</td>
<td>10.3</td>
<td>0.93 (0.48–1.80)</td>
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<tr>
<td>65-74</td>
<td>14.2</td>
<td>1.50 (0.72–3.12)</td>
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<td>1.00</td>
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<tr>
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<td>1.00</td>
<td>24.5</td>
</tr>
<tr>
<td>2</td>
<td>11.4</td>
<td>0.92 (0.51–1.65)</td>
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<td>3</td>
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<td>1.05 (0.57–1.91)</td>
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<td><strong>Non-CVD comorbidities</strong></td>
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<td>1.00</td>
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<td>1.00</td>
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<td>26.5</td>
</tr>
<tr>
<td>6000-10 000</td>
<td>5.71**</td>
<td>0.33 (0.13–0.84)</td>
<td>20.7</td>
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<td></td>
<td>&gt;10 000</td>
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</tr>
<tr>
<td>Total</td>
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<td>25.7</td>
<td>37.0</td>
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</tr>
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<tbody>
<tr>
<td>a</td>
<td>Reference group in z-test, ** $P &lt; 0.01$ &amp; * $P &lt; 0.05$ for z-test</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>b</td>
<td>Other ethnicity group also includes patients with missing or not stated ethnicity</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>c</td>
<td>Index of Multiple Deprivation 2007 (1 = most deprived, 3 = least deprived)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d</td>
<td>Non-CVD co-morbidities - asthma, mental health, depression, hypothyroidism and chronic obstructive pulmonary disease</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>e</td>
<td>Percentage of patients using statins in the group</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>f</td>
<td>AOR = Adjusted Odds Ratio</td>
<td></td>
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</table>

**Note:** Odds ratios are adjusted for all variables in the table.
10.4 Discussion

10.4.1 Main findings of the study

The introduction of the NHS Health Check, a national community based CVD primary prevention programme, was associated with significant but modest reductions in CVD risk after one year in high-risk patients with a complete Health Check. These include significant reductions in global CVD risk score, diastolic blood pressure, total cholesterol levels and lipid ratios. The reduction in predicted CVD risk score may be largely attributable to the reduction in mean total cholesterol levels (and also lipid ratio). This, in turn, may correspond to the substantial increases in statin prescription over the study period. Greater reductions in CVD risk were found in male, young, white and deprived patients than others. Although a large proportion of patients saw some benefit from the programme, only a minority crossed the English high-risk threshold (<20%). Programme benefits may be greater in those at the highest risk.

10.4.2 Comparison with existing literature and explanation of findings

Evidence of the effectiveness of systematic cardiovascular risk assessment and management programmes is limited, with very little evaluation from routine care settings. The findings of this study support previous studies conducted in trial settings (441,456,648,920), suggesting CVD screening may reduce global CVD risk score and total cholesterol levels in high-risk groups. It is noteworthy that I identified reductions in total cholesterol levels also in patients who received a partial NHS Health Check, reflecting increased statin prescribing in this group. This finding suggests that the benefits of the programme may extend beyond those patients who have a complete Health Check.

The study findings suggest that the impact of the Health Check on health inequalities may be mixed. Despite higher attendance levels (Chapter 8) (415,794), I showed no significant reduction in CVD risk after one year in south Asian and black patients, when contrasted to white patients. These findings could suggest that universal primary prevention initiatives may not impact equally across ethnic groups. Overall, there is no ethnic disparity in access to health care in the UK (787), but ethnic minorities are less likely than white patients to leave a primary care consultation with a positive outcome (921,922). A further manifestation of this might be seen here. However, further studies with a larger sample size of black and south
Asian patients are required to confirm this finding. Although there is evidence of smaller CVD risk reduction in men compared to women, despite their greater CVD risk (325), I showed a significant risk reduction after one year in men, but not in women. I also identified greater risk reduction in attendees living in more deprived areas who were shown as more likely to attend a Health Check in Chapter 8.

10.4.3 Implications for policy and clinical practice, and future research

There is growing interest internationally in implementing CVD risk assessment and management programmes as part of CVD reduction strategies (195,559,560). This study on the evaluation of the boldest such attempt, the NHS Health Check program, identified a significant but modest reduction in global CVD risk in individuals who had a complete Health Check. Although this study findings suggest that CVD risk assessment programmes, delivered in a setting with well-organised primary care, targeting patients with estimated high-risk (272,273,861) can produce potentially beneficial risk factor reductions, a number of concerns and questions about the NHS Health Check remain.

First, the uptake of the Health Check among the eligible patients in this study was about 40%. This is consistent with other studies (415,416,648), but considerably lower than the government projection of 75% uptake (417). As well as poor uptake, fewer than half of attendees had complete follow-up measurements. The public health impact of the Health Check may therefore be limited, since high uptake is essential for the high-risk based prevention programme to be effective in significantly improving health in the population (545). Efforts to enhance the attendance are therefore needed for the Health Check to be effective in improving public health.

Second, many local programs, including the one evaluated in this study, targeted individuals at high risk of CVD in their first year (415,416). Assessment of uptake and the relative gains of risk assessment in lower risk groups are required, and must be balanced against other public health policy options. These include whole population approaches, such as salt reduction and tobacco control, which are more cost-effective than high-risk approaches (143).

Third, long-term evaluation of the program in the general population is essential to determine the best prevention strategy to reduce CVD burden in the whole population. Adding intention-to-treat data in addition to my per-protocol analysis is vital to fully assess the program’s public health impact. For example, adherence to statins as a primary prevention
intervention has been previously shown to be low (892,923) and needs on-going monitoring within such programmes.

Fourth, CVD prevention strategies focused on high-risk individuals may widen health disparities (Chapter 2.9) (407). The findings of this study suggest that ethnic minorities, who are at higher risk of CVD, may benefit less from the program than whites. Further evaluation for assessing uptake and adherence to interventions in the ethnic minority groups is, therefore, needed. Targeted clinic and community-based approaches may be required to manage CVD risk in these patient groups (924). Modification must be made, if necessary, that ensure any effective disease prevention services are received equitably across all high-risk groups (925).

10.4.4 Strengths and limitations of the study

The study population is not representative of the whole UK or other international settings, but the findings may reflect the impact of the program in other urban areas with similar levels of deprivation, ethnic diversity and CVD burden. I employed a pre–post study design, which did not take into account potential changes in underlying trends of risk factors over time. My study involved high-risk patients, an initial target group in many areas in England, who are more likely to benefit from the programme. Selection bias is, therefore, a potential source of error that may have influenced the findings. However, it is important to recognize the scope of the study: I aimed to examine whether the Health Check was able to reduce CVD risk in patients who attend, not impacts across the whole population.

The small sample size of black and south Asian patients meant that there might be inadequate power to detect changes in risk factors in these groups. I could only assess statin prescription in eligible patients, with no information about adherence in the current dataset. Adherence to statins for primary prevention intervention may be low (892). Future research to evaluate the adherence to statins is needed. I was also unable to assess uptake and adherence to other interventions employed under the NHS Health Check, such as weight management and exercise promotion; because this information is not recorded in electronic medical records. The evaluation of effectiveness of lifestyle advice on diet and exercise, and weight management and exercise promotion programs provided under the programme is essential to determine effective intervention strategies for the management of CVD risk.
10.5 Key points from Chapter 10

Internationally, there is an increasing interest in adopting CVD risk assessment and management programmes as part of the strategies to reduce CVD burden. There is, however, limited information surrounding the effectiveness of such programmes on improving public health. In this study evaluating the impact of the NHS Health Check on CVD risk in a local setting after one year, the NHS Health Check was associated with significant but modest reductions in CVD risk among high-risk attendees. Further evaluation is essential to determine the overall effectiveness and cost-effectiveness of the programme, and to assess whether program costs are an efficient use of health care resources.
Chapter 11: Discussion

11.1 Introduction

In an era of increasing costs for CVD care due to increasing aging population in developed countries (131) and a financial environment in which health care costs need to be employed for higher benefit and less costly health care programmes (133), the cost-effective primary prevention of CVD has crucial importance. As part of the primary prevention strategies against CVD, there has been growing interest in employing CVD risk assessment and management programmes internationally (195,559,560). The NHS Health Check in England (195) is the first national systematic CVD risk assessment and management programme ever implemented. In this thesis, I aimed to evaluate the implementation and impact of the NHS Health Check programme during the early stages of its development. I investigated the recording and level of risk factors prior to the implementation of the programme in a local area, which provided important implications for the workload that the programme would generate. I further explored the levels of attendance to the Health Check at both local and national levels, and studied the short-term impact of the programme on CVD risk in a targeted population with high estimated CVD risk. These have important implications to practice and policy in terms of the effectiveness of the programme in improving public health. A thorough review of the literature on the importance of CVD prevention, strategies for primary prevention of CVD and relevant areas has shown that there are a number of concerns over the NHS Health Check programme. Based on the review of literature and my findings, I have determined implications for alternative approaches for more effective and cost-effective primary prevention of CVDs.

