Evaluation of a community pharmacy based cardiovascular risk assessment service

A thesis submitted in accordance with the

conditions governing candidates for the degree of

DOCTOR OF PHILOSOPHY

at

CARDIFF UNIVERSITY

Presented by

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December 2011

Welsh School of Pharmacy – Ysgol Fferylliaeth Cymru

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Acknowledgements

It would never have been possible to finish this research without the generous support of the great people around me.

I am deeply indebted to my principal supervisor Dr Dai John, Reader in Pharmacy Education and Practice at the Welsh School of Pharmacy at Cardiff University, for his guidance and incredible support throughout the research. I greatly appreciate his patience and admire his commitment to pharmacy research in general and to this research in particular. He was always available to offer his support in every stage of this research. I am exceptionally grateful to my second supervisor Professor Roger Walker, now Chief Pharmaceutical Officer for Wales, for his valuable guidance and for his amazing motivation. I was privileged when he agreed to join the research team. His expertise in the field of public health policies and in cardiovascular disease prevention was indispensable.

I would like to thank all the participants who took part in the study for their time and feedback. I am grateful to those who contributed to the two week telephone interview and those who came back to the pharmacy at the twelve month follow-up and completed the study.

I would like to thank Boots Wales for the training they provided me, the professional indemnity cover, for providing the materials and the technical support during the study period. In particular many thanks to Marc Donovan, Head of Professional Capability, who without his exceptional support the study would not have been conducted within Boots. I would like to thank Gareth Waters, Swansea Area Manager, for his vital help to solve the issues regarding the quality control of the equipment used in this research. I would like to acknowledge the support and understanding of Mike Wallington, Pharmacist Development and Deployment Manager. I would like to acknowledge the support of the very kind people in the four Boots pharmacies in Cardiff, Porthcawl and both stores in Merthyr Tydfil, particularly Joanne Morris, Carol Madeley, Sarah Ward, Gwyneth Townsend, Gavin Evans, Jayne Sheen,

Maddie Rowson and Tanya Mathias. I am especially grateful to Angela Jones who helped me in arranging for the follow-up appointments.

I would like to acknowledge Kuwait University for sponsoring me in this PhD programme and for the generous funding which allowed to pay for the transcriber of the two-week follow-up interviews and to advertise in the local newspapers which helped in the recruitment of participants. Also I am grateful to Kuwait University for funding me to present the findings of some elements of this research in two conferences.

I would like to thank Hank Du, my fellow PhD student at the Welsh School of Pharmacy, for his friendship and his encouragement. Many thanks to all of my friends particularly Ahmad Salem and Monerah Alsoraj for their continuous support throughout this research. I am also indebted to my kind friend Ali Bumajdad, Associate Professor at Kuwait University, who without hesitation signed all the paperwork on my behalf so the sponsorship was not interrupted.

I would like to thank all those who encouraged me from the very initial stages of this journey to the right end; my parents, brothers, sisters and cousins. Special mentions go to my cousin Mohammad Waheedi, Assistant Professor and Vice Dean for Student Affairs, Faculty of Pharmacy at Kuwait University, not only for his moral support but also for offering me his office every time I have been to Kuwait so I can continue to work hard on this research. Also many thanks go to my cousin Redha who was the first person to inform me about the Kuwait University scholarship plan and for encouraging me to apply for it.

Special thanks to those who always make me feel proud and fortunate for their love, support and patience:

My beloved wife Manal and my wonderful children Fatima and Mohammad.

Abstract

The aim of the study was to evaluate a community pharmacy-based cardiovascular risk assessment (VRA) service introduced into two pharmacies in south Wales. A longitudinal methodology was adopted where participants had an initial assessment with a follow-up after 12 months. Body mass index, waist circumference, blood pressure and total/HDL cholesterol levels were measured and the Framingham 10-year cardiovascular risk was estimated and communicated to patients. Demographic details and lifestyle information (smoking, alcohol, diet and exercise) were obtained via self-complete questionnaires at each consultation. A total of 172 individuals accessed the service and had either a brief assessment (n=26) without the calculation of the Framingham score or a full VRA (n=146). Mean age was 60 years (±10.3), 59% were female and 25% (37/146) were at high risk (>20%) of developing cardiovascular disease. High satisfaction with the VRA was obtained via an anonymous questionnaire provided immediately after the initial consultation (74% response rate). The short-term outcomes of the service (including recall of advice, lifestyle improvement and/or making the visit to their GP if they were referred) were reported through a semi-structured telephone interview two weeks after the initial assessment. In total 105/172 (61%) who attended the twelve-month follow-up had results of the two assessments compared using paired Student's t-test. There was a statistically significant increase in mean HDL 0.08 mmol/L (95% CI 0.02 to 0.14) and a statically significant reduction in mean systolic BP -8.5 mmHg (95% CI -11.0 to -5.9), diastolic BP -7.7 mmHg (95% CI -10.4 to -5.0) and Framingham score -1.07 (95% CI -1.9 to -0.2). A comparison between Framingham and QRISK2 algorithms showed the importance of using the most accurate tool available in estimating cardiovascular risk. This is the first study to investigate short- and longer-term outcomes of a community pharmacy-based VRA service in Wales and provides a basis for future research.

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Key abbreviations

4S	The Scandinavian Simvastatin Survival Study
AF	Atrial fibrillation
ASCOT-LLA trial	the Anglo-Scandinavian Cardiac Outcomes Trial - Lipid Lowering Arm
ASSIGN	ASSessing cardiovascular risk using SIGN
BHF	British Heart Foundation
BMI	Body mass index
BNF	British National Formulary
BP	Blood pressure
CARE trial	The Cholesterol and Recurrent Events Trial
CAS	Census Area Statistics
CHD	Coronary heart disease
CRP	C-creative protein
CVD	Cardiovascular disease
EQA	External Quality Assessment
GP	General practitioner
HDL	High-density lipoprotein
HMG CoA	3-hydroxy-3-methyl-glutaryl coenzyme A
HPS	Heart Protection Study
LDL	Low-density lipoprotein
LHB	Local Health Board
LSOA	Lower Layer Super Output Area

MEGA study	Management of Elevated Cholesterol in the Primary Prevention Group of Adult Japanese
MHRA	The Medicines and Healthcare products Regulatory Agency
MUR	Medicine Use Review
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NSAID	Non-steroidal anti-inflammatory drug
PCT	Primary Care Trust
PMR	Patient Medication Record
PSNC	Pharmaceutical Services Negotiating Committee
RA	Rheumatoid arthritis
REC	Research Ethics Committee
SOP	Standard operating procedure
TDI	Townsend Deprivation Index
The LIPID study	The Long-Term Intervention with Pravastatin in Ischaemic Disease
UK	United Kingdom
VRA	The cardiovascular risk assessment
WAG	Welsh Assembly Government (became known as the Welsh Government in May 2011)

Chapter 1: Introduction and Literature Review

1.1 General Introduction

This chapter presents background information on the epidemiology of the cardiovascular disease (CVD) in Wales, risk factors, primary prevention and the risk assessment of CVD. It also presents the literature review identifying studies conducted to evaluate the role of the pharmacist in the provision of VRA services.

1.1.1 Cardiovascular disease in Wales

CVD which includes coronary heart disease (CHD) and cerebrovascular disease, is the leading cause of death in Wales, accounting for over 10,400 deaths in 2009 and a third of all deaths (BHF 2011a). CHD accounts for about half of all deaths of CVD whereas stroke accounts for over a quarter of all CVD deaths. CVD is also one of the main causes of premature death accounting for 32% of premature deaths in men and 23% of premature deaths in women. CHD causes over 5,500 deaths a year in Wales or approximately one in five deaths in men and one in six deaths in women (Petersen et al. 2005). Around 28 people die every day from CVD in Wales and an estimated 312,000 are known to live with the condition (BHF 2011b)

The UK, of which Wales is part, has one of the highest CVD mortality rates in the world. Although mortality rates from CHD have been falling in the UK since the late 1970s and death rates from stroke have been falling throughout this century, the burden of the disease is still high (Petersen et al. 2005). Ergin et al. (2004) suggested that both primary and secondary prevention and treatment contributed to the decline in CVD mortality in the United States. The

advances in medical technology and in therapeutics led to the improvement in the survival rate following myocardial infarction and for other CVDs. As a consequence it has been proposed that more people will be living with CVD as a chronic disease and the burden of CVD will continue to rise (McDermott 2007). To address this there is a need to focus on prevention. The Welsh Government (until May 2011 referred to as the Welsh Assembly Government or WAG) acknowledged this fact in their National Service Framework (NSF) for CHD published in 2001 (WAG 2001). This report highlighted the importance of empowering patients to take responsibility for the prevention of CHD and to work intensely to decrease the number of people at risk of developing CHD.

1.1.2 Risk factors for cardiovascular disease

The term 'cardiovascular risk factor' is used generally to describe the characteristics found in individuals in epidemiological, autopsy, metabolic and genetic studies to relate to the consequent occurrence of a CVD (George and Johnson 2010). Causes of CVD have been identified as a result of prospective observational studies (Kannel 2011). The Framingham Heart Study (Section 1.1.4.1) which started in 1948 in the town of Framingham, Massachusetts, was one of the major cohort studies to identify the common factors or characteristics that contribute to CVD (Shindler 2011).

Risk factors are either modifiable (which can be altered by lifestyle changes or other interventions such as pharmacological) or non-modifiable which means they cannot be altered. Modifiable risk factors include obesity, weight

distribution, lack of exercise, lack of fruit and vegetable consumption, alcohol intake, hypertension, dyslipidaemia and diabetes. The non-modifiable risk factors include gender, age, ethnicity and family history of CVD (Yusuf et al. 2004). Deprivation is also a risk factor and has been incorporated in some cardiovascular risk assessment tools (Tunstall-Pedoe and Woodward 2006).

1.1.2.1 Age

The prevalence and incidence of CVD increase steeply with age (Table 1-1). CVD mainly affects people over the age of 50 years (Cooper et al. 2008). There is a consensus that chronologic age is a potent, independent risk for increased morbidity and mortality (Maurer 2003). According to Wald et al., age is by far the strongest determinant of CVD risk in multiple risk factor algorithms (Wald et al. 2011).

Table 1 - 1 incidence rate of cardiovascular diseases in different age groups (Hippisley-Cox et al. 2007)

	Incidence rate per 1000 person years	
Age groups	**Women**	**Men**
35-44	1.36	2.78
45-54	4.14	8.06
55-64	10.43	17.46
65-74	21.31	29.44

In a recent cost-effectiveness analysis the researchers compared screening for future cardiovascular events using age alone with screening using age and

multiple risk factors based on regular Framingham risk assessments. The researchers suggested that prescribing a statin to all people over the age of 50 years will save more lives and the cost per CVD free year of life gained will be the same as the cost of using the universal Framingham assessments, based on £200 annual cost of preventive treatment and £150 cost of a Framingham risk assessment. If the cut-off age is 55 years, however, the age screening will be more cost-effective than Framingham (the cost per CVD free year of life gained for age screening is £2,000 versus £2,200 for Framingham) (Wald et al. 2011).

1.1.2.2 Gender

The prevalence of CVD is higher in men than in women. According to the British Heart Foundation (BHF) there are about one million men living with coronary heart disease in the UK whereas half of that number are women with this diagnosis. Data comparing different regions of the UK show the prevalence of myocardial infarction is highest in Wales. Also, the mortality rate in the UK is higher in men than women, 28% of premature deaths, that is, under the age of 75, in men were due to CVD compared with 20% in women (BHF 2010). Stroke mortality rate, however, is higher in women (BHF 2011b).

The most common cause of death in women, however, is CVD and it is even more common than all cancers combined (BHF 2010). Due to the protective effect of oestrogen, women tend to be older at first presentation with CVD. As a consequence they are more likely to suffer poor outcomes of the CVD (Schenck-Gustafsson 2009). The awareness of women with regard to heart

disease has increased over the years (Mosca et al. 2011). However, in one study the majority of the participating women failed to perceive it as a leading threat to their health (Mosca et al. 2004).

1.1.2.3 Family History of CVD

The hereditary link to CHD and stroke is well established through a number of large epidemiological studies (Bensen et al. 1999; Graffagnino et al. 1994; Jousilahti et al. 1997). In a small cohort study of ninety patients with CVD and ninety control subjects a family history of ischaemic heart disease was present in 73% of patients with CVD compared with 53% of the control subjects (P = 0.019), and a family history of stroke was present in about 47% of the patients and 24% of the control subjects (P = 0.014) (Graffagnino et al. 1994). In a prospective study of 14,371 middle-aged men and women the risk ratio of stroke associated with a positive family history of stroke was 1.89 (P = 0.004) in men and 1.80 (P = 0.007) in women and the association was stronger among subjects aged 25 to 49 years than among older subjects (Jousilahti et al. 1997).

Studies usually define positive family history of CVD as fatal or nonfatal stroke or myocardial infarction, or as having a diagnosis of angina pectoris before the age of 60 years in first degree relatives. Some risk assessment algorithms, however, do not take into account the family history of stroke and they define family history as angina or heart attack in a first degree relative before the age of 60 years (Hippisley-Cox et al. 2007) or the development of coronary heart disease in a male first degree relative before the age of 55 years and a female first degree relative before the age of 65 years (JBS2 2005). For

those who have first degree relatives with CVD, they are considered as affected by genetic factors if the age of their relatives was less than 55 years at diagnosis. However, diagnosis at a young age (younger than 55 years for men and 65 years for women) could be interpreted as a hereditary link but in the absence of CVD or a diagnosis at a later stage in family members cannot rule out this link completely (Doughty 2003).

1.1.2.4 Genetic links

Genetic studies of CVD have been providing evidence of the effects of hereditary factors on CHD and stroke (Peden et al. 2011). Also there are a number of genetic studies have shown strong links of hereditary factors to the conventional risk factors of CVD, such as obesity (Segal and Allison 2002) and hypercholesterolemia (Humphries et al. 2010).

In obesity it is well known that genetic factors play a significant role. Obesity, however, is a complex problem caused by the interactions of multiple genes, environmental factors and behaviour of the individual. This complexity makes the search for obesity genes vary challenging (Comuzzie and Allison 1998). A review on the similarity of the body mass index (BMI) and other adiposity measures among twins brought up apart and together suggested that genetic factors explain 50 to 90% of the causes of obesity (Maes et al. 1997). However, there is a possibility that earlier research may have underestimated the effect of common environmental factors on obesity because the study design was such that lacked the ability to detect them (Segal and Allison 2002).

A meta-analysis identified five new genetic variants in addition to the eleven common variants associated with coronary artery disease in European populations. The authors suggested that many genes have a small effect on the CHD risk rather than a few genes having a large effect (Peden et al. 2011).

Familial hypercholesterolemia is one area in which genetic testing is currently feasible and according to one randomised control trial such testing has no significant, long-lasting adverse-effect on psychological well-being (Humphries et al. 2010).

Some internet-based commercial companies are offering genetic tests for CHD, but researchers believe that this kind of testing is premature and it has little value in the prevention of CVD (Humphries et al. 2010). As researchers continue to identify more genes associated with CHD the likelihood of producing a simple genetic test becomes impossible to be seen in the near future.

In a recent study focusing on metabolic syndrome and obesity, a genetic link was identified which could help to explain the prevalent of type II diabetes among those who have a healthy BMI, that is, < 25 kg/m^2. The identified gene expression was associated with an impaired metabolic profile, including increases in the following: visceral to subcutaneous fat ratio, insulin resistance, dyslipidaemia, risk of diabetes and coronary artery disease (Kilpeläinen et al. 2011).

1.1.2.5 Ethnicity

South Asian populations in the UK are associated with higher morbidity and mortality of CVD than Caucasians (Gholap et al. 2011), but the reasons for this are still unclear. The prevalence of conventional risk factors, such as hypertension and hyperlipidemia among South Asians contribute to this increase, but they do not account for the full extent of increased risk. It appears that there are variations, among ethnic groupings, in the role and potency of risk factors (Astin and Atkin 2010).

Traditionally, incidence of CVD among South Asians has been studied as one ethnic group. Although, South Asians are at increased risk of CVD, this underestimates the risk in some subgroups and overestimates it in others (Table 1-2). The rate of CVD of Pakistani men is almost the double of that of the Caucasians compared with about 45% increased risk in Indian men (Hippisley-Cox et al. 2008).

Table 1 - 2 Effect of ethnicity on adjusted hazard ratios (HR) for CVD. Data obtained from (Hippisley-Cox et al. 2008)

	Women	Men
Ethnic group	**HR (95% CI)**	**HR (95% CI)**
Caucasians/not recorded	1	1
Indian	1.43 (1.24 to 1.65)	1.45 (1.29 to 1.63)
Pakistani	1.80 (1.5 to 2.17)	1.97 (1.70 to 2.29)
Bangladeshi	1.35 (1.06 to 1.72)	1.67 (1.40 to 2.01)
Other Asian	1.15 (0.86 to 1.54)	1.37 (1.09 to 1.72)
Black Caribbean	1.08 (0.94 to 1.24)	0.62 (0.53 to 0.73)
Black African	0.58 (0.42 to 0.82)	0.63 (0.47 to 0.85)
Chinese	0.69 (0.44 to 1.10)	0.51 (0.32 to 0.83)
Other	1.04 (0.85 to 1.28)	0.91 (0.75 to 1.10)

1.1.2.6 Deprivation

Deprivation indices are a measure of deprivation rather than poverty. The difference between the two is that the first describes the situation when there is a lack of resources and opportunities including the lack of money, but the second one describes the lack of money. A deprivation index is used in the UK to compare how well different areas are doing in term of access to resources. Not all people living in an area of high deprivation are poor. As it is not a measure of poverty, it cannot be used as a measure of wealth. Therefore, when using a deprivation index, the least deprived areas should not be considered as wealthy areas (CDU 2010; WAG 2008).

The Welsh Index of Multiple Deprivation (WIMD) is the official measure of deprivation for Wales (WAG 2008). WIMD is based on eight different deprivation domains; income, employment, health, education, housing, environment, access to services and community safety. Even though each domain could affect other domains, for example, poor health may be related to unacceptable housing, they all reflect a specific kind of deprivation on their own.

There are 1,896 Lower Layer Super Output Areas (LSOA) in Wales, each LSOA having about 1,500 people. The LSOA is a geographical area which is designed for analysing small area statistics. All eight domains determine a deprivation score for each LSOA. The highest score equates to the area of highest deprivation. According to the deprivation sore, all LSOAs are ranked from the highest to lowest. The first 10% of LSOAs are the most deprived areas, then the second and the third groups each have 10% of LSOAs, the fourth group consists of the next 20% and the fifth group (considered the least deprived areas) constitute the remaining 50% (WAG 2008).

The Townsend Deprivation Index (TDI), on the other hand, is based on four variables; unemployment (as a percentage of all economically active residents aged over 16), overcrowding (households with 1 person per room and over), non-car ownership, non-home ownership (CDU 2010).

The level of deprivation may be associated with some CVD risk factors, such as smoking and lack of physical activity. People living in the least deprived areas are less likely to have a lifestyle which could adversely affect the risk of

CVD and vice versa for those who are from the most deprived areas (Cubbin et al. 2006). Similarly, there are some associations between the level of deprivation and the knowledge of the CVD (Cubbin and Winkleby 2005). However, even when the variations of risk factors were adjusted for, the people living in most deprived areas are at high risk of CVD. Every five unit increase in Townsend deprivation score, that is, an increase in deprivation, the adjusted hazard ratio for CVD increases 1.13 (95% CI = 1.11 to 1.14) for women and 1.06 (95% CI = 1.05 to 1.07) for men (Hippisley-Cox et al. 2011).

1.1.2.7 Hypertension

Hypertension is a major contributor to cardiovascular morbidity and mortality (Appel et al. 2011). Blood pressure measurement, therefore, is one basis for cardiovascular disease evaluation and the focus of therapy. Hypertension remains a major preventable risk factor for CVD (Aronson and Fontes 2006). The prevalence of hypertension among people aged 35–64 years old in western countries is between 28% and 55%. There is a continuous increase in age-adjusted prevalence of CVD with increasing blood pressure, even in those who have high-normal blood pressure (130-139 mmHg) (Pieske and Wachter 2008).

High blood pressure is the level of blood pressure at which there is evidence that blood pressure reduction does more good than harm (JBS2 2005). The British Hypertension Society recommend a classification of blood pressure levels (Table 1-3) to help clinicians to determine the type of intervention necessary (Williams et al. 2004).

Table 1 - 3 British Hypertension Society classification of blood pressure levels (JBS2 2005)

Category	Systolic BP (mmHg)	Diastolic BP (mmHg)
Optimal blood pressure	< 120	< 80
Normal blood pressure	< 130	< 85
High-normal blood pressure	130–139	85–89
Grade 1 hypertension (mild)	140–159	90–99
Grade 2 hypertension (moderate)	160–179	100–109
Grade 3 hypertension (severe)	≥ 180	≥ 110
Isolated systolic hypertension (Grade 1)	140–159	< 90
Isolated systolic hypertension (Grade 2)	≥ 160	< 90

1.1.2.8 Diabetes

Morbidity and mortality from CVD are two to five times higher in people with diabetes than those who are non-diabetics. The effects of smoking, dyslipidaemia, hypertension and/or hyperglycaemia further increase the risk of an individual with diabetes developing CVD (Ekinci et al. 2011; Scott et al. 2011). Two major trials, The Action to Control Cardiovascular Risk in Diabetes Study (ACCORD 2008) and the ADVANCE (Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified Release Controlled Evaluation) (Points 2008), have failed to show significant reduction in cardiovascular events in the short term with near-normal glycaemia. However, UKPDS (Holman et al. 2008) suggests that optimal glycaemic control have long-term benefits on cardiovascular risk. According to Selvin et al. (2004), however, there are limitations in studies claiming that uncontrolled glycaemia is an independent risk factor for cardiovascular disease.

1.1.2.9 Dyslipidaemia

Dyslipidaemia is defined as "an abnormal plasma lipid status" (Ballantyne 2009). Common lipid abnormalities which appear to increase the risk of CHD include elevated serum concentrations of total cholesterol, low-density lipoprotein (LDL) and triglyceride; low levels of high-density lipoprotein (HDL) (Walker and Whittlesea 2012). LDL cholesterol, the major atherogenic lipoprotein, typically makes up 60-70% of the total serum cholesterol where HDL cholesterol, lipoprotein with some evidence that it has protective properties against the development of atherosclerosis, makes up 20–30% (National Institute of Health 2002).

In countries where the diet is characterised by high saturated fat, such as Western types of diet, most of the population have levels of total cholesterol above than the desirable concentration of 5mmol/L, and LDL > 3mmol/L. Epidemiological studies have shown that the level of total cholesterol increases with age (Wilson et al. 1994). The mean total cholesterol levels among men are higher than women up to the age of 54 and then beyond that age the situation is reversed. Possible explanation is that men with high level of total cholesterol are at increased risk of death before reaching advanced age (Walker and Whittlesea 2012).

In another study 4,849 middle-aged men were followed up for 8 years with the primary outcome being CHD events. Individuals with total cholesterol to HDL ratio of more than 5.0 had an estimated risk of 19% of experiencing a CHD event in the next 8 years, but when this was combined with triglyceride levels

of equal to or more than 2.3 mmol/L the risk of CHD increased to about 27%. The authors concluded that fasting levels of triglycerides were an independent risk factor for CHD events, irrespective of serum levels of HDL or LDL (Assmann et al. 1998). It is accepted that raised fasting triglyceride (> 1.7 mmol/l) increases the risk of CVD (JBS2 2005). However, some researchers argued that triglyceride levels which currently considered normal (up to 1.7 mmol/L) are associated with an increased concentrations of the inflammation marker C-reactive protein (CRP) and they recommended that a lower fasting triglyceride level of about 1.1 mmol/L used as an optimal cut point in CHD risk assessment (Ahmad et al. 2005). Testing for triglycerides is not always convenient as fasting is always required which limits its use in the primary screening for CVD (Satta et al. 1998).

The two most common factors linked to elevated levels of serum triglycerides are being overweight (including obesity) and physical inactivity. Table 1-4 shows other factors that can affect the levels of triglyceride and lipoproteins. The raised levels of triglycerides are considered as a marker for increased risk for CHD, but the first line treatment is usually not more than lifestyle changes (National Institute of Health 2002).

Table 1 - 4 Factors which could have an effect on dyslipidaemia (National Institute of Health 2002)

	Elevated Triglycerides	Low HDL
Overweight and obesity	yes	yes
Physical inactivity	yes	yes
Smoking	yes	yes
High alcohol intake	yes	no
Very high-carbohydrate diet	yes	yes
Other diseases (e.g. type 2 diabetes and chronic renal failure)	yes	yes
Drugs (e.g. corticosteroids, protease inhibitors for HIV, beta-adrenergic blocking agents, oestrogens)	yes	yes
Genetic factors	yes	yes

Low concentrations of serum HDL are linked to increased CHD morbidity and mortality. In a community based study 2,489 men and 2,856 women aged 30 to 74 years were followed up for 12 years. The results showed that the risk of CHD was decreased significantly in those with HDL levels of higher than 1.5mmol/L and a significant increased CHD risk with HDL levels of less than 0.9 mmol/L (Wilson et al. 1998). Epidemiological data from the Framingham Heart Study, showed that a 1 mg/dl (0.026 mmol/L) increase in HDL is associated with a 2–3% decrease in CHD risk and 3.7-4.7% decrease in mortality rate (Gordon et al. 1989). One of the features of metabolic syndrome, in addition to central obesity and fasting triglyceride of more than 1.7mmol/L, is the decrease in levels of HDL (less than 1.0mmol/L in men and less than 1.2mmol/l in women) (JBS2 2005). However, in the management of CVD,

HDL levels of less than 1 mmol/L are considered a risk factor for both men and women (National Institute of Health 2002).

An elevated serum LDL level increases the risk of CHD as identified by major epidemiological studies (Feinleib 1981; Keys et al. 1984; Wilson et al. 1998). However, earlier studies measured only serum total cholesterol, but because most of total cholesterol is due to LDL and there is a clear relationship between total cholesterol and CHD from these studies, this strongly implies that an elevated LDL is an important risk factor (National Institute of Health 2002). Particle size of LDL is an important determinant of CHD risk. The presence of very low density lipoprotein (VLDL) is highly correlated with the increased risk of CHD.

The importance of apolipoproteins (apo) in studies determining the effects of dyslipidaemia on CVD has been increasing in the last decade. There has been accumulating clinical evidence that better prediction of CVD risk can be achieved by assessing the levels of apo B, a constituent of atherogenic lipoproteins such as LDL and VLDL, apo A1, a component of antiatherogenic HDL and the apo B/A1 ratio, than measuring serum LDL levels only (Dawar et al. 2011; Yusuf et al. 2004). In a study of 593 patients who were treated with a statin for secondary prevention of CHD the apo B/A1 ratio was evaluated. It was found that the levels of apo B/A1 ratio correlated with clinical outcome when corrected for standard risk factors. On the other hand the levels of the classic LDL/HDL ratio were not correlated to the CHD events. The authors

concluded that their findings add significant prognostic value of apo B/A1 over the classic lipid ratio (Liem et al. 2007).

The use of lipid-lowering medication to achieve determined cholesterol targets for primary prevention is not recommended as there is still lack of evidence of efficacy, safety and cost-effectiveness of this use (NICE 2008b). However, according to the British National Formulary (BNF) individuals with an elevated total cholesterol to HDL ratio which exceeds 6.0 will require lipid-lowering medication, regardless of the presence of other risk factors or the estimated CVD risk (BNF 2011).

For secondary prevention, there are differing guidelines in relation to cholesterol targets (Table 1-5). The cost of treatment was a key factor by certain guidelines in setting these targets. However, these guidelines are not based on a formal cost-effectiveness analysis (NICE 2008b).

Table 1 - 5 Total cholesterol (TC) and LDL targets for secondary prevention set by different guidelines

	TC mmol/L	**LDL mmol/L**
The National Service Framework for CHD (DOH 2000)	< 5	< 3
The Joint European Societies Task Force on CVD Prevention (De Backer et al. 2003)	< 4.5	< 2.5
the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (USA) (National Institute of Health 2002)		< 1.81
The Joint British Societies Guideline (JBS2 2005)	< 4	< 2
SIGN guidelines (SIGN 2007)	< 5	

1.1.2.10 Poor diet

Poor diet is high in salt, saturated and trans fats and low in fibre, fish, fruit and vegetables (Bruckert and Rosenbaum 2011). Low fruit and vegetable consumption is associated with high prevalence of ischaemic heart disease mortality (Crowe et al. 2011). The UK government recommend that individuals should have five portions of fruit and vegetables per day and it has been considered as a "proxy" for a poor diet if the individual is having low consumption of fruit and vegetables (Hotchkiss et al. 2011). In Wales, according to a survey conducted in 2009 only 34% of men and 37% of women consumed the recommended five portions of fruit and vegetables per day (BHF 2011b).

Although salt intake restriction is associated with blood pressure reduction, it is still lacking a strong evidence to support the benefits of salt restriction in reducing CVD morbidity and mortality (Taylor et al. 2011b).

According to a body of experts there are clinical and epidemiological studies to support the link between a diet high in saturated fats and CVD (Astrup et al. 2011). In Wales, about 15% of energy consumed is from saturated fat while the recommended level is not more than 10% of energy from such fat (BHF 2011b). Replacing saturated fatty acids with polyunsaturated fatty acids in the diet improves the LDL concentration and decreases the CHD incidence (Astrup et al. 2011).

A review of epidemiological studies concluded that high consumption of red meat, processed or non-processed, is associated with an increase in CHD rate, with greater risk associated with processed meat (Bernstein and Willett 2010).

Fish contains long-chain omega-3 polyunsaturated fatty acids, which include eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). These constituents considered beneficial for the heart as their intake associated with a reduction in triglycerides, blood pressure and resting heart rate (Mozaffarian et al. 2011). Also oily fish consumption is associated with the reduction of the inflammation biomarkers (van Bussel et al. 2011). In an observational study, acute coronary syndrome patients tended to live longer if they consumed oily fish several times a week than those who consumed rarely or none at all (Helmut Gohlke et al. 2011). However, people who consume fish with high salt seem to lose the protective effects as they were found at higher risk of hemorrhagic stroke (Meng et al. 2011). Similarly, there is no evidence that fried fish has CVD benefits (Mozaffarian et al. 2011).

1.1.2.11 Smoking

Smoking is a well-established risk factor for CHD and stroke. It is the major cause of preventable morbidity and mortality of CVD in the UK. Smoking is also associated with different types of cancer, respiratory diseases and stomach and duodenal ulcers. It is one of the major causes of inequalities between the upper and lower socioeconomic classes (Krska 2010).

The increase in CHD and stroke associated with smoking is underestimated by many studies, particularly earlier ones, as they tended to compare smokers

against all non-smokers, that is, they did not exclude people who were exposed to environmental tobacco smoke (passive smokers) from the non-smoker cohort (Bonita et al. 1999). According to Bonita et al. (1999) active smokers had a six-fold increased risk of stroke when compared with people who had never smoked or had quit smoking more than 10 years earlier and who were not exposed to environmental tobacco smoke.

The benefit of smoking cessation on the reduction of CHD mortality is significantly greater than any other secondary preventive therapies such as cholesterol lowering drugs (Erhardt 2009). Smoking cessation is highly cost-effective to improve cardiovascular health in smokers. The risk of all cause mortality among patients with CHD is reduced and this seems to be consistent regardless of age or gender (Critchley and Capewell 2003).

1.1.2.12 Obesity

Obesity is identified as the accumulation of excess fat or adipose tissue in the body. The BMI (Table 1-6) is one of the main measurements to determine the effect of weight on health (Maguire and Haslam 2009). Although BMI can predict health risk for CVD and cancers, it is not always accurate for two main reasons namely firstly, it does not reveal the body shape of the individual. Determining the body shape is important as the evidence is strong that central obesity is associated with higher risk of metabolic syndrome and CVD morbidity and mortality (Czernichow et al. 2011). Also BMI measurement cannot discriminate between the adipose tissue and the muscle mass. The muscle tissues have a higher density (1g/ml) than fat tissues (0.7g/ml) which

means some sportsmen could be considered obese if BMI is used on its own. Also those people who start an exercise programme may not see a reduction in BMI as they may achieve a reduction in adipose tissue but an increase in muscle mass.

Table 1 - 6 BMI and the prediction of risk to health. Adopted from (Maguire and Haslam 2009)

BMI (kg/m^2)	Category	Risk to health
<18.5	Underweight	Moderate
18.5 to < 25	Healthy weight	None
25 to < 30	Overweight	Moderate
30 to < 39	Obese	Significant
≥ 40	Grossly obese	Highly significant

On the other hand, as people with large waist circumferences have excess burden of ill health (Lean et al. 1998), when BMI is used in an adjunct to other measurements, such as waist-to-hip ratio and waist circumference it becomes more accurate in predicting risk (Table 1-7).

Table 1 - 7 BMI measurements accompanied by wais circumference. Adopted from (NICE 2006b)

		Waist circumference		
		Low (men < 94cm; women < 80cm)	**High (men 94-102cm; women 80-88cm)**	**Very high (men > 102cm; women > 88cm)**
BMI	**<30 kg/m^2**	No increased risk	Increased risk	High risk
	30-34.9kg/m^2	Increased risk	High risk	Very high risk

The abdominal obesity can affect people from different ethnic groups differently, for example, the increase of risk of diabetes and CVD is significant when waist circumference is more than 102 cm for men or 88 cm for white

women compared with an equivalent increase of risk when Asian men have a waist circumference of 90 cm in men or more than 80 cm in women (JBS2 2005).

Improvement in blood pressure and metabolic syndrome can be seen shortly after weight loss is achieved by obese individuals (Maguire and Haslam 2009). However, there are relatively little data on the effects of weight loss on the risk of diseases, for example, whether weight loss reduces the risk of CVD. The lack of data on weight loss is probably because of the fact that only a small number of individuals were able to achieve sustained weight loss (Wolin and Colditz 2008).

According to NICE clinical guideline 43 on obesity, weight management is a complex problem with no easy solutions (NICE 2006b). Behavioural weight loss interventions usually achieve short-term goals and re-gaining weight is a common problem in the longer term. Ongoing interaction with the individual concerned is recommended in order to sustain weight loss (Svetkey et al. 2008).

The recommendation made by NICE is to start with behavioural intervention to improve lifestyle which should be delivered with the support of a trained professional (NICE 2006b). Pharmacological intervention with orlistat, the only licensed agent for weight management in the UK, can be used as a second line measure.

1.1.2.13 Lack of physical activity

There is general consensus among researchers that exercise provides cardiovascular benefits. Regular exercise alone is linked with health benefits and reduction in mortality rate (Archer and Blair 2011). Significant decreases in cardiovascular and all-cause mortalities in both men and women are associated with an increase in physical activity. The association is clear even after adjusting for other relevant risk factors (Nocon et al. 2008).

1.1.2.14 Alcohol consumption

The adverse effect of alcohol consumption on health is evident through epidemiological studies in all age groups (di Castelnuovo et al. 2009). In fact, adverse effects can start before birth when the developing foetus is exposed to alcohol consumed by the pregnant woman. Alcohol is associated with a number of chronic health diseases including psychiatric, liver, neurological, gastrointestinal and cardiovascular conditions and different types of cancer. In addition an increased rate of accidents and injuries is also linked to alcohol (NICE 2010b).

Heavy drinking (Table 1-8), episodic drinking patterns or binge drinking is linked to all cause mortality including accidents and injuries. There is also a strong association of binge drinking of beer with fatal myocardial infarction. Binge drinking is associated with marked fluctuations in blood pressure and hypertension (Lindschou Hansen et al. 2011).

Table 1 - 8 Definitions for Patterns of Alcohol Use (1 unit = 10ml or 8g of pure alcohol)

	For men	For women
Moderate drinking (NHS Choices 2011a)	3 to 4 units per day on a regular basis and < 21 units per week	2 to 3 units per day on a regular basis and < 14 units per week
Heavy drinking (NHS Choices 2011a)	> 4 units per day on a regular basis or > 21 units per week	> 3 units per day on a regular basis or > 14 units per week
Binge drinking (Bell and Britton 2011)	> 7 units in a single session	> 5 units in a single session

Other cardiovascular diseases including heart failure and arrhythmias are associated with alcohol consumption (World Health Organization 2004). It is also a risk factor for hemorrhagic stroke even among moderate drinkers (Zhang et al. 2011).

The overall consumption of alcohol in the UK is similar to other Western countries (World Health Organization 2004). The per capita consumption for population older than 15 years old in the UK (10.4 litres of pure alcohol) is less than France (13.5 litres) and the rate of abstainers (those who drink no alcohol) in the UK is 12% compared with 6.7% in France. However, in 2000 the rate of heavy drinking was higher in the UK (42% for females and 39% for males) compared to 7.8% and 16.6%, respectively, in France. The rate of binge drinking is similar in both countries (Shelton and Savell 2011).

In the UK, the NHS sets guidance for sensible alcohol consumption which is not more than 3 to 4 units a day or less for men, and 2 to 3 units a day or less

for women (Shelton and Savell 2011). The evidence to suggest that low to moderate drinking has some health benefits is strong. The reduced risk of CHD is considered as the main health benefit of alcohol (Fuller 2011). However, the evidence for this protection, is limited to middle-aged and older individuals who are at high risk of CHD (Ellison 2002).

Moderate consumption of alcohol improves lipid profiles by decreasing LDL and increasing HDL. Moderate alcohol consumption is believed to reduce risk of CHD by improving the lipid profile and also by changing haemostatic factors which reduce platelet aggregation (Stranges and Trevisan 2011).

In addition to the benefits to CHD, there is evidence that low consumption of alcohol is associated with a lower risk of ischaemic stroke. There is also evidence to suggest that moderate consumption confers protection against other diseases, including diabetes (Stranges and Trevisan 2011). Red wine in particular is believed to reduce CHD (Goldberg and Soleas 2011).

Some experts have recommended that healthcare professionals should encourage low to moderate alcohol consumption to reduce the risk of CVD unless the patient with previous abuse or with religious, ethical or medical reasons for abstinence (Ellison 2002).

However, the British Heart Foundation's website advises people to not to start drinking in order to reduce CHD risk as there are other ways to risk including increasing physical activity, having a healthy diet and quitting smoking. They suggested that the benefit of alcohol as a protective against CHD still needs to be established in controlled trials (BHF 2010).

1.1.2.15 Chronic kidney disease

Chronic kidney disease, defined as an estimated glomerular filtration rate of less than 60 ml/min per 1.73 m^2 - which means all categories (mild, moderate and severe) of chronic kidney disease are included - is an independent risk factor for CVD (Weiner et al. 2004). It can increase the risk of myocardial infarction, fatal CHD, stroke and death from any cardiovascular event (di Angelantonio et al. 2010). The risk of CVD in black individuals with chronic kidney disease is increased to about twofold whereas the CVD risk of Caucasians with the disease is increased by only 13%. It has been suggested that the effect of chronic kidney disease on black people may be due to more frequent or more severe subclinical vascular disease secondary to hypertension or diabetes (Weiner et al. 2004).

Whether aggressive lifestyle intervention in patients with chronic kidney disease can reduce their substantial CVD risk is unclear (Shlipak et al. 2005).

1.1.2.16 Rheumatoid arthritis

Rheumatoid arthritis (RA) is a chronic inflammatory joint disease affecting approximately 1% of the general population (Van Halm et al. 2009). The high mortality rate among patients with this disease appears to be due to CVD. The increased CVD risk in patients suffering from RA could be due to an increase in prevalence of risk factors such as dyslipidaemia, diabetes, hypertension, obesity or impaired physical fitness. Also, RA patients are more likely to be on non-steroidal anti-inflammatory drugs (NSAID) which can decreased renal blood flow and aggravate hypertension (Boyer et al. 2011). Moreover, it may

be due to the fact that in chronic diseases such as RA unrelated conditions such as cardiovascular risk factors may be undertreated and/or the chronic inflammatory process in the disease may increase the risk of CVD (Van Halm et al. 2009).

According to Gonzalez et al. (2008) the management of CVD risk factors is less effective in reducing cardiovascular morbidity and mortality in RA patients. Further research is warranted to determine optimal approaches to achieve better outcomes (Gonzalez et al. 2008).

1.1.2.17 Atrial fibrillation

Atrial fibrillation (AF) is the most common sustained cardiac arrhythmia in the UK (NICE 2006a). Unmanaged AF can increase risk of stroke significantly. AF mainly increases the risk of stroke caused by embolism formed in the atrium rather than atherosclerosis. The risk of stroke is increased four- to five-fold in patients with AF. AF is associated with about a two-fold increase of mortality (Kannel and Benjamin 2008).

1.1.3 Primary prevention of cardiovascular disease

Acceptance and implementation of CHD guideline advice by primary care physicians, that is, general medical practitioners (GPs) in the UK, was assessed in five European countries including the UK (Hobbs and Erhardt 2002). The majority of the 754 physicians (150 in the UK) interviewed perceived the guidelines as useful. However, it was noted that the figure of UK physicians who perceived the guidelines as useful was lowest when compared to the other four countries (UK = 85%, France = 90%, Germany = 90%, and Italy = 99%).

Only 13% of physicians said that they always use risk calculator charts to estimate patients' risk of CHD. The authors concluded that GPs need more information and support on the implementation of CHD and cholesterol guideline advice.

In another study the researchers found that the age of doctors could influence their approach to managing the prevention of CVD. Older doctors when compared to their younger colleagues tended to recommend lifestyle changes over the use of medications (Tocci et al. 2011).

1.1.3.1 The use of statins in the primary prevention of CVD

The statins competitively inhibit 3-hydroxy-3-methyl-glutaryl coenzyme A (HMG CoA) reductase in the liver. HMG CoA reductase is an enzyme involved in cholesterol synthesis. There are five statins licensed in the UK; atorvastatin, fluvastatin, pravastatin, rosuvastatin and simvastatin (BNF 2011).

Reduction in total cholesterol is associated with a reduction in ischaemic heart disease mortality (Lewington et al. 2007). By using a statin within therapeutic doses, up to 50% reduction can be seen in total body cholesterol levels. Lowering LDL cholesterol by about a third can be achieved by standard statin regimens and by up to a half when higher doses of atorvastatin or rosuvastatin are used (Baigent et al. 2010). Also, there are other effects of statins on the cardiovascular system and the arterial walls affecting endothelial function, reducing inflammation (measured by CRP), down-regulating of the blood coagulation cascade, plaque stabilization and smooth muscle cell migration (Yusuf 2010).

The benefits of statins in secondary prevention have been well established in several landmark trials. The Scandinavian Simvastatin Survival Study (4S) included a total of 4,444 patients, suffering from angina or previous myocardial infarction, with initial cholesterol levels of 5.5 to 8.0 mmol/L were assigned to a control group or an intervention group over a 5.4 year median period. The 4S study demonstrated a significant reduction in overall mortality in the intervention group (Pedersen et al. 2004). The CARE (Cholesterol and Recurrent Events) trial studied 4,159 patients, who had suffered myocardial infarction, with a total cholesterol level of 6.2 mmol/L or less. It demonstrated a significant reduction in the rate of CHD mortality and nonfatal myocardial infarction in the pravastatin group. Also there was a significant reduction in stroke rate in the therapeutic group (Sacks et al. 1996). The LIPID (The Long-Term Intervention with Pravastatin in Ischaemic Disease) study randomised 9,014 patients with history of myocardial infarction or hospitalisation for unstable angina into a pravastatin group or a placebo group over a mean follow-up period of 6.1 years. Patients with broad range of total cholesterol levels had a reduction in mortality rate from CHD, overall mortality and the incidence of all pre-specified cardiovascular events when treated with pravastatin 40mg (LIPID 1998). The Heart Protection Study (HPS 2002) studied 20,536 patients with CHD, other occlusive arterial disease or diabetes which were allocated to receive simvastatin 40mg or placebo. It demonstrated a significant reduction in all-cause mortality. To date HPS is the largest study to investigate the use of statins in both primary and secondary prevention of CVD

and it showed that safety profile is acceptable as side-effects, for example, myopathy, were rare in this study.

The continued emphasis on the use of statins in the secondary prevention of CVD is seen as an important intervention in the reduction of cardiovascular events. However, it is also important not to overlook the significance of the primary prevention as 50% of all myocardial infarctions and strokes occur among apparently healthy people with levels of LDL that are below currently recommended thresholds for treatment (Ridker et al. 2008).

The West of Scotland Coronary Prevention Study Group randomly assigned 6,595 men with no history of myocardial infarction, 45 to 64 years of age, with a mean total cholesterol level of 7 mmol/L (SD = ±0.6) to receive pravastatin 40mg or a placebo over a period of mean 4.9 years. The active therapy group had a significantly lower incidence of myocardial infarction and death from cardiovascular causes without adversely affecting the risk of death from non-cardiovascular causes (Shepherd et al. 1995).

The ASCOT-LLA trial (Sever et al. 2004) assigned 19,342 hypertensive patients with at least three other risk factors of CVD and a total cholesterol of not more than 6.5 mmol/L to receive atorvastatin 10mg or placebo. It demonstrated a significant reduction of 36% in fatal CHD and non-fatal myocardial infarction in the statin group compared with placebo. The study was stopped after a median follow-up of 3.3 years as it was deemed unethical to deprive the control group from the obvious benefit of the statin, hazard ratio 0.64 [95% CI 0.50 - 0.83] (p = 0.0005).

The benefit of statin in the primary prevention of CVD was studied in a cohort of participants of 5,608 men and 997 women with a mean total cholesterol level was 5.7 mmol/L, mean LDL level was 3.9 mmol/L and below average HDL levels, were allocated to receive a statin, lovastat (not available in the UK), or a placebo for a period of an average 5.2 years. It resulted in a 37% reduction in the risk for first acute major coronary events (Downs et al. 1998).

On the other hand, no significant reduction was seen either in all-cause mortality or CHD in a study compared the use of pravastatin versus usual care in 10,355 participants with well-controlled hypertension, moderately elevated LDL and with at least 1 additional CHD risk factor. The authors suggested that the lack of significant effect could have been due to the unexpected reductions of 8% in total cholesterol and 11% in LDL at 4 years in usual care group (Furberg et al. 2002).

In the MEGA study (Nakamura et al. 2006), 7,832 Japanese with hypercholesterolemia, total cholesterol 5·7 to 7 mmol/L, but no history of CHD or stroke, were allocated in a diet group or diet plus pravastatin 10-20 mg. The therapeutic group had a significantly lower incidence of CHD post-study but there was no significant reduction in the incidence of stroke rate or total mortality when compared to the control group. A major limitation of this study is that a placebo was not used in the control group. It could not rule out that the benefit of pravastatin was not due to placebo effects.

In another study, a group of 17,802 men and women were randomly assigned to receive a rosuvastatin 20mg or a placebo. Participants were apparently

healthy with LDL levels of less than 3.4 mmol/L but with elevated high-sensitivity C-reactive protein levels. Rosuvastatin significantly reduced the incidence of major cardiovascular events and all-cause mortality. However, the trial was stopped by the study's independent data and safety monitoring board after a median follow-up of 1.9 years with no clear reason for this (Ridker et al. 2008).

According to a Cochrane review, when used for primary prevention in people at higher risk of CVD, statins can reduce all-cause mortality, combined fatal and non-fatal endpoints (CHD, CVD and stroke events) and revascularisation rates. Also it is cost-effective to use statins for primary prevention in high risk patients. However, the authors recommended a cautious approach when considering whether or not to prescribe statins for primary prevention in people with low CVD risk (Taylor et al. 2011a). These findings are in line with the current NICE guideline recommendations (Cooper et al. 2008).

1.1.3.2 The use of aspirin for the primary prevention of CVD

Aspirin at a low dose irreversibly inhibits the enzyme cyclo-oxygenase, which is required in the synthesis of thromboxane A2 (Martindale 2011). A complete suppression of platelet thromboxane synthesis can be achieved by daily doses of 20mg to 50mg over a few days. Larger doses of 150mg to 300mg can produce a maximum suppression instantly and no thromboxane A2 can be produced for about 24 hours until more platelets are released by the bone marrow. Aspirin is indicated for secondary prevention of thrombotic cerebrovascular or CVD, and following by-pass surgery (BNF 2011).

Aspirin at doses of 75mg to 150mg, according to placebo controlled trials, can reduce the risk of all occlusive vascular events, including myocardial infarction, ischaemic stroke, unstable or stable angina, peripheral arterial disease or atrial fibrillation (Weber 2002). Weber et al. (2002) conducted a meta analysis, in which 287 studies were included and involved 135,000 patients in comparisons of antiplatelet therapy versus control, the overall result was a reduction of all vascular events by about one quarter in most of high risk patients including those who never had a CVD previously.