11.2 Summary of key findings

11.2.1 Workload

The NHS Health Check requires recording of data on a range of demographic information and CVD risk factors for all participants. My findings demonstrated that a considerable proportion of eligible patients had complete CVD risk factor data. The recording of smoking status and blood pressure within last five years was particularly high, with 86.1% and 82.5% recording respectively. The recording of BMI, cholesterol and glucose levels were, however, significantly lower. The Health Check guidance requires de novo recording of all risk factor data (348). My findings, however, suggest if the programme provides flexibility in de novo
recording of data, allowing the use of recently recorded data; it would generate a smaller workload for programme providers. There were very large variations in risk factor recording between practices, most of which was attributable to patient-level characteristics. The prevalence of overweight and obesity, and high blood pressure and raised cholesterol were also high prior to the Health Check in the eligible population, suggesting that as well as screening, the management of risk would require large workload.

11.2.2 Effectiveness of the NHS Health Checks

The uptake of the NHS Health Check was lower than the Department of Health anticipated uptake of 75%, with an overall uptake of about 40% among the estimated high-risk patients targeted in the first year of the Health Checks in Hammersmith and Fulham. However, the participation among those with non-high risk in the following year matched the annual required rate, with 20% uptake among all eligible patients. There was a high practice level variation in the uptake of the Health Check.

As well as local attendance levels, I looked at the national coverage of the programme in a cross-sectional study using a single year of data (2011/2012). The national coverage of the NHS Health Check was low with a median coverage of 8.2% compared to the anticipated annual coverage of 18%. There was also a high variation in coverage (0–29%) between PCTs.

I had access to only statin prescription data as an intervention measure and assessed the change in prescription levels before and after the Health Check in those with a complete Health Check in the first year and second year of the programme. There was an increase in statin prescriptions over the Health Check in statin eligible patients (patients with an actual risk ≥ 20%). The statin prescription increased from 14.0% to 48% after the Health Check in estimated high-risk patients screened in the first year of the programme and from 19.4% to 43.1% in the non-high risk population screened in the second year. The statin prescriptions achieved in both years of the programme were lower than the anticipated statin prescription rate of 85%.

I examined the changes in CVD risk scores and risk factors after one year among the estimated high-risk patients who had a complete Health Check in the first year of the programme in Hammersmith and Fulham, comparing to the changes in risk factors in those who had a partial Health Check. There was a significant but moderate decline in CVD risk
scores, diastolic blood pressure, total cholesterol and lipid ratios after one year in patients with a complete Health Check. Patients who had a partial Health Check also experienced significant reductions in total cholesterol. The decline in cholesterol levels in patients with a complete and partial Health Check may be attributable to the increases in statin prescriptions over the one-year study period. The reduction in overall CVD risk scores in those with a complete Health Check may again reflect the reduction in cholesterol levels and in turn, the increase in statin prescriptions.

11.2.3 Inequalities

I have examined variations in the main outcomes by patient and practice characteristics, throughout the evaluation of the NHS Health Check programme, from baseline through the early stages of the programme, and demonstrated inequalities in care. Prior to the NHS Health Check, there were variations in CVD risk factor data recording by patient and practice characteristics. All risk factors were more completely recorded in women, those living in more deprived areas, black patients compared with whites, those with non-CVD comorbidities and hypertensive patients. The recording of cholesterol and glucose was greater in south Asian patients compared with whites. There was a greater recording of blood pressure, cholesterol and glucose in older compared with younger. The completeness of risk factor data before the Health Check varied highly between general practices. For example, BMI recording varied between 29.4% and 91.5%. The variation in recording of all risk factors, including smoking status, blood pressure, glucose, BMI and cholesterol, was more strongly attributed to the patient level than the practice level characteristics.

There was also variation in the uptake of the Health Check with patient characteristics. In the first two years of the NHS Health Check in Hammersmith and Fulham, the uptake was lower in younger persons, smokers and those with no ethnicity record. In the second year, among those not estimated to be at high risk, the uptake was greater in patients living in more deprived areas and in south Asian and black patients. Examining patient and practice characteristics did not explain a large proportion of the variation in the uptake between practices; total variance due to unexplained practice level factors was 16.1% in the first year of the Health Checks and 37.3% in the second year. This may be because limited data were available on practice level characteristics.
The reduction in CVD risk among patients who had a complete Health Check in the first year of the programme in NHS Hammersmith and Fulham also showed difference by patient characteristics. Male, younger, white and more deprived patients had greater reductions in CVD risk.

There were also inequalities in the PCT-level coverage of the Health Checks nationwide. PCTs in more deprived areas were significantly more likely to have higher Health Check coverage than those in less deprived areas in an unadjusted analysis and in an adjusted analysis accounting for other factors on patient socio-demographic characteristics, primary care provider characteristics and markers of need for CVD prevention. When not controlling for other factors, the Health Check coverage was significantly lower in PCTs with greater population size, greater proportion of the Health Check eligible age group and more primary care staff.

11.3 Strengths, limitations and consideration of methods

I explain the strengths and limitations of the methodological approach within each study in Chapters 7 to 10. I shall, here, discuss the strengths and limitations considering the whole work involved in my thesis.

My work evaluates the first universal CVD prevention programme in its early development stage. One of the main strengths of my work is that it is some of the first to evaluate this high profile programme using both local and national datasets. My work has therefore important implications regarding the accessibility of the programme and management of the programme in the forthcoming years.

The majority of PCTs, former commissioners of the programme, aimed to offer the Health Check to a targeted group with estimated high risk in the first year of the programme. The current literature surrounding the uptake of the programme using local-level data examined populations at estimated high risk (415,416). The uptake in high-risk and non-high risk populations may differ, for example, patients may be more motivated to attend a health check, if they are labelled as high risk or they may be less likely to attend because having high risk is correlated with poor health behaviours and therefore low willing to seek care. My analyses of programme uptake in both estimated high-risk and the remaining low-risk populations are the first showing a comparison in uptake between these populations. Further follow-up is necessary to assess the uptake in subsequent years, because more motivated
individuals may have attended the programme in the early years and the uptake may be lower in following years.

Another strength of the programme was that data used for evaluating the local delivery of the programme in Hammersmith and Fulham was derived from the dataset of a pilot local financial incentive scheme, the QOF+. This allowed me to assess how such incentive schemes could influence the uptake of the Health Check programme and also to examine exclusions or ‘exception reporting’ from the Health Check. My analysis of exception reporting within the Health Check programme is the first of its kind. Exception reporting was very high, with about half (46.4%) of the eligible patients with estimated high risk were exception reported in the first year, when a systematic (organized) screening approach with formal invitations was used. However, this was low, with only 5.7% exception reporting among eligible non-high risk patients who were screened opportunistically in the second year. These findings are important in terms of providing lessons for future programmes to be delivered under such financial incentive schemes.

Despite its strengths, my work also has a number of limitations. A key issue is around the generalizability of my findings, since the majority of my work uses data from a local area in London, Hammersmith and Fulham. The NHS Health Check delivered in NHS Hammersmith and Fulham under the local financial scheme was modified to address local needs of its population. In the first year of the local programme, an extended age range (32 to 74 year old instead of 40 to 74 year old age group) and some disease groups (CKD and hypertensive patients) that are exempt from the national programme were included. I overcome this limitation in the analysis, for example, by restricting my analysis to persons defined as eligible according to national minimum standards. Although in the analysis for the baseline completeness of CVD risk factors, I included patients with diagnosed hypertension and CKD, who are exempt from the national Health Check, I overcome much of this limitation in the analysis by using multivariable models. Another difference between the local Health Check and the national minimum requirements was that the local programme under the QOF+ required extra CVD risk factors to be recorded for the completeness of the Health Checks (including family history of diabetes and glucose testing) compared to the national minimum standards. There was, in addition, variation between the delivery of the programme under the QOF+ in the first two years, whilst each component of the Health Check was incentivised separately in the first year, all Health Check components were required to be complete in the
second year. I, again, overcome much of these limitations by determining the completeness of the Health Check according to the national minimum standards of the programme in both years to make my findings generalizable.

The other limitation surrounding the generalizability of the findings is that the population profile of the Hammersmith and Fulham is different from the general population of England. The area accommodates a highly diverse population in terms of both deprivation and ethnicity. This may limit the generalizability of my findings and the findings may not be applicable to areas with different population characteristics. However, my findings may be applicable to other urban areas with similar population profile and levels of CVD burden.

The NHS Health Check programme is the first nationwide CVD risk assessment and management programme in the world. In an era of growing importance on the CVD prevention internationally (559,560), this body of work is likely to be of interest to many countries. The findings of the work presented in this study must, however, be handled carefully when deliberating the implications for programmes being developed elsewhere. The UK health system delivers a publicly funded universal health care with well-developed primary care and general practice (926). General practice is supported by advanced information technology, including an EMR. These are important in facilitating the implementation of a universal screening programme for CVD prevention like the NHS Health Check. The findings of this study may not be directly applicable to countries with health systems that have less developed primary care and poorer information technology (578). This is because these health systems are unlikely to manage delivering a programme with such a large scope. For instance, USA has comparatively less developed primary care and my findings cannot be directly applied to the CVD prevention initiative in US, ‘the Million Hearts’ (559).

In some PCTs, the programme is administered in other settings, including pharmacies and community settings, as well as general practices. For example, in Hammersmith and Fulham, the Health Check was also offered in community settings, e.g. pharmacies, from the second year. The uptake and other outcomes of the programme may be different across different settings (794). However, my analyses using data from general practices in Hammersmith and Fulham and national data do not reflect evidence on programme outcomes in such settings. The evaluation of the programme delivered in such community settings may be necessary to increase uptake. Evidence suggests that CVD prevention delivered in pharmacies can be
effective in reducing CVD risk (927). However, implementation of CVD prevention in pharmacies could face with a number of problems, including cost for developing the service, technological difficulties, substantial work for training staff and low through-flow in pharmacies (630). I was unable to address these issues in this work, but future work is essential to assess the delivery of the programme in pharmacies by accounting for all these problems.

My work aimed to evaluate the early impacts of the NHS Health Check programme. Since my data were from the early years of the programme, I was unable to answer some of the important questions regarding the impact of the programme. Although I was able to follow-up examining short-term outcomes, including CVD risk factors, global risk score and statin prescriptions, in the estimated high-risk group, the timeframe of my work meant that I was unable to assess adherence and compliance to risk management interventions over time. It was, therefore, also not possible to examine the programme’s impact on long-term outcomes, such as CVD incidence and mortality. Another limitation of my work due to the limited timeframe was that I was unable to assess the impact of the programme on both short and long-term outcomes in the non-high risk group and in the general population, in which the consequences of the programme may be different. This is crucial in terms of evaluating the policy design and public health impact of the programme. Assessing the effectiveness of the Health Check, therefore, require data on CVD outcomes and uptake, adherence and compliance to statins and community-based interventions (e.g. weight management and physical activity interventions) through the implementation of the programme.

I have focused only on the high-risk based primary prevention of CVD and did not study other types of CVD prevention in my work, because my work aimed to assess the impacts of the Health Check programme. Patients with vascular diseases, including those with hypertension, CKD, CVDs and diabetes are not included as a target group in the Health Check, but these patients are managed separately under other prevention schemes (secondary prevention), for example the QOF. The effectiveness of secondary prevention strategies on the management of CVD risk in vascular disease groups has been widely studied elsewhere (323,928,929). The programme also excluded those not in the 40 to 74 year old age range. Evidence suggests that CVD risk exists through the whole life-course. It is essential to manage CVD risk with early and continued interventions (930). Strategies using a primordial
prevention approach are important to manage CVD risk throughout the life-course (Chapter 2.1). Evaluating these prevention strategies are beyond the scope of my study.

Finally, methodological weaknesses need to be considered as a further limitation of my work. I shall discuss the major concerns regarding the impact of some of the methods used in the analysis on my findings. The majority of analysis I conducted involved local data from NHS Hammersmith and Fulham. The data were collected from the QOF+ dataset and since the QOF+ was a pilot financial incentive scheme, the data had a number of weaknesses. The first considerable weakness was that the PCT did not generate a Read Code that represents attendance to a Health Check appointment in the first year of the programme. The population with diagnosed hypertension, CKD and diabetes before having a Health Check need to be excluded from the data, as per national guidance, when determining the eligible population. However in the absence of a Read Code specifying the date for Health Check attendance, I was unable to determine patients diagnosed with a disease after receiving a check. For this reason, the most appropriate approach to be taken was excluding all patients with a diagnosis of vascular diseases throughout the first year. This issue, however, is not valid for the second year data, which included a Read Code and date for Health Check attendance.

There was a low recording of ethnicity in the local data used in the majority of my work and missing ethnicity was an important limitation. This problem is common in health research and a variety of methods have been used to overcome this problem. The most frequently used method is to exclude patients with missing ethnicity from the analysis or combine these patients in the other ethnic group. In the analysis for assessing baseline CVD risk factor recording (Chapter 7) and the Health Check uptake (Chapter 8), I included patients with missing ethnicity in a separate ethnic category with those who did not want to state their ethnicity. In the analysis for CVD risk follow-up after one year (Chapter 10), I did not employ a separate ethnic category for missing ethnicity group, because a small proportion of the Health Check eligible group in the first year had missing ethnicity record and was appropriate to include them in the other ethnic group.

Another methodological weakness concerning the missing data is that I assumed variables as null, if data, for example smoking status, BMI (to determine overweight group), non-CVD disease groups, were missing. This may lead to underestimation of findings, but the error especially for those variables with high recording (e.g. smoking recording) and rare conditions is likely to be small.
I treat most continuous variables as categorized variables. These variables were, for example, age, deprivation (IMD scores), practice list size, number of FTE GPs and practice deprivation in the analyses using local data; and deprivation (IMD scores), proportion of ethnic minorities, proportion of population eligible for the programme, population size, number of FTE GPs and others in the analyses using national data. This might lead to loss of power and reduced correction for confounding factors, resulting in loss of valuable information. I, however, used categorized variables for presenting explicit and comprehensible information to policy makers in order to assist them in addressing different groups of populations efficiently.

In the analyses using local data, I could control outcome measures with only very limited practice-level characteristics. This was either because of mathematical reasons, as with FTE GP that was collinear with practice list size, or because data were not available, as for example with age, sex and ethnicity of GPs. This may lead to a large proportion of variation in outcomes between practices to remain unexplained.

My analysis on the evaluation of attendance to the Health Check at national level used direct data returns from PCTs, which is a potential limitation. Although uptake (population attended/population offered a Health Check) is an important measure for evaluating the policy-design of the programme, I found it not appropriate to assess the programme uptake patterns, as well as coverage (population attended/population eligible for a Health Check) (656), due to the potential limitations that data on population offered a Health Check would bring. Some PCTs use a systematic approach with formal invitations to eligible population only, some use an opportunistic approach only or some use both. Whilst the systematic screening allows a more accurate coding of eligible population offered a Health Check, with the opportunistic approach, population who was offered a Health Check was possibly less accurately reported. I, therefore, focused on the programme coverage only, which is a good measure of assessing the potential impact of the programme on population health.

In the multivariable analyses, using both local and national level data, I used multilevel models, instead of alternative methods such as ignoring the clustering or generalized estimating equations, to control for covariates and handle the clustering (lack of independence) of patients within areas. There are a number of advantages of using multilevel models compared with other methods. They can model more than two levels and allow the ranking of outcomes by group (e.g. GP practice or PCT). They allow the assessment of
variability between groups and the impact of group-level characteristics on individual outcomes. They can provide an efficient estimation of correct standard errors. Multilevel models, however, also have limitations. For example, convergence can be difficult to achieve in these models. This may be due a number of factors, such as poor choice of starting values or variables included in the model being measured on different scales.

11.4 Implications for policy and practice

11.4.1 Workload implications

The NHS Health Check programme has a great potential to generate a very large workload for general practices in England. Assessment of CVD risk and recording of risk factor data requires a vast capacity. My findings demonstrate low baseline recording of CVD risk factors, especially for cholesterol, BMI and glucose within the last five years, suggesting a large workload to complete CVD risk factor recording. The workload would be significantly higher, if all data is to be re-recorded as required under the national guidance. The NHS Health Check is commonly delivered by practitioners other than GPs, including nurses and health care assistants, even in general practices. There has been a shift in some primary care elements from GPs to nurses and health care assistants to increase the capacity of primary care. These practitioners are less costly to employ (931) and providing the responsibility of the Health Check to these practitioners may enhance the capacity of primary care in delivering the programme more cost-effectively. Although there is limited information about the capacity of the non-medical workforce in general practice, it is evident that nurses, for example, are already exposed to a large workload of cervical screening and vaccinations (931). However, there is some evidence that delivering the programme puts extra strain on general practice staff (regardless the type of practitioner) (631), it is therefore questionable if the additional workload of the Health Checks is manageable with existing resources.