The Joint British Societies guidelines on prevention of CVD in 2005 stated that subject to there being no contra-indications people over the age of 50 years who are at high risk of CVD, that is, ≥20%, without established CVD (primary prevention) should take aspirin 75 mg daily. Those who are hypertensive should have their blood pressure controlled to at least the audit standard of below 150/90 mmHg diastolic and then prescribed aspirin 75 mg daily (JBS2 2005).

The NICE guidelines for the management of type 2 diabetes in primary and secondary care, also recommend the use of aspirin 75 mg daily by those who are over the age of 50 years if blood pressure is below 145/90 mmHg. Also, the guidelines recommend the use of aspirin 75 mg daily by those who are under the age of 50 years and have significant other cardiovascular risk factors, such as the metabolic syndrome, family history of CVD, smoking, hypertension and/or microalbuminuria (NICE 2008a).

However, the benefits of aspirin in primary prevention of CVD have been questioned more recently (Berger et al. 2011). The evidence for the use of aspirin for primary prevention is not as strong as for those who had the disease previously. The risk of bleeding cannot always be justified in all of those who are at high risk but without extant CVD. The comparison between primary and secondary CVD prevention by using long-term aspirin was reported as a result of a meta analysis by Collins et al. (2009). The rate of serious vascular events, including myocardial infarction, stroke or CVD mortality and major bleeds in six primary prevention trials (n = 95,000) and 16 secondary prevention trials (n = 17,000) were evaluated in the analysis. Although the effectiveness of aspirin in the secondary prevention confirmed previous findings, the primary prevention reduction of stroke or mortality in those taking aspirin was not significant. It was only significant in non-fatal myocardial infarction (0·18% versus 0·23% per year, $p < 0·0001$) (Collins et al. 2009). This meta analysis included data for people at low, moderate and high CHD risk. The reduction in mortality rate was modest even in the high risk group.

Similarly, according to a randomised control trial conducted by Belch et al., when compared with placebo, using aspirin for primary prevention in people with diabetes, that is, at high CVD risk, was not effective at reducing the CVD risk (Belch et al. 2008).

The Medicines and Healthcare products Regulatory Agency (MHRA) stated that the use of aspirin as an antiplatelet drug is licensed for secondary prevention only and recommended that if it is used in primary prevention, which is an unlicensed use, healthcare professionals should review the benefits,

particularly the presence of risk factors for vascular disease (including conditions such as diabetes) and the risks, such as gastrointestinal bleeding. The balance of the benefits and risks should be considered for each individual (MHRA 2009).

It has been now recommended, in light of the available evidence, that patients who are on aspirin for primary prevention should be reviewed. Healthcare professionals should engage those patients in the decision about whether to continue with the treatment (DTB 2009). Table 1-9 shows the figures acquired from a patient decision aid which was produced by the National Prescribing Centre (NPC) to assist healthcare professionals in consultations with patients with no history of CVD and the treatment with aspirin is being considered (NPC 2010). The patient decision aid showed that a modest benefit can be gained by taking aspirin 75mg daily for 10 years. The aid interpreted the findings of the Collins et al. meta analysis (2009).

Table 1 - 9 Benefits and risks of aspirin in three groups of patients (each of n=1,000) who do not have existing CVD and take aspirin for the next 10 years (NPC 2010)

	5% risk of CVD	10% risk of CVD	20% risk of CVD
Number of people who will not die, have a non-fatal MI or a stroke whether or not they take aspirin	950	900	800
Number of people who will be saved from dying, having a non-fatal MI or a stroke by taking aspirin	6	12	24
Number of people who will die or have at least one non-fatal MI or stroke, whether or not they take aspirin	44	88	176
Number of people who will not have a major bleed whether or not they take aspirin	994	983	972
Number of people who will have a major bleed because they take aspirin	2	6	10
Number of people who will have a major bleed whether or not they take aspirin	4	11	18

1.1.4 Risk assessment for the primary prevention of cardiovascular disease

The cardiovascular risk assessment (VRA) tools in use (see Chapter 7) tend to divide people into three groups: those at low risk, that is, with less than 10% risk of developing CVD in the next ten years; those at moderate risk with 10-20% risk of developing CVD in the next ten years; and those at high risk, that is, greater than 20% risk of developing CVD in the next ten years. National guidelines, such as NICE (NICE 2008b) and SIGN (SIGN 2007), consider a

cardiovascular risk score of 20% or more is high risk and only those who are at high risk are candidates for preventive pharmacological intervention.

1.1.4.1 Framingham risk scores

Most of the risk assessment tools available in the UK are based on the American Framingham study although the relevance of this to the current UK population is unclear (Hippisley-Cox et al. 2007). The Framingham Heart Study was conceived in 1948, at a time when there was insufficient knowledge about the causes of CVD. The Framingham Heart Study was set up to identify the risk factors that contribute to CVD. More than 14,000 participants over five decades and representing three generations have been recruited and monitored for the development of CVD. The Framingham Heart Study has successfully identified that high blood pressure, high blood cholesterol, smoking, obesity, diabetes and physical inactivity are risk factors for CVD (Shindler 2011). As a result, the concept of CVD risk factors has become the cornerstone of advancing prevention and treatment of CVD (Folsom et al. 2003). Based on the Framingham population a risk assessment tool for estimating 10-year CVD risk has been developed.

NICE had followed the recommendation of the Joint British Societies' guidelines in using the modified Framingham equation Until March 2010 (NICE 2010a).

1.1.4.2 ASSIGN

The "ASSessing cardiovascular risk using SIGN" (ASSIGN) is a cardiovascular risk score developed in Dundee University, Scotland in 2006

(SIGN 2007). The tool was developed by following a cohort of 6,419 men and 6,618 women aged 30–74 across 25 districts of Scotland and monitoring them for cardiovascular mortality and morbidity over a year (Woodward et al. 2007). ASSIGN was the first VRA tool to use social deprivation and family history of CVD together with the classic risk factors (smoking, blood pressure, total cholesterol and HDL) (Tunstall-Pedoe and Woodward 2006).

1.1.4.3 QRISK and QRISK2

Researchers from the University of Nottingham have developed QRISK, a cardiovascular disease risk algorithm specifically for use in the UK (Hippisley-Cox et al. 2007). A second, modified version of QRISK, namely QRISK2, was launched in 2008 (Hippisley-Cox et al. 2008). In contrast to the US based Framingham model, QRISK2 is based on data derived from primary care records in the UK. The QRISK2 model is based on data from 531 practices (2.3 million patients; aged 35-74) studied from 1st Jan 1993 to 31st March 2008. In addition to the standard risk factors for CVD taken into account by Framingham, QRISK also takes account of variables relating to socioeconomic status and ethnicity (Hippisley-Cox et al. 2007). Unlike Framingham, which overestimates CVD risk in low risk population and underestimates CVD risk in high risk populations, the QRISK2 score is more accurate in predicting CVD risk (Jackson 2008). The claimed improved accuracy of QRISK2 at predicting CVD risk is due to the increased size of the data base, the type of population from which the data were derived and validated, and the inclusion of other variables. Furthermore, an independent and external validation of the QRISK2

has provided evidence to support the use of QRISK2 in favour of the modified Framingham equation (Collins and Altman 2010).

1.1.4.4 The use of circulating C-reactive protein concentration as a CVD risk assessment

C-reactive protein (CRP) is produced largely by the liver and also produced by adipocytes (Vachharajani and Granger 2009). The circulating concentration of this protein rises rapidly in response to tissue injury, infection and inflammation. It has been thought that the physiological role of CRP is a host protective by binding to molecules containing phosphocholine expressed on the surface of dead or dying cells and some types of bacteria to active then activating the classical complement pathway, which is important to help the antibodies and phagocytes to clear pathogens from the system (Thompson et al. 1999).

It has been suggested that the concentration level of CRP as a biomarker for cardiovascular risk prediction and as a selection marker for initiating statin treatment (Shah et al. 2010). There are a number of prospective studies of high quality design that have shown a strong and independent correlation between concentrations of CRP and future major cardiovascular events (Imhof et al. 2003). The link between CRP and CVD was used by some researchers to confirm the inflammatory nature of the atherosclerosis, that is, it is a marker for the inflammation of the vascular cell wall (Bucova et al. 2008). Inflammation is involved in atherosclerosis starting in early youth and advancing for decades throughout life (Kones 2010). However, it is also suggested that as CRP amplifies the pro-inflammatory effects of cytokines, the

high levels of CRP could be responsible for the inflammation rather than a result of it. In other words, high concentrations of circulating CRP should be regarded as a risk for CVD and not only a biomarker to predict the disease (Vachharajani and Granger 2009). This view remains controversial and data indicate that CRP concentration is unlikely to be a causal factor in CHD (Wensley et al. 2011). Most researchers regard CRP as an independent predictor of future cardiovascular events without confirming the direct involvement in atherosclerosis (Kones 2010).

There are also laboratory and clinical studies to show the strong association between CRP and various features of metabolic syndrome. Metabolic syndrome is diagnosed by the presence of any three of the following features; central obesity, dyslipidaemia (high triglycerides, low HDL), hypertension or impaired fasting glucose. According to Devaraj et al. (2010) the addition of CRP to the present definition of the metabolic syndrome may help identify patients at high risk of diabetes and CVD (Devaraj et al. 2010). However, as most observational studies confirming the association between CRP and CVD have been in Caucasians, caution should be exercised in extrapolating to non-Caucasions. A meta-analysis was conducted to evaluate the influence of the ethnicity on CRP concentration and concluded that a single threshold value of CRP for cardiovascular risk prediction may not accurately reflect underlying levels of cardiovascular risk. The authors were able to show variations in CRP concentration in populations of diverse ethnicity were large but only partially influenced by differences in variables related to cardiovascular risk (Shah et al. 2010). According to Khera et al. there are significant variations of mean levels

of CRP not only between different ethnic groups but also between genders. It was suggested that further research is required to determine whether variations in CRP levels among different ethnic groups and genders contribute to differences in cardiovascular outcomes, and also to determine whether thresholds for a preventative treatment should adjusted for these groups (Khera et al. 2005).

As far as the circulating CRP is concerned, the inflammatory process in atherosclerosis is relatively limited. Therefore, high-sensitivity assays have been developed and become commercially available for measuring of circulating CRP concentrations for risk prediction of CVDs (Imhof et al. 2003). The following categories can be determined by using such assays; low risk < 1mg/L, moderate risk 1-3mg/L and high risk >3mg/L (Longmore et al. 2004).

The JUPITER trial (Justification for the Use of Statins in Primary Prevention: An Intervention Trial Evaluating Rosuvastatin) claimed that patients are better managed when both LDL and CRP levels are reduced, when compared with reducing only LDL level (Kones 2010). However, an analysis from a large-scale study showed that regardless of baseline levels of CRP, statin treatment was associated with a similar reduction in cardiovascular events (Heart Protection Study Collaborative Group 2011).

The use of CRP concentrations has been suggested to augment other risk assessment tools, such as Framingham algorithm. It has been suggested as being capable of improving the predictability of Framingham when used to determine who of those at moderate risk would benefit from preventative

treatment (Dent 2010). The US Food and Drug Administration extended the indications for rosuvastatin to include asymptomatic individuals with high CRP level plus one additional risk factor. The measurement of the circulating CRP is recommended by the American Heart Association to those who are at moderate intermediate risk of CVD. The Canadian Cardiovascular Society guidelines recommended use of statins in individuals at moderate risk even those with low LDL if CRP level is high (Kones 2010).

A study conducted in Brazil, however, questioned the reliance on CRP or on CVD risk assessment tools to predict cardiovascular events as more than half of patients presenting with myocardial infarction in the study would not be considered as candidates for preventive therapy by the current CVD risk algorithms or the current thresholds of CRP concentrations (Sposito et al. 2011).

1.2 Literature Review of Pharmacy Based VRAs

A search of the literature on pharmacy based VRA services was performed to identify studies conducted to evaluate the role of pharmacy and/or the pharmacist in the provision of such services. The databases MEDLINE and EMBASE were searched from 1996 to the 24th June 2009 to inform the method of the study and to prepare for the study protocol. The same search strategy was repeated with from 1996 to present (4th November 2011) using appropriate subject headings for each database as some subject headings were available for one database but not the other. For the Embase database; the following Subject Headings were used: 'cardiovascular disease', 'risk assessment', 'pharmacy' and then all results were combined with AND. For the Medline database the subject headings were 'cardiovascular diseases', 'community pharmacy services' and 'risk assessment' and then combined with AND.

Also the following terms were used in combination to complement the search with studies on UK specific services; 'pharmac$' and 'NHS Health Check$'.

To obtain more comprehensive results, the search was not limited in either of the databases to the English Language as it was unknown whether there was any study focussing on CVD risk assessment in any of the non-English speaking countries.

Additionally, reference lists and bibliographies of the identified studies and government reports produced on the VRA services were reviewed.

1.2.1 Results of the search strategy

The results of the search strategy are summarised in Table 1-10 below. There were 14 relevant studies from Embase database which were included in this literature review. The reasons for the excluding 22 from the literature review were as follows; there were three papers on medicines adherence, three reviews, two papers studying screening services for other health problems (namely chronic obstructive pulmonary disease and sleep disorders) and two papers studying prescribing of COX-2 inhibitors, one paper studying the cardiovascular therapy under-treatment in patients with rheumatoid arthritis, one paper evaluating the use of gastrointestinal prophylaxis in NSAID patients, one paper studying the inappropriate medication use in the elderly, one a duplicate record, and 6 were editorial (n = 1), letter (n = 2), view (n = 2) or report (n = 1). Two conference abstracts were found relating to this PhD (Waheedi et al. 2011; Waheedi et al. 2010) and these were also excluded.

Table 1 - 10 Results of the search strategy of the literature review as in 4th November 2011

Embase		**Medline**	
Subject headings	**Number of papers**	**Subject headings**	**Number of papers**
Pharmacy	30339	Community Pharmacy Services	1665
Risk assessment	242089	Risk Assessment	127101
Cardiovascular disease	112838	Cardiovascular diseases	58229
Combined with AND ➔ 36 Included ➔ 14 papers		Combined with AND ➔ 7 (3 were found by Embase as well) Included ➔ Additional 4 papers	

The search using the Medline database resulted in four additional papers being identified. The search using the following terms 'pharmac$' and 'NHS Health Check$' resulted one additional study being identified by Embase database. Four papers were excluded for the following reasons; one duplicate, one identified through the previous search, one was a review on conference abstracts and one was an article on NHS Health Checks.

Table 1-11 lists the studies which were identified through the search strategy.

Table 1 - 11 Studies identified using Embase, Medline and manual search

Embase	Medline	Manual search
Amariles et al. 2005	Amariles et al. 2008	Boyle et al. 2004
Chambers et al. 2005	Carter et al. 2009	Donyai and van den Berg 2009
Crabtree et al. 2010√	Horgan et al. 2010*	Horgan et al. 2009
Didonato and May 2011	Liu et al. 2009*	Thornley et al. 2009a
Fernandez-Pinilla and Chaves 2008	Mc Namara et al. 2010*	
Horgan et al. 2010*	Simpson et al. 2001	
Kaczorowski et al. 2010	Yamada et al. 2005	
Lalonde et al. 2006		
Liu et al. 2009*		
Loo et al. 2011†		
Mc Namara et al. 2010*		
O'Donovan et al. 2010		
Peterson et al. 2010		
Sancar et al. 2011		
Thornley et al. 2009b		

* Identified by both Medline and Embase, √ Identified using the search terms method, † Identified using the search terms method and the subheadings method.

1.2.2 Literature overview- pharmacy based VRAs

A total of 23 studies were identified through the research strategy. Table 1-12 shows a list of the studies outlining the country in which they were conducted, the VRA tool used and the deprivation index used if applicable. Table 1-13 presents a summary of studies' aims/objectives, methods and key findings.

Table 1 - 12 Studies identified through the research strategy with the country they were conducted in, VRA tool and the deprivation index used, if applicable

Author(s) and year	Country	VRA tool	Deprivation index
Simpson et al. 2001	Canada	Framingham	
Boyle et al. 2004	USA	Men's Health Risk Assessment	
Amariles et al. 2005	Spain		
Chambers et al. 2005	Canada		
Yamada et al. 2005	Canada	Framingham	
Lalonde et al. 2006	Canada		
Amariles et al. 2008	Spain	Framingham	
Fernandez-Pinilla and Chaves 2008	Spain	SCORE (based on Framingham)	
Carter et al. 2009	Canada		
Donyai and van den Berg 2009	UK	Framingham	The Output Area Classification
Horgan et al. 2009	UK	Framingham	The Index of Multiple Deprivation
Liu et al. 2009	USA	Individual risk factors	
Thornley et al. 2009a	UK	Framingham	
Thornley et al. 2009b	UK	Framingham	The Output Area Classification
Crabtree et al. 2010	UK		
Horgan et al. 2010	UK	Framingham	The English Index of Multiple Deprivation
Kaczorowski et al. 2010	Canada		
Mc Namara et al. 2010	Australia	Framingham	
O'Donovan et al. 2010	Republic of Ireland	Questionnaire	
Peterson et al. 2010	Australia	Framingham	
Didonato and May 2011	USA		
Loo et al. 2011	UK		
Sancar et al. 2011	Turkey	Framingham	

Table 1 - 13 Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Simpson et al. 2001	Evaluate economic impact of the cardiovascular risk intervention by pharmacists.	The cost of an earlier study, involved 50 community pharmacies in a randomised control trial, was analyzed to describe the economic impact of the programme. The change in CVD risk was also reported.	The CVD risk decreased from 17.3% to 16.4% ($p < 0.0001$) during the 4 months. The incremental cost appeared, according to the authors, minimal from both government and pharmacy manager perspectives.
Boyle et al. 2004	Determine whether community pharmacists could encourage men to visit their physician.	A 12 week prospective cohort study recruited men aged 25-74 years with potential untreated or uncontrolled health risks, who visited any of the 30 participated pharmacies in 2002.	Up to 50% of participants were found to be at risk of hypertension, hyperlipidaemia or diabetes. 64% made their visit or waiting for an appointment.
Chambers et al. 2005	The introduction of the Cardiovascular Health Awareness Programme (CHAP)	Description of the implementation of the programme.	

Table 1 – 13 (Continued) Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Amariles et al. 2005	Investigate the relationship between knowledge and CVD risk.	A cross sectional survey of patients attending 6 community pharmacies in Andalucia, Spain was used over a period of 15 days.	257 were recruited; mean age was 61 years (SD ±10.8), male 36%, current smokers 13%, hypertensive 79%, raised cholesterol levels 42%, type 2 diabetes 20%, and CVD 23%. 36% of participants were at low CVD risk, 21% at moderate risk and 43% at high risk. According to the survey's results the degree of knowledge was considered as adequate in 61%. No significant difference in patient's knowledge was found between those at low, moderate or high CVD risk.
Yamada et al. 2005	Determine the effect of a community pharmacist intervention in patients at high risk for CHD on LDL.	Patients from another study (Tsuyuki et al. 1999) were invited to return to their community pharmacy 6 months after they had an intervention by their pharmacist to have a measure of their fasting LDL level.	162 patients (45%) returned to their community pharmacy. There was an increase of 0.07 mmol/L in the mean LDL level between original and follow up, 95% confidence interval = -0.5-0.19.

Table 1 – 13 (Continued) Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Lalonde et al. 2006	Assess the feasibility and relevance of providing a community pharmacist two different decision aids to patients on lipid-lowering or blood pressure medicines.	Patients at 10 community pharmacies were randomised to two groups, pharmacists helped patients to use a unique decision aid for each group. Patients were evaluated at baseline, two weeks, and three months after a pharmacist consultation.	26 participated in the study. All patients agreed the tools were useful. Only one-third of participants estimated their CVD risks correctly and this has not improved after the intervention. Decision making by patients improved significantly (P = 0.02).
Amariles et al. 2008	A descriptive, observational study to compare between two CVD risk assessment systems (both based on Framingham).	Including patients aged 25-74 years from six community pharmacies of Andalusia, Spain over 15 days in 2004 if they were on any medication for CVD prevention. Results were compared using the SCORE system and the Wilson-Grundy method.	A total of 257 patients, 92 male (36%), mean age was 60.9 (SD = 10.8) years. 22 participants were assessed as at high risk with SCORE system but at low risk when assessed with the Wilson-Grundy method.

Table 1 – 13 (Continued) Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Fernandez-Pinilla and Chaves 2008	Determine the CVD risk, based on the SCORE (Systematic Coronary Risk Evaluation) model, in community pharmacies.	An observational study was conducted in Spain in 362 community pharmacies. Blood pressure, cholesterol and glucose were measured.	5,334 were recruited. The mean age was 57 years; 67% were women; 67% were overweight or obese; 19% smokers; 32% hypertensive; 52% hyperlipideamia and 12% diabetic. The average mean CVD risk was 4.2. 30% were at a moderately high to very high CVD risk.
Carter et al. 2009	Describe the implementation of the CHAP (Chambers et al. 2005a)	Community pharmacists were recruited to deliver a VRA service in 129 pharmacies in Canada. Assessment results were sent to the GPs (99%) who agreed to receive them.	The number of participants who had the assessment was 15,889. (more results published by Kaczorowski et al. 2010, see below)
Donyai and van den Berg 2009	To find associations between participants' demographics and 10-year CHD risks	Analysing data from 8,287 records of a free VRA service provided by a large UK pharmacy chain from August 2004 to April 2006.	Pharmacists provided lifestyle advice for the participants regardless of their characteristics and only less than 3% were sold a product to manage the risk of CHD.

Table 1 – 13 (Continued) Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Horgan et al. 2009	A survey of participants who accessed the Heart MOT, a pilot of a community pharmacy based VRA service.	400 were sent a questionnaire 3 months after accessing the service in one of the 14 participated pharmacies in Birmingham, England during the period between April 2007 and June 2008.	176 responded to this survey. High percentage agreed that they were happy with the service (98%), consultation room (93), and that they would recommend the service (99%). The percentage plummeted in response to professionalism (77%), cleanliness (76%), confidentiality (80%) and the overall experience (76%).
Liu et al. 2009	A descriptive study of VRA service provided by the community pharmacy.	The site of the screening was at work place for workers and their dependents. 20 years of age or older, were eligible for the screening. Risk levels of CVD determined by checking BP, total cholesterol, and HDL.	The total number of patients was 452. 137 were found at high risk because of an SBP $\geq$ 140 mmHg (45%), 73 had a DBP $\geq$ 90 mmHg (24%), 81 had high total cholesterol (24%), and 55 had low HDL (16%).
Thornley et al. 2009a	Analysis of consultation times with service users.	Consultation time were recorded by the pharmacy teams in eight Boots pharmacies in the UK (see Thornley et al. 2009b)	The median time was 35 minutes (20 minutes of team member time, 10 minutes of pharmacist time and 5 minutes of paperwork)

Table 1 – 13 (Continued) Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Thornley et al. 2009b	Analysis the demography of VRA service users and evaluation of the findings.	Analysing data from a private VRA service which was provided by eight Boots pharmacies in the UK.	400 used the service, 70% were women and 72% were 50 years or over. Only 13% were from the disadvantaged socioeconomic groups.
Crabtree et al. 2010	Explore why pharmacy staff involved in one of the pilots held positive views about the NHS Health Check service.	32 semi-structured telephone interviews were conducted with a member of staff, pharmacists (n = 15), support staff (n = 13) and pre-registration pharmacists (n = 4), who were involved in the service in different pharmacies.	In general pharmacy staffs were positive with some negative views being held which might be resolved by providing educational and training support.
Horgan et al. 2010	Evaluate a VRA pilot	Data for 99% (1130 of 1141) of the participants were included for the analysis of a VRA pilot in 23 UK independent community pharmacies targeted at those aged 40-70 without known CVD.	Referral to general practice reached 70% of participants. Only 18% were referred because they were at high risk of CVD.

Table 1 – 13 (Continued) Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Kaczorowski et al. 2010	Evaluate a community pharmacy based educational programme to reduce the morbidity of CVD.	39 communities in Ontario, Canada were randomized, 20 to receive the CHAP (Chambers et al. 2005b) and the remaining 19 were to receive the usual care, i.e. no intervention. Those aged ≥ 65 years were recruited to attend educational sessions over a 10-week period. Information collected was shared with their family doctor. The primary outcome was the rate of hospital admissions for acute myocardial infarction, stroke and congestive heart failure. Analysis was by intention to treat among those aged ≥ 65 years in both groups.	A total of 129 (90%) pharmacies provided the CHAP during the 10-week period. A total of 15,889 participants had their CVD risk assessed. CHAP was associated with a significant reductions in hospital admissions for acute myocardial infarction (rate ratio 0.87, p = 0.008) and congestive heart failure (rate ratio 0.90, p = 0.029), but not for stroke (rate ratio 0.99, p = 0.89).

Table 1 – 13 (Continued) Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Mc Namara et al. 2010	Assess the feasibility of implementing a primary CVD prevention programmes into community pharmacy (A study protocol)	A longitudinal pre- and post-test pilot study with a cohort of up to 100 patients (50-74 year old) in 10 pharmacies. Community pharmacists will provide consultations to improve lifestyle, adherence to medicines and medicines management.	This paper only presented the study protocol.
O'Donovan et al. 2010	Pilot a novel paper-based questionnaire that can be used as a VRA instead of the invasive methods available like Framingham.	The questionnaire was developed, using European Society of Cardiology guidelines, for self-reporting by patients in community pharmacies. No measurement took place in the pharmacy; lipid testing and blood pressure were omitted and weight and height were self-reported by patients. Each question was assigned a weighting and then the weightings for each risk factor were added to give a score related to their CVD risk; low, moderate or high. Six community pharmacies in Northern Ireland participated in this pilot.	204 were recruited, 32% were males, mean age was 41 years (SD = ±15). BMI was 25.7 (SD = ±4.8). 102 (50%) had low risk, 80 (39%) had a moderate risk and 22 (11%) had a high risk.

Table 1 – 13 (Continued) Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Peterson et al. 2010	Assess the suitability of the community pharmacy as a place for delivering the VRA service.	The service was offered, in 14 community pharmacies in Australia to those aged over 30 years and with no existing CVD. The baseline knowledge of participants was assessed followed by an educational programme. Feedback was received through a questionnaire and a phone call.	655 accessed the VRA service. 71% females, aged 30-90 years. 7% were found at high risk, 30% had BP > 140/90 mmHg, 40% had total cholesterol > 5.5 mmol/L and 20% had HDL < 1 mmol/L. 97% regarded pharmacy as an appropriate place for the service. Knowledge improved significantly. 46% of the high risk patients indicated that they had lifestyle changes or were prescribed a new drug.
Didonato and May 2011	Measure impact of wellness screening and monitoring services provided in a community pharmacy	Participants completed a personal health assessment, CVD and diabetes risk assessments, and screening for cholesterol, blood glucose, blood pressure, and body mass index. Then those who were diagnosed with any abnormality had monthly to quarterly follow-up appointments.	95 patients enrolled and 8 were found healthy, those included in the programme were: 57 hypertension, 74 cholesterol, 24 diabetes, and 60 weight management patients.

Table 1 – 13 (Continued) Studies on community pharmacy based VRA services identified through the research strategy of this literature review

Author(s) and year	Aim/ objectives	Method	Key findings
Loo et al. 2011	Explore community pharmacists' activities and their attitudes towards the provision of the NHS Health Check.	A validated questionnaire was sent to 1301 pharmacies in the most deprived areas in England in November and a reminder in December 2009. The questionnaire was to establish whether pharmacists provided a VRA service and about their views on barriers and training needs.	The response rate was 34%. Lack of time, shortage of staff and lack of reimbursement were commonly the perceived barriers identified by pharmacists for providing VRA services. Training requirements were suggested for the use of CVD predictive tools.
Sancar et al. 2011	Assess CVD risk of patients with hyperlipidaemia	Patients with hyperlipidemia, who attended a community pharmacy for dispensing their medications (March-April 2010) were included. The demographic, clinical and medication history was directly obtained from patients and medical records. A tool based on Framingham was used to calculate CVD risk.	50 patients were included, The mean age was 57 (SD ± 9). 76% had no smoking history. 10% had a family history of hyperlipidaemia. 58% had comorbid disease. 34% had a CVD risk > 20%.

1.2.3 Discussion

1.2.3.1 Prior to the study

Prior to commencing the present study there were only three papers (Horgan et al. 2009; Thornley et al. 2009a, 2009b) found in the literature which were conducted in the UK, two of which analysed data obtained from the same service. Thornley et al. (2009a) analysed the consultation times with the service user while Thornley et al. (2009b) presented the demographic characteristics of the service users. The feedback of service users was presented by Horgan et al. (2009).

Of the eight remaining studies, five non-UK based studies evaluating interventions, with CVD management as the main element of the programmes (Amariles et al. 2005; Boyle et al. 2004; Lalonde et al. 2006; Simpson et al. 2001; Yamada et al. 2005). Although there were some similarities between these programmes none were a screening service like those provided in the UK. Chambers et al. (2005) presented a descriptive of a CVD awareness programme in Canada. Two Spanish studies evaluated different VRA tools (Amariles et al. 2008; Fernandez-Pinilla and Chaves 2008).

Studies identified in the literature prior to the study in this thesis being designed and undertaken are discussed further below (Section 1.2.3.2).

1.2.3.2 Final literature review

There were six descriptive studies of the service identified in the literature (Carter et al. 2009; Chambers et al. 2005b; Horgan et al. 2010; Kaczorowski et

al. 2010; Liu et al. 2009; Peterson et al. 2010). The role of community pharmacists in the prevention of CVD was the focus of four studies (Boyle et al. 2004; Didonato and May 2011; Lalonde et al. 2006; Yamada et al. 2005). Another four studies presented patients' characteristics (Amariles et al. 2005; Donyai and van den Berg 2009; Sancar et al. 2011; Thornley et al. 2009b). Three studies focused on the VRA tools (Amariles et al. 2008; Fernandez-Pinilla and Chaves 2008b; O'Donovan et al. 2010). Views of pharmacists and/or pharmacy support staff on the provision of the service were evaluated by two studies (Crabtree et al. 2010a; Loo et al. 2011). One study was a survey of VRA service users (Horgan et al. 2009). One paper was a protocol for a feasibility study yet to commence (Mc Namara et al. 2010). One paper evaluated the economic impact of a programme involving pharmacists' interventions (Simpson et al. 2001).

In addition to the fact that the identified studies being conducted in different countries (the UK, Republic of Ireland, Spain, Turkey, Canada and the USA) that is, in different health systems, there are also other variations in the way the services were provided. For instance, the VRA tools were not the same in all studies. One service used the absolute 10-year risk of CHD (Wilson et al. 1998) rather than the 10-year risk of CVD commonly used and recommended by the current guidelines (NICE 2008b). Tools assessing CVD risk and based on Framingham study were the most common tools used by the identified studies. However, as it was shown in the study conducted by Amariles et al. (2008) different tools could yield different results even if both were based on Framingham.

Although some studies claim they used tools based on Framingham study they included patients whose risk could not be assessed accurately by any of the tools available. For example, one study included young patients, that is, younger than 30 years of age (Amariles et al. 2008). There was a study which included patients older than 74 years (Peterson et al. 2010) with a maximum age of 90 years. Furthermore, the authors of one study (Donyai and van den Berg 2009) combined the figures for those at moderate and high risk without explaining the reasons for this. Discriminating between the three categories of risk is fundamental for providing the adequate management for each group. Other issues concerning the assessment of CVD risk, including the absence of any details of the tool being used (Amariles et al. 2005; Carter et al. 2009), the nature of the screening was unclear with only mentioning of the use of a risk assessment tool (Men's Health Risk Assessment Tool) (Boyle et al. 2004), or using individual risk factors as a method to identify people at high risk (Liu et al. 2009). In the latter study not all risk factors were reported as the data on smoking status, body weight and family history were missing. Furthermore, one study (Amariles et al. 2008) was different from other studies involving screening service in that it targeted those who were already diagnosed with hypertension, diabetes or a CVD.

In one study (Horgan et al. 2010), the referral of participants to general practice was as high as 70%. Only 18% were referred because they were at high risk of CVD. Other subjects were referred because of individual risk factors, such as BP > 140/90 mmHg and total cholesterol level > 6 mmol/L. About a quarter were referred because of their BMI $\geq$ 30 kg/m^2 or a waist circumference $\geq$ 88

cm (for women) or ≥ 102 cm (for men). The referral rate seemed to be high, as the authors agreed, which could affect the cost-effectiveness of the service.

On the other hand in another study (Liu et al. 2009) no official referral to any other healthcare professional was made because of issues regarding the contract by the company coordinating the screening; however, at risk patients were encouraged to discuss issues with their physicians.

Whether the pharmacy based screening services would help to reduce health inequalities or worsen the gap is not known. Although a pilot (Horgan et al. 2010) targeted people living in the most deprived areas, most of participants were from average and less deprived quintiles.

The VRA was not always outlined in detail in the studies. The authors of one study (Carter et al. 2009) concluded that the programme required "a balance of standardization to ensure the integrity of the intervention components and flexibility to fit the local context." without giving specific details of the assessment. The role of the community pharmacist in dealing with individuals with CVD risk factors was not mentioned by the authors of another study (Fernandez-Pinilla and Chaves 2008a, 2008b).

The main outcome of one study (Boyle et al. 2004) was determining the number of men who were seen by a physician, if were referred, by asking them via a telephone call. Although self-reporting is not necessarily inaccurate, the authors combined the number of those who had actually seen their doctor with those who said they were waiting for an appointment which could affect the

end results. This is because the telephone call could put pressure on some participants to visit the doctor or it could be a reminder to others.

One small study of 26 participants (Lalonde et al. 2006) had the advantage of being a longitudinal study which had two follow-ups, one at two weeks and the other at three months. Other studies (total number = 7) which followed participants to investigate whether there was any short-term or longer-term benefits include; Simpson et al. (2001) who investigated the changes in CVD risk four months after having had an intervention from a pharmacist, Yamada et al. (2005) who measured the changes in LDL levels 6 months after an intervention and Peterson et al. (2010) who assessed knowledge and lifestyle changes through a questionnaire and a telephone call. Kaczorowski et al. (2010) reported the rate of hospital admissions and compared them with those a year prior to the intervention (although the authors did not state how long after the intervention, the comparison was made). Horgan et al. (2009) surveyed participants three months after they accessed a VRA service and Mc Namara et al. (2010) planned in their study protocol a follow up to investigate the average change to estimated 5-year risk of CVD between baseline and six months, although this study has yet to be concluded.

Studies indentified through the search strategy in the literature review varied in their aims and objectives and their methodology. There were limitations in the studies, however not all of these limitations were discussed by the authors. There was no study specific in targeting a Welsh population, and those conducted in England were mostly observational studies without investigating

the benefit of attending the VRA service even on a short term. Of the studies in the UK, three of which had been published prior to the design and commencement of the present study described in the thesis (Crabtree et al. 2010b; Horgan et al. 2010; Loo et al. 2011).

Therefore, the current study was designed and undertaken.

1.3 Study aim and objectives

Aim:

The aim of this study was to establish and evaluate a community pharmacy based cardiovascular risk assessment service.

Objectives:

1. Examine the feasibility of establishing a VRA service in Welsh community pharmacies similar to that available in England, that is free of charge.
2. Determine how different people, including those who may be "hard-to-engage", respond to the service.
3. Examine patients' acceptance of the community pharmacy based VRA service.
4. Examine the short-term outcomes of those who accessed the VRA service.
5. Examine the longer term outcomes of those who accessed the VRA service.
6. To examine the differences, and the impact these difference could have on the service users, between the common tools available in the UK to estimate CVD risk.

Chapter 2: A longitudinal study of a community pharmacy based VRA service

2.1 Introduction

This chapter examines the feasibility of establishing a community pharmacy based VRA service. It provides the details of the method used in establishing the service in two Boots pharmacies in South Wales. Also, the chapter outlines the method used in the evaluation of the service.

The demographic profile of service users have been reported as have the results of the tests and measurements at the initial assessment and as a result of a twelve-month follow-up assessment are included as have been comparisons of the results obtained at the initial and follow-up visits.

Aim

To establish and evaluate a community pharmacy based cardiovascular risk assessment service for a Welsh population.

Objectives

- Examine the feasibility of establishing a community pharmacy based cardiovascular risk assessment service.
- Identify the demographic profile of service users.
- Determine how different people, including those from the most deprived communities, respond to the service.
- Examine at 12 months the outcome of those who accessed the community pharmacy based cardiovascular risk assessment service.

2.2 Method

2.2.1 Brief outline

The cardiovascular risk assessment (VRA) service was provided free of charge at two Boots pharmacies in south Wales; Porthcawl from 4th November 2009 until 4th August 2010, and New Market Walk, Merthyr Tydfil from 29th June 2010 until 5th August 2010. The elements of the service are outlined in Appendix 1 (Participant Journey). The VRA service comprised either a Brief Health Check or a VRA depending on inclusion and exclusion criteria. Individuals were invited to participate in the study for approximately 12 months (Figure 2-1) and were provided with participant information sheet (Appendix 2a) and consent form (Appendix 2b) in addition to the standard Boots service questionnaire and consent form (Appendix 3a).

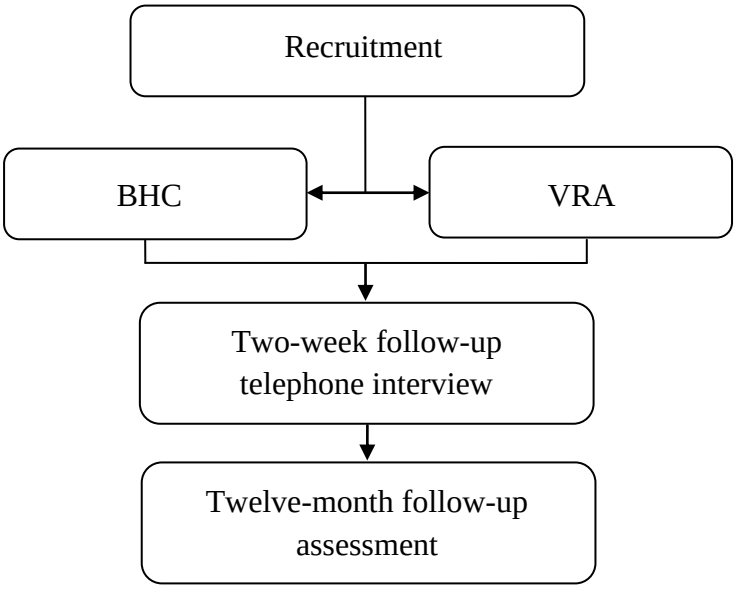

Figure 2 - 1 A brief outline of the main stages of the study.
BHC = Brief Health Check. VRA = cardiovascular risk assessment

Those who did not consent to participate in the research study but wanted an assessment without follow-up were required to complete and sign the standard Boots VRA service questionnaire and consent form before the research pharmacist performed the tests and measurements required. Their risk of CVD was calculated and appropriate lifestyle advice was provided. Those identified at high risk (Section 2.2.1.15) were advised to see their GP, and those who might benefit from other services, such as a smoking cessation clinic or weight management clinic, were signposted accordingly. Those individuals identified with pre-existing CVD were advised to see their GP. User satisfaction was assessed by a questionnaire given to all service users (Section 2.2.1.17).

Those who showed an interest in participating in the research study were asked to read the patient information sheet (Appendix 2a) and sign, if they wished to participate, the study consent form (Appendix 2b). They received the same service as other service users, but were invited to have a follow-up interview at two weeks (Section 2.2.2.3) and a follow-up consultation 12 months after the VRA service (Section 2.2.2.4).

2.2.1.1 Preparation

Although the VRA service was previously established at another Boots pharmacy, located in Queen Street, Cardiff, it was recognised that implementing it in another venue for research purposes would need different and careful steps. Initially, stakeholders for this project were identified and they were as follows; patients, general practitioners, local surgeries, local

health board, pharmacy staff, pharmacy management, Cardiff University and ethics committees.

After receiving full support from Boots at a higher level for this project, visits to the selected Boots stores were made by the research pharmacist to meet with the store managers to confirm their agreement to accommodate the study. Issues discussed include cost of equipment, time for providing the service, recruitment of participants and helping in appointment booking. Consideration was given to reduce interference with normal pharmacy activities.

Bridgend Local Health Board (LHB) was responsible for NHS services in the Porthcawl area. The LHB and two local GP surgeries were approached by the research pharmacist and by the academic supervisors. A summary of the protocol was sent to them and an opportunity was given to answer any questions they might have regarding the research. The research pharmacist queried whether the local GPs were happy with Boots referral criteria or whether they wanted to change it to suit local policies.

Indemnity issues were clarified with Cardiff University and with Boots. Professional indemnity was part of Boots contract, and research activities were covered by the university.

2.2.1.2 Ethics committee approval

In order to obtain research ethics committee (REC) approval the research application form was completed using the Integrated Research Application System. The South West Wales REC was then contacted, as the appropriate NHS REC for Porthcawl, on the 3rd August 2009 to obtain an REC reference

number that was required in order to submit the form online. A summary of not more than two A4 pages was requested to be provided to the committee before submitting the full protocol. In response to this summary information the following reply from the South West Wales REC was received by email:

"the chairman has considered the information provided as is of the opinion that as this is a service already offered by retail pharmacies in England, it does not need review by a REC and should therefore be viewed as a Service Evaluation. However, as patients are involved, the chairman suggests you email your proposal to the National Research Ethics Service (NRES) to also obtain their opinion. You can email your proposal to Queries@nationalres.org.uk."

A query was sent to NRES Queries Line to check whether the project needed a full REC scrutiny or not. Then they responded with the following:

"Based on the information you provided, our advice is that the project is not considered to be research according to this guidance. Therefore it does not require ethical review by a NHS Research Ethics Committee."

After it was confirmed that the NHS REC would not review this application because they considered it as a service evaluation, the application was submitted to the Welsh School of Pharmacy REC (Appendix 4). The WSP REC approval was received on 23rd September 2009.

2.2.1.3 The service

Brief Health Check

Inclusion criteria:

- Over 18 years old.
- Communicate in English.
- Able to give informed consent to participate.

Exclusion criteria:

- Under 18 years of age.
- Pregnant.
- Suffer from polycythaemia or haemophilia.
- Taking any of the following drugs: dopamine, methyldopa, warfarin (or other anticoagulant.)

Those who had blood disorders or who were on certain medication (Section 3.3.1.2) which made them unsuitable for taking a blood sample in community pharmacy were offered:

- blood pressure (systolic and diastolic)
- waist circumference
- BMI

Those who were suitable for taking a blood sample but unsuitable for calculating VRA (Section 2.2.1.4) were offered the measurement of:

- blood pressure
- waist circumference
- BMI
- HDL and total cholesterol level
- blood glucose (for those who were at high risk of diabetes, e.g. the obese)*

Although the Brief Health Check did not allow calculation of the CVD risk with the accuracy of the VRA, it provided sufficient information for the individual to help the individual to manage a number of CVD risk factors.

Participants were offered with healthy lifestyle advice and signposted to other services as appropriate (Appendix 5 for Porthcawl).

2.2.1.4 VRA

Inclusion criteria:

- At the age of 40 to 74 years.
- Communicate in English.
- Able to give informed consent to participate.

Exclusion criteria:

- Under 18 years of age for the Brief Health Check or under 40 or over 74 years of age for the VRA.
- Pregnant.
- Suffer from polycythaemia or haemophilia.
- Taking any of the following drugs: dopamine, methyldopa, warfarin (or other anticoagulant.)
- Diagnosed with diabetes.
- Diagnosed with hypertension.
- History of CVD.

The company's standard operating procedures for the service have been provided as Appendix 6.

The VRA comprised measurement of:

- blood pressure
- waist circumference
- BMI
- HDL and total cholesterol level
- blood glucose (for those who were at high risk of diabetes, e.g. the obese)*

Participants were provided with healthy lifestyle advice (Appendix 6b) and signposted to other services as appropriate (Appendix 5).

*Participants were asked to attend another appointment to have a fasting glucose test measurement if their initial measured glucose level was between 5.6 and 11 mmol/L (Appendix 6j). Fasting was defined as no caloric intake for at least 8 hours (JBS2 2005). Patients were provided with lifestyle advice and the necessary recommendations after the fasting glucose test.

Based on the results of this check, the risk of developing CVD in the following 10 years was calculated (Section 2.2.1.15) using the modified Framingham risk score system (Cooper et al. 2008). Participants received information and advice tailored to their needs, or were referred to their GP or other healthcare service provider as appropriate (Section 2.2.1.16 and Appendix 5).

2.2.1.5 Patient Recruitment

An advert was designed (Appendix 7a) to inform people about the availability of a VRA service. The flyer was placed in the pharmacy, in two local GP surgeries and a local caravan site. The advert was subsequently altered to specify the age groups to attract those who are eligible for the VRA (Appendix 7b).

It was distributed as a mail drop to a small number of houses in different streets in Porthcawl. To raise awareness of the service an advertisement was placed in local newspapers, The GEM on 13th May 2010 (Appendix 7c) and Merthyr Tydfil Express (Appendix 7d) on 15th July 2010.

A poster with a similar design to the advert was placed in the pharmacy window and on a board next to the dispensary where patients handed in and collected their prescriptions.

The research pharmacist checked the eligibility of those who requested an assessment when arranging for the appointments and also, for confirmation, just before conducting the tests.

2.2.1.6 Venue

The VRA service took place in a private consultation room at:

- Boots, John St, Porthcawl.
- Boots, New Market Walk, Merthyr Tydfil.

2.2.1.7 Times

In Porthcawl, the service was provided on Wednesdays from 10am till 4pm. In Merthyr Tydfil, the service was provided on Tuesdays and Thursdays from 10am till 4pm.

Participants were required to make an appointment by telephone, or by visiting the pharmacy. Walk in appointments were also available at times when there were gaps between appointments.

2.2.1.8 Duration of consultation

The time allocated for the tests and the consultation was 30 minutes (Thornley et al. 2009a). For each participant the time taken was recorded for subsequent analysis (Appendix 3b).

2.2.1.9 Staff

The research pharmacist, who was contracted with Boots and covered by indemnity, was responsible for service provision and operation. Responsibilities included:

- Ensuring all members of staff involved in the service, e.g. recruiting patients, understood the various standard operating procedures (Appendix 6a-j) and followed all instructions.
- Obtaining written consent for the Brief Health Check or the VRA from service users (Appendix 3a).
- Helping (interested) service users to complete the Boots service questionnaire (Appendix 3a) (Section 2.2.1.11).
- Measuring body weight and height to calculate BMI (Appendix 6d).
- Measuring waist circumference (Appendix 6e).
- Measuring blood pressure (Appendix 6f).
- Taking blood samples (Appendix 6c) to use in the validated equipment to determine HDL levels, total cholesterol, and glucose levels.
- Calculating cardiovascular risk using the modified Framingham score (Cooper et al. 2008) and discussing the result with service users.
- Providing counselling and written information (Appendix 5) tailored to the needs of the service user.
- Ensuring accurate documentation, recording of results and maintenance of confidentiality (Appendix 6b).

There are four measurements normally taken by a healthcare assistant where the service is established by Boots; body mass index (obtained from measuring height and weight), total cholesterol and HDL, blood pressure, and waist circumference. However, in this study only the research pharmacist was obtaining all the measurements as no one else had the training to do so as this study was based in pharmacies other than those selected by the head office to provide the service.

2.2.1.10 Blood Pressure measurement

Blood pressure was taken after sitting in the pharmacy and after completing the necessary forms in the consultation room. Therefore, a total time of sitting of at least 10 minutes was allowed before measuring blood pressure. Service users were asked to sit in a relaxed position with their arm resting on the table. Service users were asked to leave both feet on the floor as crossing legs can raise the blood pressure.

Blood pressure in both arms was measured and the higher reading was recorded. If there was a difference of more than 10 mmHg in either systolic or diastolic blood pressure between the two arms the sitting position of the concerned service user was checked. Usually it was resolved by correcting the position. If the difference between the right and the left arms was not resolved by correcting the sitting position the service user was referred to the GP as per standard operating procedure as this could be a sign of peripheral vascular disease.

If the measurement was just over 140 mmHg, that is, up to 149 mmHg and the service user had a caffeinated drink within the last hour or was feeling uncomfortable, a repeat of the blood pressure measurement in the pharmacy within a week was offered. If the service user accepted to have the repeat then the second measurement was recorded. If the service user refused to come back for a second measurement of BP then he/she was advised to repeat the check at GP surgery.

2.2.1.11 The service questionnaire

All service users were asked to complete the Boots service questionnaire (Appendix 3a) to elicit the following information required for checking inclusion and exclusion criteria and also necessary to identify risk factors:

- Age
- Gender
- Smoking status
- Demographic characteristics to include:
    - Ethnicity (Appendix 3b) based on the ethnic classification scheme which included the 16+1 ethnic categories as in 2001 census for England and Wales. The use of this scheme was necessary (Hippisley-Cox et al. 2007) to calculate CVD risk using QRISK2 (Chapter 7).
    - alcohol intake
    - smoking status
    - postcode
- Family history of CVD.
- Drug history.
- Medical history of CVD.

2.2.1.12 Cost

This was a service that was free to users.