As well as CVD risk assessment, management of risk requires significant workload in the NHS Health Check. Work for management of cardiovascular risk carries crucial importance in CVD prevention strategies; CVD risk assessment becomes ineffective without risk management interventions. My data on the baseline levels of risk factors showed that there is a high prevalence of risk factors including high blood pressure, raised cholesterol, overweight or obesity and smoking among the population eligible for a Health Check. Those with an elevated risk or risk factor identified during a Health Check are eligible for appropriate
interventions, such as statins, smoking cessation services, community based programmes for physical activity and weight management. These services also require an enormous workload. Evidence suggests that referrals to services for CVD risk management under the Health Check remain low (629). There is also considerable PCT-level variation in the availability of referral services and the capacity of services offered. The referral to risk management services by practices was poorer than anticipated by the Department of Health for cost-effective prevention of CVDs (631). These all suggest that there is no adequate capacity to manage the workload for controlling raised CVD risk factors.

The high prevalence of CVD risk factors has other significant implications, in addition to workload. There is limited evidence on the effectiveness of interventions offered under the Health Check (Chapter 2.6.1). However, even if it is assured that the risk management interventions are effective, there must be adequate funding available to employ these interventions for effective management of risk factors in high-risk patients. Another question regarding the management of high CVD risk prevalence is whether a high-risk approach is the best strategy to address this. Evidence suggests that although high-risk based strategies produce significant reductions in CVD risk factors in high-risk individuals, they are not effective in controlling CVD risk trends in the entire populations (431). Low uptake of risk management interventions (416) may also lead to limited effect on changes in CVD risk factors. Another concern is that there is an increasing trend in risk factors, such as physical inactivity and obesity (135), and it is questionable if health service based interventions alone will meet the increasing need for controlling these risk factors. Considering all these limitations regarding the risk management interventions offered under the Health Check, it can be suggested that population level interventions may have greater potential and be the best alternative to effectively and cost-effectively manage elevated risk factors, including raised cholesterol, blood pressure and overweight and obesity in the general population. These interventions include salt reduction policies in collaboration with the food industry (Chapter 2.8.2), and structural changes to the environment to manage transport systems and town planning (932).

11.4.2 Implications of uptake findings

The success of a high-risk based primary prevention programme is highly dependent on the uptake of the programme. The lower the uptake of the programme, the lower the impact on the public health of the population will be. For the success of these CVD prevention
programmes, uptake of both risk assessment and risk management interventions, also specifically adherence to interventions needs to be optimal (545). My findings from the first year of the programme showed an uptake of only about 40% that is considerably lower than the Department of Health projected uptake of 75% for cost-effective reduction of CVD risk in the population (624). Although this was from the first year of the programme and one might suggest the uptake would improve in consequent years, the target group was those at estimated high-risk and the low attendance in this group is concerning. However, the uptake was similar to studies reporting uptake among high-risk patients in other areas (415,416) and also parallel to those of CVD prevention trials (456,794). My data allowed following up the uptake in the second year of the programme and in contrary to the first year and previous literature, the uptake matched the local and national anticipated rate. The uptake in this second year of the programme was promising, although it was among those not with estimated high-risk. Those attending in this year may, however, be the most motivated patients and attendance may be lower in subsequent years.

Although I was unable to further assess the uptake of the programme using the local data, I could examine the attendance levels at national level using another attendance measure (coverage) in the third year (2011/2012) of the programme. This PCT-level analysis showed an overall median coverage of 8.2% that is well below the anticipated coverage of 18% in the particular year (636). My analysis also indicated a large PCT-level variation in the coverage and showed that there were still PCTs not employing the Health Checks in the third year of the programme, just before the targeted complete rollout of the programme (2012/2013). With such a low coverage, and no indication of greater coverage than in previous years, my analysis implies that if the coverage does not improve in the following years, the programme will not meet the target of screening eligible population within 5-years and will, therefore, not produce the anticipated impact on public health. The figures from 2012/2013 confirmed this, showing an annual coverage of again much lower (8%) than the anticipated 20% annual coverage. The uptake was also low with less than 50% and there was even a small reduction in uptake compared with the previous year (933). Public Health England found these figures ‘promising’, since they think that during the time of transition to local authorities, the uptake levels might have been more severely affected (933,934). Significant efforts to promote the attendance to the programme are essential to ensure cost-effective use of resources to improve English public health; otherwise alternative strategies may be required. Public Health England consequently declared efforts for improving the programme uptake by
supporting local authorities to achieve full rollout (to offer the programme to 20% of the eligible population and achieve an uptake of at least 75%) by 2017. Public Health England aims to deliver the programme in a more systematic manner and actively involve GPs in the efforts of improving the programme uptake by 50% (933–935).

The prescriptions of statins among both those with estimated high-risk screened in the first year (47.8%) and non-high risk screened in the second year (43.1%) were lower than the Department of Health estimates of 85% among those eligible for the intervention (624). Low uptake of statins decreases the effect of the programme on health outcomes (545). Statin uptake must also be improved. It is not possible to achieve a hundred percent statin uptake. Statins can lead to side effects and therefore there is a valid reason for patients to not accept the offer of a prescription (155). Statin prescriptions can be influenced by both patient and practitioner level factors (Chapter 2.6.2.3). From GPs’ perspective, there are a number of barriers to statin prescriptions, including concerns about high cost, large workload, over medicalization of patients and others (376). Despite wider availability of statins and uniform clinical guidance, GPs may still have doubts on the use of statins in primary prevention of CVD (936). They think that the evidence surrounding the effect of statins in primary prevention is weak and statins have very small impact on an individual. GPs also support a shared and informed decision making process in statin prescriptions in primary prevention (936). All these barriers can affect the GP statin prescription patterns and therefore statin prescription for the same patient may differ across practitioners. These barriers can, however, be overcome if adherence to clinical guidance can be achieved (180,377). Barriers for patients in the use of medication in primary prevention include concerns over side effects and long-term reliance to medication. If patients are dominant in the decision making process (377,936), these barriers can then significantly affect the therapy. Concerns can be lessened by accurate communication of high quality information on CVD risk to improve statin prescription (297,821).

My work did not cover adherence to interventions provided under the NHS Health Check. However, adherence to interventions is highly important for the success of the NHS Health Check programme, as well as the uptake. Evidence suggests that adherence to medications is particularly low when used for primary prevention. The adherence to statins when used for primary prevention has been mostly less than 50% (114,399,401). Evidence has also shown that adherence to weight management (937–939), physical activity (940,941) and smoking
cessation (942,943) interventions are low or moderate, when used in primary prevention. For example, adherence to weight management interventions was reported as 56% and 76% after 6 months in two weight-loss programmes (937,939). It is therefore essential to put substantial effort to improve the adherence to interventions, as well as their uptake, if the programme continues. If high intervention adherence cannot be achieved, this would considerably limit the effect of the programme, such that alternative strategies may be required for a greater impact. This is also applicable for other risk management interventions employed under the programme.

11.4.3 Funding implications

The workload for both risk assessment and management under the Health Check has further funding implications. The higher workload generated by risk assessment and management, the greater costs are required for the implementation of the programme. Economic modelling of the programme estimated an annual cost of between £180 and £243 million for the programme implementation (624). A modelling study suggested that for the assessment of CVD risk and management of risk in those with high-risk, an overall cost of £176 million is required if QRISK2 is used to estimate risk, and £378 million if JBS2 is used for estimation (232). There were PCTs allocating an annual cost of up to about £1.4 million per 10 000 population for the programme in one financial year (629). Local authorities (current commissioners of the programme) need to put effort and effectively manage the programme with available funding.

The management of workload generated by the programme and its costs can be more difficult during the restructuring of the NHS, while severe cuts have been applied to NHS spending (944). This may have already influenced programme commissioners to withdraw funding for the programme. My findings suggesting very low programme coverage in some PCTs and evidence suggesting some PCTs had plans of not funding the programme during 2011/2012 (the study period of my national analysis) (945) provide some support for this. There is evidence of high PCT-level variation in the funding allocated to the programme implementation in general practices (629) and the programme budget was not ring-fenced. In areas with no sufficient additional funding, general practices might have to fund the programme spending through their existing budget, although most were unlikely to do this. This might have created very large burden on practices, causing many to leave the programme or reduce their activities (631). This may be the reason for lower programme
coverage in some PCTs compared to others in my national coverage data. The structure of remuneration, therefore, acts as an important limitation. Most health care services, including the Health Check, were funded through PCTs’ annual global budget, without a ring-fenced budget. This structure was adopted by the Department of Health to provide PCTs autonomy to manage and partition their annual budgets when shaping their local services according to the needs of their populations. However, evidence from my work may suggest this funding structure prior to the NHS transition is not favourable for the Health Check, especially when the financial cuts are growing. Since preventive health programmes’ benefits are not immediate and appear restricted, finance departments may tend to not prioritise these services (945). The programme coverage and potential effect may therefore be extremely limited without adequate funding and support.

The remuneration of the public health services has undergone change after the transition of the NHS and public health budget has been ring-fenced within the whole NHS budget from the financial year of 2013/2014 (946). This system of funding allocations to prioritize specific public health services according to need is for supporting local authorities to effectively meet health needs of their local populations and to ensure provision of better health care and reduce health inequalities (946,947). A total of about £2.7 billion and £2.8 billion ring-fenced budget have been secured for funding public health services in 2013/2014 and 2014/2015 respectively. This two-year allocation of public health funding aims to provide local authorities, new commissioners of social services, a sustainable comprehension and experience of funding public health services, including the NHS Health Check, efficiently (946). Local authorities are now responsible for funding the NHS Health Check elements, including risk assessment and lifestyle interventions to manage risk (e.g. weight and physical management interventions), as well as the recently added services for alcohol consumption assessment and enhancing awareness of dementia, through the ring-fenced budget (633,948). Although cuts will be applied to many public sector budgets in 2015/2016, health sector (NHS) budget will continue to be protected and ring-fenced. Local authorities have, therefore, had adequate funding to cover the costs of the NHS Health Check (948); this may help to improve the coverage of the programme and achieve complete rollout (20% coverage per year to screen all eligible people within five years).

Insufficient funding may not be the only reason limiting the capacity of general practices and although extra funding support is available, general practices may lack workforce, space and
time to manage the programme workload. Evidence has indicated the importance of “facilitators” who assist practices in organising CVD prevention activities (443). There are also examples in real-time settings; some areas are supporting those delivering the NHS Health Check via “project support workers” for facilitating CVD screening and risk management interventions (949). As well as management of programme funding, efforts must also be made by local authorities to enhance the assistance to general practices in promoting the programme.

Another concern over the remuneration of Health Check is the method of funding the programme. The mostly preferred method of funding the programme is through LES payments, but this method has important limitations and should be used as a short-term solution for promoting preventive services (950). Some areas, including NHS Hammersmith and Fulham delivered the programme under a local pay-for-performance scheme (QOF+). My data showed, when the individual components of the programme were incentivised under the QOF+ in the first year, the uptake of complete Health Check (requiring all components of the programme to be complete) was low and lower than those of other areas funding the programme in the absence of such an incentive scheme, but through LES (415,416). Despite the evidence of effectiveness of pay-for-performance schemes in promoting practitioners behaviours, indeed improving health care quality and reducing inequalities in care (951), and preventive health services (952), my work suggests that QOF+ may not provide additional benefit over LES. My data from the second year of the programme, again funded through QOF+, showed more favourable findings; however in the absence of comparable evidence, it is not possible to comment on the potential impact of the scheme. QOF+ was continued only for two financial years and therefore the impact of the programme could not be followed-up. Thorough assessment is required for examining the effectiveness of different financial schemes on the programme delivery to discover the best method.

Local authorities (formerly PCTs), in some areas, may also face the burden of funding alternative providers, involving in delivery of the programme. More spending is required to launch the programme in settings outside of practices, since it requires more investment in assets (949), information technology and training of staff (630). PCTs had mostly used LES to fund the Health Check in general practices, but LES budget cannot be used to fund alternate providers, since it is only to fund additional services within general practices (950).
Alternate providers may therefore fail to meet the required capacity because of workload and funding limitations.

11.4.4 Implications for clinical effectiveness and cost-effectiveness of the programme

Although my analysis suggests that the introduction of the NHS Health Check was associated with significant reduction in overall CVD risk and some risk factors in a targeted population, the low uptake and follow-up rates acts as a limitation for its effectiveness. For the effectiveness of the programme in achieving great public health impacts, strong uptake and adherence to interventions (e.g. statins) is essential (545). This is not only vital for the effectiveness, but also the cost-effectiveness of the programme. The basic principle in primary prevention is to spend more on lower cost prevention strategies that can reduce CVD burden and improve health, which would in turn help to save on higher costs of clinical care after disease occurrence (949). The capacity of the programme for screening and interventions must be established and commissioned before implementation. Low uptake of the programme therefore leads spending to not help reducing CVD risk; this would in turn further reduce the programme’s cost-effectiveness.

I show that the introduction of the Health Check programme was associated with an increase in statin prescription, and in turn with a reduction in total cholesterol levels in those without a complete Health Check. This may suggest, as an alternative to universal risk assessment, with partial risk factor assessment or using risk factors already recorded in EMRs (258,275,953), it may be possible for the programme to be more effective and cost-effective in reducing CVD risk and producing significant public health benefits.

11.4.5 Implications for inequalities

There are a number of inequalities in the uptake of preventive health programmes and screening (Chapter 4.1); socio-economic inequalities (550,669) and although still questionable, ethnic variation in uptake (713,717) are among these. One aim of the NHS Health Check is also to control main inequalities in cardiovascular health in England; ethnic (35) and socio-economic inequalities are important derivers of these (19). It has been argued that high-risk prevention programmes, such as the Health Check, increase inequalities due to low uptake of screening and interventions, and low adherence to interventions among those with the greatest need (407). Regarding the screening uptake, my findings however show that the uptake is greater in those from the main ethnic minority groups in England, including
those from south Asian and black groups. The general practice participation patterns may have a direct effect on the uptake patterns in the second year (782), when an opportunistic approach was used to offer the Health Check to patients at non-high risk. The higher attendance in south Asian patients in the second year may be linked to general practice attendance patterns, since patients may be reminded for attending a Health Check during their visits; this may also be associated with practitioners’ perception of greater CVD risk in this group (885). If the mass screening approach will continue in CVD prevention activities in the UK, it is important to develop the best methods for patient invitation to improve the response in all population groups. An alternative method to improve attendance can be providing a choice of access in drop-in clinics, in addition to pre-booked appointments (949).

Despite concerns (407), the favourable uptake rates in ethnic minorities may suggest that the programme will be effective in addressing ethnic inequalities. However, my data on one-year follow-up of CVD risk in high-risk individuals may raise further questions. Albeit a small sample size in ethnic minorities, my finding of no reduction in the CVD risk in south Asians is concerning given that their statin prescription rate was similar to the white group. This suggests that high uptake is not enough for positive impact, but other factors possibly effective communication of CVD risk (921,922) and adherence to interventions may be important. Examining the impact of the programme on CVD outcomes in ethnic minorities with sufficient sample size is crucial.

Considering the impact of the Health Check on socio-economic inequalities, my findings, using both local (Hammersmith and Fulham) and national data, indicate that more deprived patients might be benefiting sufficiently from the programme, with greater attendance and lower exception reporting rates, and significant reduction in CVD risk after one year in those with a complete check. My work may, therefore, suggest the programme will not increase socio-economic inequalities in CVD burden but may moreover reduce them, in contrast to concerns surrounding the negative impact of the Health Check on socio-economic inequalities (159,407). Although national level findings were similar, local level findings, however, need interpreting cautiously, because an area-based measure of SES was used in the analyses and the data were from a small geographical area where SES differences may have been small (i.e. fairly uniform levels of deprivation in the borough (Chapters 7, 8 and 10)). A thorough assessment of the impact of the programme on different socio-economic groups,
particularly using various measures of SES (including housing, wealth, employment and etc.), is therefore necessary, if the programme is to continue.

In my analysis using local data, as well as patient level variation, there were considerable differences in the completeness of CVD risk factor recording in EMRs, screening uptake, exception reporting from the programme and statin uptake between general practices, even after controlling for patient and practice characteristics. This practice level variation can be explained by a number of potential underlying factors. GPs’ beliefs on CVD prevention, perception of risk, ability to accurately predict and communicate risk to patients can all influence the quality of preventive services (806). This factor can impact on the provision of the Health Check even if it is not directly offered by GPs; GPs may play a role in the promotion of the service (776). Controlling for the number of FTE GP was not possible in my analyses; however, practice level variations in risk factor recording and uptake of screening and statins may be partly explained by GP-level factors. Recording of medical data and uptake of screening can be also influenced by organisational capacity of general practices. For example, additional support staff, including nurses (911) and administrative staff (954) play important role in organizing preventive services and therefore improving clinical outcomes. I was not able to control the outcomes for the number of other practice staff. Part of the variation between practices may be also attributable to difference in number of additional support staff. In Hammersmith and Fulham, practices carrying out the NHS Health Check were incentivised through a local QOF scheme (QOF+). Differences in the responses of practices to the QOF+ incentives may be another reason for unexplained variation between practices.

Evidence showed that the Health Check uptake was greater in single-handed practices, when not controlled for practice list-size (794), and in practices with smaller list-size (415) in areas where the local Health Check programmes were funded through LES. However, my findings do not reflect any variation in uptake with practice list-size, but show greater exception reporting from the incentive scheme in larger practices in the second year of the programme when an opportunistic screening approach was used. Since a systematic method for invitation via formal letters was not used, the offers could only be influenced by the factors during practice visits. Evidence of shorter consultation periods in larger general practices (955) and poorer patient satisfaction of access to primary care (956) in larger practices may suggest that larger practices are less successful in promoting the programme, causing a greater refusal by
patients and therefore exception reporting. More thorough assessment of the association between Health Check uptake and general practice size is needed to determine whether this is an important factor and what strategies might be employed to address variation.