2.2.1.13 Equipment

Equipment was provided and maintained by Boots. Training was provided for the research pharmacist to ensure correct use and this included: taking blood samples, measuring blood pressure, validation and maintenance of the equipment and operation of the quality control process.

- BMI machine (Appendix 6d): weight and height measured using Davi & Cia Scale. BMI was calculated automatically by the machine.
- Blood Pressure: the validated Omron M7 upper arm BP Monitor (Coleman et al. 2008; El Feghali et al. 2007) was used. The blood pressure monitor was replaced 12 months after first use as per SOP (Appendix 6f)
- Glucose meter; CardioChek PA was used to determine both lipid profile and glucose. The device was calibrated every day (Appendix 6h).
- Cholesterol meter; CardioChek PA (Panz et al. 2005).
- A sharps bin and clinical waste bin were used in accordance with the SOP (Appendix 6i).

2.2.1.14 Quality Control

Internal and external quality control procedures were used for the CardioChek PA cholesterol/glucose meter.

The internal quality control required, as per the Boots SOP, comprised of daily check and a monthly quality control. The daily check was performed by using a special strip to confirm the sensor functioning well. This was required on every day which the service being carried out (Appendix 6h). Also, control solution

tests were carried out whenever a new pot of test strips was opened, every month or after a failed external quality assessment (EQA).

An EQA was performed every two months to ensure the device was working to the required standard (Appendix 6k).

The blood pressure monitor was replaced 12 months after first use as per SOP (Appendix 6f)

2.2.1.15 Risk score calculation

Cardiovascular risk was calculated using the modified Framingham Risk Score System (Cooper et al. 2008). The parameters required to calculate cardiovascular risk were:

- Age
- Gender
- Ethnicity
- Family history
- Smoking status
- Diabetes status
- HDL cholesterol
- Total cholesterol
- Systolic blood pressure

After the VRA was determined using the modified Framingham risk score system, participants were allocated into one of the three groups; low risk (<10% CVD risk in 10 years), moderate risk (10-20% CVD risk in 10 years), high risk (>20% CVD risk in 10 years).

All tests results were used after the consultation to calculate the CVD risk using QRISK2. This was to allow comparison of the Framingham based CVD risk assessment with that of QRISK2 (Chapter 7). This was a desk top exercise and the results were not communicated to the service user.

2.2.1.16 Advice and signposting

All service users received a copy of the assessment results form (Appendix 8) which stated the results of the assessment. Those identified at low risk were offered lifestyle advice. Individuals at moderate risk with a risk factor that could be modified, e.g. smokers, were offered specific advice on how to reduce risk and/or signposted (Appendix 5) to other services. Individuals at high risk were advised to visit their GP for further investigation (Appendix 9). Service users were also referred if their glucose level was more than 11 mmol (or if fasting glucose > 5.6 mmol), total cholesterol ≥ 7.5 mmol, systolic blood pressure ≥ 140, diastolic blood pressure ≥ 120 or a low glucose level ≤ 2.5 mmol. In addition, those who had risk factors and might benefit from other local services, such as smoking cessation and weight management, were signposted and encouraged to attend these services regardless of their Framingham score. Participants received the standard Boots literature titled 'Looking after your heart'. The pharmacist documented the advice given to the service users (Appendix 6b).

2.2.1.17 Satisfaction questionnaire

The level of satisfaction with the service was determined by inviting participants to fill in a questionnaire (Appendix 10). Results of the satisfaction survey are presented and discussed in Chapter 3.

2.2.2 Study

2.2.2.1 Recruitment

A convenience sample was used (self-selection). Those who showed interest in having the VRA (Section 2.2.1.4) were asked to consider participating in the study. It was expected that a minimum of four participants would be recruited each week and all recruitments would be completed within a six month period.

2.2.2.2 Participant information sheet and consent form

When participants attended the pharmacy to make an appointment, they were provided with the patient information sheet (Appendix 2a) and consent form (Appendix 2b). They were given the opportunity to ask questions about the objectives of the study. Participants were asked to fill in the consent form and to bring it with them when they were scheduled to have their VRA service.

Participants making appointments over the telephone were asked to provide a postal address or an email address, so the participant information sheet and the consent form could be completed prior to their appointment.

Those who preferred a walk in access to the service or had not completed a consent form in advance completed the documentation on the day but prior to the assessment. The research pharmacist would check their understanding of

the project. Participation in the research study (as distinct to accessing the VRA service) started with the first follow-up (an interview with a different researcher who did not provide the VRA service), that is, approximately two weeks after the service. This meant that even if participants signed the consent form they had enough time to change their mind if they wanted to withdraw from the study before being contacted for the two week follow-up. By participating in the service but not consenting to be part of the research study, subjects consented to their anonymised data being used for research purposes (Appendix 3a).

2.2.2.3 Two-week follow-up telephone interview

The first follow-up (Appendix 11a) was an interview and this was designed to take place approximately two weeks after undertaking the VRA. The aim of this follow-up interview was to examine participants' perceptions, commitment to the advice given by the research pharmacist and any benefit from the VRA service. A researcher (not the research pharmacist) who did not provide the VRA service contacted the participants to conduct a semi-structured interview over the telephone. The results of this follow-up are presented and discussed in Chapter 4.

2.2.2.4 Twelve month follow-up assessment

The reminder letter (Appendix 12a) was sent to each participant eleven to thirteen months after the initial tests. The aim of the reminder letter was to inform participants that the research pharmacist will contact them over the telephone to arrange an appointment.

A form (Appendix 12b) was also enclosed with the reminder letter for those who might prefer not to be contacted again, together with a free-post envelope. When completing the form, participants could either indicate if they wanted to withdraw from the study or they wanted to contact the research team rather than being contacted. If they were content to be telephoned by the researcher then they were advised that they did not need to do anything.

It was made clear that those who chose to withdraw from the study did not have to give any reason, but if they wished to share reasons for withdrawal, they were given the opportunity to do so. Some indicated on the form that they did not want the researcher to contact them but they would prefer to make the contact themselves. These records would stay 'pending' until the end of the study, and if they did not contact the research team by the end of the study they would be considered as withdrawn from the study. That is, as requested no further attempts were made to contact individuals.

After about 10 days from sending the reminder letter, the research pharmacist contacted by telephone those who did not send back the form assuming they were happy to be contacted. A diary with a flexible timing was kept to make sure the appointments offered were as convenient as possible to participants.

Several attempts were made to contact each participant, if there was no answer or if there was another reason, such as the telephone number provided by the individual was unavailable another letter was sent offering a range of dates and times. It was the individual's decision whether or not to attend at the pharmacy as the study neared completion.

A Boots colleague volunteered to contact some of the participants when it was believed that a local accent may be helpful, for example, when a participant seemed to find the foreign accent unclear over the telephone. The dates of the telephone calls and the follow-up assessments were recorded.

All follow-up assessments took place in the same Boots pharmacy where the initial assessments occurred.

During each follow-up appointment, participants were given a form (Appendix 13) to complete. This form consisted of a question to check whether or not they had a similar check between the initial tests and the follow-up, and questions about lifestyle. In addition, exactly the same questions they were asked in the initial assessment on the Boots service questionnaire (Appendix 3a) were asked again. Also, questions were asked to recall any changes to lifestyle.

Participants were also asked if there were any changes in their medical conditions since they had the initial assessments and whether or not they had started any new medications. This was to identify whether or not they met the necessary inclusion criteria and that they were not tested if any exclusion criteria for the service applied.

The tests undertaken at the initial VRA were repeated and the results relayed to the participants during the consultation. Advice was provided and when necessary referral to the GP was made.

2.2.3 Data analysis

The socio-economic status was determined by allocating participants' postcodes to a deprivation level. The two deprivation indices used in this thesis are the Welsh Index of Multiple Deprivation (WIMD) (WAG 2008) and the Townsend Deprivation Index (TDI) (CDU 2010). TDI was also used in the analysis to overcome some of the disadvantages associated with WIMD. Panel 2-1 shows the difference between the two indices.

Panel 2 - 1 The differences between WIMD and TDI

WIMD:

Areas are divided into 5 ranks as the following:

- Rank 1 (First 10% of areas, i.e. the most deprived areas)
- Rank 2 (Next 10%)
- Rank 3 (Next 10%)
- Rank 4 (Next 20%)
- Rank 5 (Next 50%, i.e. the least deprived areas)

TDI:

Areas are divided into five equal quintiles with Quintile 1 consists of the least deprived areas and Quintile 5 consists of the most deprived areas.

PASW Statistics 18 (formerly SPSS) was used for analysing the data. Chi-square test was used when comparing variables with nominal values, for example, gender and smoking status, or ordinal values, e.g. deprivation status. Mann-Whitney U test was used when comparing variables (two samples) with non-parametric continuous data, for example, age, blood pressure, and cholesterol levels. The Kruskal Wallis test was used when comparing three or

more groups with ranked data for example, comparing age distribution between categories of the number of visits. Paired-samples student t-test was used to compare the results of continuous data, for example, blood pressure, HDL, total cholesterol at the initial assessment and the twelve-month assessment.

2.3 Results

2.3.1 Overview

A total of 172 patients (Appendix 14) accessed the VRA service at the two Boots pharmacies in south Wales; 133 (77%) patients had their tests at Boots, Porthcawl between 4th November 2009 and 4th August 2010 and 39 (23%) patients had their tests at Boots, New Market Walk, Merthyr Tydfil in the period 29th June 2010 to 5th August 2010. Figure 2-2 shows the numbers of patients who accessed the VRA service, those who had the two-week follow-up and those who had the twelve-month follow-up.

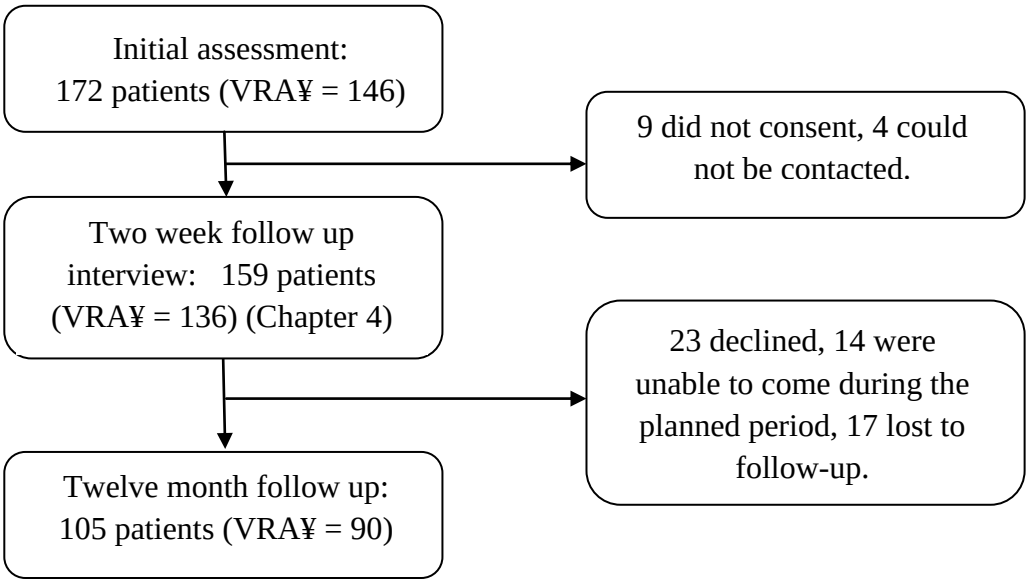

Figure 2 - 2 Number of patients at each phase of the study
VRA¥ = number of subjects who had a full VRA including the calculation of CVD risk

2.3.2 Results of initial assessments

The proportion of females was higher (59%) than males. Almost all participants (99%) were white. Demographics are shown in Table 2-1.

Table 2 - 1 Demographics of all service users in both pharmacies, Porthcawl (n = 133) and Merthyr Tydfil (n = 39)

Demographics	**Results**
Age	Mean = 60 years [range 19 to 87, SD = ±10.3]
	Number of patients (%)
Females	101 (59)
Males	71 (41)
Family history of CVD	54 (31)
Ethnicity- White	170 (99)
Pakistani	1 (0.6)
Indian	1 (0.6)
Deprivation (missing values = 4)	
1. First 10% (most deprived)	12 (7)
2. Next 10%	13 (8)
3. Next 10%	20 (12)
4. Next 20%	31 (18)
5. Last 50% (least deprived)	92 (54)

The lifestyle characteristics, that is, smoking status, alcohol consumption and the level of physical exercise as provided by self completion of the Boots form (Appendix 12), are shown in Table 2-2.

Table 2 - 2 Lifestyle characteristics of the service users

Characteristics	Results (%)
Current smokers	11 (6)
Quit smoking within the last 5 years	7 (4)
Alcohol	
None	31 (18)
Within the weekly recommended level	126 (73)
Exceeding the weekly recommended level	15 (9)
Consumption of alcohol by male participants	Mean = 11 units [range 0 to 50, SD = ±11]
Consumption of alcohol by females participants	Mean = 4.5 units [range 0 to 20, SD = ±5]
Exercise	
None	9 (5)
Some (1 or 2 days a week)	43 (25)
Moderate (3 or 4 days a week)	55 (32)
Regular (at least 5 days a week)	65 (38)

About three quarters (76%) of service users were overweight or obese (Table 2-3).

Table 2 - 3 Mean BMI and numbers of service users in each category as per Boots SOPs

	Results (%)
BMI	mean = 27.9 kg/m^2 [range 18.4 to 48.5, SD = ±4.5]
Less than 25	42 (24)
25 to 29.9	81 (47)
30 to 34.9	38 (22)
35 or above	11 (6)

The waist circumference was within acceptable limits in 29% of the participants (Table 2-4).

Table 2 - 4 Mean of waist circumference of each gender and numbers of service users in each category as per Boots SOPs

Waist circumference	Results (%)
Male mean	100.1 cm [range 78 to 124, SD = ±9.9]
Female mean	86.9 cm [range 65 to 116, SD = ±11.5]
OK† (acceptable size)	48 (29)
Increased risk‡	47 (28)
High risk$	73 (43)

† < 94 cm for men and < 80 cm for women
‡ 94 - 102 cm for men and 80 - 88 cm for women
$ ≥ 102 cm for men and ≥ 88 cm for women

Categories of participants' blood pressure and lipid profiles are presented in Table 2-5.

Table 2 - 5 Results of systolic and diastolic BP and the lipid profile of the service users

	Mean	Category	Number (%)
Systolic BP	136 mmHg (range 82-194, SD ±18.7)	< 120 mmHg	28 (16)
		< 130 mmHg	45 (26)
		130-139 mmHg	31 (18)
		140-199 mmHg	68 (40)
Diastolic BP	86 mmHg (range 49- 121, SD ±10.6)	< 80 mmHg	43 (25)
		80-84 mmHg	39 (23)
		85-89 mmHg	30 (17)
		90-109 mmHg	57 (33)
Total Cholesterol	4.83 mmol/L (range 2.75 to 7.28, SD ±0.9)	≤ 5 mmol/L	100 (61)
		5.1-7.4 mmol/L	63 (39)
HDL Cholesterol	1.3 mmol/L (range 0.62-2.49, SD ±0.42)	Low‡	62 (39)
		Ok	99 (61)
TC: HDL ratio	4.1 (range1.7-7.8, SD ±1.3)	> 6	12 (7)

‡ If HDL level < 1 mmol/L for men and < 1.2 mmol/L for women

The Framingham risk of CVD in the next 10 years was calculated for 146 service users (Table 2-8). The remaining 26 patients could not have their risk calculated for the reasons listed in Table 2-6.

Table 2 - 6 Reasons for not calculating the CVD risk. Individuals (n = 26) may have had more than one reason for being excluded

Reason	Total
Age < 35 years	1
Age > 74 years	4
Medical history of CVD	11
On BP treatment	13
Diabetic	4
On warfarin (no blood taken)	3

The subject's last visit to the GP for any reason was recorded and the answers varied between as recently as the same morning as having the VRA to 14 years ago.

The duration of the consultation, including the assessments, ranged from 15 to 50 minutes (mean = 30 minutes, SD = ± 6.6). Consultations with male participants (mean = 32 minutes, SD = ±7.5) were longer than female participants (mean = 28 minutes, SD = ±5.5) ($p = 0.003$, Mann-Whitney U test). No difference was seen in duration between younger (< 65 year old) and older participants ($p = 0.132$, Mann-Whitney U test).

Almost three-quarters of the participants (n = 128, 74%) had seen their GP during the 12 months prior to accessing the VRA service; 48 (28%) of these 128 had seen their GP in the month prior to having the assessment. The number of visits to the GP during the 12 months prior to accessing the service was as follows; 21 participants made one visit to their GP, 61 participants made two to three visits, 24 participants made four to five visits, 19 participants made 6 or

more visits. There was no significant difference between males and females in the number of visits to the GP (p = 0.584, Mann-Whitney U test). Also the distribution of age was not significantly different across the categories of the number of visits (p = 0.207, Kruskal-Wallis test).

In line with the Boots SOP, a diabetes test was offered to participants with a BMI ≥ 30 kg/m^2. However, those who were referred (n = 17) to their GP were informed that, for their convenience, they should wait until their GP visit otherwise they could result in having a fasting glucose test at the pharmacy and also at the GP surgery. Twenty participants were tested for diabetes while 12 participants stated that they wished to have it at GP surgery. The mean fasting glucose (n = 20) was 3.6 mmol/L (range from 2.2 to 4.7 mmol/L, SD = ±0.66). According to a tool developed by University of Leicester, University Hospitals of Leicester and Diabetes UK (Gray et al. 2010), there were 21 participants (12%) at high risk of developing diabetes in the next 10 years (Table 2-7).

Table 2 - 7 Risk of developing Type 2 diabetes in the next 10 years based on a score developed by University of Leicester, University Hospitals of Leicester and Diabetes UK (Gray et al. 2010) (Appendix 15)

	Total (%)
Low risk (1 in 20)	24 (14)
Increased risk (1 in 10)	64 (37)
Moderate risk (1 in 7)	63 (37)
High risk (1 in 3)	21 (12)

The total number of participants who had their CVD risk estimated was 146 (Table 2-8).

Table 2 - 8 Categories of the 10-year CVD risk estimated using Framingham based BNF charts (total number = 146)

	Total (%)
Low risk (< 10%)	63 (43)
Moderate risk (10-20%)	46 (32)
High risk (> 20%)	37 (25)

Three participants could not be allocated a WIMD rank (Table 2-9).

Table 2 - 9 The number of participants (%) in each deprivation rank and their 10-year CVD risk. (Total number = 143)

		10-year CVD risk		
		<10%	**10-20%**	**>20%**
WIMD	**Rank 1 (most deprived)**	5 (8)	4 (9)	3 (8)
	Rank 2	6 (10)	5 (11)	0
	Rank 3	6 (10)	6 (13)	2 (5)
	Rank 4	14 (23)	7 (16)	8 (21)
	Rank 5 (Least deprived)	30 (49)	23 (51)	24 (65)

2.3.2.1 Referral to GP

The total number of participants who were referred to their GP was 57 (33%) (Tables 2-10 and 2-11). About half of male participants (n = 37) were referred compared to only 20% of females (n = 20) ($p < 0.001$, Chi-square test). The mean age of those who were referred was 63 years (SD = ± 7.6) compared to 59 years (SD = ± 11.1) for those were not referred ($p = 0.01$, Mann-Whitney U test). However, there was no significant difference among those who were

referred or not referred from areas with different levels of deprivation ($p > 0.05$, Chi-Squared test).

Table 2 - 10 Reasons for referral to GP as per Boots SOPs. Some participants were referred because of more than one referral criterion

Reason	Total
High risk of CVD	33
Systolic BP of ≥ 140 mmHg	44
Diastolic BP of ≥ 120 mmHg	1
BP of < 90/60 and patient feels unwell	1
Total Cholesterol of ≥ 7.5 mmol/L	0
Glucose level of > 11 mmol/L	0
Fasting glucose level of > 5.6 mmol/L	0
Glucose level of < 2.5 mmol/L	1

Table 2 - 11 Referral as per JBS2 recommendations. Some participants were referred because of more than one referral criterion

Reason	Total
Total cholesterol HDL of ≥ 6 mmol/L	8
Diastolic BP of ≥ 100 mmHg	11

2.3.3 Results of the twelve month follow-up

This follow-up was planned to occur approximately 12 months after having the initial VRA. However, some issues with the external quality control of the equipment delayed recruitment for some participants for up to three months. The mean duration between the initial assessment and the twelve-month

follow-up was 391 days (12.8 months) [range 343 days to 525 days, SD = 34.9].

The total number of participants who had the 12-month follow-up assessment, that is, who completed the study, was 105 (61%) (Table 2-12).

Table 2 - 12 Twelve-month follow-up recruitment

	Number (%)
Subjects who had the 12-month follow-up	105 (61)
Subjects who withdrew from the study	23 (13)
Subjects said they would contact Boots for an appointment but they did not do so by the end of the study.	14 (8)
Subjects who could not be contacted	21 (12)
Subjects who did not consent to have the 12-month follow-up	9 (5)

Twenty-three participants declined the invitation to have the follow-up. Six of them voluntarily provided their reasons for the withdrawal (Table 2-13). They were not asked to provide any further explanation.

Table 2 - 13 Reasons given by participants for withdrawal from the study.

1. A participant had just moved from England before the initial assessment and he believed this study more for the Welsh population.
2. Not feeling well
3. Panicked last year, was told high BP but GP said it was normal (see comment made by Subject 2 in the two-week follow-up, Section 4.3.9)
4. Going on holiday
5. Taken to the hospital due to illness
6. Having a kidney infection

The demographics of those who completed the study were not statistically different to those who undertook the initial VRA as shown in Table 2-14.

Table 2 - 14 Main characteristics at initial assessment and at twelve month follow-up.

Characteristics	Initial assessment	12 month follow up	p value
Age	Mean = 60 years [range 19 to 87, SD = ±10.3]	Mean = 61 years [range 39 to 88, SD = ±9.7]	0.409†
	Number of patients (%)		
Females	101 (59)	57 (54)	0.275‡
Males	71 (41)	48 (46)	
Family history of CVD	54 (31)	33 (31)	0.549‡
Medical history of CVD	11 (6)	9 (9)	0.326‡
Current smokers	11 (6)	2 (2)	0.073‡
Ethnicity- White	170 (99)	103 (98)	0.882‡
Pakistani	1 (0.6)	1 (1)	
Indian	1 (0.6)	1 (1)	
Deprivation	(missing values = 4)	(missing values = 3)	0.893‡
1- First 10% (most deprived)	12 (7)	7 (7)	
2- Next 10%	13 (8)	8 (8)	
3- Next 10%	20 (12)	9 (9)	
4- Next 20%	31 (18)	23 (22)	
5- Last 50% (least deprived)	92 (54)	55 (52)	

† Mann Whitney U test. ‡ Chi-squared test

2.3.3.1 Outcome of GP referral (if) made at the initial assessment

Most of participants (n = 35, 61%) who were referred to their GP stated, either during the two-week follow-up or the twelve-month follow-up, that they made a visit as advised by the pharmacist. Only two participants indicated that they had not seen the GP by the end of the study. It was stressed to them during the 12-month follow-up that they did need to see their GP to discuss ways to manage risk factors and to reduce the CVD risk. Eight participants said during the two-week follow up they booked or would book an appointment with their GP. However, these eight did not attend the twelve-month follow-up to confirm whether or not they actually went and discussed their results with their GP or any other healthcare professional (Figure 2-3).

Five participants (four female and one male) who were not referred by the pharmacist said they had seen their GP as a result of accessing the VRA service.

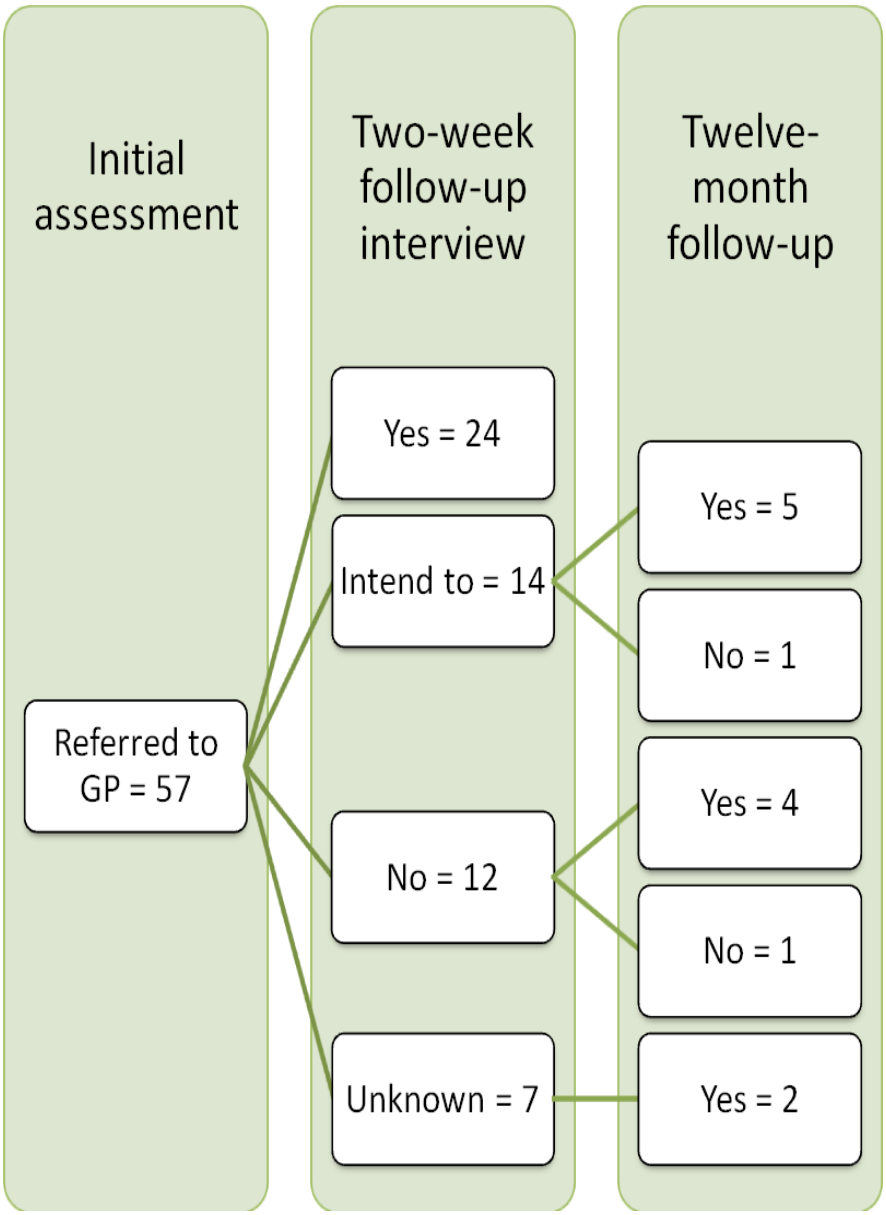

Figure 2 - 3 By the end of the study a total of 35 participants reported that they made a visit to their GP after a referral

Four subjects who did not have either of the follow-ups all of whom were male and at high risk of CVD, were provided with a referral letter for their GP from the pharmacist. Therefore, it could not be determined whether or not they went to see their GP.

Different participants responded differently to the advice given by the pharmacist. Beliefs could have played a role in shaping participants' responses. An example of participants' beliefs as an obstacle to compliance with referral is mentioned in Panel 2-2.

Panel 2 - 2 Example of patients' beliefs as an obstacle to compliance

Case 1

A 71 year old woman (Subject 109) had a systolic blood pressure reading of 194 mmHg in the pharmacy (this was the maximum SBP in the study cohort). This person stated that she usually had a blood pressure of not more than 130/80 at home. Although she was advised strongly to see her GP within 2 weeks, when she was asked whether or not she talked to her GP a month later she stated she had not. She did not attend the 12 month follow up and so it was not possible to determine the outcome.

Pharmacological intervention is one of the important methods to manage CVD risk recommended in the national guidelines (NICE 2008c). Of the 35 participants who made a visit to the GP only five participants reported a pharmacological intervention (Table 2-16 and Panel 2-3). A further participant, who was not referred by the pharmacist, stated that she discussed statin treatment with her GP. Although she was identified at low risk at the pharmacy with all acceptable parameters she stated that she had all the tests repeated again at the GP surgery. One doctor suggested that she should start a statin because the total cholesterol was 6 mmol/L but another doctor said that there was no need because her total cholesterol: HDL ratio was 3.5. This suggests

that the focus by at least some GPs is still on the total cholesterol rather than the total cholesterol: HDL ratio.

Table 2 - 15 Pharmacological changes initiated by GP as reported by participants after being referred

Participant	Outcome	Reason for referral by pharmacist
Subject 17	BP treatment (not stated)	BP (See Panel 2 - 3)
Subject 116	On felodipine 2.5mg	Systolic BP
Subject 131	On statin	CVD risk and Systolic BP
Subject 172	On statin and ramipril	CVD risk and Systolic BP
Subject 95	Orlistat to help in weight loss programme with gym referral	Low glucose

Panel 2 - 3 A pharmacological intervention was reported during the two week follow up but then it was stopped

Case 2

A 50 year old male (Subject 17) was referred to GP because of a blood pressure measurement of 170/100 mmHg. He went to see the GP who prescribed BP treatment as he confirmed it during the two-week follow-up. However, he went back to the GP as he was reluctant to take the treatment. Consequently, he was provided with a monitor to check BP over a period of 14 days. The BP was normal after he became accustomed to the measuring. The GP suggested it could be white coat syndrome. BP was measured during the 12 month follow up and it was 139/87 mmHg.

A further participant was on CVD management medication at the twelve-month follow-up. However, this was not because of the referral but because of

having suffered from a myocardial infarction and this was the only known CVD event to occur between the initial assessment and the twelve-month follow-up (Panel 2-4).

Panel 2 - 4 A CVD event was reported at the end of the study

Case 3

A 65 year old Caucasian male (Subject 47) from Merthyr Tydfil, had quit smoking more than five years ago, drank alcohol in moderation (on average two units of alcohol every week), had regular exercise, not on any medications and with a family history of CVD. He came to the pharmacy to have a VRA in August 2010 and his test results were as follows: BMI 25.6 kg/m^2, waist 92 cm, BP 128/71 mmHg, total cholesterol 3.08 mmol/L, 0.71 mmol/L, total cholesterol to HDL ratio 4.3 and he was identified at high risk of CVD. Consequently he was referred to his GP.

In the two week follow-up he confirmed to the interviewer that he had seen the GP the day after the consultation and had all the tests repeated. It was not clear what options were discussed with the GP to reduce his risk but he said he had started Omega 3 fish oil supplements.

At the twelve-month follow-up, July 2011, he reported that in April 2011 he had a myocardial infarction and he had undergone bypass surgery. Then he was prescribed atorvastatin 40mg tablets OD, bisoprolol 2.5mg tablets OD, ramipril 2.5mg capsules OD, aspirin 75mg tablets OD and clopidogrel 75mg tablets OD.

2.3.3.2 Changes to lifestyle

Participants were asked to self-complete a questionnaire (Appendix 13) how they perceived their diet and other lifestyle factors had changed since the initial assessment.

Reponses to the changes in lifestyle questionnaire are provided in Tables 2-16 and 2-17. The most common answer was “no change” for the all risk factors. Forty-four percent of participants self-reported they improved their diet by increasing fruit and vegetable intake, 39% by increasing oily fish in diet, approximately one third by reducing salt intake (39%), red meat (37%) and dairy products (33%). Ten participants (10%) admitted that their diet had worsened in at least one food type. With regard to other lifestyle factors, 38% said they had done more exercise than before and 30% had decreased their alcohol consumption. Also, there were two participants who reported successfully having stopped smoking.

Table 2 - 16 Self-reported overall changes in diet between having the initial assessment and the 12 month follow-up

	Much increased	Increased	No change	Decreased	Much decreased	Unsure	Not applicable
Red meat	0	2	60	29	10	1	3
Dairy products	1	2	66	30	5	1	0
Oily fish	6	35	58	2	2	0	2
Salt	0	1	54	28	16	4	2
Fruits and vegetables	14	32	56	1	2	0	0

Table 2 - 17 Self-reported overall changes in lifestyle factors namely exercise, smoking and alcohol intake, between having the initial assessment and the 12 month follow-up

	Started	Increased	No change	Decreased	Stopped	Unsure	Not applicable
Exercise	2	38	54	9	0	1	1
Smoking	0	0	2	1	2	0	100
Alcohol	0	3	54	31	1	2	14

However, there were some inconsistencies seen in some participants' answers to the some questions. Four participants claimed they had decreased their alcohol consumption but their number of units per week they said they consumed had increased when compared with the amount they provided at the initial assessment. Also, two people claimed that there was no change in their alcohol intake but at the initial assessment they exceeded the recommended weekly level where at the twelve-month follow-up the units they said they consumed were within the recommended weekly level (from 28 to 12 units/week and from 25 to 8 units/week). Tables 2-18, 2-19 and 2-20 summarise self-reported alcohol intake, exercise level and fruit and vegetable consumption, respectively.

Table 2 - 18 Weekly alcohol consumption at initial assessment and at follow-up as reported by participants

		follow up		
		None	**OK***	**Exceeding+**
Initial assessment	**None**	14	3↑	0
	OK*	5↓	73	1↑
	Exceeding+	0	4↓	5

At follow-up ↓ a total of 9 reported less alcohol consumption and ↑ a total of 4 reported more alcohol consumption.
*Not more than 14 units per week for women and 21 units for men where + exceeding this weekly level.

Table 2 - 19 Exercise levels at initial assessment and at twelve month follow-up as reported by participants. Categories as per Boots SOPs

		follow-up			
		None	**Some**	**Moderate**	**Regular**
Initial assessment	**None**	2	1↑	0	2↑
	Some	2↓	11	8↑	5↑
	Moderate	0	2↓	19	8↑
	Regular	0	5↓	11↓	29

At follow-up ↓ a total of 20 reported less physical exercise
and ↑ a total of 24 reported more physical exercise

Table 2 - 20 Fruit and vegetable intake at initial assessment and at twelve month follow-up

Have fruits and vegetables every day?*		follow-up	
		No	**Yes**
Initial assessment	**No**	10	9
	Yes	7	79

* The number of portions was not recorded at the initial assessment

2.3.3.3 Results of tests and measurements

Participants' BMIs were categorised into one of four groups (Maguire and Haslam 2009). Table 2-21 shows that 13 participants managed to reduce their BMI to a lower category, opposed to only two who increased from the < 25 kg/m^2 category to the 25-29.9 kg/m^2 category.

The mean BMI decreased from 27.5 kg/m^2 at the initial assessments to 27.0 kg/m^2 by the end of the study. Although this was a small change, it was a statistically significant (-0.45 kg/m^2, 95% CI -0.736 to -0.155) (Figure 2-4).

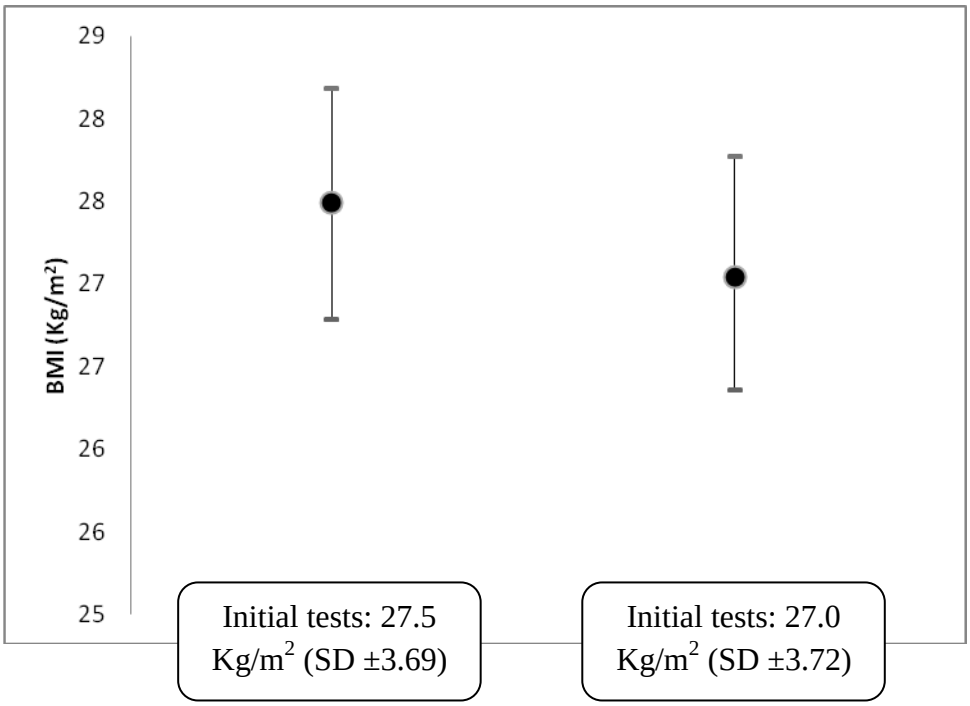

Figure 2 - 4 the mean of BMI at initial assessment and twelve month follow-up

Table 2 - 21 The number of participants who at 12 month follow-up changed, or otherwise, the category of BMI. Categories as per Boots SOPs

		Follow-up			
		< 25 kg/m²	**25-29.9 kg/m²**	**30-34.9 kg/m²**	**≥ 35 kg/m²**
Initial assessment	**<25 kg/m²**	24	2↑	0	0
	25-29.9 kg/m²	5↓	48	0	0
	30-34.9 kg/m²	0	7↓	15	0
	≥ 35 kg/m²	0	1↓	0	3

At follow-up ↓ a total of 13 their BMI decreased to a lower category and ↑ two increased to a higher category

Figure 2-5 shows a small change, non-statistically significant, in mean waist circumference; - 1.1 cm (95% CI -2.3 to 0.1). Table 2-22 shows the numbers of participants who reduced or increased their waist circumference to another level of risk, as categorised in Boots SOP (Appendix 6e).

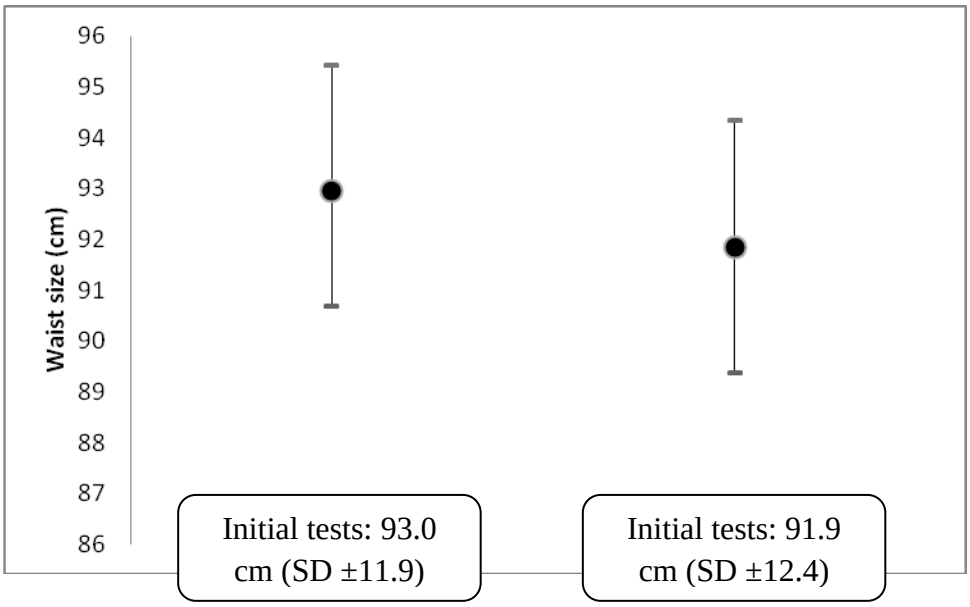

Figure 2 - 5 the mean waist circumference at initial assessment and twelve-month follow-up

Table 2 - 22 The number of participants who at 12 month follow-up changed, or otherwise, the level of risk determined by the waist circumference. Categories as per Boots SOPs

		Follow-up		
		OK†	**Increased risk‡**	**High risk$**
Initial assessment	**OK†**	24	5↑	0
	Increased risk‡	1↓	14	7↑
	High risk$	1↓	14↓	33

At follow-up ↓ a total of 16 their circumference decreased to another category and ↑ a total of 12 increased
† < 94 cm for men and < 80 cm for women
‡ 94 - 102 cm for men and 80 - 88 cm for women
$ ≥ 102 cm for men and ≥ 88 cm for women

The difference in the mean systolic blood pressure at initial assessment and at the twelve month follow-up was statistically significant. There was a reduction of 8.5 mmHg (95% CI -11.0 to -5.9). This was similar for the difference in the mean diastolic blood pressure; -7.7 mmHg (95% CI -10.4 to -5.0) (Figures 2-6 and 2-7).

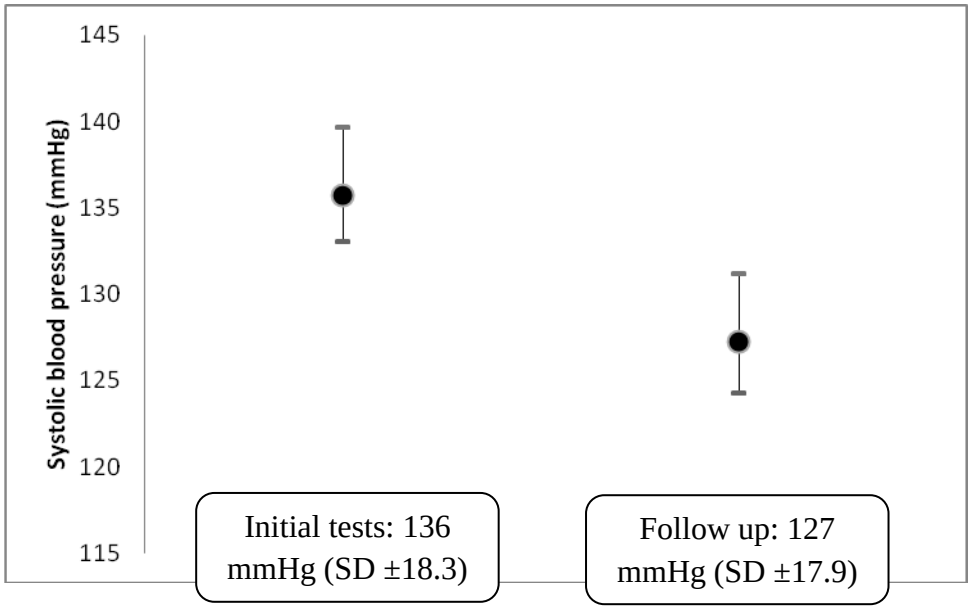

Figure 2 - 6 the mean systolic blood pressure at initial assessment and at the twelve-month follow-up

About half of the subjects (n = 51) improved their systolic blood pressure (Table 2-23), and 57% improved their diastolic blood pressure (Table 2-24) at the twelve-month follow-up.

Table 2 - 23 The numbers of participants at each category of systolic blood pressure (mmHg). Categories as per JBS2 (JBS2 2005)

		Follow-up			
		<120	**120 -129**	**130-139**	**140-199**
Initial assessment	**<120**	13	4↑	0	0
	120-129	21↓	6	1↑	1↑
	130-139	4↓	8↓	5	2↑
	140-199	4↓	4↓	10↓	22

At follow-up ↓ a total of 51 their systolic BP decreased to another category and ↑ a total of 8 increased

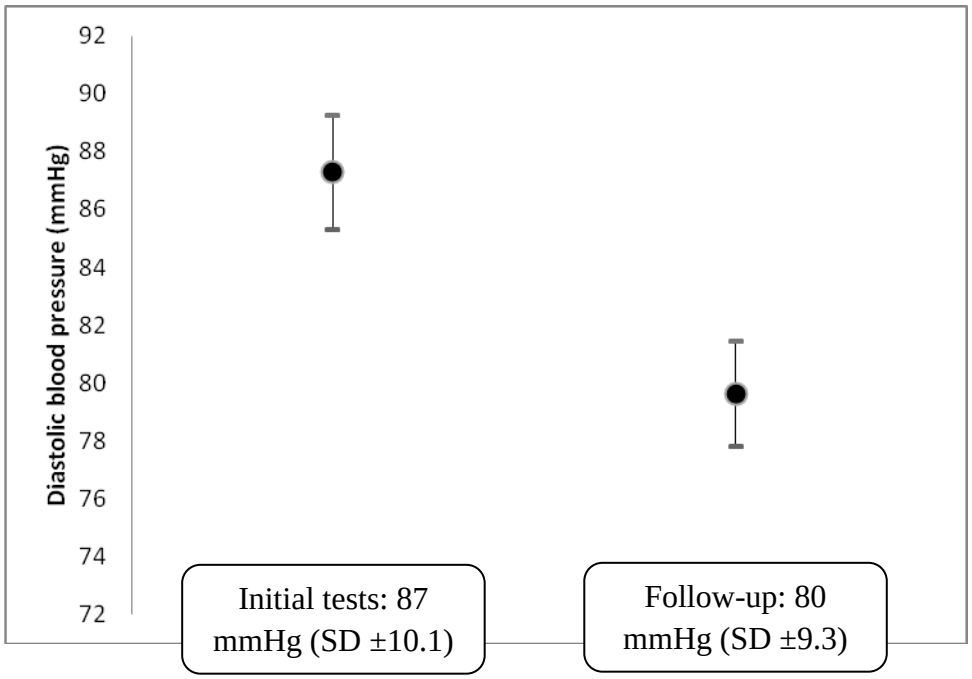

Figure 2 - 7 the mean diastolic blood pressure at initial assessment and at the twelve-month follow-up

Table 2 - 24 The number of participants at each category of diastolic blood pressure (mmHg). Categories as per JBS2 (JBS2 2005)

		Follow-up				
		<80	**80-84**	**85–89**	**90-109**	**≥110**
Initial assessment	**<80**	20	2↑	2↑	1↑	0
	80-84	16↓	2	2↑	0	0
	85–89	10↓	6↓	4	1↑	0
	90-109	11↓	7↓	9↓	11	0
	≥110	0	0	0	1↓	0

At follow-up ↓ a total of 60 their diastolic BP decreased to another category and ↑ a total of 8 increased

The mean total cholesterol level increased slightly by 0.06 mmol/L (95% CI -0.11 to 0.23) (Figure 2-8). This increase was not statistically significant. Also the mean total cholesterol: HDL ratio did not change significantly; -0.15 (95%

CI -0.35 to 0.05) (Figure 2-9). The numbers of participants and the changes in their total cholesterol and the total cholesterol: HDL ratio are shown in Tables 2-25 and 2-26, respectively.

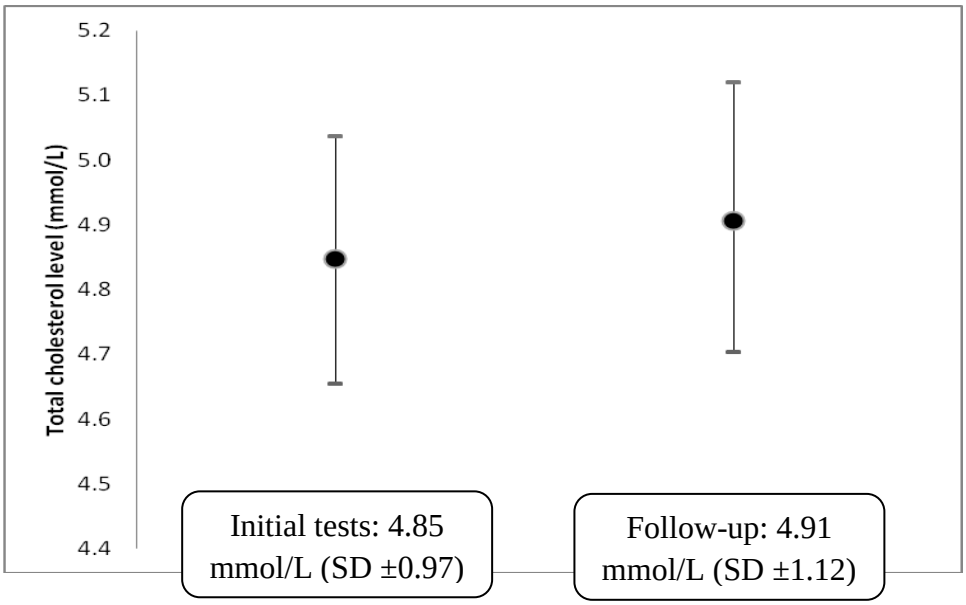

Figure 2 - 8 the mean total cholesterol at initial assessment and at the twelve-month follow-up.