My work also demonstrated a high variation in the Health Check coverage between PCTs in the analysis using national data. This variation is possibly due to inequalities in programme delivery between practices. There are a number of factors possibly influencing lower coverage in PCTs (Chapter 9.4.3). Extra support in terms of funding the programme, and assistance to and effective training of programme providers are essential to ensure equitable delivery of the programme between PCTs.

11.4.6 Policy recommendations for successful cardiovascular disease prevention

The NHS Health Check is among England’s major public health strategies, entailing a huge workload and expenditure. Exiting literature, however, presents very limited evidence on the success of this or similar high-risk strategies in CVD prevention and raises crucial concerns about the programme’s structure and application (159). I have explained the implications of my findings for both the continuation of the programme in its current format or for replacement with alternative approaches. I shall here outline the policy options for primary prevention of CVD considering the threats to the success of the programme from existing literature and my findings.

The first policy option for CVD primary prevention in the UK is maintaining the current situation; hence continuing the implementation of the universal NHS Health Check programme. My work indicates a number of limitations to the effectiveness of the programme, based on my findings and previous literature, which suggest that alternative policy options should be considered. Nevertheless, if the current programme is maintained, a number of possible changes or further improvements that my work has reflected can be adopted to enhance the effectiveness, cost-effectiveness and equity of the programme.

My findings raise a question about the requirement of de novo recording of all CVD risk factor data in a Health Check appointment. I showed that there was a substantial amount of CVD risk factor data recording within the patient EMRs before the implementation of the programme. Kumar et al. (949) also demonstrated that majority of Health Check attendees, as well as non-attendees, had a recent contact with general practice and had recent clinical data recording prior to the Health Check invitation. De novo recording of risk factor data requires
extra workload and will generate unnecessary expenditure. It may also not significantly add to the risk assessment (953). One implication of my study for the modification of the NHS Health Check is consenting the use of recently recorded risk factor data, especially those requiring high-cost blood testing (e.g. lipid levels).

Another option to enhance the effectiveness of the universal Health Check can be using a targeted approach in the first instance. Patients can be prioritised for screening invitations based on their CVD risk scores estimated using existing medical record data. This method can allow the identification of the bulk with the highest CVD risk factors and therefore earlier management of their risk. Another advantage of this will be enhancing the equity in screening, inhibiting the access of a younger woman without elevated risk factors to screening prior to an older man with elevated risk, for example, who is obese and smoker. My findings using Hammersmith and Fulham data demonstrated a considerable amount of complete CVD risk factors recording prior to the Health Check, which may suggest that the prioritisation using existing records can be efficient (258). My work also demonstrates that the Health Check is associated with a modest reduction in CVD risk in a targeted group with high estimated risk in the first year of the programme. Caution must, however, be taken to ensure high uptake, which can limit the impact of the programme in this pre-selected group (Chapters 8 and 10).

The impact of the Health Check programme may improve when it is modified based on the implications in my work; however previous literature and my findings suggest that there are still a number of potential factors limiting the effectiveness of the programme. It should primarily be noted that the evidence surrounding universal screening for CVD prevention prior to the NHS Health Check is scarce. Although evidence and my data from NHS Hammersmith and Fulham demonstrated reductions in CVD risk and risk factors in Health Check attendees (326,456,648), there are a number of limitations to high-risk based CVD prevention. Although CVD prevention trials were effective overall, the majority risk factor reductions were in high-risk individuals, since interventions address only those with elevated risk factors and overall risk (326,438,454,456). High-risk based primary prevention may not therefore be effective in producing population-wide trends in risk factors (431) and the impact of the programme on population at low or medium risk is therefore dubious. The evidence behind the effectiveness of high-risk based CVD prevention programmes on CVD hard outcomes is also scarce; however this may be due to methodological flaws (442).
Another important limitation addressed in existing literature and also my findings is that poor uptake can significantly limit the impact of the high-risk based prevention (456,648).

Previous evidence also reflects a number of potential weaknesses regarding brief lifestyle interventions and risk communication (Chapters 2.6.1.1 and 4.4.2). These interventions are provided to Health Check attending populations regardless of their risk level and are therefore vital, since their success may also determine the impact of the programme on low or medium risk population. Inappropriate communication of risk may limit the perception of risk by a patient and hence the potential health outcomes (838). The programme is carried out by health care assistants in a number of areas; however, the level of training and skill of these providers in risk communication are questionable. There are also questions over the brief lifestyle interventions undertaken as part of the Health Check. Although brief interventions are effective when delivered by experienced practitioners, evidence behind their effectiveness when delivered by non-clinical staff or those not specialised is scarce (644). Follow-up may be important in the success of brief lifestyle interventions, which is not quite possible for most of the Health Check attendants, especially those at non-high risk (330). Flaws in delivery of risk communication and brief lifestyle interventions may negatively affect the population-wide effectiveness of the programme and even lead to unnecessary harm to patients.

If these outlined limitations for the effectiveness of the programme cannot be eliminated, it will be crucial to adopt alternative policy options. I have addressed the need for alternative strategies through my discussions on the implications of my findings. The primary alternative policy option for CVD prevention is to adopt population level approaches for controlling CVD risk factors (135). The evidence surrounding the effectiveness of population level approaches in CVD prevention are discussed in Chapter 2.8. Population based strategies are suggested as having greater potential of reducing CVD risk and events in general population than high-risk based approaches, thus than the NHS Health Check (Chapter 2.9) (82,518,544). One of the major strengths of these approaches is that individual level factors, including patient behaviour, perception of risk and others (for example, behavioural factors potentially affecting the uptake of interventions) cannot limit the effectiveness of these strategies (545). Evidence proves the effectiveness of population level interventions addressing CVD risk factors (160), such as smoking (462,477), salt intake (493) and trans-fats (512,516). Policies restricting consumption of food with high-fat or high-sugar content
and facilitating the organisation of transport systems and environment to enhance physical activity of populations are also other examples to population based approaches for CVD prevention (932). Population level approaches are not only clinically more effective, but may also be more cost-effective, and even cost saving than high-risk based strategies (547). Polypill is a population-based intervention in CVD prevention and although there is growing evidence surrounding its effectiveness (522,532), there are still questions about its widespread use, particularly if applied to low and medium risk populations (524). Nevertheless, Polypill is a possible approach to be considered for CVD prevention; therefore, further thorough evaluation of its effectiveness and cost-effectiveness in population level prevention of CVDs is essential. Overall, although there is strong evidence over the effectiveness of population level strategies, the UK government has concentrated on the high-risk based approach in primary prevention of CVD.

Secondary alternative policy option for CVD primary prevention is again to continue with a high-risk based primary prevention programme, but along with significant modifications. The programme can be transformed into an entirely targeted approach focusing only on those at high CVD risk, so that the programme will not be universal any more. My work represents a number of implications for implementing a targeted approach in high-risk prevention. In the targeted approach, high-risk patients can be pre-selected using existing risk factors data in EMRs, substituting missing data with population estimates from national health survey (276). Risk factor data are then used to generate CVD risk scores, which is a more effective method for discriminating between patients than single risk factors (544). Complete data are not essential for accurate pre-selection using risk scores, however enhanced data recording is important to efficiently target patients (257,258,273,275,953). As my findings and previous evidence (873) demonstrates, CVD risk factors, particularly smoking status and blood pressure, are already well recorded in EMRs. High-risk patients can therefore be efficiently targeted without a need for extra data collection.

There are a number of advantages of employing a targeted high-risk prevention approach over a universal strategy. There is growing evidence surrounding the greater cost-effectiveness of targeted approach compared with universal methods (272,274,275,460,957). Marshall (273) has already suggested adoption of a targeted CVD prevention approach in the UK. Benefits of universal CVD risk assessment programmes are greater in those at the highest risk, while gains in those at low risk are restricted (350,454). This therefore suggests
a targeted approach can be effective. My data from prior to the NHS Health Check in Hammersmith and Fulham suggest that the Health Check has potential for generating a huge workload for risk assessment and management interventions. Another advantage of the targeted approach, therefore, is that it generates significantly lower workload for risk assessment compared to the universal screening, since it only screens a smaller proportion of population. This indeed reduces time required for risk assessment, number of tests and measurements to be undertaken, and therefore the programme spending (274). The large workload potential of the universal NHS Health Check has implications for lower service quality, with greater costs. In the current financial environment, it is important for the NHS to deliver more quality service with less health care costs (133,949).

The large workload generated by the universal programme requires large spending into CVD risk assessment, which may indeed limit resources allocated for promoting programme uptake and risk management interventions. High and equitable uptake is important for the effectiveness of high-risk based prevention approaches (407,545). Existing evidence and my data suggest inequalities in the uptake of screening. My data from Hammersmith and Fulham demonstrate lower uptake in men and in patients who smoke. It is suggested that since those in greater need tend to benefit less from high-risk prevention approaches, e.g. the NHS Health Check, using a high-risk based approach can widen health inequalities (407,548). However, a targeted approach instead may enhance overall programme uptake and efficiently address those with the greatest need, helping to reduce health inequalities.

There will be greater resources allocated to risk assessment, if a targeted approach is used. Targeted approach helps to enhance the efficiency of staff time, which can in turn improve the success of invitations (by both allowing sustained invitations and increasing contact with patients during invitations), increase programme access hours and facilitate screening in drop-in services (274,949). Greater resources available for risk assessment and management can enhance the quality of service provided (274). This may therefore lessen the limitations of the programme, including those regarding the effectiveness of brief lifestyle interventions and risk communication. If greater resources become available, commissioners can then promote additional services, which target specific populations in greater need. Resources can, for instance, be used to employ community events that can improve access not only in general population, but also in hard-to-reach groups (417). Using additional resources, more population-based strategies can also be adopted to promote population level CVD risk
reduction. More effective CVD primary prevention can be obtained if population based approaches are employed in combination with high-risk based strategies (145).

The universal approach has, however, some advantages over the targeted approach. Firstly, since it screens the entire population, it has greater potential to identify all risk factors in a population. However, this is associated with further limitations. The first concern is that the cost-effectiveness of a strategy is important, as well as its overall benefit. It is, therefore, essential to determine the most cost-effective approach that has the potential to generate the greatest risk reduction (257). For this reason, the additional benefits of a universal approach must be balanced against a targeted method (273). The consequent concern is regarding the coverage of the universal approach. My findings of low local-level uptake and national-level coverage may imply that a well organised targeted approach, supported by promotions for enhancing uptake, may produce benefits comparable to a universal approach.

The second considerable advantage of using a universal approach is that it may enhance the awareness of primary care about CVD prevention. Preventative services delivered by primary care are likely to produce substantial benefits, particularly if delivered as part of a well-organised and dedicated programme. One of the objectives of the Health Check programme is to identify patients with increased risk of diabetes, CKD and hypertension and even those with undiagnosed diseases. For example, it was designed to identify a large proportion of those with undiagnosed diabetes or IGT. CVD risk can be reduced and poor health outcomes can be prevented more effectively, if these conditions are managed earlier (196,348). Evidence, however, suggests a universal screening can be ineffective in identification of those at increased risk of diabetes or with diabetes and a targeted approach of screening those at high-risk may be more effective (958). There are, in addition, still concerns over the best method for diabetes screening (646,959).

In the current financial environment of restricted funding for health care costs (133), the NHS, and now, local authorities, may need to comprehensively consider transforming the existing policy of universal CVD risk assessment into a targeted approach, which may have greater potential for more effective and cost-effective reduction of CVD risk. The Health Check programme was developed during a period, when the NHS had sustained growth in funding. However the implementation of the programme started in more stringent times, when the financial growth was fading. The government spending on the UK health services (NHS) increased from £69,079 million to £121,305 million (2010/2011 prices) between 2000
and 2011. Although the growth in real terms annual spending was 8.8% between 2000 and 2005, the greatest growth in spending throughout the history of the NHS, the spending has declined substantially after 2005 (960). When the financial environment was favourable during the invention of the programme, the perceived potential benefits of the universal approach in CVD prevention might be more appealing. However, due to current financial restrictions in health care costs, adopting the most cost-effective approach is essential (273).

The decision on the development of a universal CVD prevention programme might not be exclusively based on existing evidence, but influenced by politics. Since universal interventions address entire population, they can play a role in shaping the political thoughts of voting population. This may be the reason for significant attention paid to the introduction of NHS Health Check by the English government, as well as the Department of Health. It is suggested that the introduction of the programme was rushed because of political reasons (961). The decision on delivering a universal approach seems to have been taken before sufficient modelling. The modelling compared the effectiveness and cost-effectiveness of different universal methods only with no screening in place, but not with a targeted approach (417,624). Political factors may also influence the time frame of the programme; the minimum Health Check dataset (634) and the call-recall system (348) were not established prior to the programme implementation. These may lead to flaws in the programme delivery; low programme coverage demonstrated in my findings from the national data may suggest that these influenced the programme coverage in the recent years.

Rose (135,145) formerly suggested the use of a combination of both high-risk and population based strategies for more effective prevention of CVDs. The high-risk based strategies employed, in addition to population strategies, can be either in the form of a targeted or universal approach. However, targeted screening appears to be the better option based on the previous evidence, the implications of my findings, and the evidence on the political influences in the implementation process of the NHS Health Check.

11.5 Future research

My work assesses the NHS Health Check in its early development years, with the data from the first three years of the programme. Public Health England announced the support for the continuation of the programme after the NHS transition, with an extra commitment to increase the programme uptake (934,935). Monitoring of the attendance in the following
years is therefore essential. If the attendance rates continue to be low, effective methods and interventions must be developed to improve coverage of the programme. Alternatively, the programme resources may be better transferred to other potentially more cost-effective strategies. Modelling studies to compare the Health Check with alternative strategies are therefore important to help policy makers to decide on the future of the programme. These alternatives could be population based primary prevention approaches (545) and also more targeted high-risk strategies (258,275), providing the supportive evidence behind both strategies.

Because of limited data availability, I was able to assess the levels of statin prescription only, but future work on compliance with statin prescriptions by including pharmacy prescription data into the analysis is essential. Lifestyle and community interventions are an important part of the Health Check and form a large proportion of the interventions available under the programme. However, there is limited evidence on the uptake and adherence to these interventions and their effectiveness on changing behaviours, particularly when they are provided after a general practice referral. High uptake and effectiveness of these interventions is important. There is therefore need for further research on the uptake of, adherence to and effectiveness of these interventions.

The evidence behind the effectiveness of universal high-risk based CVD prevention programmes is scarce; monitoring CVD outcomes during the programme implementation is therefore vital. In the initial phases, medium-term outcomes, such as CVD risk factors (e.g. blood pressure, lipid levels, smoking, etc.) and global risk is needed. Although I was able to assess the uptake of the programme in both high-risk patients and rest of the population using data from Hammersmith and Fulham, the impact of programme on intermediate outcomes could only be examined in the high-risk group. Since majority of the Health Check workload will originate from the rest of the eligible population, outcomes must also be examined in this group. In the long run, it is also essential to assess the impact of the programme on hard outcomes, including CVD incidence, hospital admissions and mortality. One of the aims of the Health Check is to promote the early detection of undiagnosed vascular diseases, including hypertension, diabetes and CKD. Future assessment of the programme impact on the diagnosis of these diseases is, therefore, warranted. Outcome data also need to be used to assess the cost-effectiveness of the programme. This is vital for decisions on the continued funding and support of the programme.
The Health Check is delivered across a number of settings, but the evidence on effectiveness in alternative settings is limited. Uptake of screening and interventions and effectiveness of the programme must, therefore, be examined in settings other than general practices. Risk factor data recorded during a Health Check by an alternative provider need to be transferred to patients’ primary care EMRs. If this is not done, risk assessment will not be adequately useful and also it can lead to duplication of work in general practice (962). Workload implications of monitoring secondary recording of risk factor data are therefore required. Evidence suggests that there are a number of barriers to the implementation of the programme in pharmacies (630). Future work for directly comparing the effectiveness and cost-effectiveness of the programme between providers is also important.

Hammersmith and Fulham is a local area with unique characteristics of large diversity in terms of ethnicity and deprivation. It may therefore be different from other areas and whole England. Attendance and outcomes of the programme must be examined elsewhere. It is also essential to monitor data across the whole nation to comprehend the impact of the programme on English public health. The Health Check dataset (634), as well as nationally representative datasets, for example, the Clinical Practice Research Datalink (CPRD) (963) and QRESEARCH (223) will be useful for this purpose.

There are a number of potential physical and psychological harms associated with CVD risk assessment and management in the primary prevention (Chapter 4.4). Work to continually assess general harms of CVD risk assessment and management is essential to lessen any adverse outcome. Assessing the effectiveness of risk communication and brief lifestyle advice interventions is also important for this purpose. One of the concerning potential harm of the programme is that it may be highly reassuring in those identified as at the lowest or even moderate CVD risk (844). Since the evidence surrounding the scope of the programme for false reassurance is limited and this would have important implications for the impact of the programme, future qualitative studies examining Health Check experiences of patients, responses to the programme and views on the CVD primary prevention is required.

11.6 Conclusions

The Department of Health adopted a significant CVD primary prevention policy for managing the CVD burden in England. The NHS Health Check programme is basically a high-risk based CVD prevention strategy, despite being a universal strategy offered to entire
population meeting the eligibility criteria. The programme is the first of its kind ever implemented in the world, therefore has strong potential to provide important evidence for primary prevention of CVDs to policy makers and health care professionals internationally.