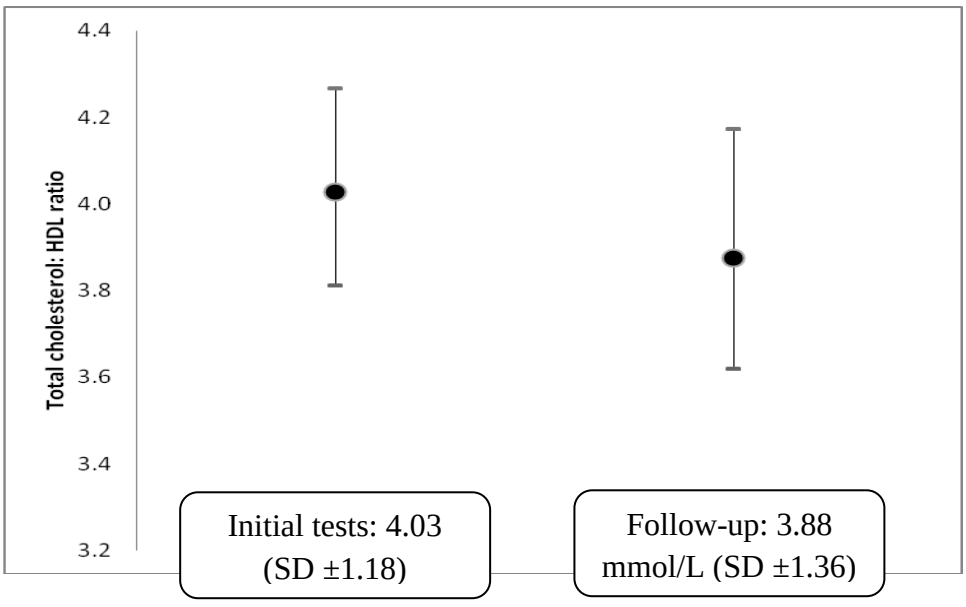

Figure 2 - 9 The mean of total cholesterol: HDL ratio and initial assessment and follow up

Table 2 - 25 The numbers of participants and their total cholesterol. Categories as per Boots SOPs

		Follow-up		
		≤ 5mmol/L	**5.1-7.4 mmol/L**	**≥ 7.5 mmol/L**
Initial assessment	**≤ 5mmol/L**	46	16↑	0
	5.1-7.4 mmol/L	8↓	31	1↑
	≥ 7.5 mmol/L	0	0	0

At follow-up ↓ 8 their total cholesterol decreased to another category and ↑ a total of 17 increased

Table 2 - 26 The numbers of participants and their total cholesterol: HDL ratio. > 6 is considered high risk (BNF 2011)

		Follow-up	
		≤ 6	**> 6**
Initial assessment	**≤ 6**	84	6
	> 6	4	1

There was a small but a statistically significant increase in the mean HDL of 0.08 mmol/L (95% CI 0.02 to 0.14) at the twelve month follow-up (Figure 2-10). Fourteen participants improved their level of HDL compared to seven participants where there was a decrease in their HDL level at the twelve month follow-up (Table 2-27)

Table 2 - 27 The numbers of participants and their HDL level. Categories as per JBS2 (2005)

		Follow-up	
		OK*	**Low‡**
Initial assessment	**OK***	58	7
	Low‡	14	20

* HDL level considered OK if it is ≥ 1 mmol/L for men and ≥ 1.2 mmol/L for women,
‡ if HDL level < 1 mmol/L for men and < 1.2 mmol/L for women

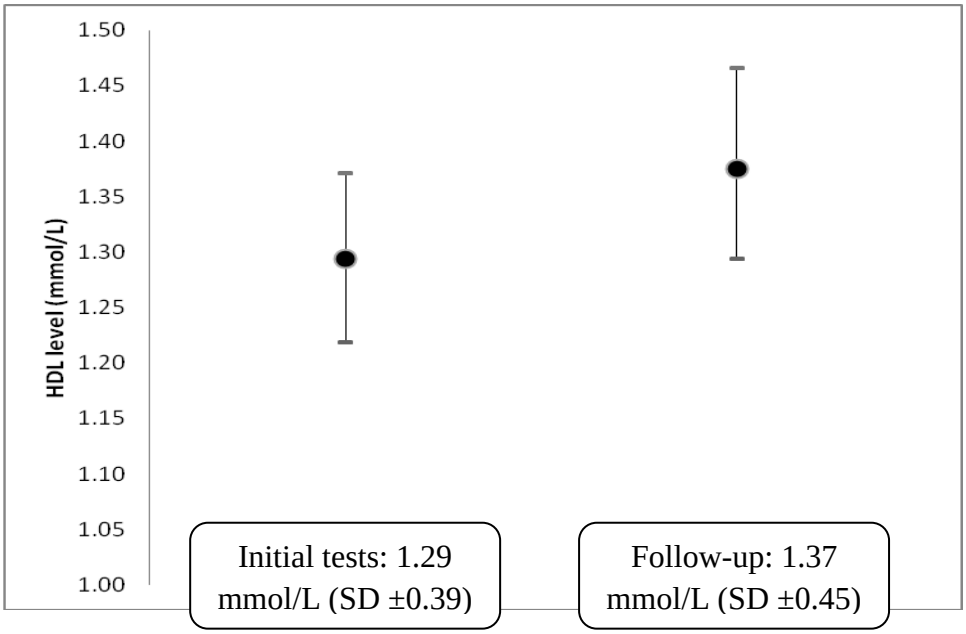

Figure 2 - 10 The mean HDL at initial assessment and at the twelve-month follow-up

2.3.3.4 Calculating Framingham risk at the twelve-month follow-up

Of the 146 participants who had their 10-year CVD risk calculated at the initial assessment, 90 participants completed the study (that is, attended the twelve-month follow-up). Five could not have their risk calculated because of the exclusion criteria; three exceeded the age limit (older than 74 years), one had had a myocardial infarction during the past year and one had started

antihypertensive pharmacotherapy and a statin. Therefore, only 85 participants had their CVD risk recalculated at this follow-up and the results show that their mean Framingham score was significantly reduced (Figure 2-11). The difference was -1.07 (95% CI -1.9 to -0.2). When data were adjusted for age, that is, using the age at initial assessment the difference was even greater; -1.5 (95% CI -2.4 to -0.6).

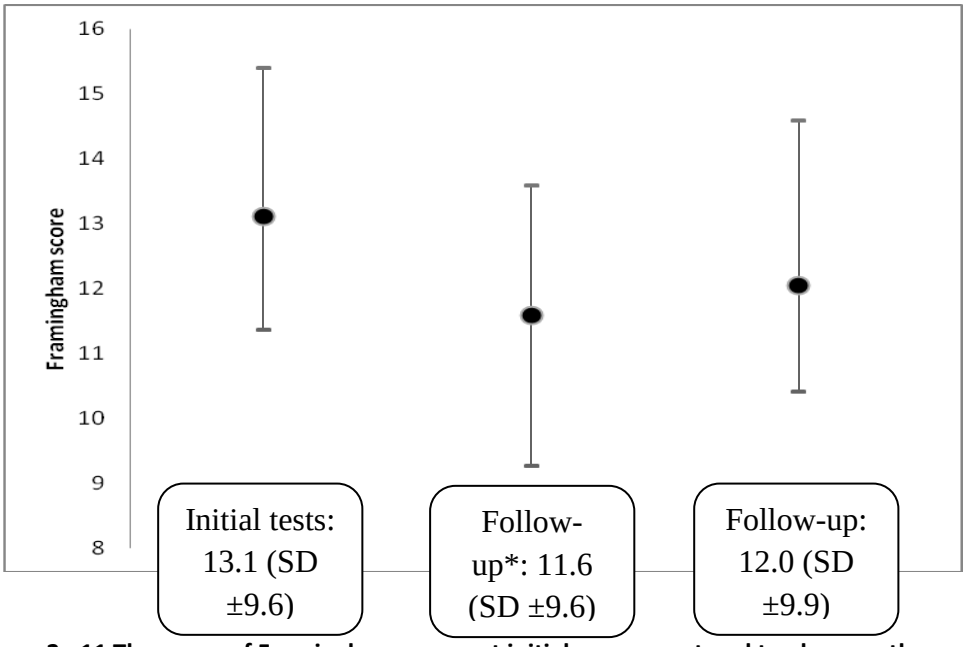

Figure 2 - 11 The mean of Framingham scores at initial assessment and twelve month follow-up. * Scores adjusted for age.

Table 2-28 shows the number of participants in each category of the Framingham CVD risks. No age adjustment was made to the results, that is, Table 2-28 shows the Framingham scores exactly as they were communicated to the participants.

Table 2 - 28 Framingham scores as communicated to participants at initial assessment and at twelve month follow-up

		Follow-up		
		<10%	**10-20%**	**>20%**
Initial assessment	**<10%**	40	1↑	0
	10-20%	6↓	18	3↑
	>20%	0	3↓	14

At follow-up ↓ 9 their CVD risk decreased to a lower category and ↑ 4 increased

Of the four participants who had their CVD risk increased, three accessed the service at Boots Porthcawl and one at Boots Merthyr Tydfil. On the other hand, six participants from the Porthcawl cohort and three participants from the Merthyr Tydfil cohort had their risk decreased.

2.4 Discussion

2.4.1 Overview

This was the first study in the UK to follow-up participants who had a VRA in a community pharmacy after a period of twelve months. The study was successful in recruiting 172 participants (146 had a full VRA and 26 had a brief assessment) and it was successful in following up 61% (n = 105) of these participants to the end of the study.

2.4.2 Methodological considerations

This study was a longitudinal pre- and post test cohort study. The main outcomes were either objective, such as changes to Framingham scores, changes to blood pressure, lipid profiles and BMI or subjective, such as self-reported lifestyle changes. Blood pressure measurement, however, is less objective than blood tests and it can be a source of bias (Vera-Cala et al. 2011).

The VRA service was affected by some limitations including the use of a Framingham based risk assessment tool (Chapter 7) instead of the more accurate QRISK2 and also the questionnaire used allowed for obtaining limited information on lifestyle (Section 8.4). Although these limitations were identified prior to the start of the study, it was decided that no changes would be made as, for indemnity reasons, the relevant Boots SOPs had to be followed thoroughly. Also when the study began the Framingham tool was the recommended tool by NICE (NICE 2008b) and this recommendation was only changed in March 2010 (NICE 2010a).

The service provided was similar to that being provided by other Boots pharmacies and the relevant Boots SOP was followed thoroughly. The pharmacist attended the same training session other pharmacists had before providing the service. There is, however, a major difference between the service in this study and in other Boots pharmacies as the pharmacist in this study conducted the tests and the consultations whereas in other Boots pharmacies pharmacy technicians usually involved in the tests. This was identified as a limitation and it is discussed further in Chapter 8.

The venues for providing the service were selected with different factors being taken into consideration. Boots at Porthcawl was chosen first because of convenience principally as the research pharmacist had worked at that pharmacy in the past and undertook occasional weekend locum work and because of the level of support that was offered by the store manager and pharmacy staff. Boots at Merthyr Tydfil, however, was chosen because Merthyr Tydfil had the highest proportion of the most deprived areas in Wales (WAG 2008). Choosing a pharmacy surrounded by areas with high deprivation for evaluating the VRA service was in line with the aims of the Heart MOT pilot (Horgan et al. 2010). However, in our study fewer participants were recruited in the pharmacy with high deprivation. Reasons for this were unknown. The availability of the service may have had an effect in that the recruitment period for Merthyr Tydfil was six weeks on only two days each week compared with approximately eight months at Porthcawl.

The literature review (Chapter 1) revealed that most of the identified studies (n = 6) were descriptive studies (Carter et al. 2009; Chambers et al. 2005b; Horgan et al. 2010; Kaczorowski et al. 2010; Liu et al. 2009; Peterson et al. 2010). However, one study (Yamada et al. 2005) followed up participants six months after an intervention. Also another paper (Mc Namara et al. 2010) was identified which was a study protocol with a primary outcome of changes in the modified Framingham scores between baseline and at six month follow-up. There were also secondary health outcomes mentioned in the study protocol including change to blood pressure, lipid profile, random blood glucose, waist, BMI, and depression score. The shorter follow-up time of these studies was considered a limitation and the twelve-month period was considered more appropriate for the present study. The duration of the PhD programme prevented an even longer follow-up period being used.

The proportion of participants (61%) who completed the study, that is, those who attended the twelve-month follow-up assessment, was relatively high when compared to other pre- and post cohort studies in pharmacy practice. For example, in the study conducted by Yamada et al. only 45% returned to the pharmacy. In this study patients who had an assessment and education by community pharmacists were invited to revisit the pharmacy to have an LDL test as the main outcome was changes to LDL level (Yamada et al. 2005). However, in another study evaluating the role of pharmacist in diabetes care, the first follow-up, at six months, succeeded to recruit 72% but in the second follow-up, at twelve months, only 43% were recruited (Cranor et al. 2003).

2.4.3 Characteristics of the participants

The characteristics of participants were similar in some respects to other studies involving the community pharmacy in the primary prevention of CVD, in that the majority were Caucasians and the average age was over 50 years old (Amariles et al. 2008; Sancar et al. 2011; Thornley et al. 2009b).

There were more female participants in this present study than males and this was the case in most studies which were identified in the literature review except for two studies and they are as follows: Horgan et al. (2010) which had 60% and Boyle et al. (2004) which had 100% men. However, Horgan et al. (2010) evaluated a service used marketing strategies to target men and this was the reason for succeeding in attracting more men than women and Boyle et al. (2004) being male was one of the inclusion criteria. Men have been identified as one of the hard-to-engage groups (World Health Organization 2007). In one study men were only 29% of the sample (Peterson et al. 2010), other studies had also low proportions, including 30% (Thornley et al. 2009b), 32% (O'Donovan et al. 2010), 33% (Fernandez-Pinilla and Chaves 2008a), and 36% (Amariles et al. 2008).

Participants' ages ranged from 19 to 87 years in the present study. The forthcoming national VRA service in Wales is expected to be available free of charge for those who are between 40 and 74 years of age (WAG 2010), which is in line with the NHS Health Check in England (DOH 2008c). Six participants would have been ineligible to the expected national service because of their age; two under 40 years old and four over 74 years old. Also

individuals who were already diagnosed with a CVD or known to be at high risk of developing CVD are very likely to be ineligible for the expected national service. Twenty-three participants were in this category and they would be unlikely to receive a free of charge service. The reason this study included this number (n = 26) of participants in this category (ineligible for the expected national VRA service in Wales) because the first advert (Appendix 7a) was similar to the standard Boots advert for this private, non-NHS service which did not have these exclusion criteria. The proportion may have been higher if the advert had not been amended to list all the inclusion and exclusion criteria (Appendix 7b).

Participants from the most deprived areas were less represented in this study as 7% only were from this group whereas this group makes up 10% of the general population (WAG 2008). The percentages of those who resided in the most deprived areas and used the two pharmacies in this study could not be determined because of technical and confidentiality issues. Therefore, no comparisons could be made at the local level.

2.4.4 Lifestyle of the participants

Promoting a healthy lifestyle is one of the priorities in Wales as unhealthy behaviours are not uncommon (BHF 2011b; Wales Centre for Health 2009). For example 25% of adults reported as current smokers (WAG 2007), the proportion of those who exceed the recommended weekly alcohol consumption is just above 40% for men and about 34% for women (Wales Centre for Health 2009) and the proportion of people who do not have an acceptable level of

physical activity is about 70% (NHS Wales 2006). However, those who attended the VRA service self reported a healthier lifestyle than the general population as only 6% of participants reported that they were smokers, 9% had unhealthy drinking habits and 5% were physically inactive. A higher proportion, about a quarter, of participants admitted that their diet did not always include vegetables and fruits. One explanation that our study attracted mainly the "worried well", which is a similar outcome of a study evaluating a web-based health risk assessment (Colkesen et al. 2011).

Another, explanation is that as lifestyle information was captured by self-completing the service questionnaire which could be a source of social desirability bias. Social desirability bias affects the validity of lifestyle surveys where participants have the tendency to provide a more positive image of themselves (van de Mortel 2008). van de Mortel (2008) argues that social desirability bias was more likely to occur when reporting a socially sensitive behaviour such dietary/alcohol intake or physical activity in this study. It cannot be determined whether it was social desirability bias behind the relatively high percentage of participants who stated that they were leading a healthy lifestyle or the study sample was healthier than the general population because participants were not evaluated, for example by using Marlowe-Crowne Social Desirability Scale, to check if they were more likely to give a positive image about themselves (van de Mortel 2008). However, as it was not reflected on their body weight (76% were overweight or obese) the risk of social desirability bias cannot be overlooked.

2.4.5 Initial assessment

There were 40% of participants who had a systolic BP of more than 140 mmHg. This is double the proportion of people who have raised blood pressure in Wales as suggested by that the British Heart Foundation (BHF 2011b). Liu et al. (2009) reported that 45% of their study sample had a systolic BP of more than 140 mmHg whereas Peterson et al. (2010) reported a lower proportion of 30%. Other studies which were identified in the literature review reported the mean systolic BP rather than the proportion of individuals with high BP. Reasons for this high proportion in the present study could include the fact that BP measurements were not repeated over a period of time and that there may have been some anxiety in participants leading to a community pharmacy variant of white coat syndrome.

About two-fifths of participants (39%) had a total cholesterol level of more than 5 mmol/L. Cholesterol levels are not collected routinely in Wales (BHF 2011b). Therefore, no comparison with the general population can be made. However, it is expected that the prevalence of those with a total cholesterol level of more than 5 mmol/L is similar to England which is higher than the study population, that is, 58% for men and 61% for women (BHF 2010). Although the level of more than 5 mmol/L is considered high, according to the guidelines in place, by itself a high total cholesterol level is not a cause for referral as long as it is less than 7.5 mmol/L (Appendix 6b).

Low HDL levels to a point that could increase the risk of CHD significantly (Wilson et al. 1998) was seen in 39% of participants. Also 12 participants had a

total cholesterol: HDL ratio of more than 6 which required an intervention (BNF 2011), therefore they were referred to their GP.

A diabetes risk assessment tool was developed by University of Leicester, University Hospitals of Leicester and Diabetes UK and adopted by Community Pharmacy Wales for a health promotion campaign in Wales (Brennan 2011). According to this assessment tool only 14% of all participants had a low risk of developing diabetes in the next 10 years. The remaining participants were at increased (37%), moderate (37%) or high risk (12%). Mostly, participants' diabetes risk was elevated because of their age, BMI and/or waist circumference.

In the present study, one third were referred to their GP because of their CVD risk (n = 33) and/or because of having a significant risk factor (n = 47), for example a high cholesterol level. High blood pressure was the most common risk factor as it was found to be present in 44 participants who had been referred. As was expected, male or older participants were statistically significant more likely to be referred, but there was no significant difference between participants from areas with different levels of deprivation.

Despite the fact that it is more likely that large numbers of individuals with high risk will be identified in deprived areas (Soljak et al. 2009), in this study 31% of those who came from the least deprived areas were estimated, using the Framingham charts, to be at high risk of CVD while only 25% of those who came from the most deprived areas were at high risk. One explanation is that those who came from the most deprived areas were not representative of their

communities. This could be a disadvantage of relying on the deprivation indices to determine the socio-economic status as a geographic area of high deprivation sometimes consists of wealthy individuals. On the other hand, an area with low deprivation sometimes consists of a pocket of deprivation (NHS Westminster 2011).

2.4.6 Twelve-month follow-up

By the time of the twelve-month follow-up, a total of 67 participants had withdrawn from the study. However, the demographics of the study participants at the twelve-month follow-up were not statistically different to those at the initial assessment.

The main outcome of the referral to GP has shown that most participants have made a visit to the GP as advised by the pharmacist, 35 participants confirmed their visit versus two who stated that they did not. This is a 95% achievement compared to 64% of that reported by Boyle et al. (2004) who combined the figures of those who made their visit and those who were waiting for an appointment. Although this suggests a success of the service in that service users who needed to see the GP were convinced to make the visit, we could not obtain an accurate outcome of their visit to the GP. Most of the referred participants stated that GPs recommended lifestyle changes as opposed to pharmacological intervention.

There were some inconsistencies seen in some participants' answers to lifestyle questions. Some participants indicated that they modified lifestyle in one question but no change could be identified when comparing their answers with

the information they provided at the initial assessment. This may be due to that participants were estimating on both occasions rather than keeping a diary for a period of time prior to the assessments.

More than a third of participants self-reported an improvement in lifestyle and of those who had been identified to be at high risk of CVD at the initial assessment, 80% (n = 16) reported a lifestyle improvement. This was a higher proportion than that reported by Peterson et al. (2010) (46%). However, as discussed above a limitation to the present study is relying on self-reporting of lifestyle modifications. For example, there were four participants who claimed that they had decreased their alcohol consumption but their self-reported weekly units of alcohol had increased at 12 months when compared with the initial assessment. This could suggest that some responses were subject to social desirability bias as some individuals prefer to portray a more positive image of themselves, for example, to health professionals (van de Mortel 2008).

It was not expected that a single interaction with the pharmacist would result in a successful, maintained behavioural change, indeed this was not a study aim. Participants were expected to have different personal and family circumstances which would support or hinder any change. Personal and family circumstances were not evaluated in this study, thus the effect of this on the study results was unknown.

Theories on health behaviour have been developed and applied to understand the nature of behavioural change (Nutbeam and Harris 2004). According to the

transtheoretical model (Stages of Change model) which was developed by Prochaska and DiClemente (1984) change would occur depending on the readiness of the individual. The model consists of five stages which help to determine how close the individual to the behavioural change:

1- Precontemplation: person not intending to make any decision results in healthy behavioural change.
2- Contemplation: person considers the change but not ready to act on.
3- Determination: person committed at this stage to take action.
4- Action: person starts the action that is a behavioural change.
5- Maintenance/Relapse: depending on whether or not the behavioural change is sustained this stage can be a mark for success or failure.

Therefore, it was expected that participants who were at the determination stage would be closer to change than those who were at the precontemplation stage. This would be recommended as a further area of research.

A recently published report by NHS Health Scotland shows that there is a gap between understanding messages that promoting a healthy lifestyle and attitudes toward health (Bromley et al. 2011). For example, 87% of adults in Scotland knew that eating five portions of fruit and vegetables a day is good for their health. However, only 22% ate at least five portions of fruit and vegetables a day. This confirms what behavioural change theories are suggesting that providing the information by itself is not always enough when helping people to adopt a healthier lifestyle.

There was a statistically significant reduction in mean BMI but not in mean waist circumference. The reduction was a small but the number of participants who moved to a BMI and waist circumference categories of a lower risk were more than those who moved to a higher risk category. Although changing from a higher BMI category to a lower category was important and encouraging for the participants concerned, there was not always a large reduction in weight. For example, of those who were overweight at the initial assessment but their weight was normal at the twelve-month follow-up, the BMI of one person changed from 25.2 kg/m^2 to 24.7 kg/m^2 while another person changed from 27.1 kg/m^2 to 22.2 kg/m^2.

The mean systolic and diastolic blood pressures decreased significantly and about a half of participants their blood pressure changed from a category of a higher risk to a lower risk, for example eight participants (including Subject 116 who was prescribed felodipine 2.5mg) their systolic blood pressure was between 140 and 199 mmHg to less than 130 mmHg. In comparison Yamada et al. (2005) reported more individuals with hypertension at the follow-up than the baseline (73% versus 61% respectively).

Although it was hoped that the improvement in lifestyle would be reflected on the lipid profile, there was a small increase in the mean total cholesterol. This increase was not statistically significant. One participant, a 55 year old man, who had a decrease in waist circumference from 109 cm (high risk) to 96 cm that is, a lower risk category than before, had an increase in his total cholesterol level from 5.75 mmol/L to 8.11 mmol/L. This case contradicted the evidence

that reduction in abdominal obesity is associated with improvement in dyslipidaemia (Ferland and Eckel 2011). In contrast, there was a significant increase in mean HDL and 14 participants improved their levels from low to an acceptable level versus seven participants who had their HDL levels deteriorated.

The average Framingham score decreased from 13.1% to 12.0% (11.6% with adjusted age) and this reduction was statistically significant. The risk (as communicated by the pharmacist without any age adjustment) of six participants decreased from moderate to low risk and three from high to moderate risk. However, the extent of the change in Framingham scores varied, for instance, one participant (Subject 70) had a reduction from 32% to 18% whereas the risk was increased from low to moderate risk for one participant; from 8% to 10%. Also it was increased from moderate to high risk for three participants; from 19% to 22%, 14% to 26% and 17% to 26%. Therefore, this study reported the change in the mean Framingham score and not only the changes in categories, even though they are important as they determine the intervention the clinician should make.

Most participants who were referred to the GP stated that they made such a visit. It was noticeable that a statin was not prescribed in almost all those who had been referred because of their CVD risk, only two participants out of 33 confirmed that they had been prescribed a statin. For primary prevention of CVD, NICE recommends that statin should be offered for those who have risk

of ≥ 20% in the next 10 years, as estimated using an appropriate CVD risk assessment tool (NICE 2008c).

Recommending lifestyle changes over pharmacological intervention was seen in certain situations (Tocci et al. 2011). However, in this study it was not possible to know whether recommending lifestyle changes was the preferred approach by GPs in the management of those who were identified at high risk of CVD after they had been referred by the pharmacist. It was not clear whether or not GPs agreed with the results of the tests the participants had in the pharmacy.

NICE emphasises that before making a decision on whether to prescribe statin, the risks and benefits of statin treatment should be discussed with the patient in the light of other factors such as other health issues and life expectancy (NICE 2008c). Therefore, it was possibly the patient who preferred the lifestyle changes over taking the statin.

There are a number of factors which might have affected the participants' response to the advice. All participants who attended the twelve-month follow-up assessment had had a telephone interview approximately two weeks after the initial assessment which could have been a reminder for them to follow the advice. Also, most of those who had been referred to the GP made their visit. The GP could have succeeded in helping the participants to make the lifestyle changes as those who made their visit were more likely to have reported a lifestyle improvement. Other possible explanations are discussed in the limitations in Chapter 8.

2.4.7 Limitations and future research

The limitations of this study and suggestions for future research are discussed in Chapter 8.

2.4.8 Conclusion

This was an exploratory longitudinal pre- post study which assessed participants initially and twelve months later. The study explored the demographic characteristics of the participants and presented the tests results of the initial assessment and also results of the twelve-month follow-up assessment. No significant difference in CVD risk was seen in participants who came from areas of different levels of deprivation. The study showed a statistically significant change in the mean blood pressure, HDL and Framingham scores.

Chapter 3: Access to, and patient satisfaction with, the VRA service - anonymous survey

3.1 Introduction

This chapter presents a study conducted to evaluate the accessibility of the VRA service and the level of satisfaction of the service users.

As part of clinical governance which is highlighted in the community pharmacy contract with the NHS, pharmacists in England and Wales are required to give patients the opportunity to feedback on the their level of satisfaction for the services they provide (RPS 2011a). This is usually done internally as part of an audit process which means the results of such surveys are not necessarily published. Particularly, satisfaction with VRA services has not been reported to a significant extent.

For the VRA service to achieve its objectives as a prevention strategy the service should be highly accessible by the public. Therefore, there was an emphasis by the government in England on the suitability of the venue for the provision of the service (DOH 2008c).

Pharmacy is readily accessed by the general public, for example a pharmacy-based smoking cessation service was found to be more readily accessible when compared to another setting (Bauld et al. 2011). In a Needs Assessment Study for community pharmacy travel medicine services, the results suggested that travellers would be prepared to use the community pharmacy to receive both travel advice and immunisations (Hind et al. 2008). Long opening hours of some community pharmacies have improved patient access to services (Bellingham 2008). Taking advantage of the pharmacy's unique position in the

community and delivering more local services would make healthcare more accessible (Richards 2009).

Even though the community pharmacy as a location for delivering the VRA service was considered by the government as suitable, an appropriate private consultation room would also be considered as important. The consultation room was introduced to the community pharmacy setting as a requirement for certain services, such as the Medicine Use Review (MUR) and the supervised administration of controlled drugs, under the Community Pharmacy Contract with the NHS (PSNC 2004). For this study the consultation room for providing services under the pharmacy contract was used to provide the VRA service. Also, the training and skills of the health professionals are essential to ensure the success of any programme involving screening and consulting the service users (DOH 2008c).

The objectives of the present study were to:

- identify reasons for requesting a free, non-NHS VRA service provided by two community pharmacies in Wales
- evaluate patient satisfaction with the service.

3.2 Method

A questionnaire (Appendix 10) was devised to measure the level of satisfaction of those who accessed the VRA service which was provided by two community pharmacies, at Porthcawl and Merthyr Tydfil, from November 2009 to August 2010. Also the questionnaire was used to find out why service users chose to have the assessment in the community pharmacy.

Although the questionnaire was developed specifically to help achieve the objectives of this study, other questionnaires from other studies (Horgan et al. 2009; Knowsley PCT 2008; Stewart et al. 2008) were reviewed and questions used adapted, as appropriate, in consultation with academic supervisors. The questions and the tool were reviewed internally by academics within the School and independently reviewed and approved by the School Research Ethics Committee.

The questionnaire was kept anonymous with only gender and age group being identified. Other questions were included to determine type of assessment they had, how they found out about the service and the reasons for having the check. Anonymous questionnaires are usually used to increase response rate and to encourage participants to report negative views unreservedly (Smith 2010).

The questionnaire consisted of 16 statements where participants were asked to indicate their level of agreement to each statement using 5 point Likert scale. There was a mixture of positive and negative statements, therefore scores of negative statements were reversed in order to check the overall satisfaction. The questionnaire focused on acceptance of community pharmacy as a venue

for the service, and the satisfaction with the pharmacist as a service provider. The sixteen statements consisted of seven statements related to the experience in general of having the health assessment (statements a, b, c, d, n, o and p), and nine statements related to their interaction with the pharmacist (statements e to m).

There were two open questions for participants to write what they thought would improve the service and what other comments they might have with regard to the service.

Participants were given the questionnaire with a free-post envelope at the end of the consultation and were asked to post it back after completion at their convenience. As this survey was anonymous, non-responders could not be identified. Therefore, no follow-ups or reminders were sent to them.

Data were analysed using descriptive statistics using the statistics programme PASW Statistics 18.

3.3 Results

Of the 172 people who accessed the VRA service in the two community pharmacies, 127 returned the questionnaire giving a response rate of 74% (Table 3-1).

Table 3 - 1 Demographics of satisfaction questionnaire respondents compared with all service users. * More people indicated they were over 74 than the actual number; this was probably because of confusion over which box to tick

Demographics	Satisfaction questionnaires returned (%)	Service users (%)
Females	74 (58)	101 (59)
<40 years old	2 (2)	2 (1)
40-49 years old	13 (10)	29 (17)
50-59 years old	34 (27)	45 (26)
60-74 years old	73 (57)	92 (53)
>74 years old	6* (5)	4 (2)
Total	127 (74)	172 (100)

A total of 35 participants (28%) had had a similar check in the past. Most of these 35 (66%) indicated that they had it at GP surgery (Table 3-2).

Table 3 - 2 Places where participants had a similar check before (total number = 35)

Place	Number (%)
GP surgery	23 (66)
Community pharmacy	8 (23)
Workplace	4 (11)

Ten participants had such check three to six months prior to accessing the pharmacy VRA service (Table 3-3).

Table 3 - 3 Time of the previous check (Total number = 35)

Time	Number (%)
Three months	6 (17)
Six months	4 (11)
One year	8 (23)
Two to four years	9 (26)
Five or more years	8 (23)

The numbers of respondents who had the full cardiovascular risk assessment was 116 (91.3%) and 11 (8.7%) had undertook a brief health check.

About half of the respondents (n = 63) said that they found out about the service through an advert in a local newspaper. The remaining respondents found out about the service having seen a leaflet (n = 19, 15%), via Boots pharmacy staff (n = 19, 15%), from a friend or family member (n = 15, 11.8%), from seeing a notice at the pharmacy counter (n = 7, 5.5%) or from their GP (n = 1, 0.8%).

Respondents reported varying reasons for accessing the VRA service (Table 3-4). They had the option to choose more than one reason. Most of them (n = 106, 83.5%) indicated that “it was an opportunity to have my health checked out”.

Table 3 - 4 The reasons why the participants had decided to have the assessment. Statements in descending order of responses, (for the right order see Appendix 10).

Reason for having the health check	Number (%)
"It was an opportunity to have my health checked out"	106 (84)
"I take care of my health"	48 (38)
"It's more convenient than making an appointment with my doctor"	33 (26)
"I was encouraged by a family member or friend"	17 (13)
"I was worried about my health"	15 (12)
"Pharmacy staff told me about it"	13 (10)
"I don't get to see my doctor"	6 (5)
"To confirm the results of a similar check I had elsewhere"	3 (2)
Other (people stated their reasons)	9 (7)

Table 3-5 shows the responses to each statements of the questionnaire. About half (n = 63, 52%) of respondents indicated that their worrying about their health was the same before and after the assessment (in statements h and i). Twenty-two (18%) were more worried and 36 (30%) were less worried after having the assessment. The majority of respondents (n = 102, 81%) had trust in the pharmacist before the assessment and their trust remained the same after the assessment whereas 6 (5%) had less trust and 18 (14%) had more trust after the assessment.

The medians for individual statements were; 5 (n = 7), 4 (n = 8) and 3 (n = 1). No respondent disagreed with the statement 'I am totally satisfied with the cardiovascular risk assessment service'. Only two agreed with 'I would rather have had this health check in my doctor's surgery'.

Table 3 - 5 Patient satisfaction items and responses to each item.

Questionnaire statements	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Median
a. I am totally satisfied with the cardiovascular risk assessment service. (m/r = 1)	79 (62)	44 (35)	3 (2)	0	0	5
b. The staff were friendly. (m/r = 1)	94 (74)	32 (25)	0	0	0	5
c. The staff made me feel comfortable. (m/r = 1)	91 (72)	35 (28)	0	0	0	5
d. There was sufficient privacy in the consultation room. (m/r = 1)	66 (52)	51 (40)	5 (4)	3 (2)	1 (1)	5
e. I found it difficult to tell the pharmacist about some private things. (m/r = 8)	5 (4)	2 (2)	20 (16)	55 (43)	37 (29)	4†
f. The pharmacist explained everything to me in a way I could understand. (m/r = 1)	71 (56)	55 (43)	0	0	0	5
g. The pharmacist gave me sufficient opportunity to ask questions. (m/r = 2)	74 (58)	48 (38)	3 (2)	0	0	5
h. I was worried about my health BEFORE having the cardiovascular risk assessment service. (m/r = 5)	7 (6)	17 (13)	50 (39)	28 (22)	20 (16)	3†
i. I am worried about my health AFTER having the cardiovascular risk assessment service. (m/r = 6)	5 (4)	19 (15)	35 (28)	39 (31)	23 (18)	4†

() the number inside brackets indicates the percentage. † Scores of negative statements are reversed. m/r = Missing response

Table 3 – 5 (Continued) Patient satisfaction items and responses to each item.

Questionnaire statements	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Median
j. The consultation time with the pharmacist should have been a little longer.	0	7 (6)	29 (23)	72 (57)	19 (15)	4†
k. The pharmacist informed me about the results of the tests without making me worried. (m/r = 1)	61 (48)	59 (47)	4 (3)	2 (2)	0	4
l. I had trust in the pharmacist's ability to perform the cardiovascular risk assessment service before I saw him for the check.	45 (35)	65 (51)	15 (12)	1 (1)	1 (1)	4
m. My trust in the pharmacist remains the same after the cardiovascular risk assessment service. (m/r = 1)	56 (44)	62 (49)	4 (3)	4 (3)	0	4
n. I would rather have had this health check in my doctor's surgery. (m/r = 2)	0	3 (2)	55 (43)	51 (40)	16 (13)	4†
o. I would recommend the cardiovascular risk assessment service to other people.	78 (61)	49 (39)	0	0	0	5
p. Some things about the cardiovascular risk assessment service could have been better. (m/r = 7)	1 (1)	10 (8)	38 (30)	46 (36)	25 (20)	4†

() the number inside brackets indicates the percentage. † Scores of negative statements are reversed. m/r = Missing response

The number of those who ticked agree or strongly agree for statement p was eight. They provided their suggestions on how to improve the service by answering (table 3-6) the first open question.

Table 3 - 6 Comments and suggestions made by respondents in their response to the first open question

Identified theme	Responses to open question 1	Gender	Age group (years)
Critical of measurement/ assessment	*"Waist size was taken with my clothes on."*	Male	50-59
	"There was no question about stress."	Female	50-59
Critical of the place of the BMI machine	*"The weight, height and BMI machine was in the middle of the shop. Not private enough for me."*	Female	60-74
	"The room we were in was rather small and had to go into shop for weighing."	Female	60-74
	"Just the booth and weighing scales which were in the middle of the shop."	Female	50-59
Critical of the booking system	*"I was not advised when booking app that the blood test could not be completed (on warfarin)"*	Male	60-74
Suggesting additional elements to the service	*"Possibly immediate treatment if needed."*	Male	60-74
	"ECG should be available if possible"	Female	50-59

Thirty-nine respondents answered the second open question, of which more than half expressed their satisfaction. Table 3-7 provides the participants' responses.

Table 3 - 7 Examples of the responses to the second open question. Some responses had more than one theme

Identified theme	No of responses	Examples		
		Quote	Gender	Age group (years)
Satisfaction with service	22	*"I was pleased to be able to have this service and look forward to year time to see if I have taken the advice given and it worked."*	Female	60-74
		"An excellent opportunity to receive information about my health and has had the effect of making me aware of certain actions I need to take to improve my health. Thank you."	Male	50-59
		"Thank you very much that I was able to have this evaluation of cardiovascular risk assessment without having to go to GP surgery or hospital clinic."	Female	60-74
		"I found the check far less stressful than having to attend one at my local GP's surgery"	Female	50-59
		"If the results of the consultation are not entirely positive its difficult for the pharmacist not to worry you! Apart from this it was a very satisfactory experience."	Male	50-59
Satisfaction with pharmacist	7	*"It was convenient for me, I had it during my lunch break hour. Pharmacist very helpful and gave me good advice."*	Female	40-49

Table 3 – 7 (Continued) Examples of the responses to the second open question. Some responses had more than one theme

Identified theme	No of responses	Examples		
		Quote	Gender	Age group (years)
		"The pharmacist noted that my BP readings were high and recommended that I refer to my Doctor. This I have done, readings and blood tests are being undertaken at the present time. I am grateful to the pharmacist for his advice."	Female	60-74
Satisfaction with information provided or advice	3	*"I am very grateful for [] Test and results and I am far better informed as to improve of my overall health!!"*	Male	40-49
Too much information/ worry/ uncertainty	3	*"Too much information by way of page after page unfamiliar terminology is useless to the elderly & less-informed.* *1- the elderly will forget it, almost immediately and then worry about what they have forgotten. (Thank you very much for worrying me with too much information)* *2- lots of people do not understand unfamiliar terms. Truth is, when answering Yes or No they really mean don't know… Actually!"*	Male	60-74
Critical of lack of privacy	3	*"Scales are in a very public and busy area, obviously because of space. Also as the consulting area is at the side of the pharmacy, while ones are waiting for prescriptions, conversations can be heard, again possibly because space is limited."*	Female	60-74

Table 3 – 7 (Continued) Examples of the responses to the second open question. Some responses had more than one theme

Identified theme	No of responses	Examples		
		Quote	Gender	Age group (years)
Expressed desire for more often checks	2	*"I would like to have had the test for diabetes but had already had something to eat. When I phoned Boots I was told it was OK. The pharmacist explained that as all the other tests were OK he felt there probably was no need."*	Female	50-59
Critical of the booking system	2	*"When I made the appointment to have the risk assessment which my sister told me about I didn't realize it was for people up to the age of 74."*	Female	75 or over
Suggested that the government should fund this service	2	*"I would like to see everyone have this test done, if the government would fund this cardiovascular risk assessment."*	Male	40-49
Satisfaction with the time spent	2	*"It was a simple procedure and only took about 30 minutes of my time."*	Male	60-74
Critical of the measurement	2	*"BP monitor varies in results"*	Male	60-74
Prefer GP surgery over pharmacy	1	*"I would rather have had this check in GP surgery because I am familiar with my own GP."* (Patient stated that she had a similar test within 3 months at GP surgery)	Female	75 or over

Table 3 – 7 (Continued) Examples of the responses to the second open question. Some responses had more than one theme

Identified theme	No of responses	Examples		
		Quote	Gender	Age group (years)
Required written information	1	*"I would have felt better if you had access to paperwork similar to this available, giving more information in layman's terms of what to avoid and what would be beneficial. Having said that the pharmacist answered all my questions in my language, but as I said above if it was on paper at my hands I could always check with it for my use."*	Male	60-74
Critical of the questionnaire	1	*"Statement L- Unable to inform opinion, such as trust, not having seen the person before.* *Statement M- Had improved, therefore question ambiguous. Was happy with treatment and pharmacist"*	Female	60-74
Other	1	*"I have trust and respect for the Welsh School of Pharmacy and in Boots."*	Female	60-74

Although respondents were mostly satisfied, some reported some dissatisfaction with the service. The perceived lack of privacy in the pharmacy, particularly with regard to location of the weighing scales, led to most of the criticisms made by respondents in their answers to either of the open questions. Also, three respondents expressed their dissatisfaction with regard to the information they received when they made the booking.

3.4 Discussion

This anonymous survey shows high respondent satisfaction with the community pharmacy-based VRA service. They were satisfied with the pharmacy in that it was convenient and with the pharmacist, whom they trusted as a healthcare professional. The survey also explored the reasons why respondents had requested the assessment.

The method used in this survey was a self-complete questionnaire given to those who accessed the service provided in the two pharmacies, namely Boots in Porthcawl and in Merthyr Tydfil. The free post envelope was provided to assist in achieving as high a response rate as possible. The survey was anonymous so that respondents could indicate their real opinions and such an approach is commonly used in social science research (Naik Panvelkar et al. 2009). This service was free to users and the respondents were self-selecting and perhaps well-motivated and so these factors may contribute to the high satisfaction with the service. Also, as with all studies it may be that the non-responders were not as satisfied and that may be one reason why they did not respond.

- <u>High level Satisfaction</u>

The high satisfaction level was similar to that seen in the Heart MOT, a pilot of a community pharmacy based VRA service which was taken place in Birmingham, England. This study took place in 14 pharmacies across the city from April 2007 to June 2008 (Horgan et al. 2009) and reported 98% agreeing or strongly agreeing that they were happy with the Heart MOT service;

equivalent to the 97% in the present study. Another study showed a high satisfaction with the VRA service was conducted in Australia as 71% of the respondents regarded the screening as worthwhile and 98% rated the consultation as good or excellent (Peterson et al. 2010).

All respondents in the present study either agreed (39%) or strongly agreed (61%) with the statement "I would recommend the cardiovascular risk assessment service to other people." Horgan et al. (2009) reported that 99% of respondents would recommend the service to others. It was not clear, however, if such a statement was constructed as a five-point Likert item or as a Yes/No question.

The medians of seven statements were 5 indicating the very high overall level of satisfaction with the following elements of the service; total satisfaction, friendly staff, made to feel comfortable by staff, sufficient privacy, explanations were understandable, sufficient opportunity to ask questions and would recommend the service to others.

- Response Rate

Only 44% responded to the Heart MOT survey, the authors considered this as reasonable as only a single mailing was used. The response rate of the survey conducted by Peterson et al. (2010) was 53%. In contrast, the present study achieved a 74% response rate. This may have been due, at least in part, to the pharmacist providing the service being the person who provided the questionnaire to the subjects. However, more subjects were given the

questionnaire in both studies compared to the present study; 400 in the Heart MOT and 655 in the study conducted by Peterson et al. (2010).

About half of the respondents (n = 63) in the present study found out about the service through an advert in the local newspaper. Horgan et al. (2009) reported that 64% of respondents found out about their service in the pharmacy. This may be due to the differences in recruiting strategies in each service.

- Privacy and confidentiality at the pharmacy

Privacy in the consultation room was seen as sufficient by 92% of respondents and that was also similar to what Horgan et al. (2009) reported (93%). However, both the privacy within and the size of the consultation room were criticised by one respondent in her response to the first open question. Also, a further five criticised the location of the weighing scales as these were located outside the consultation room and they believed this affected their privacy. Although these were small numbers this is an important issue and may prevent others from accessing pharmacy based services, as was found by others (Hirst et al. 1999) in a focus group study conducted prior to the pharmacy contract requirement for a private consulting room if providing advanced services. In the Heart MOT study, even though 93% of participants were happy with the consultation area about a quarter of the respondents rated the overall experience negatively and one of the reasons was the consultation facilities (size or privacy). In a more recent study, the size of the consultation room was considered by community pharmacists as one of the barriers for the success of the Medicines Use Review (MUR) service, which requires a private

consultation between pharmacist and patient (Latif et al. 2010). In a study using semi-structured interviews to explore patients' opinions of MURs, 8 of 23 patients criticised the size of the consultation room although no-one raised the issue of lack of confidentiality or privacy (Iqbal and Wood 2010).

- The Pharmacy as a place for the VRA service

Peterson et al. (2010) reported that 97% of respondents regarded the community pharmacy as an appropriate place for such a service. In the present study survey the following statement was the third most commonly reason selected (by 26% of participants) as the reason for having the test in the pharmacy: "It's more convenient than making an appointment with my doctor". Only 2% agreed with the following statement: "I would rather have had this health check in my doctor's surgery." This may suggest that the pharmacy is seen as a convenient place to access and to receive services by at least some individuals. Of course, those accessing the service were self-selecting and those who would prefer such a service from their doctor or nurse would be expected to be less likely to have participated.

- Waiting time for the assessment

Horgan et al. (2009) stated that respondents criticised the waiting time for the assessment. Horgan et al. (2009) stated, also, that most of respondents (128, 73%) were able to access the service straightaway. The promptness of the service considered one of the advantages of the community pharmacy. However, the survey conducted by Horgan et al. (2009) did not prove that the service was available most of the time for walk in customers; it only showed

that most of the respondents had the assessment straight away. It would have been more useful to determine the proportion of people who were sent away because of the unavailability of the service. In the present study, however, this was not measured in this survey as the majority of participants had to book an appointment because the service was provided on a specific times/days of the week.

- Information provided to the service users

The clarity of information was criticised by one respondent to this survey. This issue was raised also by three respondents in the study conducted by Horgan et al. (2009). However, the vast majority of the respondents in the present study agreed (43%) or strongly agreed (56%) with the following statement "The pharmacist explained everything to me in a way I could understand".

- Reason for requesting the VRA service

The majority of the respondents (84%) in this survey chose the following statement as their reason for requesting the assessment: "it was an opportunity to have my health checked out". Only 2% indicated that they had the assessment to confirm the results of a similar check they had elsewhere. Although this is a small percentage, test duplication is a major issue and should not be overlooked as it can affect the cost-effectiveness of the service, for example, if the NHS were to pay.

One respondent in the present study stated that they would have preferred to have the service at a GP surgery as she was known to the GP. Iqbal and Wood

(2010) reported that with regard to another service (the MUR) one patient was known to the pharmacy which made it the preferred place over the GP surgery. This emphasised the importance of engaging with pharmacy users.

- The questionnaire and questions

Thirty-five respondents stated that they had a similar check in the past. It is unclear whether or not they had a full VRA on a previous occasion or by similar check they meant any element of the assessment, for example, a cholesterol test. Therefore, this question was not as clear and should be changed if the survey is to be repeated. The instrument was not piloted, although it was subject to review by academic colleagues. The reason for not piloting was that this was a new service and that limited numbers would be recruited and we wanted the same questions asked of all respondents.

Although the majority agreed (47%) or strongly agreed (48%) with the following statement: "The pharmacist informed me about the results of the tests without making me worried", more respondents were worried after the service than before. One explanation that they were happy with the way the message was delivered even though the results were not as they hoped. One respondent stated a similar opinion: *"If the results of the consultation are not entirely positive its difficult for the pharmacist not to worry you!..."*

3.4.1 Limitations

The questionnaire used in this survey was constructed through searching the literature and then the identified instruments were discussed with academic supervisors and used. Only one of the instruments found during the search (Stewart et al. 2008) was derived from rigorous qualitative work but it should be noted that it was not developed for evaluating a VRA service. Not having the instrument formally subject to a pilot is another limitation.

Although the response rate was high, a limitation that may affect generalisability to the service users is that non-responders may have held different views. There is evidence to suggest that when people are less satisfied with the care provided they are less likely to respond to a satisfaction survey (Naik Panvelkar et al. 2009).

The use of anonymous questionnaires prevented linking of responses to the questionnaire with the results of the VRA. There is a possibility that those who were identified at low risk were more satisfied than those who were at high risk. Also, those who were referred to their GP may have found the service more satisfactory. Peterson et al. (2010) coded the questionnaires so the results in their study were linked and therefore, these were confidential rather than anonymous questionnaires. We had decided, however, against any coding as this would involve a third party to handle/analyse the data. Also, it was hoped that by omitting the codes we would avoid preventing negative responses and would achieve a high response rate.

3.4.2 Further Work

For future research it would be important to develop a validated instrument specific for the measurement of satisfaction of those who access the VRA service at the community pharmacy. Some of the questions may not have been as clear to the participants as we would have liked. For example, it was not clear whether respondents who indicated that they had a similar check in the past had a full VRA or cholesterol only. Also, one respondent stated that although her trust in the pharmacist improved as a result of the VRA she disagreed with the following statement: "My trust in the pharmacist remains the same after the cardiovascular risk assessment service."

Reasons why those who wanted to have the service at a GP surgery, although the numbers were small, selected to have it at the pharmacy are unknown. More work needed to investigate this.

3.4.3 Conclusion

The anonymous survey of those who accessed a community pharmacy based VRA service showed high satisfaction and acceptance with the service by those who returned the self-complete satisfaction questionnaire. Most service users were made aware of the VRA after having seen an advertisement in a local newspaper. The venue was considered convenient in comparison to the doctor's surgery to receive this service by one third of the respondents.

Chapter 4: Views and experiences of those who accessed the VRA service – the two-week follow-up telephone interview

4.1 Introduction

This chapter presents a study reporting the short term outcomes through a semi-structure telephone interview with the VRA service users which was conducted approximately two weeks after accessing the service.

Community pharmacy based services, including the VRA service, require more research in order to demonstrate the value of these services for the patients and healthcare system (Roberts and Kennington 2010b). Research on quality and outcome is essential to help the continuity of pharmacy practice to evolve in response to changing healthcare needs and marketplace competition (Roberts and Kennington 2010a). The effectiveness of a service has been determined by evaluating patients' knowledge, skills, expectations and acceptance as well as by evaluating short and long term clinical outcomes (Bereznicki et al. 2011; Cranor and Christensen 2003; Naik Panvelkar et al. 2010).

The time specified for the follow up to measure the short term outcomes depends on the type of the concerned outcomes. Improvement in clinical outcomes in a study evaluating pharmacist intervention was measured seven to nine months after the first intervention in one study (Cranor and Christensen 2003). The final follow up in a study evaluating adherence to medication among diabetic patients was at six months after the initial pharmacist intervention (Clifford et al. 2006). However, the follow up was conducted straight after an educational campaign on public attitudes towards antibiotics in a study assessing the impact of such campaign (Radosevic et al. 2010). Similarly, in a study focusing on pharmaceutical care to hypertensive patients,

the level of knowledge was assessed before and after the intervention but the final assessment was six months later (Oparah et al. 2006).

Semi-structured interviews have been used as a method in pharmacy practice research to assess the level of knowledge of a specific condition, the ability to self-manage their condition and to determine patients' expectations and acceptance to a service provided by the pharmacy. Also the semi-structured interview has been used to evaluate patient satisfaction (Bereznicki et al. 2011; Naik Panvelkar et al. 2010).

In order to try to minimise interviewer bias, it is important to determine who should conduct research interviews and how much the interviewer should know about the research subject. Although it is advisable that the interviewers familiarise themselves with the aim and objectives of the research project, it is also important that some information which could bias the interviewers or compromise their objectivity should not be shared (Waltz et al. 2010).

Although the improvement in clinical outcomes has been used by most research on patient commitment to change or adherence to the advice provided by a healthcare professional, there are certain research areas where self-reporting is used as the main methodological strategy, for instance when assessing outcomes in smoking cessation studies (Velicer et al. 1992). Assessing patients' knowledge, understanding of the advice and their attitude towards certain behaviours can be useful to predict the possibilities of following the advice provided by the pharmacist as there is a link between

patients' beliefs and behavioural changes, according to research conducted on health behaviour change (Nutbeam and Harris 2004).

The aim of this follow up was to explore the users' views and experiences by a researcher who did not undertake VRA.

The objectives of this study were to:

- Explore participants' views of the pharmacy as a place to provide the VRA service.
- Identify reasons for undergoing the assessment.
- Examine the participants' recall of, and compliance with, the advice given by the pharmacist.
- Determine the number of participants who reported taking action to reduce their CVD risk or made any changes to improve their lifestyle.

4.2 Method

Individuals who accessed the VRA service (Section 2.2 for more details of the service) in Porthcawl and Merthyr Tydfil were invited to participate in a follow-up to explore their views and experiences. Those who agreed were asked to indicate in the consent form (Appendix 2) – the preferred method - whether they preferred to have a telephone interview with a researcher (other than the research pharmacist) or to complete a form they would receive in the post.

The two-week follow-up interview was the first follow-up planned to take place approximately two weeks after accessing the VRA service. A methodology consisted of a semi-structured interview was chosen in order to cover specific issues with the regard to the VRA service and in the same time to provide the opportunity to the participants to elaborate on matters when they felt it was necessary. This approach was the most appropriate to answer the study objectives; studying both specific issues (identifying reasons for accessing the service) and broad issues (exploring participants' views). Also, the telephone interview was used as opposed to face to face interview to maximise convenience to the participants and increase the response rate (Smith 2010). An interview schedule (Appendix 11a) was developed and it consisted of two main parts; about the participant background and the assessment they had at the pharmacy. After an introduction and confirming the participant was on the telephone, the interview started with questions to gain a brief background about the participant including, how the participant was made

aware about the service, whether or not he/she had a similar check in the past and the reasons for deciding to have the assessment at the pharmacy this occasion and whether or not they knew anyone with CVD. Then there were questions about the tests and advice they had received.

A researcher (DNJ) who did not provide the VRA service contacted the participants, who consented, to conduct a semi-structured interview over the telephone (Appendix 11a). Otherwise a form (Appendix 11c) was sent by post to those who did not consent to have the telephone interview and to those who could not be contacted by telephone.

The interviewer was only provided with the contact details of the participant, date and time the assessment was undertaken and whether or not the Framingham based 10-year CVD risk was calculated (and communicated to participants). The interviewer was not provided with any other documentation or information prior to the interview in order to reduce potential bias.

The telephone interview was audio-recorded. When participants filled in the consent form they indicated if they were happy for the interview to be audio-recorded. The interviewer confirmed that they were still happy with having the conversation audio taped before the start of the interview. If the participant did not want the interview to be recorded the interviewer did not record the interview and instead made brief written notes.

All recorded interviews were transcribed *ad verbatim* by an independent transcriber. A code was given to each participant to ensure confidentiality.

Each code was double-checked to ensure that all transcripts were linked correctly to the same record in the data set collected during the VRA. All quotes used were double-checked by the researcher (SW) and confirmed to be *ad verbatim*, by listening to the tapes and reading the transcripts. The transcripts were anonymised during transcription. Data were subjected to descriptive content analysis, that is, transcripts were reviewed to identify responses to the questions in the schedule and were then categorised and coded systematically (Neuendorf 2002). Data are presented as frequencies. Qualitative excerpts from interviews have been used in the results section of this chapter to provide examples of responses under each theme.

The satisfaction with the service was determined by the anonymous questionnaire that participants were asked to complete and send by post and is reported in Chapter 3. However, in this follow-up participants were asked whether or not they had recommended the service. This type of question usually is seen in satisfaction surveys as an indication of how well the service is perceived by the service user. Some participants also chose to express their satisfaction when they answered the open question at the end of the interview;

- Is there anything that you would like to tell me about the test or the service at Boots that I have not asked you about, something that we have not covered?

Inclusion criteria

All participants must have consented to have the follow-up and undergone an assessment at Boots, Porthcawl or Merthyr Tydfil during the period between 4th November 2009 and 5th August 2010.

Study population

All participants of this study were invited to participate in the follow-up telephone interview.

Ethical considerations

Ethical approval was sought and obtained from the Welsh School of Pharmacy Research Ethics Committee (Section 2.2.1.2). The consent form included a section against which participants could indicate whether or not to participate in this stage of the research and if so, if they wished to be interviewed by telephone interview or to be sent a form in the post. Additional verbal consent was obtained by the interviewer at the beginning of the telephone interview for the interview to be recorded. The participants were reassured that no sensitive information would be discussed and they had the option to ask for the recording to be stopped whenever they felt it should stop. Transcriptions were anonymised to maintain confidentiality and a unique code was used for each participant.

4.3 Results

4.3.1 Overview

Out of the 163 who consented to have the two week follow-up, a total of 153 participants completed the telephone interview after undertaking the VRA at Boots and six completed the posted questionnaire. The remaining four could not be contacted. One-hundred and twenty four participants accessed the service at Boots, Porthcawl and 35 participants at Boots Merthyr Tydfil. Total response rate was 92% of all service users (159 out of 172) who had accessed the VRA service between 4 November 2009 and 5 August 2010.

Participants had the follow up interview on average 23 days (SD = ±10.6) after they had accessed the VRA service (range from 14 to 91 days; mode = 19 days).

An example interview is included (Appendix 11b).

4.3.2 Identified themes

During the interview transcription and analysis process, themes and sub-themes were identified (Table 4-1).

Table 4 - 1 Identified themes and sub-themes

Themes and subthemes
1. Awareness of the service
2. Similar test in the past:
2.1. Setting of previous test
3. Awareness of any relatives, friends or acquaintances with CVD
4. Reasons for undertaking the tests
5. Framingham risk communicated during consultation:
5.1. Recall of Risk
5.2. Referral to GP outcome
5.3. Feelings when risk was communicated
5.4. Usefulness of being told risk
6. Attitudes towards lifestyle advice:
6.1. Alcohol
6.2. Diet
6.3. Weight
6.4. Smoking status
6.5. Exercise
7. Changes in lifestyle or medications as a result of the VRA
8. Satisfaction with, and recommendation of, the VRA service:
8.1. Satisfaction with the service
8.2. Recommendations of the service

4.3.3 Awareness of the service

Most (n = 61) participants in the study were made aware of the service from an advert placed within the pharmacy (either a notice on the pharmacy counter or a leaflet) (Table 4-2).

Table 4 - 2 Participants were made aware of the service from different sources

Source of information about the service	Number (%)
An advert placed within the pharmacy	61 (38)
An advert in the local paper	60 (38)
Informed by a family member or a friend	27 (17)
Informed by pharmacy staff	8 (5)
A leaflet from a local caravan site	3 (2)

4.3.4 Similar tests in the past

There were 34% (n = 54) of participants who had undergone a similar test to the VRA in the past.

The most common setting where the participants had a similar test in the past was in a GP practice (n = 36):

> *"Well I do have one with my surgery. Sometimes they go down, they take my, they cholesterol, and they take my blood pressure, and my sugar level well basically."* (Subject 117)

Other participants that had undertaken similar tests in the past were at varying settings, included hospital (n = 1), insurance company (n = 1), workplace (n = 8) and a community pharmacy (n = 1). Seven participants did not specify the place where they had the similar tests in the past.

4.3.5 Awareness of any relatives, friends or acquaintances with CVD

Participants were asked whether they knew people, including family members, friends, colleagues or neighbours who were suffering from a CVD. About a quarter (n = 41) of participants mentioned one person only who was living or had lived with a CVD, 19% (n = 29) mentioned two people, and 35% (n = 54) mentioned three or more:

> *Interviewer: is there anybody in your family who has or has had heart disease*
> *Subject 16: yes*
> *Interviewer: ok and if you don't mind me asking who would that be... what relation?*
> *Subject 16: my father's side is my father um all his brothers have had heart problems... his sister.*

Twenty-five (16%) people said they did not know anyone suffering from CVD.

4.3.6 Reasons for undertaking the tests

Participants were asked about the reasons which prompted them to undertake the VRA. Just less than a third of participants (n = 48, 30%) gave a general reason such as:

> *"I just thought it was good it was just a good opportunity to do a lot of things in one go really have a few tests in one go"* (Subject 28)

> *"well it was for both uh myself and my husband uh really just to you know sort of check out on our health and um uh you know to see if um uh we need to change our lifestyle really"* (Subject 85)

The service was considered by five participants as a good opportunity to double check the results of tests they had at GP surgery:

> *"Basically um I'm coming up 75 I normally have them done fairly regular with the doctor... so I thought I'll just double check type of thing you know"* (Subject 1)

Risk factors (Table 4-3) were mentioned by participants as reasons for requesting the VRA. Age was the most common risk factor mentioned:

> *"I'm 60 next year and uh just to find out the lay of the land really"* (Subject 4)
>
> *"um it was just because I'm getting older now and uh thought I take the precaution you know it was offered as a free test so I went for it"* (Subject 27)

Table 4 - 3 Risk factors mentioned by participants as reasons to undertake a VRA

Reason	Number (%)
Age	37 (23)
To check cholesterol level	24 (15)
Family history of CVD	21 (13)
Being overweight or obese	13 (8)
To check blood pressure	10 (6)
Medical history of CVD	7 (4)
To have a Diabetes test	4 (2)
Poor diet	3 (2)
Waist size	1 (1)

BMI, diet, family history, cholesterol, blood pressure and diabetes were also mentioned by participants as reasons to access the VRA service:

> *"um well just my wife and uh myself we I suppose were both concerned about our weight at the moment and uh had nothing to lose by going sort of thing"* (Subject 60)

> *"well I'm overweight"* (Subject 8)

> *"Basically, to kick start me going on a diet really, and trying to get a bit healthier, so yeah."* (Subject 126)

> *"mainly because um my father died of um a stroke and I was a bit just concerned about sort of whether there were any factors that I could do to sort of prevent there's a bit of a medical history of sort of heart attacks and things in the family I wanted to see whether or not if I was at risk of anything"* (Subject 39)

> *"I was keen to get my um to find out what my cholesterol was"* (Subject 35)

> *"Well I have been having problems with blood pressure, and I thought well have it checked up"* (Subject 88)

> *"I was a little concerned I think about um maybe diabetes because I'm a bit of a chocoholic"* (Subject 78)

Seventeen participants mentioned two or more risk factors which prompted them to request the VRA:

> *"Well, you know, I'm nearly 50, and I thought, you know, that's the sort of time you need to keep an eye on your health, I think. Probably, felt like I could lose a bit of weight, so I thought I better have a check and see what came up, you know? Cholesterol levels, that sort of thing."* (Subject 132)

Other reasons for accessing the VRA service, other than the classic risk factors, participants mentioned; convenience (n = 4) and being encouraged by a relative or a friend (n = 9).

One participant added that finding out about CVD risk as one of the reasons which prompted to decide to have the tests:

> *"Well that's partly why I went as well because it says that they will tell you that [the CVD risk]"* (Subject 38)

A further four participants mentioned other reasons which could not be linked to the nature of the tests or the risk factors

> *"I've had quite a low period over the last few weeks at myself personally and um I was sort of trying to sort of um alleviate sort of and put myself back on a even keel so I thought well you know some good positive news or some bad news might motivate me to do something about it you know what I mean"* (Subject 11)

> *"because I haven't been feeling good over the past months"* (Subject 83)

4.3.7 Recall of Framingham risk communicated during consultation

Participants who had their risk calculated (n = 136) were asked during the interview if they could recall the pharmacist talking about the CVD risk, either in terms of high, moderate and low risk, or as a percentage.

The majority (n = 96, 71%) of participants who had their risk calculated successfully recalled their individual risk in comparison with their record in the main study results (Chapter 2).

However, 40 participants (29%) were unable to correctly recall their risk. Some participants discussed other results calculated during the VRA:

> *"He said, with the problem I have, I tend to have blood pressure, which goes up and down..."* (Subject 89)

The participant went on further to discuss the results of their BMI:

> *"Quite pleased with the results, yes, you know, he said it was about 23% my body count (sic), it was about 23."* (Subject 89)

As shown in Table 4-4, participants who were found to be at low risk were more likely to recall the CVD risk as communicated by the research pharmacist than those who were found to be at high risk ($p < 0.001$, Pearson Chi-square). Twenty-five (19%) participants understated their CVD risk:

> *"Well he didn't leave me with an impression that I was even a moderate risk, I think I'm low."* (Subject 33, moderate risk)

On the other hand, five (8%) participants overstated their CVD risk:

> *"I think I was a medium with the blood pressure. The blood pressure was up a bit."* (Subject 120, low risk)

Table 4 - 4 The number (%) of participants who were able, or otherwise, to recall CVD risk as communicated by the research pharmacist. ‡ One participant said she had no risk. † Including those 8 participants who said their risk 20% instead of "more than" 20%

Risk of CVD	Recalled	Understated	Overstated	Unable to recall/ unclear
Low	50 (82)	1‡ (2)	5 (8)	5 (8)
Moderate	34 (79)	6 (14)	0	3 (7)
High	12 (38)	19† (59)	0	1 (3)

A further six participants could not remember discussing specific risk with the pharmacist researcher:

> *"No, didn't mention it."* (Subject 125)

Some participants did not fully understand how the Framingham risk percentage was interpreted in terms of high, moderate and low risk:

> *"I think it was moderate to high I think, or 20%, I don't know, that's moderate is it? I'm not sure. It was about 20%."* (Subject 132)

> *"I think I've got it here; the risk was 10 to 20%. I don't know if that is small, not sure to be honest with you."* (Subject 124)

Some participants were not convinced that the risk score provided an accurate reflection of their risk. Participants believed they were at lower risk than that calculated by the pharmacist researcher:

> *"Well, I'm not actually disputing, but I don't agree, I disagree with a bit of what they said, they said I was at high risk, but I sort of exercise as I go out to work, he said I was overweight, but I don't think I was that overweight..."* (Subject 115)

> *"20%, in his opinion, considering. Well, I don't know how he can say that, you know, he sort of diagnosed that I was somewhat overweight, except that I personally know that I do things, regards exercise, daily for years no, which entitles me to believe that internally, regards cardio, and so on and so forth, I should be OK, like."* (Subject 139)

However, one participant who was also at high risk was of the opinion that the score was an accurate reflection of their risk, taking into account individual risk factors:

> *"Well, taking account of my age, and what-have-you, and you know, I suppose that's a reasonable, and of course, I'm slightly overweight a bit. I thought I was fairly reasonable prognosis, you know?"* (Subject 146)

4.3.8 Participants referred

As a result of the VRA, 51 (32%) participants had been referred to GP for further investigation. By the time of the two week follow-up, 45% (n = 23) of all those who were referred visited their GP:

> *"yes I took um the pharmacist suggested I go which and took the results with me and I went the following day"* (Subject 47)

Further 14 (27%) participants indicated that they intended to visit their GP to discuss the results:

> *"I've arranged a follow up test in the doctors"* (Subject 27)

However, 12 (24%) participants (7 of them were identified at high risk) did not intend visiting their GP practice. One participant openly stated:

> *"I don't see any urgency; I haven't been actually and don't intend to…I don't feel any urgency to go to the doctors if I'm honest"* (Subject 146)

One participant agreed to discuss the results with the doctor but admitted that he could not see the value of it:

> *"Well yes... I'll go and see what the doctors got to say now and... I think personally it's a bit of a waste of time, but there we go we'll go on his recommendation"* (Subject 6)

Two participants were referred but the issue of seeing the GP was not discussed during the interview.

4.3.9 Usefulness of participants being told individual risk

Participants who had had their CVD risk calculated were asked if it was useful to be told of their individual risk (14 out of 136 were not asked this question). The majority (n = 118, 87%) believed it was of use:

> *"Oh yes, yeah, yeah, yeah. You were just confirming what I knew already, yes."* (Subject 136)

> *"uh yes... well I just think uh if it had been the other way and it had been high risk I could have done you know something to change my lifestyle really"* (Subject 65)

Only four participants thought it was not useful to be told the individual risk of developing a CVD. One participant believed it was not useful to be told of their risk of future CVD:

> *"Not for me no…"* (Subject 126)

The other believed it was not useful to her, but it was useful to her husband due to his weight:

> *"Not for me personally, because I just felt that everything I do with my life is OK, but having said that my husband is two stone overweight and I know that, and I think him being told that by somebody else was useful."* (Subject 137)

One participant who was found to be at high risk could not see the usefulness of being told the individual risk of CVD:

> *"That's a moot point, I was alright going in, I felt worse coming out."* (Subject 121)

One participant thought it was not useful because it reminded her of losing her mother at a young age:

> *"no no and you know it was a pain I mean I was only 20 when my mother died and it was quite a painful thing always been a painful thing for me so it just brings that back really"* (Subject 2)

4.3.10 Attitudes towards lifestyle advice

Advice on maintaining a healthy lifestyle was provided by the pharmacist researcher during the VRA. The results are discussed under five sub-themes: namely alcohol intake, diet, weight, smoking and exercise. The follow-up interview explored participant recall, compliance and barriers to advice provided by the pharmacist researcher, information to which the interviewer was unaware.

Alcohol intake

The Boots service questionnaire required participants to state how many units of alcohol they consumed on a weekly basis (Appendix 3a). The form provided examples of what beverages constituted to particular units of alcohol, thus enabling the participant to calculate their weekly intake. There was generally a lack of understanding of the interpretation of alcohol intake, particularly in terms of volume and concentration:

> *"My alcohol intake is very moderate, I live on my own, so very cautious about not wanting to have alcohol, drinking on my own. So socially, when I have friends or family here, or when I'm with friends or family. But equally if I have a special Sunday roast, then I will open a bottle of wine, [unclear] you know. Then I'm quite happy to do it, but it would last, a bottle would last me 4 days, so I don't think to heavily."* (Subject 141 – 3 units weekly)

> *"It was discussed, yes. And I drink moderately. Red wine twice a week, usually."* (Subject 143 – 2 units weekly)

Participants were sometimes vague in terms of the alcoholic beverages they consumed weekly, often unable to explain the full extent of their habits:

> *"…he said what is your intake of alcohol? And I said, very little."* (Subject 120 – 0 units weekly)
>
> *"…few bits and all that."* (Subject 139 – 20 units weekly).

Furthermore, one participant alleged that individuals are untruthful when it comes to explaining their alcoholic habits, often underestimating their intake:

> *"Yes, I give him my units and he said that was alright. Nobody tells the truth about alcohol units do they? They don't do they, it's one of those thing isn't it, they always knock about 5 pints a week off, at least. But he said it was alright. I got a feeling he didn't quite understand what I said so I didn't push him on it."* (Subject 121 – 12 units weekly)

Two participants admitted to drinking in excess of their weekly allowance, both individuals accepted the pharmacist's advice in attempting to reduce their intake in the future. Their comments came 20 and 19 days, respectively, following the VRA:

> *"Yeah, we mentioned that [alcohol] …it can be decreased. It wasn't excessive..."* (Subject 125 – 24 units weekly)
>
> *"I will reduce the amount of units of alcohol I drink in a week."* (Subject 123 – 18 units weekly)

One participant was inconsistent in the number of units provided on the data collection form with the figure given during the follow-up interview:

> *"I don't think he was concerned about it [alcohol intake], I was quite truthful, I said 15 units a week."* (Subject 122 – 12 units weekly)

Diet

Participants were given the options during the consultation of stating to the pharmacist researcher that they either ate at least five portions of fruit and vegetables everyday or whether they did not:

> *"…we have a pretty good diet…the diet we're on, we always have our 5 fruits and veg."* (Subject 131)

Not all participants accepted the advice provided by the pharmacist, as they disliked the food type that was recommended:

> *"I don't particularly like fish to be honest."* (Subject 137)

> *"…we do try to watch our food. My husband eats a lot of fruit, but I'm not a fruit lover. So I don't eat so much fruit as I should."* (Subject 117)

Weight

About a fifth (22 out of 120) of participants who were informed that they were overweight and have been recommended to lose weight disregarded the information and advice provided:

> *"He said I was overweight, but I don't think I was that overweight."* (Subject 115)

One participant stated:

> *"Now I'll be honest with you, if I was 11 stone 10 or 8 stone 10, I would look seriously ill."* (Subject 124)

One participant believed it was not an ideal time of the year to lose weight:

> *"It's the wrong time of the year to diet."* (Subject 116)

Two participants had concerns relating to the methods used in measuring individual weight. One issue related to confidentiality:

> *"The discussion of my weight took place there [on the shop floor], rather than back in the consulting room…I mean I wasn't unduly upset about it, but I don't think it was, it would've been better to have kept it in the consulting room…the scales are in the middle of the store so I mean I was quite happy about that, but I think the discussion should've taken place in the consulting room."* (Subject 134)

The other related to the methods used in measuring individual weight:

> *"…when I was weighed and I said shall I take my shoes off and the pharmacist said it's up to you, when I think if you're looking at body mass index there should be a more consistent approach to weight. I know your shoes and your coat are only a relatively small amount but to somebody like me who was 3 or 4 pounds overweight, that could make quite a difference, you know what I mean? I did think it should be more consistent and that should everybody should be asked to take their shoes and coat off or nobody should."* (Subject 137)

One participant noted that it would have been of use to have been put in contact with a dietician:

> *"No, he weighed me and, what I have, on everyone of these tests that I have, including the one in Porthcawl, what'll be a good idea at the end of them, if they say you've got to diet, or something like that, is to put you in touch with the dietician."* (Subject 128)

One participant commented that it would have been useful if the annual consultation follow-up was sooner, therefore would be more likely to modify their lifestyle:

> *"…when I discussed it with the lady who recommended, who told me about it, we agreed that it would have been more helpful to*

> *use if we've been returning sooner, rather than in 12 months. We would've been more likely to modify our lifestyle, diet etcetera, if we've been say going back in 2 months or something, you'd see a difference in my weight."* (Subject 138)

Smoking

The data collection form gave the participants four options relating to smoking habit: 'never smoked', 'quit over five years ago', 'quit within the last five years' or 'current smoker' (Table 4-5).

Table 4 - 5 Smoking status of participants who had the two week follow up interview (n = 158)

Smoking status	Number (%)
Never smoked	98 (62)
Quit over five years ago	49 (31)
Quit within the last five years	6 (4)
Current smoker	5 (3)

One participant who had quit smoking over five years ago described his smoking habit prior to quitting:

> *"I did yeah, but I used to smoke, I smoked a pipe for 30 but I haven't smoked for 15 years at least."* (Subject 127)

Some participants who had previously smoked did not expand on their past habit:

> *"Well he just asked if I smoked and I said no."* (Subject 130)

One participant stated on the data collection form that they had never smoked, however somewhat inconsistent with their previous response to the data collection form:

> *"No, I don't at the moment. I did smoke when I was in school, which is 30 years ago. I did smoke for about 4 or 5 years until the age of 28 or 29."* (Subject 122)

There were five smokers in the study and the pharmacist signposted them to a helpline:

> *"Yeah, he did actually say that, [cough] excuse me, there was a help line, I think, that I could get in touch with if I wanted to. So I, actually he wrote it down, for me. I haven't done anything about it yet though, unfortunately."*(Subject 144)

The difficulty of changing habits with regard to smoking was reflected during the interview with one participant:

> *"Yeh so let's hope I can achieve either both give up smoking or lose weight or at least one isn't it."* (Subject 9)

One participant was not clear about the advice he received with regard to smoking:

> *Interviewer: did he talk about smoking with you?*
> *Subject 153: yeh he did yeh yeh*
> *Interviewer ok and is that did he advise you to try and cut down or...*
> *Subject 153: yes yeh*

Exercise

The majority of participants interviewed who did not undertake regular exercise, and did not suffer from concurrent conditions were aware that they did not undertake enough exercise. They accepted the advice and were actively looking to increase levels of physical activity:

> *"I have just retired, so hopefully I'm going to get a dog."* (Subject 128)

> *"Yes, he said, I could do. Could do a bit more exercise, I'm determined to go swimming this year"* (Subject 89)

Some of those who were advised to improve their exercise intensity and regularity provided at least one reason as to why they have not accepted the advice. There were three themes: injury and morbidity factors, time limitations and weather conditions.

Injury or morbidity factors acted as a barrier to six participants in accepting the advice provided by the pharmacist:

> *"I can't do a lot of exercise, you know, training, because I've got two detached tendons in my ankle so I'm a bit limited"* (Subject 135)

> *"I told him I do exercise. I walk down town every day, but my problem was I used to play a lot of golf and I got this arthritis in the back and the neck and I've had to pack up golf…"* (Subject 121)

Being too busy was a reason for not undertaking regular exercise:

> *"He asked me if I exercise and I said no not really, but I'm just a very, very busy woman anyway. I'm always on the go."* (Subject 144)

> *"…I'm extremely busy…"* (Subject 143)

One participant stated that he was unable to take part in more regular exercise due to the extreme weather conditions:

> *"…I told him I exercise. I used [unclear] I don't know, about 3, 3 and a half miles from work, so usually cycle if the weather's good, unlike this time of the year, where I do a lot less, obviously."* (Subject 115)

4.3.11 Changes in lifestyle or medications as a result of the VRA service

In this section, the data about any initiation of change is presented while Section 4.3.10 presented the ability to remember the advice and whether or not they accepted the advice. Even though there was no direct question in the interview schedule to ask participants what changes they have made, some participants provided some information about this matter. About a third (n = 52) mentioned at least one change in their lifestyle or medications. Only one person said he had been prescribed a medication by the GP:

> *"yeh I took the referral letter from Boots over to the GP's and the doctor did another test again, it was high... so she prescribed some medication"* (Subject 17)

A further person (Subject 34) who already was on blood pressure treatment said that the doctor had doubled the dose of his medication:

> *"pharmacist said because I think it was my blood pressure was quite high it was reading um I did go back to the doctor although he found it a lot lower than the pharmacist found um he did uh double my dose of my medication"* (Subject 34)

Four participants said they started to take a fish oil supplement since they had the tests at the pharmacy.

Most participants (n = 28) who mentioned the lifestyle changes said they have improved diet since they had the tests:

> *"I don't put salt on to anything but of course since I've been there actually I tend to look at things I buy and I have had quite a shock*

> *as to the content of salt in various foods that I didn't think you know were a high risk."* (Subject 5)

Thirteen participants said they have been trying to lose weight, including one participant mentioned the waist size:

> *" he did say like 4 inches off my waist and since he told me I am more wary of it then"* (Subject 40)

Starting or doing more exercise was mentioned by 11 participants:

> *"I've started swimming and everything and walking."* (Subject 19)

Five participants said that they reduced alcohol consumption:

> *"I told him how much how many years I've been drinking... and I know myself it's far too much and since I've been there I've cut down I've cut down at least 25 units a week"* (Subject 111)

A further participant did not give the details of the change she had made:

> *"I tend to take more notice now of what I'm doing and how it affects me."*(Subject 45)

4.3.12 Satisfaction with, and recommendation of, the VRA service

Recommendation of the service

Participants were asked if they had recommended the service to anyone. Almost two third of participants (n = 103, 65%) had recommended the service to at least one person:

> *Interviewer: Have you recommended the Boots service to anybody else, if you don't mind me asking?*
>
> *Subject 141: I have, yes. Quite a few of my friends. I think about 4 of have already, 3 of the have certainly had it and I think*

> *there's another one, who has an appointment made to come down some time fairly soon.*

A further 43 (27%) participants who had not recommended the service stated that they would in future if an opportunity to do so arose and it was appropriate for them to recommend the service:

> *Interviewer: Have you recommended the service to anyone else that you can remember?*
> *Subject 117: No, I don't think we have. No, I don't think we have. The advert is, was on the counter in the pharmacy in Porthcawl, in Boots.*
> *Interviewer: Do you think you would recommend it, or make people aware of it, or is it something that you wouldn't do?*
> *Subject 117: Oh I would yeah, absolutely, not a problem at all.*

One participant has not recommended the service, however, this was mainly due to a family bereavement:

> *Interviewer: Have you recommended the risk assessment to anybody else?*
> *Subject 145: Well I haven't really, no…*
> *Interviewer: Because of the circumstances?*
> *Subject 145: Yeah.*

Those who did not, or would not, recommend the service gave reasons other than dissatisfaction:

> *"Not really because most of my friends are ok I think... you know"* (Subject 99)
>
> *"No I haven't... I don't have many friends really"* (Subject 93)
>
> *"it was well advertised and it's up to people to take advantage of it really"* (Subject 1)
>
> *"I don't pressurise or recommend things to anybody really...[] because you know it's really really personal"* (Subject 76)

Satisfaction with the service

Some participants expressed their satisfaction with the service and with the pharmacist:

> *"...yes I enjoyed the experience with him"* (Subject 4)
>
> *" well he [the pharmacist] did which I thought was very good he did actually explain the cholesterol result which I've which has never been explained to me before so I thought that was quite good because then I understood it better"* (Subject 38)
>
> *"He [the pharmacist] was ready which suits me because I'm not one that likes to hang around for half hour for people, everything was prompt everything was done as I would have expected it to be done"* (Subject 52)

However there were some participants who criticised certain elements of the service, such as the reaction of Subject 2 and Subject 121 when they were asked about the usefulness of being told individual risk (Section 4.3.9). Also Subject 134 was critical of the place of the weighing machine which was reported as being in the middle of shop. Another example of a criticism of the service was from one participant could not have the full range of tests because he was on warfarin:

> *"It was only that factor I think because I travelled from Cowbridge down to Porthcawl I might have I might have thought twice if... if I'd known beforehand if somebody said to me there's a limited amount you can ask beforehand because they are just booking the appointments at Porthcawl the girls do there you know... if somebody had asked me are you on any drugs such as warfrin something like that I would have then told them and they could have explained to me well we will be able to do these tests but we won't be able to do the others"* (Subject 28)

4.4 Discussion

The two week follow-up interview was a useful method of gaining an insight in the participants' views of the service. It also captured short-term self-reported outcomes including lifestyle changes or starting pharmacological therapy. The two week follow-up interviews gave participants the opportunity to comment on the service and to express their level of satisfaction to an individual who did not provide the service. It allowed the exploration of the views and perceptions of 92% of the service users.

The general literature review presented in Chapter 1 was also relevant to this study. There is a gap identified in the literature for studies conducted in the UK that explored the views and experiences of individuals who have accessed community pharmacy based VRA service. As this study was an exploratory a qualitative method was the method of choice (Kairuz et al. 2007). A semi-structured interview, rather than an in-depth interview, was chosen because of the intention of including all participants rather than a small sample in this follow-up. Semi-structured interviews have been widely used in pharmacy practice research as a data collection tool (Abu-Omar et al. 2000). Qualitative analysis of the collected data from interviews of varying depth including the semi-structured interviews can be helpful in exploring the reasons behind the decisions people make in certain situations (Kairuz et al. 2011). A method involving telephone interviews has been used in pharmacy practice research conducted in the UK particularly when the opinions and views of pharmacists and pharmacy staff were being explored (Cowley et al. 2010; Crabtree et al.

2010a; Paudyal et al. 2009). This study has shown that the telephone semi-structured interview is useful with patients as well. It reduced the time constraints on both the participant and the researcher and helped to achieve a high response rate.

Patient satisfaction with the VRA service was measured by an anonymous survey (Chapter 3) and also by giving the opportunity to participants during the two week follow-up interviews to comment on the service in general. Using two different methods approach to examine the same issue, that is, triangulation, is useful to increase reliability of the results (Kairuz et al. 2007). It is acknowledged that it was not possible to link response provided in the questionnaire immediately post-consultation (as these were anonymous) with individual responses at interview.

The aim of having a researcher who did not provide the VRA service to conduct follow-up interviews was to provide a situation in which the participant could comment freely on all elements of the VRA service. Subjects were aware that the interviewer was from the Welsh School of Pharmacy although he was independent of the VRA service. The interviewer had the opportunity to examine short term outcomes including any changes made by the participants, their knowledge of CVD risk, and compliance with referrals to health professionals. There is a consensus among researchers that an independent evaluation is important to attempt to increase validity to the findings (Smith 1998).

More than two-thirds of participants had their follow-up interview between 14 and 21 days following the tests at the pharmacy. While it was planned that the telephone interview should take place approximately two weeks following the VRA, it was acknowledged that it would be unrealistic for both the researcher and participant to be free at the same time. It was decided that having flexibility with the interview time would not affect the results providing it would take place within an acceptable timeframe; that is, after enough time so that participants had the chance to reflect on the information they received, but not too long after the VRA so that they could remember the details of the experience. However, there was a time when it was impossible to be as rigid as we would have liked with that timeframe because of participants' circumstances, for example, a husband and wife asked to have the interview three months following the VRA because they were going on a holiday. Also some participants had their tests just before the busy period of Christmas holiday which meant the interview had to be after the New Year.

About a third of participants had had a similar test in the past. The majority of those who had previous tests had them within a GP practice, followed by workplace. Duplication of VRAs would increase the cost of the service on the NHS if it was the funder. However, it is unknown whether those who had a similar test before were due for another test by the time they visited the pharmacy. It is recommended by the Department of Health that the testing is repeated every 5 years (DOH 2008c). The service was accessed by patients with pre-existing CVD conditions, five of whom said they chose to have the tests at the pharmacy to double-check the results they had with their GP.

The findings show that 43% of participants were made aware of the service after visiting the pharmacy, either from seeing an advert placed in the pharmacy or being informed by a member of staff. However, it was recognised that the most effective method of attracting individuals to the service was the advert which was placed in the local paper. This method attracted 38% of participants even though it was only used in the last three months whereas other recruitment methods continued over the nine months of providing the service. The findings of this study proved that the use of the local media was effective in attracting people to a screening service such as the VRA service. However, it could not show whether it is the best method to attract those living in the most deprived areas (Chapter 2) and/or those who did not access health services, for example, NHS primary care services or community pharmacies.

More than half of participants mentioned at least one risk factor when they were asked about the reasons which prompted them to request an appointment for the VRA. This finding may indicate that people respond well to an advert if curries a meaningful message to them. As the Welsh Government pointed out, the marketing materials for the VRA service should be designed and piloted to confirm they deliver the message (WAG 2010). Service providers in the future may want to include key risk factors on the marketing materials if they want to attract people with potentially high risk or hard to reach. As the number of risk factors increases in a person the risk of developing a CVD increases.

The literature search did not identify any relevant UK studies which evaluated people's response to the risk when it is communicated by the pharmacist. Even

when the search was extended to other healthcare professionals and other settings there is a gap in the literature on what people do with particular pieces of information and whether or not they understand it or remember it.

On the other hand, CVD risk perception in the general population has been investigated. Women tend to underestimate their CVD risk because until late 1980s it was perceived, even among health professionals and researchers, that mainly men are affected by the disease (Hammond et al. 2007). This was the main reason for not recruiting women in large trials conducted in the past. However, in this study women represented only 27% (seven out of 26) of those who underestimated their risk.

Although the majority were able to recall their CVD risk as communicated by the pharmacist, those who were identified at moderate or high risk were less likely to remember. Those people needed to recall more than the low risk group. However, there was no evidence to suggest that being able to remember the Framingham risk is linked to the way people would act on the issues which increases the risk. To confirm a link between the understanding of the CVD risk and the compliance with the advice provided by the pharmacist may require further research.

Service providers in the future may need to provide tailored educational materials which explain the interpretation of the CVD risk in order to reduce the likelihood of having similar confusion as it was the case in 29% of participants in this study.

About one-third of participants was referred to GP for further investigations. This included patients who were referred because they were identified at high risk of CVD and those who were referred because of an issue with one of their risk factors, such as having a high blood pressure. Of those who were referred, it was established that 45% made their visit to their GP. If this percentage was combined with that for the participants who said they intended to go to their GP, it would reach 73%. In another study (Boyle et al. 2004) of patients who were referred, because they were found to be at risk of hypertension, hyperlipidaemia or diabetes, 64% made their visit or were waiting for an appointment.

About a quarter of those who were referred said they did not want to see their GP, seven of those were found to be at high risk which means 22% of the high risk participants would not be seen by GP. It is important to find ways to increase compliance with referral as this could affect the cost-effectiveness of the service. One suggestion for consideration would be to require the pharmacist to provide relevant information directly to a patient's GP so at least the GP was made aware of the results and could follow-up as appropriate.

The majority of participants found that it was useful to be informed of CVD risk whether they were compliant with the referral or not. Only one person who was referred but did not go to the GP thought it was not useful as this was perceived as a painful reminder of the loss of her mother. There were a further three participants thought it was not useful to be informed about their

individual risk. These were not referred and all thought they had a low risk (one of them was identified at high risk).

Participants were asked about the advice related to adapting to, and maintaining, a more healthy lifestyle which was provided by the pharmacist. Although the discussion generated interesting points regarding the difficulty of behavioural change, it was not possible to measure their accuracy in interpretation of the advice. This was because the advice provided was not documented in any detail. Examples of some inconsistencies, however, were evident between self-reporting of alcohol intake and what some participants said what their consumption actually was.

Diet was the most common lifestyle change participants reported having made since they had the tests at the pharmacy. Improvements to diet were attempted by some participants either to help them in their weight loss effort, to reduce their blood pressure (by reducing salt intake) or improving their lipid profile (by eating more oily fish). Other changes reported included starting or doing more exercise or reducing alcohol intake.

The service was recommended to others by 65% of those who had the tests and further 27% said they would recommend it if there was an opportunity to do so. Only a few people said they would not recommend the service for different reasons even though they expressed their satisfaction with the service. One participant said he would not recommend any health check and not only this one because “it is really personal”.

4.4.1 Limitations

The time of the follow-up interview could not be kept within the original agreed timeframe of two weeks because of the circumstances some participants had. There were some participants (34%) had their follow-up interview in the fourth week, or later, following their tests even though the primary aim was to have it approximately two weeks following the test. Two participants had a period as long as three months following the VRA. This could have been an extra time to reflect on the results and make any changes but also this period could have been too long to remember the details of the tests and the advice provided.

Although the interviewer who conducted the two-week follow-up interviews did not provide the VRA service, he was the principal supervisor and a member of the research team. There is a risk of researcher bias which could have been reduced by having an independent researcher.

Not all patients had the telephone interview as one participant did not consent for receiving any phone call, and also those who could not be contacted were sent a questionnaire covering all the questions in the interview schedule. This resulted in six participants completing the questionnaire instead of having the full discussion with the researcher.

Some participants were not asked all the questions in the interview schedule. For example, 14 participants were not asked whether or not they found it useful to be informed about their individual risk of developing CVD. It was clear that this question was omitted when the participant said they did not have the VRA.

However, this was not always the case, as the reasons for omitting this question was not clear in 11 of the cases which led to missing data. More missing data was a result of not including a direct question in the interview schedule to ask participants about lifestyle changes they have made. One way to overcome this, which itself has limitations, would be to conduct a structured interview.

The documentation of the details of the advice provided by the pharmacist during the consultation was not possible because of time constraints. Consequently, participants' understanding of the advice or their ability to remember the details of it could not be investigated. If the consultation had been audio-recorded then this would have been possible following transcription but the subjects would need to consent and if they had been recorded this may have affected what they said to the pharmacist.

4.4.2 Conclusion

The two-week follow-up interviews were conducted by a researcher who did not provide the VRA service. The study achieved 92% response rate which means the study population was well-represented. Participants were given the opportunity to express their views about the VRA service in detail and provided some useful explanation and clarification. This was the first study in the UK that the short-term outcomes of a VRA service being evaluated.

Chapter 5: Deprivation status and utilization of a non-NHS community pharmacy based VRA service

5.1 Introduction

This chapter presents a retrospective analysis of data collected from a VRA service other than the service of the main study. A major difference between this service and that of the main study is that in order to access this service customers were required to pay a charge.

Community pharmacy has an important role in helping tackle health inequalities (DOH 2003). A number of activities have been identified which may contribute to this agenda including the provision of screening services, particularly if they can reach out to the more deprived sectors of society or individuals who are more 'hard to engage' in healthcare (DOH 2005).

To target the 'hard to engage', it is essential to have a basic understanding of the individuals themselves and how to attract them to the service. There is no single definition, however, for this term. The 'hard to engage' or the 'hard to reach' is a term often used differently and is context dependent. The Department of Health has issued a leaflet called 'Addressing inequalities – reaching the hard-to-reach groups' as part of the National Service Framework (DOH 2002). Although no definition of "hard to reach" is included therein, it is clear that it targets people from deprived areas, those with lower levels of education, insecure employment, disability or from a minor ethnic group. The following have been identified as 'hard to reach': culturally and linguistically diverse communities, young, elderly, disabled and homeless people. Other difficult to engage groups included drug users, sex workers, those on low incomes, high rise apartment dwellers, faith based communities, businesses

(traders), single parents, newly arrived residents, gay and lesbian people, problem gamblers and residents of hostels and boarding houses. Some rural populations may also be considered 'hard to reach' (Meredyth et al. 2008).

In Wales the use of deprivation indices, such the Townsend Deprivation Index (TDI) and the Welsh Index of Multiple Deprivation (WIMD), is generally used to determine the socio-economic status. However, it is not a measure of wealth and it should not suggest that all individuals living in an area of high deprivation are poor (CDU 2010; WAG 2008).

According to Hippisley-Cox et al. (2011) there is an association between deprivation and risk of CVD as those who live in most deprived areas are at high risk of CVD (Section 1.1.2.6).

Recent work has indicated that if a VRA service is provided free of charge, recruitment across all socio-economic groups can be achieved (Horgan et al. 2010).

Whether a service that requires customer payment will attract such a broad range of individuals is unknown. The present study was undertaken to explore this.

The aim of this study was:

- To explore whether a VRA service that requires customer payment attracts individuals from areas of different levels of deprivation.

5.2 Method

A retrospective analysis of data obtained from a private VRA service was conducted. The service was provided by a large, city centre Boots pharmacy with a catchment area from across South Wales and beyond. Individuals aged 40 to 74 years were eligible and charged £10 to access the service.

Records of those who accessed the service during the period between January 2008 and September 2009 were retrieved to capture the data (Table 5-1) needed for the analysis by using a data collection tool (Appendix 16). As the data were already existed, a retrospective methodology was adopted. The data collected as part of the service included information as provided by the customer, results of tests and measurements performed by a trained pharmacy assistant and 10-year CVD risk as calculated by the pharmacist.

Table 5 - 1 The data collected using the data collection tool (Appendix 15)

Source	Data
Information provided by service users by self-completion of a questionnaire	• Postcode • demographic characteristics • lifestyle (smoking, alcohol and exercise)
Results of tests and measurements performed by a trained pharmacy assistant	• body mass index • waist circumference • systolic blood pressure • blood glucose • total cholesterol • HDL
Results provided by the pharmacist	• CVD risk estimated using Framingham based charts

The Welsh School of Pharmacy ethics committee granted ethics approval prior to accessing patients' records held at the pharmacy. NHS Research Ethics Committee approval was not sought as this was a private service not part of the NHS.

Residential postcodes for individuals were allocated to one of five deprivation quintiles (Q1 = least deprived; Q5 = most deprived) using the Townsend Deprivation Index (CDU 2010). The Townsend Deprivation Index was used in this study instead of the Welsh Index of Multiple Deprivation in order to include all individuals in the analysis whether they live in Wales or England. Table 5-2 shows the proportion of the Welsh population in each Townsend quintile.

Table 5 - 2 Distribution of the Welsh population in the Townsend deprivation quintiles

	Wales	**England and Wales**
	(Number of Census Area Statistics wards)	
Q1 (least deprived)	23% (198)	20% (1768)
Q2	10% (86)	20% (1769)
Q3	17% (143)	20% (1769)
Q4	28% (245)	20% (1769)
Q5 (most deprived)	22% (193)	20% (1769)

The characteristics and results of those who came from the Q1 were compared to those of their counterparts who came from the Q5. Statistical tests used include Chi-squared test and Fisher's exact test, for nominal data and Mann-Whitney U test for interval data (non-parametric). Data were analysed using the statistics programme PASW Statistics 18.

5.3 Results

A total of 132 adults had their CVD risk assessed. Table 5-3 shows the demographics and lifestyle characteristics of service users.

Table 5 - 3 Demographics of all service users

Demographics	**Results**
Age	Mean = 60 years [range 41 to 74, SD = ±8.1]
	Number of patients (%)
Females	95 (72)
Males	37 (28)
Family history of CVD	29 (22)
Ethnicity- White	124 (94)
Other	7 (5)
Not provided	1 (0.8)
Current smokers	16 (12)
Alcohol	
None	32 (24)
Within the weekly recommended level	91 (69)
Exceeding the weekly recommended level	9 (7)
Exercise	
None	11 (8)
Some (1 or 2 days a week)	49 (37)
Moderate (3 or 4 days a week)	48 (36)
Regular (at least 5 days a week)	24 (18)

About two thirds of service users were overweight and three-quarters had increased abdominal adiposity (Table 5-4).

Table 5 - 4 BMI and waist circumference of all service users

	Results (%)
Mean BMI	26.9 kg/m^2 [range 19 to 39, SD = ±3.9]
Less than 25	43 (33)
25 to 29.9	64 (48)
30 to 34.9	22 (17)
35 or above	3 (2)
Waist circumference:	
OK (acceptable size)	31 (24)
Increased risk	37 (28)
High risk	62 (47)

Results of systolic blood pressure measurements and cholesterol tests are summarised in Table 5-5. Also Table 5-6 shows the results of the 10-year CVD risk of all service users.