The evidence prior to the programme implementation demonstrates a number of limitations surrounding the success of high-risk based strategies, the methods used to identify the high-risk individuals, the communication of risk between practitioner and patients, and potential psychological impacts on participants. These weaknesses have all generated concerns regarding the potential success of the NHS Health Check programme.

My findings raise a number of concerns about the delivery of the NHS Health Check. My work suggests that the NHS Health Check has a great potential of generating considerable workload, through both assessment of CVD risk and management of risk in high-risk patients, to programme providers. In the early years of the Health Check in a local setting, the programme uptake was significantly lower than the anticipated in a targeted group with estimated high-risk, although matched the local and national required rates in the non-high risk population. The uptake of statins, an important intervention provided to the identified high-risk group, in attendees and those eligible for the intervention was also poor. Although the programme implementation was associated with decline in CVD risk in estimated high-risk patients attending the programme, declines were modest in magnitude and the public health impact is possibly limited by poor uptake. The annual national coverage of the programme in the third year of the national implementation was poor, again suggesting the programme may generate limited public health impact.

My work illustrates that there were no socio-economic or ethnic inequalities in the attendance levels at both local and national levels, but there were occasionally improved attendance in these groups with greater need. This goes some way to mitigate the concerns over the negative impact of the programme on health inequalities and suggests the programme may even reduce the inequalities. There is, however, need for further assessment of programme attendance in these groups in different settings, including pharmacies and other community settings. In contrast to uptake findings, the trends in CVD risk after one year in ethnic minorities were not reduced relative to whites, but this may be due to limited sample size. There is therefore a need for further assessment of change in CVD risk in ethnic minorities using sufficient sample sizes. The variation in attendance levels between practices and PCTs requires attention. Local authorities, the current commissioners of the Health Check, need to
manage this variation by supporting preventive activities through effective assistance to practices.

It is essential to consider alternative strategies for effective CVD prevention, because of the limitations, particularly poor attendance levels, identified throughout my work. Population-based and targeted approaches can be widely adopted in English CVD prevention policy as significant alternative or as complementary strategies to the NHS Health Check. There is growing support over population-based prevention strategies; evidence suggests that population-level measures for managing CVD risk may have greater potential of producing overall public health benefit than a high-risk based approach. A targeted approach of screening pre-selected patients with estimated high-risk is another option. The favourable levels of risk factor data in existing general practice EMRs and the availability of basic methods to substitute missing data can make it possible to feasibly pre-select patients to be targeted.

The primary prevention of CVDs is becoming more crucial, particularly in high-income countries, including the UK, which have more aging populations. Growing CVD burden associated with an aging population will lead to a substantial growth in health care expenditures, potentially threatening the financial viability of health systems. We are currently in an era of financial crisis, where cost-effectiveness of health services is extremely crucial, such that there is need for delivering higher quality services with less spending (133). Although adopting a universal strategy for CVD prevention is ideal, if the English Health Check programme will continue with its existing framework, there is need for further efforts to maintain adequate funding for the programme. Population-based strategies for managing CVD risk factors in entire populations, along with a targeted Health Check programme to address those at high-risk, however, need to be thoroughly deliberated by policy makers for more cost-effective prevention of CVDs.
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Appendices

Appendix 1 - Supplementary materials

Table 28: Ethnic group categories used in the 2001 census

<table>
<thead>
<tr>
<th>Ethnic Group</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>White</td>
<td>A British</td>
</tr>
<tr>
<td></td>
<td>B Irish</td>
</tr>
<tr>
<td></td>
<td>C Any other White background</td>
</tr>
<tr>
<td>Mixed</td>
<td>D White and Black Caribbean</td>
</tr>
<tr>
<td></td>
<td>E White and Black African</td>
</tr>
<tr>
<td></td>
<td>F White and Asian</td>
</tr>
<tr>
<td></td>
<td>G Any other mixed background</td>
</tr>
<tr>
<td>Asian or Asian British</td>
<td>H Indian</td>
</tr>
<tr>
<td></td>
<td>J Pakistani</td>
</tr>
<tr>
<td></td>
<td>K Bangladeshi</td>
</tr>
<tr>
<td></td>
<td>L Any other Asian background</td>
</tr>
<tr>
<td>Black or Black British</td>
<td>M Caribbean</td>
</tr>
<tr>
<td></td>
<td>N African</td>
</tr>
<tr>
<td></td>
<td>P Any other Black background</td>
</tr>
<tr>
<td>Other ethnic categories</td>
<td>R Chinese</td>
</tr>
<tr>
<td></td>
<td>S Any other ethnic category</td>
</tr>
<tr>
<td>Not stated</td>
<td>Z Not stated</td>
</tr>
</tbody>
</table>
Figure 17: The nationwide distribution of PCT-level Health Check coverage
Table 29: Levels of clinical measurements at baseline (Year 1: July 2008 - November 2009) and follow-up (Year 2: December 2009 – March 2011) in patients who had a complete Health Check at baseline, and a complete rescreen at follow-up (N= 643)

<table>
<thead>
<tr>
<th>Risk Factor Levels</th>
<th>Year 1</th>
<th>Year 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking Status(^{a}) (% - 95% CI)</td>
<td>40.7 (36.9-44.6)</td>
<td>36.4 (32.7-40.1)</td>
</tr>
<tr>
<td>Systolic Blood Pressure (mmHg - 95% CI)</td>
<td>135.4 (134.3-136.6)</td>
<td>133.9 (132.8-135.0)</td>
</tr>
<tr>
<td>Diastolic Blood Pressure (mmHg - 95% CI)</td>
<td>80.8 (80.1-81.5)</td>
<td>79.4 (78.7-80.1)</td>
</tr>
<tr>
<td>BP &gt;= 140/90 (mmHg) (% - 95% CI)</td>
<td>11.2 (8.75-13.6)</td>
<td>7.9 (5.8-10.0)</td>
</tr>
<tr>
<td>BMI (kg/m(^2) - 95% CI)</td>
<td>27.5 (27.1-27.8)</td>
<td>27.6 (27.2-27.9)</td>
</tr>
<tr>
<td>BMI ≥30 kg/m(^2) (%) - 95% CI</td>
<td>24.7 (21.4-28.1)</td>
<td>26.1 (22.7-29.5)</td>
</tr>
<tr>
<td>BMI ≥25 kg/m(^2) (%) - 95% CI</td>
<td>69.5 (66.0-73.1)</td>
<td>70.1 (66.6-73.7)</td>
</tr>
<tr>
<td>Total Cholesterol (TC) (mmol/L - 95% CI)</td>
<td>5.25 (5.16-5.33)</td>
<td>4.97 (4.88-5.06)</td>
</tr>
<tr>
<td>Total Cholesterol ≥ 6 mmol/L (%) - 95% CI</td>
<td>26.0 (22.6-29.4)</td>
<td>17.3 (14.3-20.2)</td>
</tr>
<tr>
<td>Total Cholesterol ≥ 5 mmol/L (%) - 95% CI</td>
<td>57.7 (53.9-61.5)</td>
<td>47.7 (43.9-51.6)</td>
</tr>
<tr>
<td>HDL(^{b}) (mmol/L - 95% CI)</td>
<td>1.25 (1.22-1.28)</td>
<td>1.27 (1.24-1.30)</td>
</tr>
<tr>
<td>Lipid Ratio (TC/HDL - 95% CI)</td>
<td>4.44 (4.34-4.55)</td>
<td>4.15 (4.04-4.26)</td>
</tr>
<tr>
<td>Global Risk (JBS2 - 95% CI)(^{c})</td>
<td>28.2 (27.3-29.1)</td>
<td>26.2 (25.4-27.1)</td>
</tr>
</tbody>
</table>

\(^{a}\) Proportion of patients who smoke  
\(^{b}\) HDL: High density lipoprotein  
\(^{c}\) Baseline age was used to calculate CVD risk at two time points.
Appendix 2 – Publications and outputs from the thesis

Journal Articles

  
  **Artac M and Dalton ARH obtained and constructed the dataset. Artac M maintained the dataset and carried out all statistical analyses. Artac M made significant contribution to interpretation of data and drafted the paper.**

  
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Presentations


- Uptake of the NHS Health Check Programme in an Urban Setting: Cross-sectional Study”: Oral Presentation at Imperial College, School of Public Health PhD Symposium in London, UK, July 2012.


- Evaluation of NHS Health Checks in Hammersmith and Fulham: Oral Presentation at Imperial College London, Department of Primary Care and Public Health Weakly Seminars in London, UK, November 2010.

- Evaluation of the NHS Health Check Programme in Hammersmith and Fulham Primary Care Trust: Poster Presentation at Imperial College, School of Public Health PhD Symposium in London, UK, June 2010.
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