Table 5 - 5 Systolic blood pressure and lipid profile of all service users

	Results: mean
Systolic BP	125 mmHg (range 90 to 174, SD = ±15.4)
Total Cholesterol	4.91 mmol/L (range 3.05 to 8.78, SD = ±0.98)
HDL cholesterol	1.27 mmol/L (range 0.64 to 2.26, SD = ±0.35)
Total Cholesterol: HDL ratio	4.1 (range 2.3 to 7.9, SD = ±1.1)

Table 5 - 6 Results of 10-year CVD risk calculated using the Framingham based BNF charts

	Number of patients (%)
Low risk (< 10%)	85 (64)
Moderate risk (10-20%)	35 (27)
High risk (> 20%)	12 (9)

Those who were identified at high risk were referred to their GP. Other reasons service users were referred to their GP include high blood pressure 15 (11%) and high fasting glucose 7 (5%).

There were 124 (94%) service users who had a valid postcode and therefore could be allocated a deprivation quintile (Table 5-7). Of the 124 service users there were 33 (27%) males and 117 (94%) Caucasians.

Table 5 - 7 Individuals within each quintile

Townsend Deprivation Quintiles	No. (%)
Q1 (Least deprived)	43 (35)
Q2	13 (11)
Q3	23 (19)
Q4	19 (15)
Q5 (Most deprived)	26 (21)

There were no significant differences in demographic characteristics or lifestyle between Q1 and Q5 except the mean age of subjects in Q1 was higher and the proportion of smokers in Q5 was higher (Table 5-8).

Table 5 - 8 Comparison of lifestyle of individuals from Q1 and Q5. (%)

	Q1	Q5	p value
Mean age (years)	63 (±7.1)	56.9 (±7.9)	0.001§
Smokers no. (%)	1 (2)	5 (19)	0.026†
Alcohol consumption			0.428*
None	9 (21)	7 (27)	
Low/moderate	32 (74)	16 (62)	
Unhealthy	2 (5)	3 (11)	
Exercise			0.657*
None	2 (5)	2 (7)	
Low	17 (40)	9 (35)	
Moderate	17 (40)	8 (30)	
Regular	7 (16)	7 (27)	

§ Mann-Whitney U test. † Fisher's exact test. * Chi-squared test

± = standard deviation

Also no significant difference was found in BMI or in waist circumference between Q1 and Q5 (Table 5-9).

Table 5 - 9 Comparison of BMI and waist circumference of Q1 and Q5 patients

	Q1	Q5	p value
Mean BMI (SD)	26.1 (±3.4)	27.4 (±3.7)	0.105§
Waist circumference			0.263**
OK	14 (33)	4 (15)	
Increased risk	11 (26)	9 (35)	
High risk	17 (40)	13 (50)	

§ Mann-Whitney U test ** Fisher's exact test

The difference between the mean systolic blood pressure of those from the least deprived areas and the mean of the most deprived areas was not

significant. This was the case for the total cholesterol, the HDL and the total cholesterol: HDL ratio (Table 5-10).

Table 5 - 10 Comparison of means (SD) of subjects in Q1 and Q5 patients. Statistics: Mann-Whitney U test

	Q1	Q5	p value
Systolic BP	129.4 mmHg (±14.7)	127.6 mmHg (±18.2)	0.488
Total cholesterol	4.78 mmol/L (±0.89)	5.02 mmol/L (±0.98)	0.207
HDL	1.21 mmol/L (±0.28)	1.30 mmol/L (±0.32)	0.334
Total cholesterol to HDL ratio	4.07 (±0.92)	4.07 (±1.27)	0.585
Glucose	5.24 mmol/L (±0.85)	5.59 mmol/L (±1.40)	0.762
Fasting glucose	5.21 mmol/L (±0.86)	5.36 mmol/L (±1.39)	0.892

Although the percentage of those who were identified at high risk was higher for the Q5 individuals than the Q1 individuals, the difference was not statistically significant (Table 5-11).

Table 5 - 11 Individuals at low, moderate and high CVD risk

	Q1	Q5
Low risk (<10%)	25 (58)	17 (65)
Moderate risk (10-20%)	14 (33)	4 (15)
High risk (>20%)	4 (9)*	5 (19)*

* p = 0.282 Fisher's exact test

5.4 Discussion

The aim of this study was to explore whether a VRA service that requires customer payment attracts individuals from areas of different deprivation levels. Of the 132 individuals who had a VRA in the pharmacy, 124 (94%) had accurate postcodes so they were allocated to their deprivation quintiles.

To date, no studies in the literature were found which evaluated the accessibility of a non-NHS VRA service according to deprivation. Horgan et al. (2010) suggested that if a VRA service is provided free of charge, recruitment across all socio-economic groups can be achieved.

Of the service users (n = 124) who could be allocated a deprivation quintile, 21% resided in the most deprived areas. This proportion was higher than other individuals from areas of less deprivation (Q2 and Q4). It was similar to the proportion (19%) of participants from Q3. However, the proportion of those living in the most deprived areas was lower than the proportion (35%) of those living in the least deprived areas (Q1).

Although there was a levy of £10 to access the service, the proportion of those who were from the most deprived areas was similar to the 'Heart MOT' pilot (19%) which was free of charge and directed at the most deprived areas (Horgan et al. 2010).

The present study compared the results of those from the most deprived areas with those from the least deprived areas. There was no significant difference in tests results nor referrals to GP between the two groups.

More effort is needed to be invested to increase access to services for deprived populations to tackle health inequalities (Richards 2009). However, some clusters of the society, for instance ethnic minorities, tend to utilise the health system including the pharmacy services less frequently (Jerrell and Sakarcan 2009). This study originally aimed to see whether this VRA service was accessible by the "hard to engage" groups, including men, elderly, unemployed, those from low-income households and minor ethnic groups. However, as the study was conducted retrospectively only limited information was available to determine whether or not any of those who accessed the service were from a hard to engage group other than being male, elderly or from an ethnic minority.

The service recruited fewer men (28%) than women. It is probably the location of the pharmacy, being in a large shopping centre. Other studies showed also the proportion of male service users is quite low; for example, in one study conducted in Australia only 29% were males (Peterson et al. 2010) and in another study conducted in Northern Ireland males were just under one third (32%) of all participants (O'Donovan et al. 2010).

Only 6% of the service users were from an ethnic minority background. It is estimated that in Cardiff, the capital city of Wales, 10% of the population are ethnic minorities (Welsh Goverment 2010).

5.4.1 Limitations

The data were obtained from a single pharmacy and only a small number of subjects had accessed the service over an 18 month period which means about

seven assessments every month. It was less likely to detect any difference in test results because of the small number of individuals at each deprivation quintile.

The study was retrospective which limited the evaluation only to those who had a valid residential postcode in their records. Also, because of the limited information in records, the identification of the 'hard to engage' groups could only be limited to men, ethnic minorities and those living in the most deprived areas.

Although deprivation indices are commonly used as an indicator for socio-economic status, it does not provide sufficient information about the individual concerned, such as their income, wealth, education and occupation (CDU 2010). There is a possibility that a wealthy person living in an area with higher deprivation access the service and he or she cannot be representative to the people with low socio-economic status. Poorer individuals living in communities with high deprivation are most likely to have the worst health outcomes (Stafford and Marmot 2003). Therefore, the use of deprivation indices in small sample size studies is probably less useful than in larger studies where the sample is more representative of the area of deprivation in general.

These limitations prevent any generalisability of the results.

5.4.2 Conclusion

This study has shown that a paid for community pharmacy VRA service was accessed by a group of individuals including those from the most deprived areas. There was no significant difference between the proportions of individuals from the least and most deprived areas referred to their GP because of CVD risk.

Although, the service was not designed to target high deprivation or hard to reach groups, males and non-Caucasians were under represented in the study, suggesting that groups known to be more difficult to engage may be less likely to access and thereby benefit from a community pharmacy based screening service which levies a charge.

Chapter 6: Analysis of the medicine use review data in a Boots pharmacy in Wales with a focus on cardiovascular diseases

6.1 Introduction

This chapter presents a retrospective analysis of data obtained from an MUR service in one of the venues where the main study (that is, the VRA service) was conducted. A comparison was made between the demographic characteristics of those who accessed the MUR service and those who accessed the VRA service.

The Medicines Use Review (MUR) is an advanced service provided by accredited pharmacists as part of the current Community Pharmacy Contract with the NHS in England and Wales. The service is a consultation between the pharmacist and patient on medicines for chronic conditions (PSNC 2004).

There is a fixed fee for every MUR that is completed (£23, 2011). The maximum number of MUR for any pharmacy to provide is 400 per year, unless an agreement with the Local Health Board was obtained (NHS Wales 2011).

According to The Pharmaceutical Services Negotiating Committee (PSNC), the body representing pharmacy contractors for England, the aim of the MUR is to improve the use of medicines by helping patients understand the treatment they are on, identifying any issues with their treatment, and find possible solutions to solve the identified issues (Panel 6-1).

Panel 6 - 1 The definition of the Medicines Use Review by the Department of Health (Blenkinsopp et al. 2007).

A Medicines Use Review aims "with the patient's agreement, to improve his knowledge and use of drugs by in particular:

a- establishing the patient's actual use, understanding and experience of taking drugs;

b- identifying, discussing and resolving poor or ineffective use of drugs by the patient;

c- identifying side effects and drug interactions that may affect the patient's compliance with instructions given to him by a health care professional for the taking of drugs; and

d- improving the clinical and cost effectiveness of drugs prescribed to patients thereby reducing the wastage of such drugs."

There have been several published studies evaluating the MUR service since it was introduced in April 2005 (Blenkinsopp et al. 2008; Blenkinsopp et al. 2007; Latif and Boardman 2008; Latif and Boardman 2007; Latif et al. 2011; Portlock et al. 2009; van den Berg and Donyai 2010). The adoption of the MUR service was evaluated after the first year of implementation through a questionnaire sent to primary care organisations and structured telephone interviews of Strategic Health Authority in England and the Welsh Government in Wales. Payment for providing MURs in the first year of the service was claimed by 38% of community pharmacies. Pharmacies from multiples were the highest in implementing the service undertaking about 84% of all MURs. Views identified from the survey and the structured telephone

interview suggested that MURs had considerable potential but progress was slow. A number of barriers were identified by the study including lack of remuneration for the implementation of the new service and the suitability of the place for the service. Other barriers were more specific to the independently owned pharmacies such as lack of corporate system to share the work (Blenkinsopp et al. 2007).

The progress in the provision of the MUR service in England and Wales in its second year was evaluated by Blenkinsopp et al. (2007). Community pharmacies from a stratified random sample (n = 733) of 31 primary care organisations in England and Wales were included in this study. Routinely collected data were analysed retrospectively. There was an increase (from 38 to 67.2%) of community pharmacies providing the MUR service in the second year of implementation, a more than fourfold increase in the total number of MURs provided (n = 62,559), with the mean number of MURs increasing from 36 to 85 MURs per pharmacy. The domination by multiples as providers of MURs (82%) continued in the second year of implementation with 78% of those not providing MURs being independents. Twenty-one independents had no MURs in the second year even though they were existing MUR providers in the first year. Only a small number of pharmacies (11 out of 733) provided the maximum number of 400 MURs for the year. The authors suggested the successful adoption of the MUR service was less likely to occur in independents when compared with the multiples (Blenkinsopp et al. 2008)

A prospective study using questionnaire feedback evaluated the outcome of MURs targeted at patients with asthma. A total of 965 individuals who received an MUR from community pharmacies (n = 46) in the Hampshire and Isle of Wight Local Pharmaceutical Committee area during July to December 2007 were surveyed. The service identified more than a third of individuals as primarily non-adherent (prescriptions not dispensed) and about two thirds as secondary non-adherent (prescriptions dispensed but medication not used). Adherence issues identified included difficulty using the inhaler (281, 29%), incorrect beliefs about their medicines (236, 24%), and due to other medicines issues, e.g. side effects (141, 15%). The response rate to the questionnaire was 24% (n = 230). A third of the respondents used the MUR service to gain more confidence. The authors reported high satisfaction with the service among respondents. Feedback from the small number of GPs (15 out of 46) who responded to the questionnaire was positive as 12 agreed that community pharmacists have an important role to play in the management of asthma and 11 agreed that the service is of benefit to asthmatic patients (Portlock et al. 2009).

Community pharmacists' attitudes toward the MUR service were evaluated by a survey which identified a number of barriers that community pharmacists perceived (Latif and Boardman 2008). Barriers identified included the availability of an adequate consultation room, the time and trained pharmacy support staff. The number of MUR performed was affected by the number of hours the pharmacist worked per week with those working more than 20 hours

a week performed significantly more MURs than those who work less than 20 hours.

The consultation skills of community pharmacists were criticised by one study (Latif et al. 2011). The authors suggested that MUR sessions tended to be brief and closed questions used by the pharmacists which did not give patients the opportunity to ask questions. Also, the authors suggested that the MUR had limited effect on patient knowledge.

A retrospective audit of MUR forms was conducted in August 2008 which included all community pharmacies of a large multiple chain within a specific district in South-East England (n = 33) (Donyai and van den Berg 2009). The audit aimed to evaluate MUR forms completed during a one month period, June 2008. A total of 464 MUR forms (46% male) from 17 (51.5%) pharmacies were received and included in the analysis. The mean of items per patient was 5.03 (range 1–17) and only 3% of patients were on one item. The most common type of medicines (45.1%) in all MUR forms were related to the cardiovascular system, but the proportion of patients on these medicines was not reported. Recommendations reported in 34% of the submitted MUR forms and they were as the following: lifestyle recommendations (24.7%), interactions and contraindications (23.4%), adherence (34.8%), synchronisation of repeats (3.2%) and patients advised to talk to their GP (32.9%). This audit which used a readily available tool (RPSGB 2009) did not seem to evaluate the quality of each recommendation in the submitted forms.

Patients' satisfaction with the MUR service was discussed at the 2010 conference of Health Services Research and Pharmacy Practice (Donyai and van den Berg 2009). The researchers pointed out the importance of measuring patients' satisfaction. As there was a limited number of satisfaction questionnaires to evaluate pharmacy services the researchers were developing a specific questionnaire to be used in MUR satisfaction surveys. Interviews of those who received an MUR were being conducted to "identify relevant concepts and develop a conceptual framework to inform item development for a Patient Reported Outcome Measure questionnaire bespoke to the MUR".

Community pharmacy has been recognised as a crucial player in the healthcare system to tackle health inequality (DOH 2003). Many primary care organisations have commissioned services such as the provision of emergency hormonal contraception and quit smoking services through pharmacies. Some pharmacies have been chosen to take part in these schemes because they have been located in areas with higher deprivation in order to reduce health inequality (DOH 2005). However, any evidence to support the contribution of pharmacy in reducing health inequality is lacking. Ideally pharmacists should be encouraged to actively target the hard to engage groups when they promote healthy choices, signpost healthcare services and when they directly provide service.

The government has stated that the MUR service should be targeted to those who would benefit the most from the service. This came after a criticism made by the DOH of the way pharmacists conduct MURs, which was highlighted in

the 2008 White Paper (DOH 2008b). It suggested that some MURs are of limited quality and patients on a single prescribed medicine being selected as an easy way to reach their targets (McDonald et al. 2010). The surge in conducting high number of MURs in the last financial month of the year was also thought to affect the quality of MURs (DOH 2008b). The DOH emphasised that primary healthcare organisations should prioritise MURs to meet local health needs. It has been suggested MURs be targeted at individuals who have been discharged from hospital and those taking medicines associated with high hospital readmission rate, e.g. diuretics, non-steroidal anti-inflammatory drugs and antiplatelet drugs (Livingstone 2010). Other groups with possible adherence issues could also be targeted and include those who receive polypharmacy and/or treatment with complex regimens (Bangalore et al. 2007).

Community Pharmacy Wales is the body responsible for liaising with the Welsh Government and for negotiating the contractual terms for the provision of the NHS community pharmacy services including the MUR service (CPWales 2011a). Up to now most of the English National Pharmacy Contract negotiated by PSNC has been adopted by the Welsh Government (PSNC 2011). However, this is expected to change as Welsh contractual arrangements continue to differ from those in England.

In Wales, two new relevant services have been introduced recently. The targeted MUR service was introduced on 1st December 2011 which required community pharmacists to provide half of MURs to patients from selected

groups and they include those taking antihypertensive medicines, with respiratory diseases, those taking high risk medicines such as lithium, NSAIDs and warfarin, and those being prescribed a medication they no longer require (RPS 2011b). A second service introduced in Wales on 1st November 2011 is the Discharge Medicine Review Service which requires the pharmacists, in addition to ensuring patients have the maximum benefits from their treatments, also to check for discrepancies in medications between prescriptions issued by the hospital and the GP (CPWales 2011b).

No published study to date has evaluated the accessibility of the service according to the socio-economic status of the patient or focussed on MURs relating to medicines used in CVD.

The aim of this study was to explore these issues using MUR records from a Boots pharmacy.

Aim

The aim of this study was to retrospectively analyse the MUR data obtained from the forms completed in Boots pharmacy, Porthcawl, South Wales.

Objectives

- Identify the proportion of MURs completed for those who were receiving cardiovascular medications.
- Determine the number of issues identified in the MUR.
- Determine the proportion of issues to be resolved by the pharmacist, GP and patient.

- Explore whether the MUR service has been accessed by a range of individuals living in areas of different levels of deprivation.
- Compare the deprivation status of patients who have received the MUR service with those who have accessed the VRA service.
- Determine whether those considered hard-to-reach were likely to be recruited for the service.
- Determine whether the demographical characteristics of individuals who had MURs at the start of the year would be different when compared with those who had MURs at the end of the financial year.

6.2 Method

Although anonymous data were collected, the Welsh School of Pharmacy ethics committee was approached to have the protocol to be reviewed. Ethics committee approval was obtained in September 2010 prior to the collection of data.

As the data was previously available in the pharmacy, a retrospective design was chosen for this study. The research pharmacist was a Boots employee. As a consequence, and as part of the normal provision of NHS care, access was possible to the patient data stored in the pharmacy. The anonymous data required for the study were acquired from the MUR forms (Appendix 17) completed during the period from April 2009 to March 2010. The data were entered into two Microsoft Access files using a password protected notebook computer. The first file was used to enter a unique identification code for each patient and their postcode. The second file was used to enter the same identification code and the remainder of the data collected. Each file was protected by a different password from the other file and from the computer's main password. A screenshot showing the data collection form within Access is provided (Appendix 18). The analysis of the anonymous data was then carried out at the Welsh School of Pharmacy. The data were mainly obtained from the hard copies of the completed MUR forms, however, occasionally when information was missing, for example postcode or age, the Patient Medication Record (PMR) within the pharmacy was used to access this information.

The expected number of MURs was 400 which was the maximum number of MURs any pharmacy can claim for per year. The collected information included date of review, gender, age, postcode, number of medicines, number of identified issues, type of CVD medicine as classified by the BNF (2011) if used and the person responsible for any action recommended.

The issues counted from the MUR forms were anything raised by the pharmacist which could include a counselling point, an issue with compliance, a suspected adverse effect, a drug-drug interaction, or provision of life-style advice.

The demographics of those who accessed the MUR service at the start of the year were compared with those who received an MUR at the end of the financial year. This analysis was undertaken to see if pharmacy staff were more or less likely to approach certain groups of clients towards the end of the year.

Postcodes for individuals were allocated to one of five deprivation ranks using the Welsh Index of Multiple Deprivation (WIMD). Rank 1 being the most deprived areas and Rank 5 the least deprived (WAG 2008). Townsend Deprivation Index (TDI) (CDU 2010) was also used in the analysis to overcome some of the disadvantages associated with WIMD.

Descriptive data and frequencies were calculated using PASW Statistics 18. The socio-economic status of those who received an MUR was compared to those who had a VRA using Pearson Chi square test.

A request to Boots head office was made for a list of postcodes of those who received prescriptions from the pharmacy to compare their socio economic status with the MUR service users. Permission to access the full postcode of each patient was not forthcoming because of technical difficulties and confidentiality concerns. However, a list of incomplete postcodes, only the postcode sector (e.g. PO16 7), was provided for the period 1st February 2009 to 31st January 2010.

6.3 Results

Four hundred and five MURs were undertaken in 2009/10; the pharmacy was remunerated for the first 400 MURs only. One hundred and fifty (37%) of recipients were male, mean age was 60.5 years and almost half of service users were elderly, that is, 65 year old and over. Only 15 patients (4%) were on a single prescribed medicine. The majority of patients (71%) were on CVD medicines (Table 6-1).

Table 6 - 1 Summary of characteristics of all MUR users

Characteristic	Number (%)
Gender: Male	150 (37)
Female	255 (63)
Mean age	60.5 years (ranged from 18 to 88 years and SD = ±15)
Elderly	186 (46)
Median number of items	4 (Range 1 to 12 items)
Patients on CVD medicines	289 (71) (Range 1 to 6, median 2 items)

The majority of the service users were from the least deprived areas whether their socio-economic status was determined by WIMD or TDI (Table 6-2).

Table 6 - 2 Socio-economic status according to WIMD and TDI determined by postcode of residence

	WIMD	TDI
	Number (%)	**Number (%)**
Most deprived	Rank 1 = 1 (0.3)	Q5 = 10 (3)
	Rank 2 = 3 (1)	Q4 = 162 (40)
	Rank 3 = 50 (13)	Q3 = 1 (0.2)
	Rank 4 = 97 (25)	Q2 = 0
The least deprived	Rank 5 = 243 (62)	Q1 = 231 (57)
Total	391 (missing* = 11)	404 (missing* = 1)

* missing = patients who could not be allocated to a deprivation area

When using TDI, more patients were considered from the most deprived areas. This could not be compared with the socio-economic status of users of the pharmacy in general because of the limited information received from Boots head office. However, the list of the postal sectors received from the head office showed that 77% of pharmacy users who dispensed their prescription from 1st February 2009 to 31st January 2010 were from the surrounding 13 Lower Layer Super Output Areas (LSOA). According to WIMD eight out of these 13 LSOAs were in rank 5 (the least deprived), three LSOAs were in rank 4 and two were in rank 3 (non of these LSOAs were in rank 2 or 1). The remaining 23% of patients came from different areas with different levels of deprivation, and some of them were from the most deprived areas. With the limited information received from the Boots head office, however, it was not

possible to determine exactly what the proportion was for those who resided the most deprived areas.

According to TDI, 77% of patients came from 9 Census Area Statistics (CAS) wards, four CAS wards were categorised as Q1 (least deprived), four CAS wards as Q4, and one CAS ward as Q5 (most deprived).

There was no significant difference ($p > 0.05$, Pearson chi-square test) in the socio-economic status between those who received an MUR and those who accessed the VRA service in Porthcawl (Table 6-3). On the other hand, when TDI was used the difference was significant ($p < 0.001$, Pearson chi-squire test) between the proportions of users living in the most deprived areas in each service (Table 6-4).

Table 6 - 3 Comparison of socio-economic status of VRA clients versus MUR clients according to WIMD (p > 0.05, chi-square test)

WIMD	VRA	MUR
	Number (%)	Number (%)
Rank 1 (Most deprived)	0	1 (0.3)
Rank 2	3 (2)	3 (1)
Rank 3	12 (9)	50 (13)
Rank 4	25 (19)	97 (25)
Rank 5 (Least deprived)	89 (69)	243 (62)
Total	129 (4 missing)	394 (11 missing)

Table 6 - 4 Comparison of socio-economic status of VRA clients versus MUR clients according to TDI (p < 0.001, chi-square test)

TDI	VRA Number (%)	MUR Number (%)
Q5 (Most deprived)	14 (11)	10 (2)
Q4	37 (29)	162 (40)
Q3	7 (5)	1 (0.2)
Q2	6 (5)	0
Q1 (Least deprived)	65 (50)	231 (57)
Total	129 (4 missing)	404 (1 missing)

The majority of treatment regimens were once daily doses with 87% of patients' medicines being prescribed as such (Table 6-5). A third of patients were on medication with "As directed by the prescriber" as the directions for use on the label.

Table 6 - 5 Treatment regimen frequencies for patients who received an MUR. Some patients had different treatment regimen frequencies for different drugs (so %s add up to >100%)

Dose frequency	Number (%)
Once daily	354 (87)
At night	156 (39)
Twice daily	143 (35)
Three times a day	78 (19)
Four times a day	84 (21)
When required	58 (14)
As directed	124 (31)
Weekly	22 (5)
Monthly	3 (1)

About a third of patients (34%) who received an MUR were on lipid regulating drugs. Table 6-6 shows the proportion of patients on each class of CVD medicines.

Table 6 - 6 Class of CVD medicine by BNF Chapter 2 subheadings (Number of patients = 289)

Class of CVD medicine	Number (%)
Positive inotropic drugs	2 (1)
Diuretics	52 (18)
Anti-arrhythmic drugs	3 (1)
Angiotensin-converting enzyme inhibitors	85 (29)
Angiotensin-II receptor antagonists	27 (9)
Nitrates	15 (5)
Calcium-channel blockers	46 (16)
Anticoagulants	17 (6)
Antiplatelet drugs	79 (27)
Lipid regulating drugs	137 (47)

Most MURs (n = 396, 98%) identified at least one issue and a few identified up to four issues (Table 6-7). According to the MUR forms, not all issues required an action by any person and some issues were required more than one person to resolve (Table 6-8). Only eight patients were referred to other healthcare professionals.

Table 6 - 7 Number of issues per MUR (total number of issues = 672)

Number of issues	Number of patients (%)
No issues	9 (2)
One issue	158 (39)
Two issues	203 (50)
Three issues	32 (8)
Four issues	3 (1)

Table 6 - 8 Person who was asked by pharmacist to action the issue. Some forms had > 1 selection (n = 31 forms)

Issue(s) to be actioned by	Number (%)
Pharmacist	26 (7)
Patient	14 (4)
GP	6 (2)
Practice nurse	2 (1)

Characteristics including age, gender and deprivation status of the first 50 patients who received an MUR were similar when compared to the last 50 patients who had an MUR in the financial year 2009-2010 (Table 6-9).

Table 6 - 9 Comparison between characteristics of the first 50 patients and the last 50 patients (p > 0.05, chi-square test)

	First 50 patients	Last 50 patients	P value
Elderly	29 (7%)	21 (5%)	> 0.05
Male	18 (4%)	21 (5%)	> 0.05
WIMD rank 3	6 (2%)	6 (2%)	> 0.05
rank 4	13 (3%)	15 (4%)	
rank 5	29 (7%)	28 (7%)	
TDI Q 5	0	1 (0.2%)	> 0.05
Q 4	23 (6%)	24 (6%)	
Q 1	27 (7%)	25 (6%)	

6.4 Discussion

6.4.1 Overview

The MURs were undertaken mainly by individuals who were from the least deprived areas. When compared with the VRA service, significantly fewer people from the most deprived areas (TDI) accessed the MUR service. The recruitment strategies were different for each service. but it would be helpful to investigate further whether the different types of services attract people from different areas of deprivation.

6.4.2 Major findings

The data was obtained for a full financial year (from 1st April 2009 to 31st March 2010). This was important because anecdotal reports suggested that the recruitment was different during the financial year as more patients were recruited at the end of year which means pharmacies focus on quantity rather than quality of MURs.

The MUR service at Boots Porthcawl was accessed by 405 patients over a whole financial year. Female patients accounted for 63% of patients and the average age was 60.5 years (with a range from 18 to 88 years). Ethnicity was not recorded in the MUR form. For future research and auditing purposes the ethnicity should be included to monitor how ethnic minorities are utilising these services.

Although pharmacists were aware of, through training and the briefings they received from their managers, the maximum number of MURs that the

pharmacy would be remunerated for the pharmacy exceeded the 400 MURs in the year. It was unknown whether these extra MURs were done as a tool of recording an intervention or to refer to other healthcare professionals as the reason behind this was not explored.

- Proportion of MURs for patients with CVD

More than two thirds of those who had an MUR were on one or more CVD medicines. It was not clear whether the pharmacist was actively targeting patients on CVD medicines. Since 1st December 2011 patients with CVD became one of the groups to be targeted to receive an MUR in Wales (RPS 2011b). The proportion of medicines for the cardiovascular system was reported as the highest (45%) by a retrospective audit (Donyai and van den Berg 2009), but the proportion of patients on CVD medicines was not reported.

- Number of issues identified in the MUR

The majority of MURs raised at least one or two issues. Most of these issues did not specify who was the person responsible to deal with them, with only eight patients being referred to other healthcare professionals. Mostly the pharmacist was required to action the identified issues.

Many of the patients were on a treatment with a complex regimen and there was a number of patients who were receiving polypharmacy. These would benefit from such a service to identify any compliance issues. However, the types of issues were not explored by this study and it was not recorded how many of the issues identified were compliance issues.

The demographic characteristics of service users confirmed others' work to suggest that men are less likely to take advantage of health services available. The study confirms also the work by van den Berg and Donyai (2010) that pharmacists did not target easy patients to perform MURs as only few MURs were provided to patients with a single medication treatment.

- The proportion of issues to be resolved by the pharmacist, other healthcare professionals and patient

Out of 405 MUR forms conducted in this pharmacy, only 31 MURs (48 issues) specified the person who should action the recommendations. It was unclear if this means the majority of the issues raised (total number = 672) did not require any action or there were incomplete forms included. The pharmacist, according to the MUR forms, had to deal with 26 issues whereas eight patients were referred to other healthcare professionals.

- The socio-economic status of the service users

The majority of the Boots pharmacy users in Porthcawl come from the less deprived areas. Also, the surrounding residential areas are mostly of lower deprivation. However, this does not fully explain why the MUR service was accessed by a low proportion of those living in the most deprived areas. In order to address health inequalities, the pharmacy should adopt a new strategy to encourage those from the most deprived areas to receive the MUR.

The demographic characteristics of the first and the last 50 MURs were similar which suggest that patients were not recruited differently on the basis of these

characteristics in the beginning and at the end of the financial year. Furthermore, it is not possible to generalise as the data were collected from one pharmacy and only for one year.

When comparing with other services, the number of men was expected to be low. They need to be targeted and encouraged to have the review.

- The deprivation status of patients who received the MUR service compared with that of those who accessed the VRA service

The proportion of the MUR patients with low deprivation status was significantly lower than those who accessed the VRA service at the same pharmacy, that is, 2% versus 11% respectively ($p < 0.001$, Pearson chi-squire test). However, the proportions of both services were lower than the general population (20%) (CDU 2010).

6.4.3 Limitations

Although the focusing on one pharmacy allowed looking into the data in more detail, the evaluation of such data from a single pharmacy was not enough to provide a complete picture of what is going on in pharmacy with regard to the MUR service. The results of this study cannot be generalised across the UK.

In this study deprivation as a surrogate marker for socio-economic status of the service users was determined by using two different indices. The WIMD was used because it was the index recommended by the Welsh Government when assessing local needs. However, when using WIMD 50% of the Welsh population are considered as being from the least deprived areas and only 10%

from the most deprived areas. This division was a problematic in the present study as the sample size was small and that limited the statistical tests which could be used to compare the two services.

As this was a retrospective study, it was limited by the extent of the availability of information in the MUR forms. Some forms were not complete in term of demographic data and other data. Also as no clinical data was acquired to go in the MUR forms, the indication of some CVD medications could not be confirmed whether they were for a CVD or for another condition.

In addition, other 'hard to engage' groups, for example ethnic minorities, could not be confirmed if they were received the service as ethnicity was missing from the MUR form.

The results would have been more meaningful if it was possible to compare the demographics of those who received an MUR with the average pharmacy users in general. The deprivation status of the pharmacy users was estimated by a list of incomplete postcodes obtained from Boots head office because, for technical problems and concerns over confidentiality, the complete postcode of each patient was not provided. However, even with a complete list there will be a limitation in using this method as postcodes of the pharmacy users include all those who have their prescriptions dispensed at the pharmacy, that is, those who have their medicines delivered are not excluded. In other words, even if the list provided was complete there is still uncertainty about who actually visits the pharmacy and being offered an MUR and who have other means to collect their medications. Even if the pharmacy is offering the service to all

those who visit the pharmacy, it is expected that some of the pharmacy users will be missed by the current recruitment strategy.

The evaluation of the quality of the MURs was not one of the objectives of the study. Therefore, even though the number of issues was high, it was unknown whether these MURs were all of good quality.

No follow-up was made with regard to any outcomes of the MUR service. It could not be determined whether those who were referred to other healthcare professionals actually went to see their GP or nurse as recommended by the pharmacist. It was unknown whether or not any of the issues identified by the pharmacist through the MUR sessions were resolved. However, it is important to note that this was not an aim of the study. Future work is warranted to address these issues.

6.4.4 Conclusion

This retrospective study analysed 405 MUR forms conducted over 12 months in one community pharmacy in South Wales. A total of 672 drug-related issues were identified by the pharmacists. The median number of items per patient was 4 and only 3.7% of patients were on a single item. More than two thirds (71%) of patients were on one or more CVD medications.

This study helped to identify the demographic characteristics of the MUR service users at Boots Porthcawl which allowed the comparison with the participants of the main study (the VRA service). This comparison failed to show a clear difference between the two groups.

Chapter 7: Comparison of cardiovascular risk estimates derived from Framingham and QRISK2 algorithms

7.1 Introduction

This chapter compares the results obtained from two CVD risk assessment tools available in the UK when used in the same population. The main study population (Chapter 2) was used to calculate the risk using both the Framingham based BNF charts and the QRISK2 calculator.

The estimate of an individual's 10-year risk of CVD is the first step currently used in the Wales government's preventative strategy to combat the increase in CVD morbidity (WAG 2010). The prediction of CVD must be as accurate as possible in order for the preventative measures to be appropriate and in line with the national guidelines (SIGN 2007).

A number of tools have been developed to calculate risk, including charts, tables, computer software and website tools, which are based on algorithms such as Framingham risk score (Shindler 2011), ASSIGN (SIGN 2007) and QRISK2 (Hippisley-Cox et al. 2008).

When estimating an individual's risk of CVD there is consensus that a combination of risk factors needs to be taken into account rather than the extent or severity of any single factor (Hippisley-Cox et al. 2007).

The BNF charts (BNF 2011) are based on the American Framingham study although the relevance of this to the current UK population is unclear. The Framingham Heart Study was conceived in 1948, at a time when there was insufficient knowledge about the causes of CVD. At the time CVD was increasing in prevalence and becoming the leading cause of morbidity and mortality in developed countries as infectious diseases came under control. The

Framingham Heart Study was set up to identify the risk factors that contribute to CVD. More than 14,000 participants over five decades and representing three generations have been recruited and monitored for the development of CVD. The Framingham Heart Study has successfully identified that high blood pressure, high blood cholesterol, smoking, obesity, diabetes, and physical inactivity are risk factors for CVD (Shindler 2011). As a result, the concept of CVD risk factors has become the cornerstone of advancing prevention and treatment of CVD. Based on the Framingham population a risk assessment tool for estimating 10-year CVD risk has been developed.

Until March 2010, NICE had followed the recommendation of the Joint British Societies' guidelines in using the modified Framingham equation (NICE 2010a). The Joint British Societies' guidelines acknowledged the fact that Framingham was not derived from similar populations particularly with regards to ethnic minorities. Therefore, results obtained using the modified Framingham equation would be 1.4 times higher for people originating from the Indian subcontinent (JBS2 2005).

The Scottish cohort based risk assessment tool, ASSIGN, is the first tool to include social deprivation and family history of cardiovascular disease in the equation as well as the classic risk factors (Table 7-1) (Tunstall-Pedoe and Woodward 2006).

Table 7 - 1 Risk factors taken into account in CVD risk assessment tools

Modified Framingham	ASSIGN	QRISK2
Age	Age	Age
Gender	Gender	Gender
Current smoker	Current smoker	Current smoker
Systolic blood pressure	Systolic blood pressure	Systolic blood pressure
Angina or heart attack in a 1st degree relative < 60 years	Angina or heart attack in a 1st degree relative < 60 years	Angina or heart attack in a 1st degree relative < 60 years
Diabetes	Diabetes	Diabetes
Total Cholesterol: HDL ratio	Total Cholesterol: HDL ratio	Total Cholesterol: HDL ratio
		On blood pressure treatment
		BMI
	Deprivation	Deprivation
Ethnicity		Ethnicity
		Atrial fibrillation
		Chronic kidney disease
		Rheumatoid arthritis

Researchers from the University of Nottingham have developed QRISK, a cardiovascular disease risk algorithm specifically for use in the UK (Hippisley-Cox et al. 2007). The modified version of QRISK, QRISK2, was launched in 2008. By entering more information, including ethnicity, presence/absence of a diagnosis of rheumatoid arthritis and chronic kidney disease and atrial

fibrillation, the QRISK2 is more accurate in predicting the risk than the original QRISK (Hippisley-Cox et al. 2008). In contrast to the USA based Framingham model, QRISK2 is based on data derived from primary care records in the UK. The original validation of QRISK2 did not require recruitment and monitoring of participants and this contributed to a much larger study population than obtained in the Framingham study (Jackson 2008). The QRISK2 model is based on data from 531 practices (2.3 million patients; aged 35-74) studied from 1 January 1993 to 31 March 2008 (Hippisley-Cox et al. 2008). In addition to the standard risk factors for CVD taken into account by Framingham, QRISK2 also takes account of variables relating to socioeconomic status and ethnicity (Hippisley-Cox et al. 2007).

Unlike Framingham which overestimates CVD risk in lower risk populations and underestimates CVD risk in higher risk populations, the QRISK2 score is more accurate in predicting CVD risk (Jackson 2008). The claimed accuracy of QRISK2 is due to the increased size of the data base, the type of population from which the data were derived and validated, and the inclusion of other variables.

Furthermore, an independent and external validation of the QRISK2 has provided evidence to support the use of QRISK in favour of the modified Framingham equation (Collins and Altman 2010). Individuals are either classified at low (<10%), moderate (10-20%) or high (>20%) risk of suffering from a CVD event within the next 10 years. However, its relevance has been somewhat questioned for the use on Northern Europeans' demographies

(Hippisley-Cox et al. 2007). Although Framingham has been modified to accommodate UK populations, it over-predicted 35% of individuals at low risk of CVD over the next 10 years, as well as over-predicting those at moderate risk. Framingham also under-predicted 13% of individuals found to be at a high risk of CVD. Researchers from University of Nottingham have developed a CVD risk algorithm for the use in the UK demography, QRISK (Hippisley-Cox et al. 2007).

The accuracy of Framingham compared with that of QRISK2 in one study (Collins and Altman 2010) is shown in Figure 7-1. Patients who had their CVD risk underestimated by the modified Framingham when compared with QRISK2 tended to be older, have been treated for hypertension, have a family history of coronary heart disease, and have a diagnosis of type 2 diabetes, rheumatoid arthritis, or atrial fibrillation (Collins and Altman 2010).

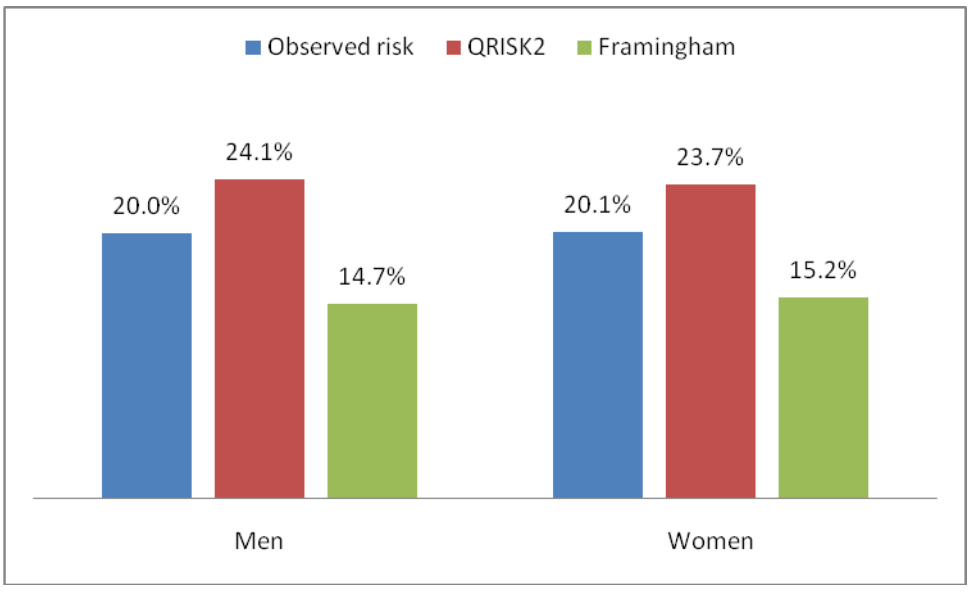

Figure 7 - 1 Comparison of Framingham and QRISK2 with the observed CVD events among those who were reclassified by QRISK2 as high risk from low/moderate. Data obtained from Collins and Altman (2010)

Another feature is available when using the QRISK2 calculator which is a heart age tool (QHeartAge) to communicate the CVD risk in more meaningful way. QHeartAge works out the typical age of a person of the same sex and ethnicity that normally has the same 10-year QRISK2 score (Hippisley-Cox 2011). For example, it could provide a false reassurance if a 50 year old woman was just told she had a low risk if it was 9% as a woman of this age her typical risk would be 3%. Therefore, by communicating the QHeartAge (which is in this case is 64) will help the clinician to highlight the danger if risk factors are ignored. If the subject has a CVD risk estimate that is typical for his/her age, the QHeartAge will be equal his/her chronological age.

Aim

To compare the cardiovascular risk estimates of those who accessed a community pharmacy based VRA service using the Framingham based BNF charts and the QRISK2 algorithm

Objectives

- Determine the proportion of individuals who had their CVD risk underestimated by Framingham algorithm when compared with the risk calculated using QRISK2.
- Determine the proportion of individuals who had their CVD risk overestimated by Framingham algorithm when compared with the risk calculated using QRISK2.
- Explore the differences in the CVD risk factors between those who had their risk calculated similarly by Framingham and QRISK2 algorithms, those who had their risk underestimated and those who had their risk overestimated.

7.2 Method

The VRA service was provided free of charge by Boots pharmacies in Merthyr Tydfil and Porthcawl, Wales, from November 2009 to August 2010 (Chapter 2). Individuals who had their Framingham risk estimated were included in this analysis. All test results were used anonymously to calculate the CVD risk using QRISK2. This was done to permit comparison of the Framingham based CVD risk assessment with that of QRISK2. This was a desktop exercise and the results were not communicated to the service user.

Information collected through the VRA service, obtained by a questionnaire and measurements, was sufficient to calculate the Framingham score. That included; age, gender, smoking status, family history of CVD, diabetes status, total cholesterol, HDL cholesterol and systolic blood pressure.

However, another data collection form was devised to capture the other parameters required to calculate cardiovascular risk using QRISK2. Information collected by this form included; ethnicity (Appendix 3b) based on the 16+1 classification, and whether the patient suffered from atrial fibrillation, chronic kidney disease or rheumatoid arthritis.

Deprivation was determined by the patient's residential postcode. Townsend Deprivation Index is used in this analysis for the reason that it is the same deprivation index used by QRISK2 algorithm. Each quintile represents 20% of the population: the first quintile (Q1) comprises the 20% least deprived areas in England and Wales. While the last quintile (Q5) represents the 20% most deprived areas.

The QRISK batch processor, version 2.1, software was used to obtain the estimates of the individuals' CVD risk based on QRISK2 algorithm.

PASW Statistics 18 was used for analysing the data. Chi-square test was used when comparing variables with nominal values, for example, gender and smoking status, or ordinal values, e.g. deprivation status. Mann-Whitney U test was used when comparing variables (two samples) with continuous data, for example, age, blood pressure, and cholesterol levels. The Kruskal Wallis test was used when comparing three or more groups with ranked data for example, when comparing age in each group of CVD risks (low, moderate and high). Patients' ages were compared with their QHeartAge, that is, the typical age determined by their QRISK2 score, by using paired-sampled student t-test.

7.3 Results

A total of 146 people had their CVD risk assessed, 107 (73%) from Porthcawl and 39 (27%) from Merthyr Tydfil. Table 7-2 shows the results required in the calculating CVD risk by both Framingham and QRISK2 algorithms.

Table 7 - 2 Risk factors required in calculating CVD risk by both Framingham and QRISK2 algorithms of service users who had their CVD risk estimated

Risk factor	Results
Age	59 years (range 38 to 74, SD = ±9.3)
Females	87 (60%)
Males	59 (40%)
Family history of CVD	44 (30%)
Current smokers	10 (7%)
Quit smoking ≤ 5 years	6 (4%)
Systolic BP	135 mmHg (range 82 to 194, SD = ±18.3)
Total Cholesterol	4.87 mmol/L (range 2.75 to 7.28, SD = ±0.87)
HDL cholesterol	1.29 mmol/L (range 0.62 to 2.47, SD = ±0.42)
Total Cholesterol: HDL ratio	4.1 mmol/L (range 1.9 to 7.8, SD = ±1.3)
Ethnicity- White	144 (99%)
Pakistani	1 (0.7%)
Indian	1 (0.7%)

Table 7-3 shows risk factors required in calculating CVD risk by QRISK2 algorithm only. All service users were non-diabetic and no one was on blood pressure treatment nor suffered from chronic kidney disease.

Table 7 - 3 Risk factors required to calculate CVD risk by only the QRISK2 algorithm

Risk factor	Results
BMI	mean = 27.7 kg/m^2
	(range 18.4 to 44.9, SD = ±4.3)
< 25 kg/m^2	37 (25%)
≥ 25 and < 30 kg/m^2	68 (47%)
> 30 kg/m^2	41 (28%)
Deprivation	5 (3%) could not be allocated to a deprivation quintile.
Q1 (Least deprived)	53 (36%)
Q2	6 (4%)
Q3	7 (5%)
Q4	48 (33%)
Q5 (Most deprived)	27 (18%)
Atrial fibrillation	2 (1%)
Rheumatoid arthritis	6 (4%)

Table 7-4 lists other characteristics related to the cardiovascular system but not taken into account by either of the algorithms, such as alcohol intake, the level of physical activity and whether the user had daily intake of fruits and vegetables.

Table 7 - 4 Lifestyle factors that could affect the cardiovascular system but not taken into account by either Framingham or QRISK2

Lifestyle factor	Results
Alcohol-	
No alcohol intake	25 (17%)
Alcohol intake within the recommended weekly limits	111 (76%)
Alcohol intake exceeding the recommended weekly limits	10 (7%)
Daily intake of vegetables and fruits	110 (75%)
Exercise-	
No exercise	8 (6%)
Exercise- some (1-2 days a week)	33 (23%)
Exercise- moderate or regular (3 days or more per week)	105 (72%)
Waist circumference	92.7 cm (range 65 to 124, SD = ±12.6)
OK (acceptable size)	42 (29%)
Increased risk	39 (27%)
High risk	60 (41%)

By using Framingham CVD risk algorithm, a total of 63 (43%) individuals were at low risk, 46 (32%) moderate and 37 (25%) high risk of developing CVD in the next 10 years. However, 44 of the cases (30%) had their risk overestimated (n = 25; 17%) or underestimated (n = 19; 13%) when compared with results calculated by QRISK2 algorithm (Table 7-5). This was a statistically significant difference ($p < 0.001$, Chi Squared test).

Table 7 - 5 Estimates of CVD risk compared between Framingham and QRISK2 algorithms.

			QRISK2		
			Low	Moderate	High
		Total	66	46	34
Framingham	Low	63	54 (86)*	9 (14)‡	0
	Moderate	46	12 (26)†	24 (52)*	10 (22)‡
	High	37	0	13 (35)†	24 (65)*

(%), * estimates similar by both algorithms, ‡ risk underestimated by Framingham, † risk overestimated by Framingham

The differences in estimates derived from Framingham and QRISK2 were similar ($p > 0.05$, Chi Square test) for both pharmacies in Porthcawl and Merthyr Tydfil (Figure 7-2).

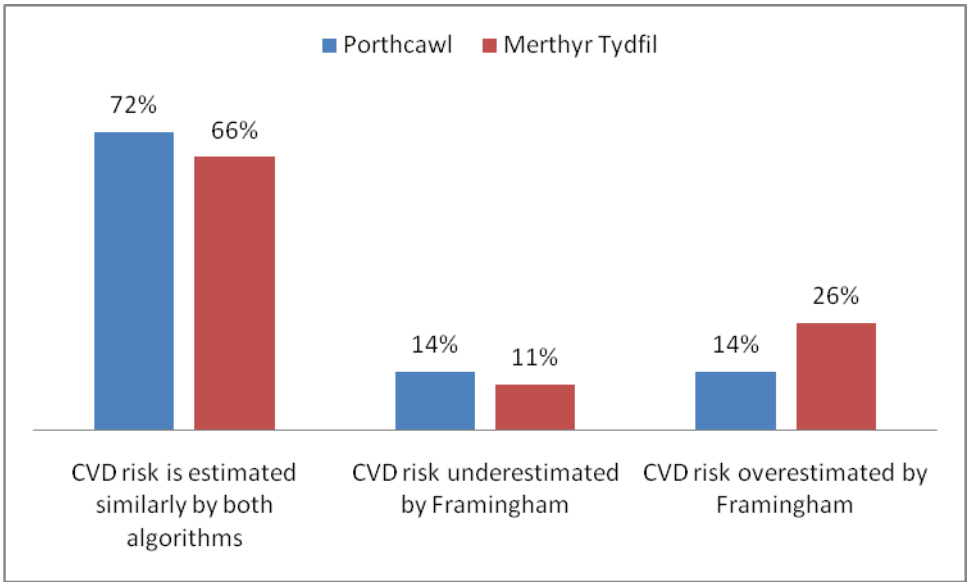

Figure 7 - 2 The differences in estimates of Framingham and QRISK2 algorithms between Porthcawl and Merthyr Tydfil

No significant difference was found ($p > 0.05$, Chi Square test) between different deprivation areas (Figure 7-3).

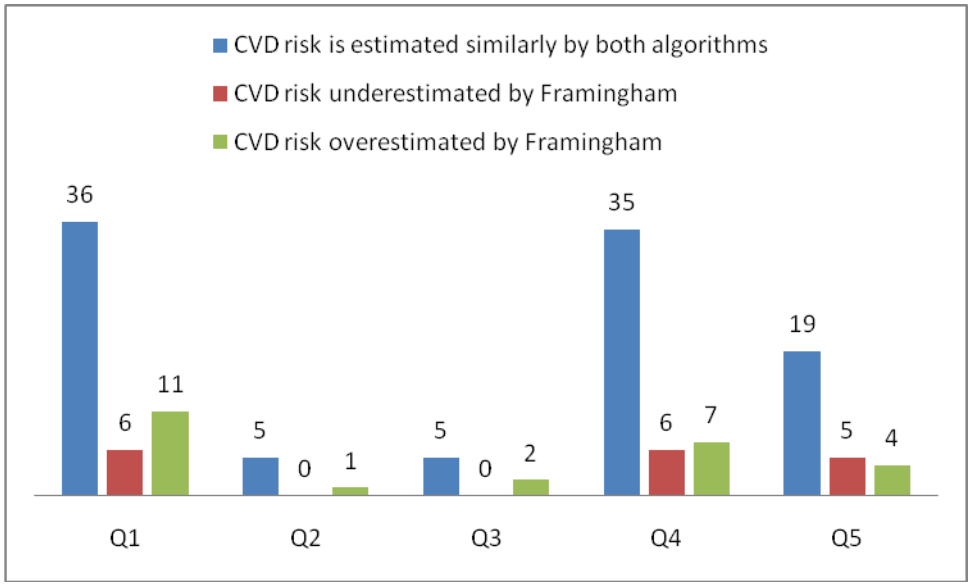

Figure 7 - 3 The differences in estimates of Framingham and QRISK2 algorithms between the 5 deprivation quintiles

People who had their CVD risk underestimated by Framingham tended to be older ($p < 0.001$, Kruskal Wallis test) (Figure 7-4).

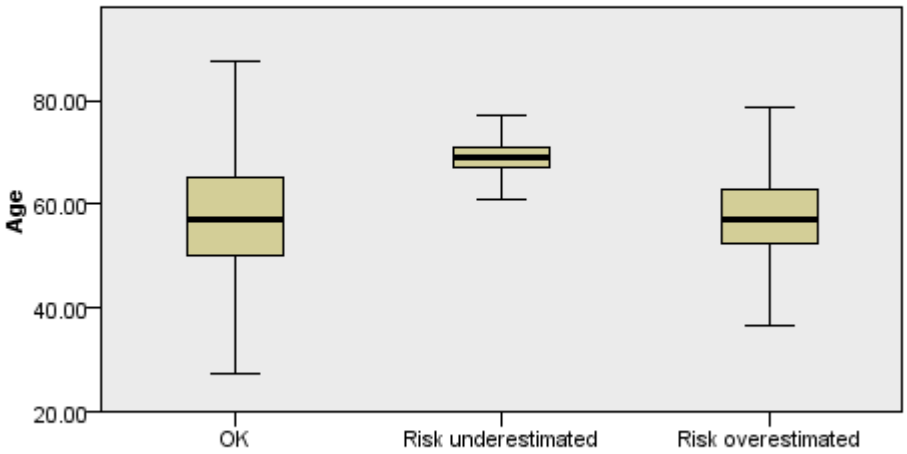

Figure 7 - 4 Differences in estimates of Framingham and QRISK2 compared with age

Higher ($p < 0.05$, Kruskal Wallis test) systolic blood pressure measurements were seen in those who had their risk overestimated (Figure 7-5).

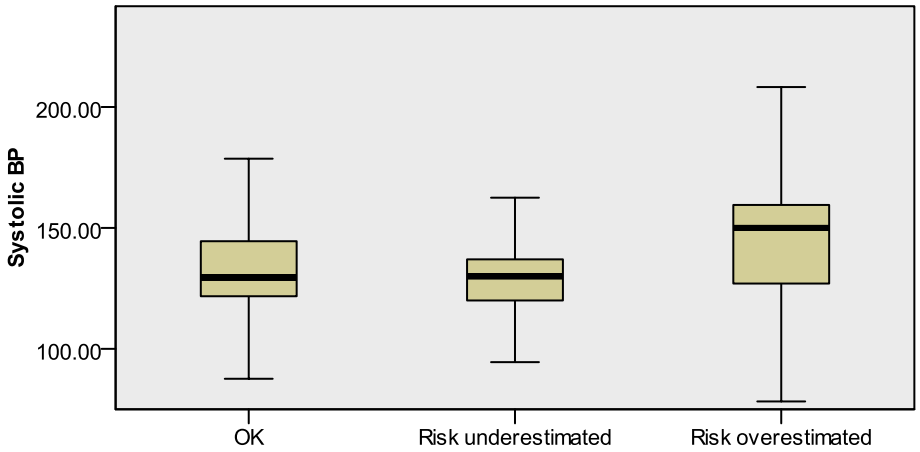

Figure 7 - 5 Differences in estimates of Framingham and QRISK2 compared with systolic BP measurements

Lower levels ($p < 0.05$, Kruskal Wallis test) of total cholesterol to HDL ratio were seen in those who had their risk underestimated (Figure 7-6). No other significant difference in any of the other risk factors were found between the three groups of estimates.

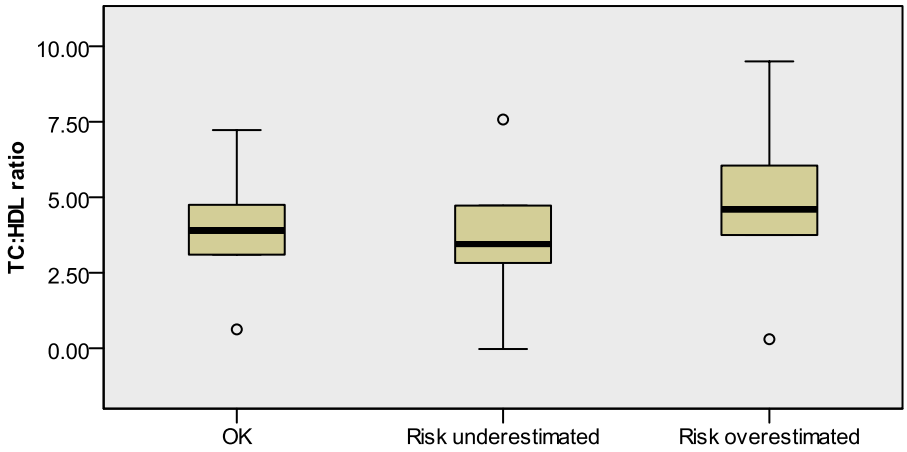

Figure 7 - 6 Differences in estimates of Framingham and QRISK2 compared with measurements of total cholesterol: HDL ratio.

A total of 53 subjects (36%) were referred to their GP for further investigation. Reasons for referral (Chapter 2 for more details) included a score of >20%

using the modified Framingham algorithm, high blood pressure and/or high total cholesterol.

The typical age (mean 61, SD ± 10.7) determined by the QRISK2, QHeartAge, was significantly different ($p < 0.001$, paired-sampled student t-test) from the actual age (mean 59, SD ± 9.3) of the service users (Figure 7-7).

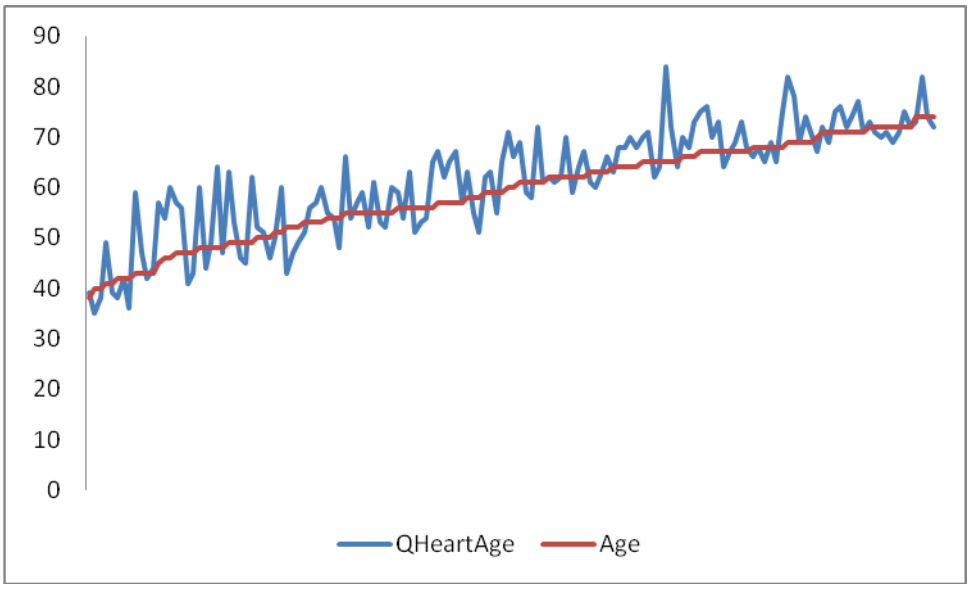

Figure 7 - 7 Actual age of individuals compared with the age (QHeartAge) determined by their QRISK score.

7.4 Discussion

The estimates derived from the modified Framingham algorithm and QRISK2 were significantly different when applied to data obtained in this present study sample. About a third of service users had their risk underestimated or overestimated by the modified Framingham algorithm when compared with those obtained using QRISK2.

The BNF charts, which are based on Framingham, overestimated the risk of 17% (n = 25) of participants (12 were identified at moderate risk instead of low risk and 13 were identified at high risk instead of moderate risk). On the other hand, the BNF charts underestimated the risk of 13% (n= 19) of the participants (9 were identified low instead of moderate and 10 were identified moderate instead of high).

The evidence is mounting to support the notion that QRISK2 is more accurate than Framingham for use in England and Wales (Collins and Altman 2010). Therefore, by using the BNF charts 13 participants were referred unnecessarily and 19 were given a false reassurance. If a generalisation can be made, this means by using the less accurate modified Framingham tool even in a Caucasian population, there will be a number of people being unnecessary referred and possibly prescribed medication not proven to be cost-effective for them, and perhaps exposing them to unwanted side-effects of prescribed medication. Similarly, by using this less accurate tool, a number of people are given a false reassurance where they actually need to be referred and helped to reduce their risk of developing CVD.

In addition to the accuracy of QRISK2, other advantages it has including the availability of features which could help clinicians to interpret the data to the layman, such as QHeartAge. For example, when someone is in his/her early 40s the chance that the CVD risk would be less than 10% even though their parameters are higher than the way they should be at. Therefore, these individuals could have their QHeartAge in late 50s or even 60s. Knowing the typical age for the person of same sex and ethnicity who would have this QRISK2 score, may be more encouraging and/or meaningful for the patient to make lifestyle changes. In the same way, healthy men over the age of 60 years would be always at moderate or high CVD risk. They would be reassured if they found their QHeartAge is lower than their actual age.

Having clear objectives prior to the start of the study allowed for the design of an appropriate data collection form to capture all the data needed. Knowing whether the service user suffered from rheumatoid arthritis, for example, was required for calculating CVD risk when using QRISK2 algorithm but not required when using the Framingham algorithm. Even though QRISK2 was not used as part of the service, the data collection form captured this information for later use. Similarly, QRISK2 uses different classification of ethnicity than the one used by the modified Framingham. The data collection form captured ethnicity using the 16+1 classification which was important to have an accurate calculating of risk.

The estimates derived from QRISK2 were not communicated to participants. The main reason for communicating Framingham estimates only was the fact

that the Boots SOP specified that the Framingham based BNF charts are to be used when estimating the 10-year CVD risk. Also, the local GP surgeries were expected to follow NICE guidelines which had recommended the modified Framingham, that is the BNF charts until March 2010 (NICE 2010a). It is very important that pharmacists use the same tool used by the GPs otherwise patients might receive conflicting information about their risk management.

7.4.1 Limitations

The VRA service was accessed by a relative small number of subjects. Also, the number of venues for providing the service was limited to two pharmacies only, at Porthcawl and Merthyr Tydfil. Most individuals (73%) had their CVD risk estimates done in Porthcawl.

The demographic characteristics of the study subjects were not representative of the general population. There were only two non-Caucasian people included in the study. Most participants came from the least deprived areas (Q1), followed by Q4 which means there was no appropriate spread between all deprivation quintiles. The genders were not equally represented with only 40% being males.

7.4.2 Conclusion

All participants (n = 146) who had their CVD risks estimated using the Framingham based BNF charts in the main study (Chapter 2) were included in this analysis to calculate their CVD risk again using QRISK2.

The BNF charts overestimated the risk of 17% (n = 25) of participants and underestimated the risk of 13% (n= 19) of the participants. Those who had their risk overestimated might have been put through unnecessary anxiety and were possibly subject to a pharmacological intervention. On the other hand, those who had their risk underestimated were given a false reassurance and may have missed out on opportunity to have the necessary interventions.

Chapter 8: General Discussion

8.1 Introduction

This chapter discusses the main findings in relation to the overall aim and objectives. The limitations are also discussed with the possible implications the findings might have for the practice and future research regarding the provision of cardiovascular risk assessment (VRA) services from the community pharmacy.

8.2 General findings

The aim of the thesis was to evaluate a community pharmacy based VRA service.

Since April 2009 the VRA service became part of the pharmacy enhanced services in England, that is, pharmacies being remunerated if they provide it for their local population (PSNC 2011). However, in Wales it was privately available at pharmacies on a limited scale.

The following objectives were determined to help to achieve the aim of this PhD thesis:

1. Examine the feasibility of establishing a VRA service in Welsh community pharmacies similar to that available in England, that is free of charge.
2. Determine how different people, including those who may be "hard-to-engage", respond to the service.
3. Examine patients' acceptance of the community pharmacy based VRA service.

4. Examine the short-term outcomes of those who accessed the VRA service.

5. Examine the longer term outcomes of those who accessed the VRA service.

6. To examine the differences, and the impact these difference could have on the service users, between the common tools available in the UK to estimate CVD risk.

The VRA service was established and was provided free of charge in two community pharmacies in South Wales. This was the first objective achieved. The VRA service was accessed by 172 individuals who provided their demographic details and some information about their lifestyle through self-completing a questionnaire. Then they had tests and measurements of blood pressure, total cholesterol, HDL, BMI and waist circumference. A total of 146 (85%) participants had their Framingham 10-year CVD risk calculated. All participants then had a consultation with the pharmacist where they had an advice tailored to their needs and if necessary they were signposted to the relevant services and/or referred to their GP. It is estimated that using the Framingham risk assessment tool would identify about 15% of those who aged 35 to 74 years in England and Wales as being at high risk (Collins and Altman 2010). The results of this study, however, showed that 25% of participants were at high risk. One explanation is that the present study included a higher proportion of older people, who are at greater risk (Hippisley-Cox et al. 2007). The method and the results are discussed in more detail in Chapter 2.

The second objective, that is, determining how different people respond to the service was also discussed in Chapter 2. However, two different, smaller studies were designed in order to understand this issue further and they are discussed in Chapters 5 and 6. Chapter 5 analysed the demographic characteristics of users of another service provided privately by a different Boots pharmacy. The aim of this study was to determine the effect that socio-economic status could have on the accessibility of the service when a charge was applied to the service users. This service was chosen because it was considered, with the exception of the charge, similar to that of the main study, however, there were other differences identified and they are discussed in the limitations in this chapter.

A comparison was made between the characteristics of the participants who had an assessment at Boots Porthcawl and those who had an MUR at the same pharmacy and this comparison is discussed in Chapter 6. This comparison was made to see if either of the two services was more likely to attract those who live in the most deprived communities.

Patients' acceptance of the VRA service was the third objective of this thesis and it was evaluated by two different methods which are an anonymous survey (Chapter 3) and a telephone interview (Chapter 4). The results from the anonymous survey show a high satisfaction among respondents with the VRA service they received at a community pharmacy. This was similar to other satisfaction surveys of those who accessed a VRA service (Horgan et al. 2009; Knowsley PCT 2008). The two week follow-up interview was conducted by a researcher, who did not provide the VRA service, in order to gain an insight in

the participants' views after having the assessment. The response rate was higher than the anonymous survey (92% versus 74% respectively). The two week follow-up interviews gave participants the opportunity to comment on the service and to express their degree of satisfaction.

The two-week follow-up interview was more in depth in contrast to the anonymous survey. It was timed to give participants a chance to reflect on the advice they had in the pharmacy and implement any changes. Also, the results were linked to the main study findings whereas in the anonymous survey the results were analysed separately. This follow-up helped to achieve the fourth objective as the short-term outcomes, as they were communicated by the participants, were evaluated.

The reported short term outcomes were identified as an initiation of lifestyle changes, a visit to their GP or nurse if they were referred and starting a pharmacological treatment if they were prescribed by their GP. Fifty-two participants (34%) reported a change, mostly to lifestyle with only one person stating that he had been prescribed medication. There was no direct question in the interview schedule about these changes, therefore those who did not mention a change could also have made some changes. Of those who were referred to their GP 45% stated that they made their visit by the time they had the two-week follow-up.

The evaluation of the longer-term outcomes of the VRA service was the fifth objective and they are discussed in Chapter 2. Participants (n = 105, 61%) who attended the twelve-month follow-up had the results of the two assessments

(pre- and post) compared using paired-samples Student's t-test. There was a statistically significant reduction in mean systolic and diastolic blood pressures and the mean Framingham score. There was also a statistically significant increase in mean HDL.

The improvement seen in the results collected at the twelve-month follow-up probably because those who were ready to make lifestyle changes participated in the study, that is, self-selection to participate in the study. Also participants knowing they were going to be tested again could have made them keen to put an extra effort to improve their lifestyle. Also it is unknown how many of those who declined the invitation to attend the twelve-month follow-up did not want to have the repeat tests because their lifestyle had worsened or had not improved over the previous year, that is self-selection as to continuation in the study could have been made in participation in the twelve-month follow-up.

The sixth objective of this thesis was achieved by the analysis presented in Chapter 7 where the comparison between Framingham CVD risk tool and QRISK2 algorithm was made. Although the estimates of CVD risk calculated by QRISK2 were not communicated to the participants, it identified potential problems which could occur when the GP uses one tool and the pharmacist uses the other. The BNF charts which are based on Framingham overestimated the risk of 17% (n = 25) of participants and underestimated the risk of 13% (n= 19) of the participants. There was an independent validation of QRISK2 which suggested a higher accuracy than Framingham (Collins and Altman 2010). Therefore, by using the BNF charts 13 participants were referred unnecessarily and 19 were given a false reassurance.

8.3 The future of the national VRA service

The impact assessment of the national VRA in England (NHS Health Checks) concluded that the service is cost-effective with the most benefit if it was universal for those aged 40 to 74 years and repeated every five years (DOH 2008a). However, Chamnan et al. (2010) estimated the population impact to be similar with a lower cost if the VRA service is available to those who aged 50 to 74 years. The authors argued that the Department of Health modelling depended on an incomplete data set whereas they used data from a prospective cohort thus less missing data.

Another strategy suggested, which may have a similar impact with a significantly lower cost, is stratification of people before they are invited for a VRA. Patients' data collected routinely by GP practices is suggested for use to stratify people so that only individuals at certain risk will be invited for a VRA (Chamnan et al. 2010). The authors did not discuss whether only those who are registered with a GP surgery will benefit from this strategy. Horgan et al. (2010) in an analysis of a pilot VRA data identified four individuals who were not registered with a GP surgery. The authors stated that by targeting areas with higher deprivation more of those who are unregistered with a GP surgery will be identified and helped. Also, the response to an invitation needs to be evaluated as other screening services shown that this approach is less effective in lower socioeconomic groups (Thomas et al. 2005; Tseng et al. 2001) . As a consequence, there is a risk that by relying on invitation systems this will lead to the widening in the health inequalities gap.

Providing the service only in neighbourhoods with high deprivation will not reduce health inequalities to a desired level. However, "proportionate universalism", that is, actions applied in an intensity proportionate to the level of deprivation is more effective in reducing the gap between the most deprived and the least deprived (Marmot 2010).

Wald et al. (2011) suggested that prescribing a statin to all people aged 55 years or over will be more cost-effective than either the use of Framingham or QRISK2. However, there were some concerns expressed in the media by healthcare professionals with regard to screening using age only instead of risk assessment tools. Those concerns were mainly about the adverse effects that many people who do not need any treatment will be at risk of. Also the issue of "over medicalisation" of the population was raised. The cost benefit analysis included only Framingham risk assessment which is less accurate than QRISK2 algorithm (NHS Choices 2011b).

Evidence of postcode lotteries in the English NHS Health Checks has been found, that is, different geographical areas have different standards of the VRA service and the risk reduction services (Graley et al. 2011). For example, there are some Primary Care Trusts (PCT) which only provide the service to those who are registered with a GP surgery in the same trust whereas other PCTs provide it to all residence regardless whether or not they are registered with a GP surgery. Guidelines should be in place for service providers to ensure minimum standards are met.

8.4 Limitations

This section discusses the limitations which are related to the main study in general terms whereas limitations related to specific elements are mentioned in the relevant chapters.

The VRA service was established with the aim to examine the impact such a service would have on those who access it. It was important for the VRA service to be as similar as possible to those available at pharmacies elsewhere, such as Boots Healthy Heart service and the English NHS service. However, there were inherent differences which could not be overcome. A major difference is that the VRA service in the main study was provided solely by the research pharmacist. This included helping individuals in completing the service questionnaire, through conducting all the tests and measurements and finishing with the consultation and provision of advice. Also, the research pharmacist was not part of the pharmacy team which means we did not investigate the possible impact of this service on the workload of the pharmacy.

The VRA service was available at two community pharmacies only. This is a small number compared to other studies conducted in the UK (Donyai and van den Berg 2009; Horgan et al. 2010; Thornley et al. 2009b). The sample size was also small in comparison to these descriptive studies. However, more participants in this study were recruited when compared to the sample size specified by Mc Namara et al. (2010) in their protocol for a longitudinal pre-

post study, and more than the participants (n = 26) in the study conducted by Lalonde et al. (2006).

Lack of blinding is an important limitation affecting the validity of results of pharmacy practice research (Charrois et al. 2009). Another limitation is the fact that the research pharmacist, who had had a major role in study design, was the provider of the service and also being the evaluator of its effectiveness. Researcher bias in qualitative research has been studied where the interviewer could be a source of potential bias to the results (Chenail 2011). Even though the role of the researcher in this study is different from the role of the interviewer in qualitative research, the potential researcher bias cannot be disregarded. Similarly the interviewer who conducted the two-week follow-up interviews was one of the research team which means there was a risk of bias.

The research pharmacist took blood pressure measurements, which might be considered a subjective outcome (Vera-Cala et al. 2011), at the initial assessment as well as the twelve-month follow-up assessment. This possible bias could have been reduced if another person, for example a trained pharmacy assistant took these measurements.

The absence of a control group, to compare the results with, means that the positive outcomes that were seen in the study cannot be confidently attributed to the VRA service. Participants were informed through the patient information sheet (Appendix 1) about the details of the study and they knew about the time of the twelve-month follow-up. The knowledge could have made them to take the opportunity as a challenge and they might have put an extra effort more

than they would have done if it was a one off assessment. At the initial assessment some participants had mentioned that they would make a great deal of effort to achieve the agreed goals by the time of the twelve-month follow-up. The two-week follow-up also could have helped participants to follow the lifestyle advice they had at the initial assessment. The reminder letter participants received before the twelve-month follow-up could have been a reminder for a behavioural change. A methodology which includes a control group and randomises participants would be needed to study the real effect of the service.

A limitation with regard to the recruitment strategy includes self-selection, a convenience sample, which means participants of the present study were likely to be particularly interested in their health. This would make them unrepresentative of the general population (Smith 2010).

Lifestyle information was not collected through using a detailed questionnaire which is based on rigorous academic research. The Boots service questionnaire (Appendix 3a) helped to elicit brief information about participants' lifestyle. Although more information was obtained during the consultation, it was not possible to use it in the data analysis, for example some participants stated that their weekly alcohol consumption was within the recommended level but during the consultation they admitted that this amount of alcohol tend to be on one or two nights (binge drinking). When comparing the self-reported lifestyle characteristics of the participants with the national statistics for Wales (NHS Wales 2006; WAG 2007; Wales Centre for Health 2009) it seems that a higher

proportion of the participants were leading a healthy lifestyle than the general public. This was not reflected, however, in terms of their body weight as 58% in the present study were either overweight or obese.

One of the objectives of this study was to investigate whether the VRA service would be accessible to those who live in communities with the highest deprivation. The first venue (Boots at Porthcawl), however, was chosen because it was the most convenient. It was not located in a surrounding of the most deprived areas and it was not either located in an area with high proportion of ethnic minorities. Therefore, the second venue (Boots at Merthyr Tydfil) was chosen because it was located in a borough with the highest fraction of the most deprived areas in Wales (WAG 2008). Even though the second venue was added to evaluate the service in different venues, most of the data (77%) were collected from Porthcawl.

Recruitment strategy was less effective in recruiting more of those who would be considered from the "hard-to-engage" groups, for example only 41% were men and only two participants were non-Caucasians. Also, those who were recruited in the study seemed to have a healthier lifestyle than the general population in Wales. This would make the study sample less representative which adds another reason against generalisability.

The original advert (Appendix 7a) listed inclusion and exclusion criteria which were different from those for the forthcoming NHS VRA service. There were several participants who could not have their CVD risk calculated because of their medical history. Those participants would have been ineligible for an

NHS service if it was available in Wales. Eventually, in March 2010 the second version of the advert (Appendix 7b) was designed to ensure that only those who would be eligible for such a service were recruited. The first version was designed with the intention that it would be similar to the official Boots advert for the company private service.

Certain groups of people could have been recruited if the service was available in places outside the pharmacy, such as churches, mosques, community centres, rugby clubs and caravan sites. This could have increased the range of demographics of the participants.

The flexibility was limited in the times the service was available. Providing the service during normal office hours on one or two days a week might not be convenient for those who are in full time jobs. It would have been more attractive to those people if the service was available everyday or even at the weekends. Pharmacies opening long hours, such as those located at retail parks (edge of town pharmacies) or supermarket pharmacies could have been a suitable alternative. Also in comparison with where the service is normally provided the VRA service in this study probably less accessible as the service at other Boots pharmacies is usually provided every day including the weekends and more likely to be available without the need for an appointment.

Although the twelve-month follow-up assessment examined the longer-term outcomes, this period is not long enough to examine whether or not the lifestyle change, if any, is maintained. There is lack of evidence that lifestyle improvement, such as an increase in physical activity, achieved by health-care

professional interventions is sustained for periods of more than one year (Lawton et al. 2009).

Although the response rate (61%) for the twelve-month follow-up was not low when compared with other studies (Cranor et al. 2003; Yamada et al. 2005), other studies achieved higher response rate. Recruitment for follow-up appointments is challenging particularly when no incentive is available. Incentives can increase the follow-up recruitments up to 100% as in the case of another study evaluating diabetes care which was conducted in the USA this rate could have been improved by offering incentives to participants (Garrett and Bluml 2005). The use of technology, such as emails and text messages, to remind participants shortly before the appointment time could have helped to increase the response rate as a handful of participants booked an appointment to have the follow-up, but they did not show up. This could have increased the sample size of the whole study as there were some missing appointments at the initial assessments as well which resulted in loss of potential participants.

There is a possibility that the Framingham VRA tool used in this study, the BNF charts, is going to be replaced by QRISK2 by the time the service is available nationally in Wales. As it is mentioned in Chapter 7 there are differences in the results, therefore by using another VRA tool some of the data would be less relevant to the future national service.

8.5 Implications for practice

This thesis confirmed what is already known that effective communication channels with GPs need to be established so that relevant information is shared

to prevent test duplication and to maximise the service' benefits. Making the VRA service available in more than one place and delivered by different providers would encourage some individuals to access the same service several times (WAG 2010). Subsequently, there would be an increase in the cost and a loss of resources.

If the Welsh Government decided to roll out the free-of-charge VRA service across Wales and community pharmacy is included, pharmacy staff should inform the service users that service is exactly the same regardless of where it is provided. Advertising materials should make it clear to the public that all VRA services are the same and there is no need to have the test more than once.

Local GP surgeries and pharmacies should agree on which VRA tool to be used. It is important that the most accurate tool and relevant to the population is used. The QRISK2 was developed and validated in England and Wales and there is cumulative evidence to suggest that it is more accurate than the Framingham based tools when used in British population (Collins and Altman 2010). Clinicians should abandon the use of less accurate tools to prevent overestimating or underestimating CVD risk of their patients, therefore preventing the unnecessary anxiety for some and false reassurance for the others.

During the consultation, the time is limited to go through all the health changes which the service user might need to make if he/she has multiple risk factors. For example, a smoker who needs to lose weight and increase physical activity

will not have enough time to deal with each issue during a single consultation. The limited time of the consultation is dealt with currently by signposting the service user to the relevant services. However, other approaches may be useful to increase efficacy, such as posting reminder letters and written information after the consultation to encourage individuals to follow the advice that they had from the pharmacist.

The VRA service was not as accessible as it was hoped to be for the "hard-to-engage". Health inequalities are increasing in Wales between the most deprived areas and the least deprived areas. People in the least deprived areas can expect to live in good health for 18 to 19 years longer than those in the most deprived areas (Public Health Wales 2011). The gap in the life expectancy is widening as well; the difference is now 9.2 years for men (previously 8.6) and 7.1 for women (previously 6.5). Taking into account health inequalities, such a service should target those who live in the most deprived areas.

Although men and certain ethnic groups are at higher risk of CVD in general they were under-represented in this study. A report published by Heart UK, a charity which aims to raise awareness of the risks of high cholesterol and to decrease preventable premature deaths caused by CVD, criticised the uptake of the English NHS Health Checks as patchy and made a number of recommendations to overcome the obstacles to the progress the service facing including about the strategies which should be in place for the service to reach those who are less likely to respond to such services (Heart UK 2011).

Recruiting individuals from the hard-to-engage groups, such as men, ethnic minorities and those with a lower social-economic status will present a challenge for the service provider. Recruitment strategies that aimed to attract such groups should be developed and tested. Heart MOT, a pilot which was aimed at men was successful in attracting a higher percentage of men than it is the case in similar services (Horgan et al. 2010). The importance of attracting individuals from the most deprived communities in that the service would help to reduce the health inequality gap (Jain et al. 2011; Richards 2009).

8.6 Future work

In this study the outcomes of the referral were evaluated after being communicated by the participants during the two week follow-up interview and the twelve-month follow-up assessment. Further research is required to evaluate the outcomes of the referral using a method with more accuracy, for example requesting feedback directly from the GP surgery.

Recently the universal cardiovascular risk screening, currently available in England and expected to be rolled out across Wales, was described as not evidence-based policy (Katikireddi et al. 2011). The authors suggested that evidence is in favour of the targeted risk screening. Whether this criticism will change health policy in England and Wales is still unknown. For community pharmacy to continue in this favourable position as a provider of the VRA service, it is essential that collaboration is maximised between GPs and pharmacists as targeted screening will depend on the routine data available at

GP practices. To find out the extent of how GPs are willing to work with pharmacists to drive this policy forward needs to be investigated.

There are other approaches being developed and piloted in primary care settings (Cox et al. 2011) and in community pharmacy (Mc Namara et al. 2010) where the intervention includes a novel programme to assess CVD risk and also several sessions to manage CVD risk factors. However, to date no studies have been published to describe similar approaches here in the UK.

The uptake of invitations for the VRA service also requires investigation. Based on other screening services (Thomas et al. 2005; Tseng et al. 2001), different ethnic groups and socioeconomic groups are expected to respond differently to the invitations. Furthermore, more research is needed on different recruitment strategies including how to invite people, for example, whether the use of technology can be included, and what formats and languages should be used for promotional and recruitment materials, to address health inequalities.

The provision of the VRA service by the pharmacy team in unconventional places, such as local caravan sites, churches, mosques and in community centres, needs to be evaluated. A similar service was provided in Hindu temples by other healthcare professionals was effective in identifying high prevalence of modifiable risk factors for CVD (Rao et al. 2011).

The cost-effectiveness of a universal NHS VRA service will depend on the number of high risk people identified and the available risk reduction services (Dalton et al. 2011). Further work is needed to see if the community pharmacy

can target those who will mostly benefit from the screening and from any intervention the pharmacist can make to reduce the risk of developing CVD.

8.7 Conclusion

The VRA was established in two community pharmacies in South Wales and evaluated in this PhD thesis. The study recruited 172 individuals who had their CVD risk factors evaluated and 85% (n = 146) had communicated to them their 10-year CVD risk estimated by using the Framingham based BNF charts.

All study participants had the opportunity to provide their feedback anonymously on the service they received. A response rate of 74% (n = 127) was achieved to this anonymous survey. The results show a high satisfaction among respondents with the VRA service they received at a community pharmacy.

Participants' recall and understanding of the pharmacist's advice were explored during the two-week follow-up interview which was conducted by a researcher who did not provide the VRA service. The response rate was 92%. Short-term self-reported outcomes reported include change to lifestyle (34%) and having made a GP visit if referred by the pharmacist (45%).

The longer-term outcomes of those (n = 105, 61%) who attended at the twelve-month follow-up assessment were investigated. There was a statistically significant reduction in mean systolic and diastolic blood pressures and in and the Framingham score. There was also an increase in the mean HDL. However, the improvement seen in the results could not be attributed to the VRA service because of the absence of the control group.

There were major differences in the estimates of the 10-year CVD risk of the same sample when QRISK2 was used instead of the Framingham based BNF charts. Community pharmacist providing the VRA service should open communication channels with GPs in order to use the same VRA tool the GPs are using.

To date this is the first study to investigate short-term and longer-term outcomes of a limited community pharmacy-based VRA service in Wales.

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List of publications

Muir D, Waheedi S, Donovan M, Walker R and John DN. (2012). A non-NHS, free of charge, community pharmacy-based cardiovascular risk assessment service: the views and experiences of the service users. *International Journal of Pharmacy Practice*. Abstract accepted. In press

Waheedi S, Walker R and John DN. (2012) An analysis of medicines use review documentation in one community pharmacy. *International Journal of Clinical Pharmacy* 34, p. 184.

Waheedi S, Donovan M, Walker R and John DN. (2011). Reasons for requesting and patient satisfaction with a free, non-NHS, community pharmacy-based vascular risk assessment (VRA) service. *International Journal of Pharmacy Practice* 19 (S2), pp. 39-40.

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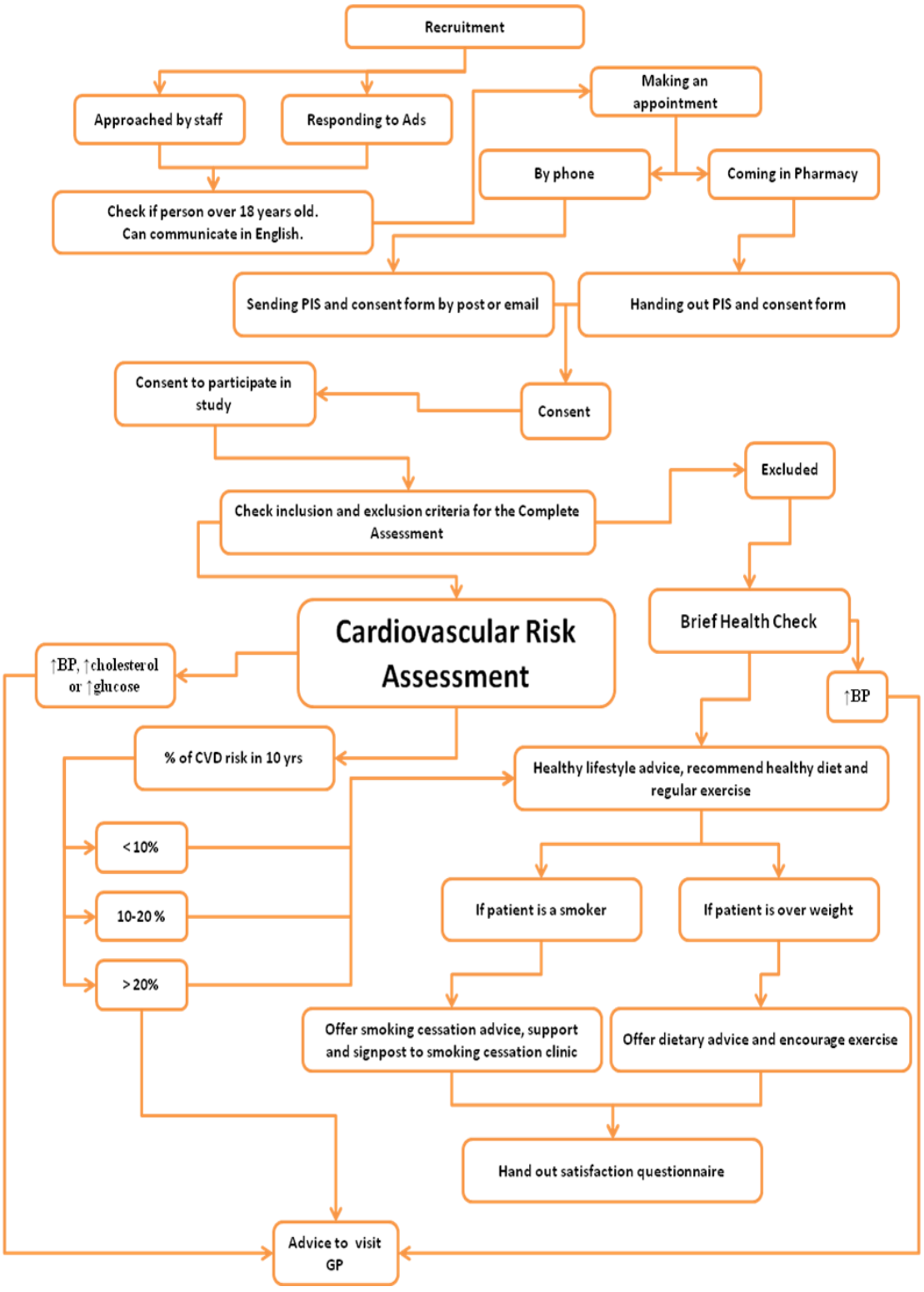
Waheedi S, John DN, Donovan M and Walker R. (2010). Deprivation status and utilization of a non-NHS community pharmacy based cardiovascular risk assessment service. *International Journal of Pharmacy Practice* 18, pp. 61-62.

Appendices

Appendix 1: The participant journey through the VRA service



Appendix 2a: Participant Information Sheet

Evaluation of a cardiovascular risk assessment service

You are invited to participate in a study. Before you decide whether or not to participate, please take the time to read the following information. It is important you understand what is involved and the reasons behind the study. You are free to discuss the information with others if you wish. Please do not hesitate to ask any questions.

Thank you for reading this.

What is the purpose of the study?

We have started to provide a cardiovascular risk assessment service, free of charge, at Boots, Porthcawl. The aim of the study is to evaluate this service which consists of an assessment of your risk of developing cardiovascular disease (heart attack or stroke) in the next 10 years. As part of the service we will provide you with information and advice to help you make lifestyle changes to reduce your cardiovascular risk. We would like to follow-up people who use this service for 12 months. We are interested to find out how they deal with the information and advice we provide. Therefore, two follow-ups have been planned.

Who are the researchers and who is funding the research?

The research team is based at Welsh School of Pharmacy, Cardiff University and consists of Mr Salah Waheedi (a community pharmacist/research pharmacist), Dr Dai John and Professor Roger Walker. The data will be collected by Mr Waheedi. The research is

funded by Cardiff University and has been approved by South West Wales Local Research Ethics Committee (subject to approval).

Why have I been invited to participate in this study?

You have been invited to participate because you expressed an interest in undertaking a cardiovascular risk assessment at Boots, Porthcawl.

What is expected of me?

After you have had the cardiovascular risk assessment service we would like to contact you on two further occasions and I would like to ask for your consent to do this. Information about the cardiovascular risk assessment service is provided in the 'Look after your hear' flyer. The service usually takes between 25 to 40 minutes. You are not expected to agree to anything that you do not want to. The following sections will describe in more detail what is expected.

1) Two-week follow-up interview

This interview will be over the telephone and will take place approximately two weeks after the cardiovascular risk assessment service. It is expected that the interview will take about 10-15 minutes but it may be longer. A researcher will phone you to obtain your views and to see if you have any comments you want to share. The researcher will ask you about the advice you were given. The interview will be audio recorded, with your permission, or the researcher will take brief notes. If at any time you feel that the audio recording should be stopped then you are free to say so.

2) Twelve month follow-up

Approximately 11 months after the cardiovascular risk assessment service you will receive a reminder letter about this study and then you will be contacted to make an appointment for an interview in the pharmacy. If appropriate we will repeat all the tests you initially had as part of the cardiovascular risk assessment service. The additional assessment you will have in this follow-up will allow comparison of your new results with the results from your initial assessment. With the reminder letter we will enclose a pre-paid envelope which you can send back in case you wish to withdraw from the study or do not want to be contacted by telephone.

Do I have to take part?

It is up to you to decide whether to consent. If you decide to consent please read and sign the consent form enclosed. Please bring along both signed copies of the form to the pharmacy or sign them in the pharmacy before you have the cardiovascular risk assessment service. One copy is for your own records. You can withdraw your consent at any time without giving a reason. If you require more information please feel free to contact myself (Mr Waheedi: contact details below) or my project supervisor (Dr Dai John: contact details below), this does not commit you to participating.

How will my information be used?

When collecting information and data we will ensure confidentiality at all times. Any published information will not identify your involvement in the study. A copy of the consent form, satisfaction questionnaire and result documents will be kept securely in the Welsh School of Pharmacy. The

information we retain on university computers, however, will contain no personal data, only a reference number.

Your name and address will not be kept for any longer than is needed to complete the study. It is anticipated this will be no longer than three years. Your details will only be seen by the research team.

Who can I contact for more information?

We are more than happy to discuss any issues you may have regarding the research project. Our contact details are as follows:

Research pharmacist:

Mr Salah Waheedi, Welsh School of Pharmacy, Cardiff University, Redwood Building, King Edward VII Avenue, Cardiff. CF10 3NB

Telephone: 0776559690 E-mail: waheedis2@cf.ac.uk

Research project supervisor and pharmacist:

Dr Dai John, Welsh School of Pharmacy, Cardiff University, Redwood Building, King Edward VII Avenue, Cardiff. CF10 3NB

Telephone: 029 208 75804 E-mail: johndn@cf.ac.uk

Thank you for taking the time to read this information.

Appendix 2b: Consent form

Consent Form

Project title: Evaluation of a cardiovascular risk assessment service

Please read the following statements and put your initials in the boxes next to the statements that you consent to. Please also sign and date the form below.

(If you do not agree with any of the following statements do not initial the box)

- I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions. ☐
- I understand that my participation is voluntary and that I am free to withdraw my consent at any time, without giving a reason. ☐

➢ I agree to the following stages (please initial next to each stage that you will participate in):

1) Two-week follow-up interview

I agree to an interview over the telephone at a mutually agreed time to take place approximately 2 weeks after receiving the service. ☐

I agree for the interview to be audio-recorded ☐

2) Twelve-month follow-up consultation

I agree to a member of the research team contacting me in approximately 11 months to arrange a follow-up consultation. ☐

I agree to a consultation in the pharmacy at a mutually agreed time approximately 12 months after the receiving the service. ☐

I agree to have the cardiovascular risk assessment repeated to help determine if the programme has been effective. ☐

I agree to Mr Waheedi storing my contact details so that he may contact me as agreed. ☐

I would like a copy of a summary of the study results to be sent to me when it is available. ☐

My contact details are – (Please print)

Name .....

Address .....

.....

Telephone no. ..... Mobile phone no.....

E-mail address .....

Signature ..... Date .....

Name of Researcher: Mr Salah Waheedi, Welsh School of Pharmacy, Cardiff University

Signature of the researcher..... Date .....

Appendix 3a: Boots service questionnaire and consent form

PRIVATE AND CONFIDENTIAL

Health Check customer questionnaire

Welcome to the Boots Health Check.

Please complete all sections of this questionnaire before your appointment so we can tailor the service to your needs.

Suitability

Are you under 18 years of age?	❑y ❑n
Are you taking any of the following drugs: Dopamine, Methyldopa or Warfarin?	❑y ❑n
Could you be pregnant?	❑y ❑n
Have you had a heart attack or stroke in the last 12 weeks?	❑y ❑n
Do you have a blood disorder? (i.e. haemophilia, polcythaemia)	❑y ❑n

Personal information

Title: Mr / Mrs / Miss / Ms / Other: _____ Surname: _____

First name: _____ Gender (male/female): _____

Date of birth: _____

Address: _____

_____ Postcode: _____

Telephone: _____

Email address: _____

Advantage Card no.: _____

Ethnic origin: _____

White ☐ Indian ☐ Pakistani ☐ Bangladeshi ☐ other Asian and Chinese ethnicity ☐

Other ethnic group ☐

GP name: _____

GP address: _____

_____ Postcode: _____

Customer declaration

- The service has been explained to me and I consent to being tested
- The information I have given is to the best of my knowledge true, accurate and complete and there is no reason why I should not take part in this service
- I understand that Boots will use and store this information in accordance with the Data Protection Act in order to maintain my Boots health record
- I understand that Boots may use and share anonymous information from this service with carefully selected third parties, strictly for the purpose of medical research and statistical analysis. Boots will not share your personal details with anyone outside the Boots group of companies
- I consent to Boots, where appropriate, disclosing my results and discussing any implications of the results and any related diagnosis with my GP.

From time to time Boots may like to send information on their services and products by telephone, post or email. I am happy for Boots to use my details for this purpose. ❑y ❑n

In order to make sure we are meeting the needs of our customers, Boots may contact some customers for feedback. I am happy to be contacted in this way. ❑y ❑n

Signed: _____

Date: _____

97-06-631 59999/02 CUSTOMER QUESTIONNAIRE

Medical history

01	Have any of your close family members had a heart attack, stroke or angina? (i.e. Father / Brother – under 55 and/or Mother / Sister – under 65)	❑y ❑n
02	Have you previously experienced heart problems? (e.g. coronary heart disease, heart attack, angina, stroke or any other disease affecting the arteries, blood vessels or heart)	❑y ❑n
03	Are you receiving treatment for high blood pressure?	❑y ❑n
04	Do you have high cholesterol or any other condition that requires you to take medication to lower your cholesterol? (e.g. familial hypercholesterolaemia [FH])	❑y ❑n
05	Do you have kidney problems? (e.g. chronic kidney disease, renal dysfunction, diabetic nephropathy)	❑y ❑n
06	Do you have type 1 or type 2 diabetes?	❑y ❑n
07	Have you ever been found to have high blood glucose? (e.g. in a health examination, during an illness, during pregnancy)	❑y ❑n
08	Are you currently taking any medication either prescribed or over the counter?	❑y ❑n

If yes please state:

Name of medication	Dose (daily)	How long taken

Lifestyle

On average, how many units of alcohol do you drink per week? _____

Note: 1 unit = approx. ½ pint of beer / lager / cider, a small glass of wine, a single measure of spirits

Don't drink alcohol ☐

Do you smoke?

Yes ☐ No ☐

If yes: How many cigarettes do you smoke per day? _____

If no: Never smoked ☐ Quit within the last 5 years ☐ Quit more than 5 years ago ☐

How often do you eat vegetables, fruit or berries?

Every day ☐ Not every day ☐

What are your exercise levels per week?

In the past week, on how many days have you accumulated at least 30 minutes' moderate-intense activity, such as brisk walking, cycling or active recreation?

0	1	2	3	4	5	6	7
	Light		Moderate		Regular		

Appendix 3b: Supplementary data collection form

Evaluation of cardiovascular risk assessment service

1. Participant's reference number_____
2. Is participant registered with a local GP: ☐ Yes ☐ No
3. When was the last time the participant went to see the GP_____
4. How many times in the past 12 months has the participants been to the GP_____
5. Does the participant suffer from Rheumatoid Arthritis ☐ or Atrial Fibrillation ☐

Duration of the assessment:

Start time:	Finish time:	Performed by:

Ethnicity:

☐ White or not stated

☐ Indian

☐ Pakistani

☐ Bangladeshi

☐ Other Asian

☐ Black Caribbean

☐ Black African

☐ Chinese

☐ Other ethnic group

Appendix 4: The Welsh School of Pharmacy REC form

19/10/07 v1.0

Welsh School of Pharmacy, Cardiff University

Research Ethical Approval Form

We are grateful to the School of Social Sciences for permission to adapt their form for our use.

PLEASE NOTE BEFORE COMPLETING YOUR APPLICATION:

1. **Illegible handwritten applications will not be processed so please type if necessary**
2. **Do not submit an application to the School Research Ethics Committee (SREC) if your research is with the NHS or NHS-linked – refer instead to NHS Local Research Ethics Committee. See http://www.nres.npsa.nhs.uk**
3. **Research with children normally requires:**
   1) permission from the relevant institution
   2) consent from parent or guardian
   3) assent from the child, after being provided with age-appropriate information
4. **Information on data management, collecting personal data: data protection act requirements, can be accessed via:**
   http://www.cardiff.ac.uk/schoolsanddivisions/divisions/corps/cocom/index.html
5. **Information on Research Ethics (including Ethical Issues in Research – informed consent etc.) can be accessed via the University's Research and Commercial Division web pages via:**
   http://www.cardiff.ac.uk/schoolsanddivisions/divisions/racdv/resgovethics/ethics/index.html
6. **Supervisors are responsible for the contents of information sheets and consent forms.**

Title of Project:

Evaluation of a community pharmacy based cardiovascular risk assessment service

Name of Student:

Salah Waheedi

Name(s) of Supervisor(s):

Dr Dai John. Professor Roger Walker.

Form checked by:

Name_____Signature_____Date_____

1

19/10/07 v1.0

Recruitment Procedures

		Yes	No	N/A
1	Does your project include children under 16 years of age?		X	
2	Does your project include people with learning or communication difficulties?		X	
3	Does your project include people in custody?		X	
4	Is your project likely to include people involved in illegal activities?		X	
5	Does project involve people belonging to a vulnerable group, other than those listed above?		X	
6	Does your project include people who are, or are likely to become your clients or clients of the department in which you work?	X		
7	Does your project **ONLY** recruit participants as patients and/or NHS staff and/or will the study be undertaken on NHS premises? **If yes, refer to NHS for approval/advice INSTEAD.**		X	
8	Does your project involve staff or students in the School?		X	
9	Does your project include people for whom English / Welsh is not their first language?	X		

Consent Procedures

		Yes	No	N/A
10	Will you tell participants that their participation is voluntary?	X		
11	Will you obtain written consent for participation?	X		
12	If the research is observational, will you ask participants for their consent to being observed prior to the study commencing ?			X
13	Will you tell participants that they may withdraw from the research at any time and for any reasons and that they do not need to give reasons for withdrawal?	X		
14	Will you give potential participants an appropriate period of time to consider participation?	X		

19/10/07 v1.0

Project Summary

Please provide further brief information on the overall project proposal below and include information on each of the following:
Broad Research question(s),
Proposed Methods,
Subjects including approx. numbers,
Method(s) of recruitment,
Other information as appropriate

Research question (exploratory study): Is a community pharmacy based cardiovascular risk assessment service effective in managing CVD risk factors?

The cardiovascular risk assessment service will be provided free of charge at Boots, Porthcawl. Individuals will be invited to participate in the study over a 12 month period and will be provided with a participant information sheet and consent form, in addition to the standard Boots service questionnaire and consent form. Those who do not consent to participate in the study but want an assessment without follow-up will be required to complete and sign the standard Boots service questionnaire and consent form prior to service provision. Individuals identified at high risk will be advised to see their GP, and those who might benefit from other services, such as a smoking cessation clinic or weight management clinic, will be signposted accordingly. Those individuals with pre-existing CVD may be advised, in exceptional circumstances, to see their GP. User satisfaction will be assessed by a questionnaire given to all service users.
Those who wish to participate in the study will be asked to read the patient information leaflet and sign, if applicable, the study consent form. They will receive the same service as other service users, but will be invited to have a follow-up interview at two weeks and a follow-up consultation 12 months after the cardiovascular risk assessment service.

Participants will be those who want to have the CVD risk assessment. The target recruitment number will be 100. Potential participants responding to the flyers will approach the pharmacy staff and be referred to the research pharmacist. Pharmacy staff may also inform people visiting the pharmacy for other reasons as to the availability of the service.

Declaration of Supervisors

As the supervisor(s) for this student project, I/we confirm that I/we believe that all research ethical issues have been dealt with in accordance with University policy and the research ethics guidelines of the relevant professional organisation.

Date	Name	Signature
Date	Name	Signature

4

Appendix 5: Services local to Porthcawl Boots

Smoking cessation

Stop Smoking Wales
0800 085 2219
www.stopsmokingwales.com

Specially trained staff offer:

- guidance
- advice
- information and
- free access to counseling and support groups across Wales.

Weight management

Weight Watchers (Private*)
Tel: 0845 0705116 WeightWatchers.co.uk
* Other private services are available upon request.

Alcohol advice and support

Welsh Alcohol Helpline
0800 6 33 55 88

Healthy eating

A food co-operative is a simple system through which you can access fresh fruit, salad and vegetables on a weekly basis at affordable prices. Local produce is accessed as much as possible (quality and price permitting) and bought in bulk benefiting and encouraging local farmers. Local sourcing means:

· money you spend is kept within the region
· food miles are reduced

The savings from the bulk buying are then passed on to the members so that the fruit and vegetables are sold at reasonable prices. There are several co-

operatives currently running in the County Borough of Bridgend and to find out where these co-op's are please contact Catherine Webb/ Ann Davies on 01656 754465
The food cooperatives are run by volunteers who sort the produce, take orders for the following week and the money.
For further information and assistance in setting up a Food Coop contact:

Richard Reast on 01443 402317 or email: richard.reast@rru.org.uk

Physical activity

Healthy Living Department – Bridgend County Borough Council

The Healthy Living Department currently provide a number of initiatives aimed at those people wanting to increase their levels of physical activity. These include an Exercise Referral Scheme, free swimming for the over 60's and for under 16's during the school holidays and the Bridge Card membership. For further information about any of these activities or to find out what's on in your local leisure centre please click on the following link: http://www.bridgend.gov.uk/Web1/groups/leisure/documents/services/004417.hcsp

Walk your Way to Health

A local walking group is currently being run by Groundwork Bridgend and Neath Port Talbot. These short walks take place every Thursday morning starting at 11am and take place at various venues throughout the Borough of Bridgend including Bryngarw Country Park, Park Slip Nature Reserve and along the Garw Valley Community Route. The walks are led by trained walk leaders and are graded to suit different levels of ability. To find out more about these walks or to request a timetable, please phone 01656 727800

For those people who prefer longer walks the Ramblers Association have the following two groups within the County Borough of Bridgend. Please click on the appropriate link to find out more:

Bridgend and District Ramblers http://www.bridgendramblers.org.uk/

Maesteg Ramblers http://www.maestegramblers.org.uk/

Mental Health

HOW WE CAN IMPROVE AND MAINTAIN OUR MENTAL HEALTH

Have you got the right balance between work, or other daytime occupation, social life and any other activities?

With one in four adults likely to experience a mental health problem in the course of one year, we all need to take action to ensure that we can enjoy the best possible mental health we can.

Good mental health is generally being able to

- Develop emotionally, creatively intellectually and spiritually
- Sustain satisfying personal relationships
- Face problems, resolve them and learn from them
- Be confident and assertive
- Be aware of others and empathise with them
- Use and enjoy special time on our own
- Play and have fun
- Laugh, both at ourselves and at the world about us

Mental health problems can range from the worries and distress we all experience as part of everyday life; to a disabling anxiety disorder; from mild to severe depression; to desperation and suicide; or to a complete loss of touch with everyday reality. Sometimes these problems can cause real and lasting damage, both to ourselves and to others about us. Fortunately many of the people who experience mental health problems can get over them or learn to live with them, especially if they can get the right help early on.

How can we help ourselves?

There are many ways we can help ourselves, these include

- Making time to do the things we enjoy
- Taking moderate physical exercise
- Cutting down on coffee, alcohol, nicotine and other addictive substances
- Remembering and acknowledging the things we like about ourselves
- Keeping things in perspective
- Developing and keeping friendships
- Listening to and respecting other people, even when we disagree with them!

This does not guarantee a problem-free life but can lead to more self-awareness and being able to recognise when things are going wrong.

Looking after yourself or even putting yourself first is not always being selfish

but about being realistic about our own mental health needs, and this can then help us to help others.

Information about local voluntary or statutory mental health services can be found by contacting your local GP for one of the following Community Mental Health Teams (CMHT) – Bridgend, Porthcawl, Maesteg, Ogmore and Garw Valley, West Vale.

Mental Health Matters Wales Tel: 01656-767 045

BAVO Tel: 01656 810 400

Gofal Cymru Tel: 01656-647722

Hafal Tel: 01656-729191

Other Services

Appendix 6a: Boots SOP, Consultation

Boots Healthy Heart Service Consultation

Describing the advice and process to follow when providing a Healthy Heart service consultation.

PROCESS STEPS	RESPONSIBLE
1. Take customer's name and confirm appointment in diary. Take customer to the consultation area and where appropriate bring chaperone notice to their attention.	Pharmacist Or authorised team member
2. Confirm tier / price / voucher scheme that customer requires and check that customer is eligible for service.	
3. If customer is not eligible explain reasons for exclusion and refer to GP if appropriate.	
4. If customer is eligible, explain the structure of consultation. Check that the customer understands what is involved and that they are giving informed consent to take part in service.	
5. Complete lifestyle questionnaire and note any relevant information from PMR (if customer has PMR).	
6. Conduct Tier 1 of consultation; BP, BMI and waist measurements as per SOP 306, 304 and 305.	
7. If customer has chosen Tier 2, confirm whether customer wants cholesterol or glucose and test as per SOP 303.	
8. If a fasting glucose test is identified as appropriate after a glucose test, explain test and book appointment (or refer to GP). Follow SOP 310 when completing fasting glucose test. Go to step 13.	
9. If customer has chosen Tier 3, check cholesterol / HDL / Glucose as per SOP 303.	Pharmacist
10. Ensure all details from Tier 3 tests have been completed on HHS paperwork and decide whether customer has pre-existing CVD or other factors that exclude a risk assessment.	
11. If risk assessment is appropriate calculate 10 year CVD risk using BNF and transfer to HHS paperwork. Go to step 8.	
12. If customer is excluded from risk assessment, explain why CVD risk charts are not appropriate to them and go to step 8.	
13. Once consultation is complete ensure all advice is recorded as per SOP 302. Ensure records are only accessible by authorised team members and kept for at least 10 years.	Pharmacist Or authorised team member

KEY POINTS

Exclusion from HHS
Under 18
Pregnant
Polycythaemia or haemophilia
Taking dopamine, methyldopa, or warfarin
Had a heart attack or stroke in last 12 weeks

- ✓ Ensure all details and results have been completed on Healthy Heart paperwork.
- ✓ Fasting test is appropriate if glucose levels are 5.6 to 11.0 mmol/l.

Exclusion from CVD risk
People with CHD, diseases affecting the arteries, blood vessels and heart
Familial hypercholesterolaemia or other inherited dyslipidaemias
Chronic kidney disease, including renal dysfunction, and diabetic nephropathy
Diabetes type I and II
Hypertension

The CVD risk assessment guidance and chaperone policy can be found in your training manual.

ACCOUNTABLE SIGNATURE:	DATE:	VERSION: 1 review due : 01/07/2010 © Boots UK 2008	SOP:301

Standard Operating Procedure PS/JP080608

Appendix 6b: Boots SOP, Health Advice

Advice and Record Keeping for the Healthy Heart Service

Describing the advice and records to be made as part of the Healthy Heart service

PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. Following a Healthy Heart Service (HHS) consultation, explain CVD risk where calculated to the customer. 2. Discuss changes the customer could make to their lifestyle to reduce the risk to their cardiovascular health and help them decide appropriate actions to take. Refer to glucose and cholesterol interpretation tables.	Pharmacist	⚠ Check the customer fully understands the information given and has the opportunity to ask questions.
3. Record advice given and any patient educational materials supplied onto the HHS paperwork. 4. If GP referral is appropriate explain the reasons to the customer and print out/copy GP referral letter x2. All pharmacists must use their professional judgement on whether to refer a customer to their GP. The box in the key points section is to assist you and intended as a guide only.		⚠ Make sure that you do not alarm the customer unnecessarily.
5. Ensure action plan is competed even if referring to GP and review report with the customer. Ask the customer to sign both copies of the report. 6. Provide the customer with a copy of their questionnaire and action plan, the GP referral letter (if appropriate), the heart health advice leaflet and any other relevant advice leaflets. Signpost customer to any products or services that may be useful to them.		**GP referral for Boots Healthy Heart Service** Glucose > 11.0 mmol 10 year CVD ≥ 20% Total cholesterol ≥ 7.5 mmol[1] BP ≥ 240/120 (or ≥ 140/90 following a recheck, dependant on local guidelines) BP ≤ 90/60 if patient feels unwell Fasting glucose > 5.6mmol/l Low glucose ≤ 2.5mmol/l
7. Process payment if appropriate and if customer has a Patient Medication Record, make a record of the following in the patient notes field: - That they have attended a HHS consultation - Date of the consultation - Pharmacist name - Store Number - If the customer was referred to the GP 8. Place the signed customer questionnaire in an envelope with customer's full name on the outside. File envelope alphabetically in designated secure filing facility. 9. Complete customer log and ensure all equipment has been put away and the consultation area clean and tidy.	Pharmacist Or authorised team member	✓ Ensure records are only accessible by authorised team members and kept for at least 10 years.

ⓘ The cholesterol and glucose test interpretation tables and cuatomer log can be found in your training manual.

ⓘ Send one copy of the questionnaire to Pharmacy Marketing monthly during the pilot:

Pharmacy Marketing
Boots Support Office
Fern House
53-55 High Street
Feltham
Middlesex, TW13 4HU

[1] http://www.heartuk.org.uk//new/pages/prof/advice_as04_diagnostic.html

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Standard Operating Procedure PS/JP080608

Appendix 6c: Boots SOP, obtaining blood sample

CardioChek PA Test Preparation and Obtaining Blood Sample

Measure a customer's TC, HDL, glucose (or combination) as part of a Boots professional service

PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. Wash your hands and collect the equipment that you will need to complete the test (hard surface wipes, CardioChek PA, test strips, memo chip, lancets, sharps bin, pipettes, alcohol wipes, gauze, water and plasters).	Pharmacist Or authorised team member	✓ IQC tests are the Check-strip tests and control solution tests (Ref SOPs 307 and 308).
2. Check that the EQA and IQC records are up-to-date. If necessary, complete IQC tests.		
3. Explain the test procedure to the customer and make sure that you have their informed consent to complete the test.		✓ Informed consent may be verbal or written, depending on the service you are offering.
4. Put on gloves and an apron (optional) and swab the test area with a hard surface wipe. Wipe the CardioChek window with a damp gauze swab and switch on the CardioChek.		✓ Ensure new gloves are worn for each new customer.
5. Insert the relevant memo chip into the CardioChek, with the ribs on the test strip facing upwards.		⚠ Make sure that the LOT number on the memo chip and test strip match and are in date.
6. Identify which hand is to be used and make sure that the customer's hands are as warm as possible to encourage good blood flow to the fingers.		✓ Asking the customer to rub their hands together, wash their hands in warm water, or let the arm hang loosely by their side will help.
7. Select the best site for the sample. Clean the finger using an alcohol wipe then wipe the finger with a gauze swab soaked in water. Dispose of used swab in clinical waste and allow site to dry.		✓ Avoid the middle or 'pad' of the finger or a finger with a tight ring.
8. Prepare finger pricking device and prick the inside edge of the finger. Dispose of device in sharps bin.		
9. After a few moments, apply gentle pressure from the base of the finger until a small drop of blood forms. Wipe this drop away using the gauze swab.		
10. Continue to gently milk the finger from the base upwards until a large drop of blood forms. Obtain sample of blood using pipette and ensure sufficient blood has been drawn into pipette.		⚠ If there are any air bubbles in the sample or insufficient blood drawn into pipette, discard it and repeat steps 7 to10, using a new pipette and new test site.
11. Ask the customer to apply pressure to the wound with the gauze swab.		
12. Apply the sample onto the sample well of inserted test strip. Make sure all blood from the pipette is dispensed and the CardioChek display changes to 'testing'.		
13. Offer the customer a hypoallergenic plaster to apply when the bleeding stops.		
14. When the result appears in the meter display, record it on the service paperwork. Remove the test strip and check that there is a uniform colour in each circle on the back. If the result is unexpected or the colour is not uniform, repeat test.		⚠ The colour in each circle may not be the same, this is fine as long as the colour in each circle is spread out evenly.
15. Provide any advice relevant to the service being offered and dispose of waste as per SOP 309.		

ⓘ If glass or Drummond pipettes are being used, instructions for their use can be found in the training manual.

ⓘ Information on preparing the finger pricking device and using PTS test panel test strips, (including interpretation of the back of the test strip) can be found in the training manual.

ACCOUNTABLE SIGNATURE:	DATE:	VERSION: 1 review due : 01/07/2010 © Boots UK 2008	SOP:303

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Appendix 6d: Boots SOP, BMI calculation

BMI Calculation

Process to follow to determine a customer's BMI as part of Boots professional Service

PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. Explain the procedure to the customer and take them to the BMI machine.	Pharmacist Or authorised team member	⚠ Use a BMI monitoring card where appropriate.
2. Ask customer to remove outdoor wear/ bulky clothing and shoes.		
3. Follow instructions on the BMI machine to obtain customer's BMI.		✓ Ensure the weight is recorded in kilograms,.
4. Where a BMI machine is not available, use weighing scales to obtain customer's weight.		
5. Measure customer's height using appropriate equipment and make a note of the customer's height in meters.		✓ Ensure the height is recorded in meters,.
6. Calculate BMI using kg / m^2 or BMI wheel.		
7. If BMI calculation is part of Healthy Heart Service, record weight, height and BMI on Healthy Heart Service form and give BMI card where appropriate. Continue consultation as per SOP301.		
8. If BMI calculation is **NOT** part of Healthy Heart Service, provide advice to customer regarding BMI and record on appropriate paperwork.		

Body Mass Index (BMI) interpretation table

BMI Score	Classification and advice
Less than 18.5	Lean BMI, indicating low body fat. Can be desirable eg. athlete. However a low BMI can indicate weight is too low which may lower immunity to disease. If BMI and body weight low, may want to consider gaining increased muscle
Between 18.5 and 24.9	"Healthy weight" – customer should aim to stay within this range
Between 25 and 29.9	"Overweight" – customer should aim to lose some weight or at least prevent any further weight gain
Between 30 and 34.9	"Obese" – losing weight will improve your customer's health
More than or equal to 35.0	"Very obese" – losing weight will significantly improve your customer's health. Further support may be required.

ACCOUNTABLE SIGNATURE:	DATE:	VERSION: 1 review due : 01/07/2010 © Boots UK 2008	SOP:304

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Appendix 6e: Boots SOP, waist measurement

Waist Measurement

Process to follow to take a waist measurement as part of Boots professional service

PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. Explain the measurement procedure to the customer and ensure the customer agrees for the measurement to be taken.	Pharmacist Or authorised team member	⚠ If the customer does not agree for the measurement to be taken continue with next stage of healthy heart service. Ref SOP 301.
2. Ask customer to remove outdoor wear/ bulky clothing covering the waist area.		
3. Using the waist measurement tape, measure around the customer's trunk at the navel. Ensure the tape measure is snug and remains horizontal as per photo below. 		✓ If customer prefers to hold the tape themselves, guide them to hold It in the correct place.
4. Make a note of the measurement and calculate risk using waist measurement table.		
5. If the measurement is part of the Healthy Heart Service consultation, discuss risk with customer and record measurement and risk on HHS form. Continue with consultation as per SOP 301.		
4. If the measurement is **NOT** part of the Healthy Heart Service, provide advice to customer regarding risk and record on appropriate paperwork.		

What should your waist circumference be?

**If your customer is South Asian, they have a lower threshold because they are genetically predisposed to an increased risk of heart disease (South Asian is defined as those people originating from the Asian subcontinent e.g. Pakistan, Sri Lanka, India and Bangladesh)"*

Please note that these are guidelines for risk factors and not definitions of obesity.

Tables adapted from National Obesity Forum, www.nationalobesityforum.org.uk

Please note, 1 inch = 2.5 cm

Waist circumference interpretation table

Gender and ethnicity	Okay	Increased Risk	High Risk
Non-South Asian Males	Less than 94cm (37")	Between 94 and 102cm (37-39")	More than or equal to 102cm (40")
South Asian Males			More than or equal to 90cm (35")
Non-South Asian Females	Less than 80cm (32")	Between 80 and 88cm (32-34")	More than or equal to 88cm (35")
South Asian Females			More than or equal to 80cm (32")

ACCOUNTABLE SIGNATURE:	DATE:	VERSION: 1 review due : 01/07/2010 © Boots UK 2008	SOP:305

Standard Operating Procedure PS/JP080608

Appendix 6f: Boots SOP, blood pressure measurement

Blood Pressure Measurement

Measure a customer's blood pressure as part of a Boots professional Service

PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. Check that the blood pressure monitor is less than 12 months old.	Pharmacist Or authorised team member	⚠ Blood pressure monitors used in Boots services should be replaced every 12 months in accordance with guidance in the operations/training manual.
2. Explain the test procedure to the customer and check that you have their informed consent to take the measurement. Ask whether they have had their blood pressure measured recently and, if so, what the result was.		✓ Informed consent may be verbal or written, depending on the service you are offering.
3. Take the customer to the consultation area. Ask customer to remove any bulky upper layers and to sit and relax for five minutes. 4. After 5 minutes check the customer is seated comfortably with their feet flat on the floor.		✓ It is not necessary for the customer to remove thin shirts or blouses as the machine can detect blood pressure through thin layers of clothing.
5. Wrap the cuff around the upper arm. Position it carefully and ensure that it fits closely but does not pinch the arm. On the **left** arm, the marked edging should sit on the inside of the elbow joint and the tube should be kept even with the middle finger. On the **right** arm, the tube should run under the elbow and parallel with the little finger. 6. Rest the arm on on the table and ensure that the patient's hand is relaxed.		✓ The cuff supplied with the Omron M7 is suitable for arm circumferences of 22cm to 42cm.
7. Press the on/off button and wait for the zero and heart symbol to be displayed. Ask the customer not to talk or move whilst the cuff is inflating or deflating. Press the start button & release within 3 seconds.		✓ If an error message occurs, ask the customer to remain still and quiet. Check the cuff is fitted properly, wait 1-2 minutes then retry.
8. The cuff will inflate and then automatically deflate. This takes about 30 seconds. Read the systolic and diastolic values from the display and immediately record on appropriate paperwork. 9. Remove cuff from customer's arm and repeat procedure after 5 minutes on the other arm. Read the systolic and diastolic values from the display and record on appropriate paperwork. 10. Remove the cuff and record the highest BP reading taken, and the arm used to obtain reading on the appropriate paperwork.		✓ Note any sub-optimal conditions for the test, e.g. the customer is anxious or nervous, is a smoker who has smoked in the last 20 minutes, has had any caffeine in the last 20 minutes, regularly drinks more than four units of alcohol daily, non-compliance with medication.
11. Consult Blood pressure interpretation chart and give any advice appropriate to the service being provided. If part of the Health Heart service, continue consultation as per SOP 301.		✓ If a customer returns to recheck BP and it is still raised, refer to GP as appropriate within your local referral guidelines.

Blood Pressure interpretation table

BP reading (mmHg)	Interpretation and advice
Less than 90/60	Low Blood Pressure. If patient feels well, referral is unnecessary. If heart condition is suspected and customer is unwell refer to GP[1]
Between 90/60 and 129/84	BP in normal range, review in 1year
Between 130/85 and 139/89	BP in upper range of normal, measurement is acceptable but on high side, give lifestyle advice and recommend customer has review in 1 year
Between 140/90 and 199/109 *(140/85 – 199/109 for BPWLP)*	BP is raised, remove cuff, record result and advise the customer to get it rechecked in 2 weeks
Between 200/110 and 239/119 *(200/110 – 219/119 for BPWLP)*	BP is raised, remove cuff, record result and advise the customer to get it rechecked within the nest few days. They must not ignore this reading
Greater than 240/120 *(220/120 for BPWLP)*	BP is significantly raised, remove cuff, record result and advise the customer to visit their GP immediately or go to Accident and Emergency[2]

[1] Blood Pressure Association guidance. Accessed at www. blood-pressure-monitoring.org
[2] Numbers and ranges taken from the BHS treatment guidelines. Advice on screening provided by the BPA

ACCOUNTABLE SIGNATURE:	DATE:	VERSION: 1 review due : 01/07/2010 © Boots UK 2008	SOP:306

Standard Operating Procedure PS/JP080608

Appendix 6g: Boots SOP, monthly quality assurance

Complete Control Solution Tests on the CardioChek PA

Completing control solution tests for the CardioChek PA as part of a Boots professional service. Test should be carried out monthly, after opening new test panels and after RED EQA result

PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. Insert a date-valid MEMO-chip from the packet of test panels you are testing.	Pharmacist Or authorised team member	⚠ If the date and time are not set correctly on the CardioChek it will not identify out of date test panels or MEMO-chips.
2. Turn the CardioChek meter on by pressing either button, and check that the date and time are set correctly.		✓ Ensure that the control solution(s) and test panels are in date, and test panel lot number matches the memo strip lot number from the test panels being used.
3. At the "INSERT STRIP" display, press the "ENTER" button and "RUN TEST" will appear in the display. Press the "NEXT" button twice to reach the "UTILITY" menu.		
4. Press "ENTER" and then press the NEXT button to display "RUN CONTROL". Press ENTER to begin the test.		
5. Guide the test panel into the analyser, with the ribs facing upwards and immediately close the cap on the packet of test panels.		
6. "APPLY SAMPLE" will be displayed. Add a small drop of the first control solution. Do not allow the lip of the bottle to touch the test strip. The control solution must be applied within 2 minutes of removing the strip from the packet.		✓ Use Multichemistry-control solutions for GLUCOSE and CHOL + GLU panels. Use Multichemistry control solutions **and** HDL control solutions for CHOL + HDL, or CHOL+HDL+GLUC panels.
7. Record result on the QC log.		
8. If the test result is outside the expected range repeat steps 1-7. If this test result is still outside the expected range, call BHR Technical Support Line for advice. Record details on the Quality Control (QC) log and **DO NOT** proceed until any problems with the CardioChek machine have been rectified and the test passed.		✓ BHR Technical Support line : 0845 4509323 ✓ If Issues are unresolved contact your RPM.
9. If the analyser passes the test, document the result in the QC Log. Repeat test with all other control solutions and test panels.		✓ Store control solutions in the fridge.
10. When you are satisfied that all necessary control solution tests have been passed and the results recorded, commence testing.		✓ Ensure all Cardiochek machines in store are tested.

ⓘ Quality control logs can be found in the operations/training manual.

ACCOUNTABLE SIGNATURE:	DATE:	VERSION: 1 review due : 01/07/2010 © Boots UK 2008	SOP:307

Standard Operating Procedure PS/JP080608

Appendix 6h: Boots SOP, daily quality assurance

Complete the Check Strip Test on the CardioChek PA

Complete the daily Check-Strip test fro the CardioChek PA, as part of a Boots professional service

PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. Turn the CardioChek meter on by pressing either button, and check that the date and time are set correctly.	Pharmacist Or authorised team member	⚠ If the date and time are not set correctly on the CardioChek it will not identify out of date test panels or MEMO-chips.
2. When "INSTALL MEMO CHIP " or "RUN TEST" is displayed, press the "NEXT" button twice to reach the "UTILITY" menu.		
3. Press the "ENTER" button. The meter will display "CK STRIP." Press "ENTER" again to begin the test.		
4. Insert the Check-Strip into the analyser, with the ribs facing upwards. The test will start automatically.		✓ The "Check Strip Test Log" can be found in the service Operations / training manual.
5. If the analyser passes the test the display will read "CK Strip Passed." Document the result on the "Check Strip Test Log".		
6. If the analyser fails the test, record this result on the "Check Strip Test" Log. Clean the optical window with a damp gauze swab, check that the Check-Strip is not dirty or damaged and then repeat steps 1-6 using a spare Check Strip where available. Document the actions taken on the "Check Strip Test Log".		⚠ **DO NOT** use cotton wool to clean the optical window.
7. If the analyser passes the test, document the result in the "Check-Strip Test Log." If the analyser fails the second test, call the BHR Technical Support Line. Do not perform any more tests using the analyser until any problems with the analyser have been identified and rectified and it passes the Check-Strip Test.		✓ BHR Technical Support line : 0845 4509323

Quality control logs can be found in the operations/training manual.

ACCOUNTABLE SIGNATURE:	DATE:	VERSION: 1 review due : 01/07/2010 © Boots UK 2008	SOP:308

Standard Operating Procedure PS/JP080608

Appendix 6i: Boots SOP, waste disposal

Dispose of Waste after a Test using the CardioChek PA

Dispose of clinical waste and sharps using the 'double glove' technique following a test as part of a Boots service

PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. Place the used pipette with the used lancet into the sharps bin.	Pharmacist Or authorised team member	
2. Undo the apron neck and waist ties (if apron being worn) and gather all of the waste materials (except for the lancet and pipette which are in the sharps bin) into the apron lap. Roll up the waste into the apron and hold it all in the palm of one hand.		
3. Remove the glove and make sure that all waste materials stay inside it by pulling the glove from the wrist down over the hand.		
4. Place the glove containing the waste on the table. Holding the CardioChek machine with your degloved hand, remove the test panel from the machine with your gloved hand.		
5. Hold the used test panel and the glove containing the remaining waste in your gloved hand.		
6. Remove the glove, making sure that all materials stay inside, by pulling the glove from the wrist down over the hand. Knot the end of the glove and place in the clinical waster bin if your clinical waste bin is not in the consultation room. 7. Place the knotted glove in a tray and carry it back to the dispensary. In the dispensary, remove the glove containing the waste and put it in the clinical waste bin.		

ACCOUNTABLE SIGNATURE:	DATE:	VERSION: 1 review due : 01/07/2010 © Boots UK 2008	SOP:309

Standard Operating Procedure PS/JP080608

Appendix 6j: Boots SOP, fasting glucose test

Fasting Glucose Test

Conducting a fasting glucose test as part of a Boots professional service.

PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. When customer arrives at the pharmacy, confirm name and appointment in diary and take customer to the consultation area.	Pharmacist Or authorised team member	✓ If appropriate bring the chaperone notice to their attention.
2. Explain the structure of the consultation and describe the process that will occur. Check customer understands what is involved and that they are giving informed consent to take part in the service.		
3. Confirm how long the customer has fasted and record on appropriate form.		
4. Take blood glucose measurement following SOP 303 and enter results onto appropriate form.		
5. Provide advice using the guidance in the glucose interpretation table.		
6. If the test is part of the Healthy Heart Consultation, continue with consultation as per SOP 302.		

The Chaperone policy can be found in the training manual.

Glucose Test Interpretation

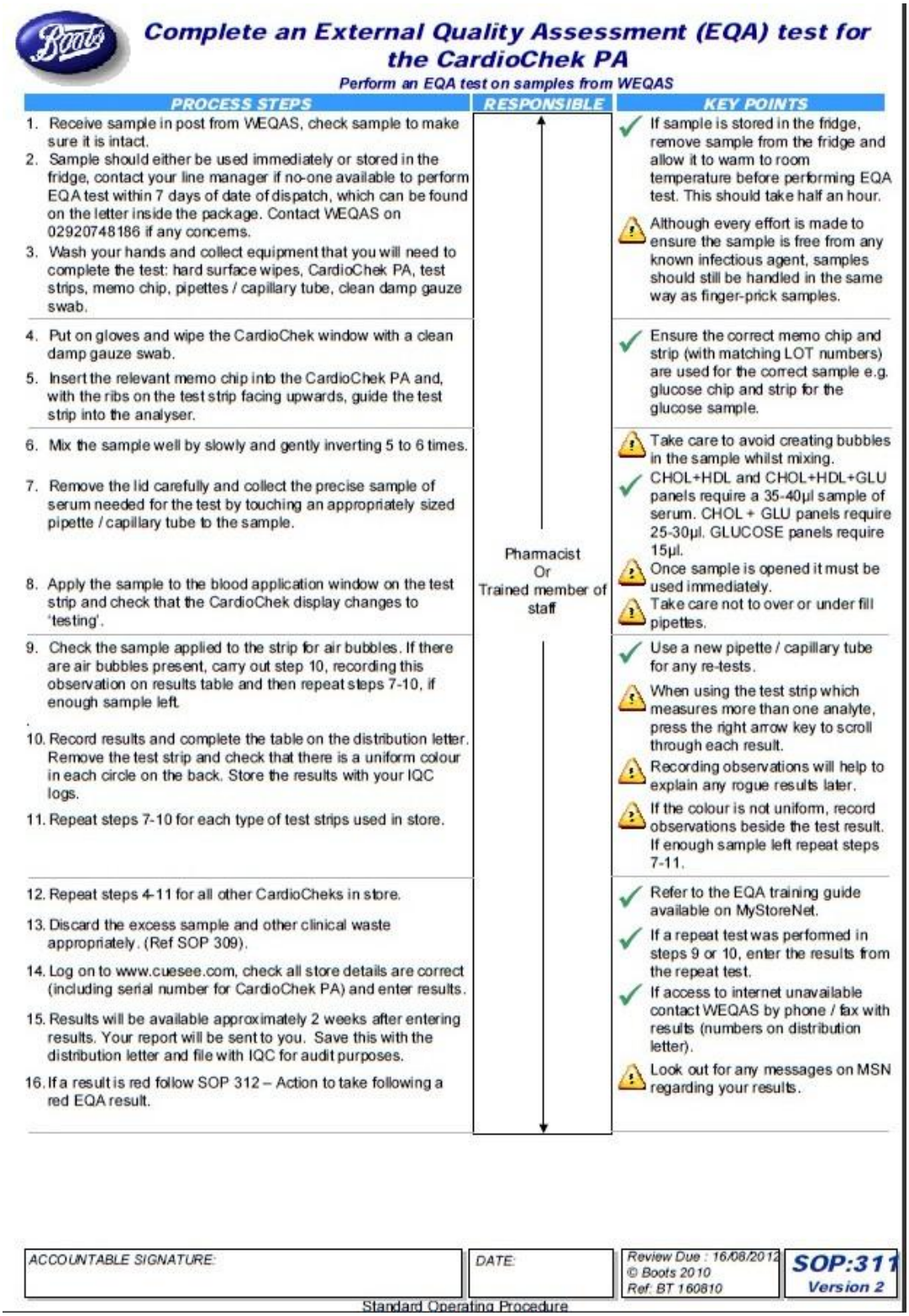
Fasting Glucose		Glucose	
Less than 2.5mmol/l	Danger of hypoglycaemia. Make sure the customer takes some food or water containing sugar e.g. chocolate bar, Glucogel etc. Refer to GP for tests. (NHS Direct)	Less than 2.5mmol/l	Danger of hypoglycaemia. Make sure the customer takes some food or water containing sugar e.g. chocolate bar, Glucogel etc. Refer to GP for tests. (NHS Direct)
Between 2.5 and 5.6mmol/l	No action	Between 2.5 and 5.6mmol/l	No action
Between 5.6 and 6.0mmol/l	See GP in 1-2 weeks	Between 5.6 and 11.0mmol/l	Refer for fasting test
Between 6.1 and 11.0mmol/l	See GP in 7 days	More than 11.0mmol/l	Refer to GP in 1-2 days
More than 11.1mmol/l	See GP in 1-2 days		

(Based on values in the RPSGB Practice Guidance " Care of people with diabetes except hypoglycaemia" 2004)

ACCOUNTABLE SIGNATURE:	DATE:	VERSION: 1 review due : 01/07/2010 © Boots UK 2008	SOP:310

Standard Operating Procedure PS/JP080608

Appendix 6k: Boots SOP, external quality assurance



Complete an External Quality Assessment (EQA) test for the CardioChek PA

Perform an EQA test on samples from WEQAS

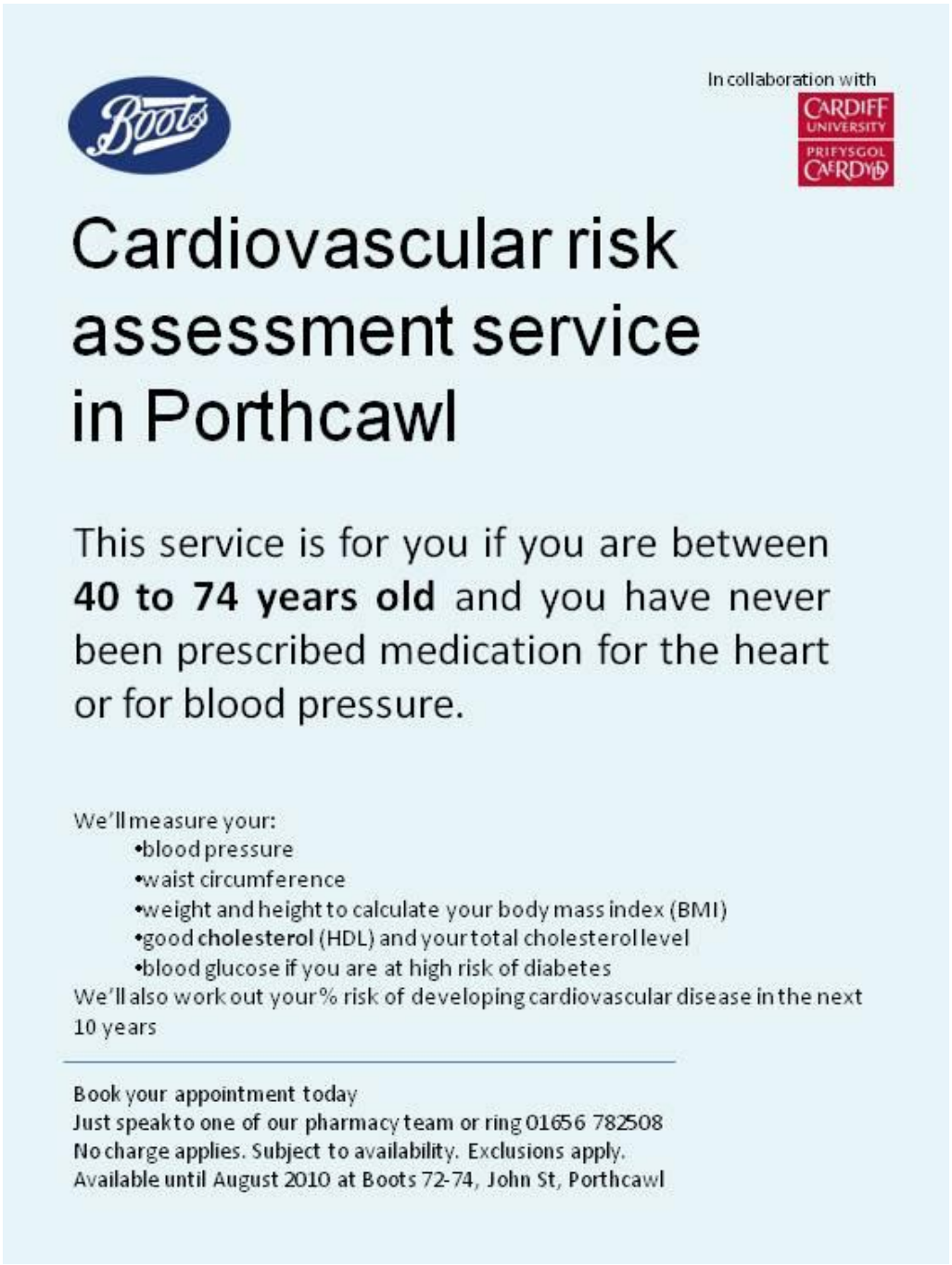
PROCESS STEPS	RESPONSIBLE	KEY POINTS
1. Receive sample in post from WEQAS, check sample to make sure it is intact. 2. Sample should either be used immediately or stored in the fridge, contact your line manager if no-one available to perform EQA test within 7 days of date of dispatch, which can be found on the letter inside the package. Contact WEQAS on 02920748186 if any concerns. 3. Wash your hands and collect equipment that you will need to complete the test: hard surface wipes, CardioChek PA, test strips, memo chip, pipettes / capillary tube, clean damp gauze swab.	Pharmacist Or Trained member of staff	✓ If sample is stored in the fridge, remove sample from the fridge and allow it to warm to room temperature before performing EQA test. This should take half an hour. ⚠ Although every effort is made to ensure the sample is free from any known infectious agent, samples should still be handled in the same way as finger-prick samples.
4. Put on gloves and wipe the CardioChek window with a clean damp gauze swab. 5. Insert the relevant memo chip into the CardioChek PA and, with the ribs on the test strip facing upwards, guide the test strip into the analyser.		✓ Ensure the correct memo chip and strip (with matching LOT numbers) are used for the correct sample e.g. glucose chip and strip for the glucose sample.
6. Mix the sample well by slowly and gently inverting 5 to 6 times. 7. Remove the lid carefully and collect the precise sample of serum needed for the test by touching an appropriately sized pipette / capillary tube to the sample. 8. Apply the sample to the blood application window on the test strip and check that the CardioChek display changes to 'testing'.		⚠ Take care to avoid creating bubbles in the sample whilst mixing. ✓ CHOL+HDL and CHOL+HDL+GLU panels require a 35-40µl sample of serum. CHOL + GLU panels require 25-30µl. GLUCOSE panels require 15µl. ⚠ Once sample is opened it must be used immediately. ⚠ Take care not to over or under fill pipettes.
9. Check the sample applied to the strip for air bubbles. If there are air bubbles present, carry out step 10, recording this observation on results table and then repeat steps 7-10, if enough sample left. 10. Record results and complete the table on the distribution letter. Remove the test strip and check that there is a uniform colour in each circle on the back. Store the results with your IQC logs. 11. Repeat steps 7-10 for each type of test strips used in store.		✓ Use a new pipette / capillary tube for any re-tests. ⚠ When using the test strip which measures more than one analyte, press the right arrow key to scroll through each result. ⚠ Recording observations will help to explain any rogue results later. ⚠ If the colour is not uniform, record observations beside the test result. If enough sample left repeat steps 7-11.
12. Repeat steps 4-11 for all other CardioCheks in store. 13. Discard the excess sample and other clinical waste appropriately. (Ref SOP 309). 14. Log on to www.cuesee.com, check all store details are correct (including serial number for CardioChek PA) and enter results. 15. Results will be available approximately 2 weeks after entering results. Your report will be sent to you. Save this with the distribution letter and file with IQC for audit purposes. 16. If a result is red follow SOP 312 – Action to take following a red EQA result.		✓ Refer to the EQA training guide available on MyStoreNet. ✓ If a repeat test was performed in steps 9 or 10, enter the results from the repeat test. ✓ If access to internet unavailable contact WEQAS by phone / fax with results (numbers on distribution letter). ⚠ Look out for any messages on MSN regarding your results.

ACCOUNTABLE SIGNATURE:	DATE:	Review Due : 16/08/2012 © Boots 2010 Ref: BT 160810	SOP:311 Version 2

Standard Operating Procedure

Appendix 7a: Advert v1

Appendix 7b: Advert v2



Appendix 7c: The GEM advert (for Porthcawl)

Thursday, May 13th, 2010 *Thank you for saying you saw it in The GEM*

A closer look at PORTHCAWL

Boots

in collaboration with CARDIFF UNIVERSITY PRIFYSGOL CAERDYDD

Cardiovascular risk assessment service in Porthcawl

This service is for you if you are between **40 and 74 years old** and you have never been prescribed medication for the heart or for blood pressure.

We'll measure your

- **blood pressure**
- **waist circumference**
- **weight and height to calculate your body mass index (BMI)**
- **good cholesterol (HDL) and your total cholesterol level**
- **blood glucose if you are at high risk of diabetes**

We'll also work out your % risk of developing cardiovascular disease in the next 10 years.

Book your appointment today

Just speak to one of our pharmacy team or ring 01656 782508

No charge applies. Subject to availability. Exclusions apply.

Available until August 2010 at Boots, 72-74 John Street, Porthcawl.

Boots free heart check

A free cardiovascular check-up is available every Wednesday at Boots, Porthcawl.

People aged between 40 and 74 can make an appointment to have a 30-minute check-up and consultation with the pharmacist to assess their risk of developing heart disease, or having a stroke.

The service is available for individuals who have not already been diagnosed with a heart condition, stroke or diabetes.

Users will be given free advice on the action to take to lower their cardiovascular risk.

The service is provided free of charge as part of a unique project with Cardiff University and will run until August 2010.

The Sidoli Family a century of Italia

SIDOLI'S has been family-run for 50 years. Originally opened by Pietro and Gianna Sidoli in 1960, the business is now run by their three sons, Mario, Luigi and Tino.

The family also took over Pietro's 16 years ago. Their Esplanade venue boasts 15-20 assorted ice-cream flavours and is favoured as an alfresco/mingling, suntrap/sea view must!

Sidoli's has opted for the popular strawberry and vanilla ice cream favourites.

Both serve paninis, toasties, popular main meals, a gateaux selection and their signature - freshly ground Italian coffee and home-made ice cream – you choose...

A warm welcome is assured.

Celebratin

OUR SPECIALITIES:

Freshly Ground Italian Coffee and Home Made Italian Ice Cream

Call into one of our cafés soon

18 John Street, PORTHCAWL

PIETRO'

ICE CREAM & COFFEE PARL

The Esplanade, PORTHCAWL

Walters Shoes – a full range of cu

Walters Shoes in Porthcawl are official stockists of one of the hottest brands this summer – FitFlop.

Developed in the UK, FitFlop sandals stimulate your leg and bottom muscles ev you take a step, re your aching feet. T lous choice of styl casual or sparkly, women, men and k As well as FitF Shoes have great

Home and Colonial Foods has something to tempt everyone

IT is nice to be greeted by smiling faces where nothing is too much trouble – and that is what's offered at Home & Colonial Foods.

Tasting some of the delectable cheeses and salamis before buying – at the invitation of the staff – ensures a fun and friendly shopping experience.

With glorious and heaving displays, the powerful aromas waft out and around the shop. Hot Welsh cakes are cooked on a griddle, roast pork and beef joints are visible in the

gots add to the temptation.

This spring, Home & Colonial have made sure that every customer has something to look forward to, by supplying a new range of healthy, ready made meals – roast vegetables, pasta and creme fresh to go!

For the summer, new olives and anti pasta will be available along with picnic hampers, containing treats like pork and pickle, or turkey, and

It's a happy third birthday to Shoes 22!

SHOES 22 of Porthcawl are celebrating their third birthday – and three successful years of fitting children's feet.

The shop continues to attract more and more families from all over the UK.

Shoe22 owner Elizabeth Fry explained: "Our success is based on high quality, beautifully designed and well made shoes – all of which are handpicked by myself for the shop – along with an expert fitting service which is second to none.

"Our staff are trained continuously to ensure we have the very highest standards.

"I would like to thank all our loyal customers for their support over the last three years and look forward to welcoming new clients!"

Shoe22 is recommended by podiatrists and is a Member of the Children's Foot Health Register and a member of The Society of Shoe Fitters!

shoe22

Appendix 7d: Merthyr Tydfil Express Advert

8 EXPRESS WalesOnline.co.uk Thurs

in brief

Risk assessment

Boots in New Market Walk, Merthyr Tydfil, is offering a free cardiovascular risk assessment service until next month.

The service is open to those aged between 40 and 74 years old, who have never been prescribed medication for the heart or for blood pressure.

During the check-up the chemist will measure blood pressure, waist circumference, weight and height compared to BMI, cholesterol level and blood glucose levels and be able to calculate your risk of developing cardiovascular disease in the next 10 years.

For further information on the cardiovascular service availability or to book an appointment, contact Boots on 01685 723088.

Tapest

A young boy and girl concentrate on one of their patches PICTURE: Richard Williams ©

One little girl is perfecting the skill of textiles

PLACES of interest to five year olds in Merthyr Tydfil are the subject of a large tapestry being made in one of the borough's primary schools.

The Wales Millennium Centre, Cardiff, began working with 200 five-year-old children across Wales last year, in celebration of the fifth anniversary of the centre opening.

Each year they run a project with the children until they turn 21 and they aim to provide a broad range of experiences by working with different arts professionals, in different art forms.

This year, pupils at Twynyrodyn Community School have been working with internationally acclaimed textiles artist Cefyn Burgess.

Samantha Mendez
samantha.mendez@walesonline.co.uk

The little ones have created individual textiles panels to illustrate places of interest in their town and these will be sewn together by Cefyn to create a large tapestry which will be hung in the school.

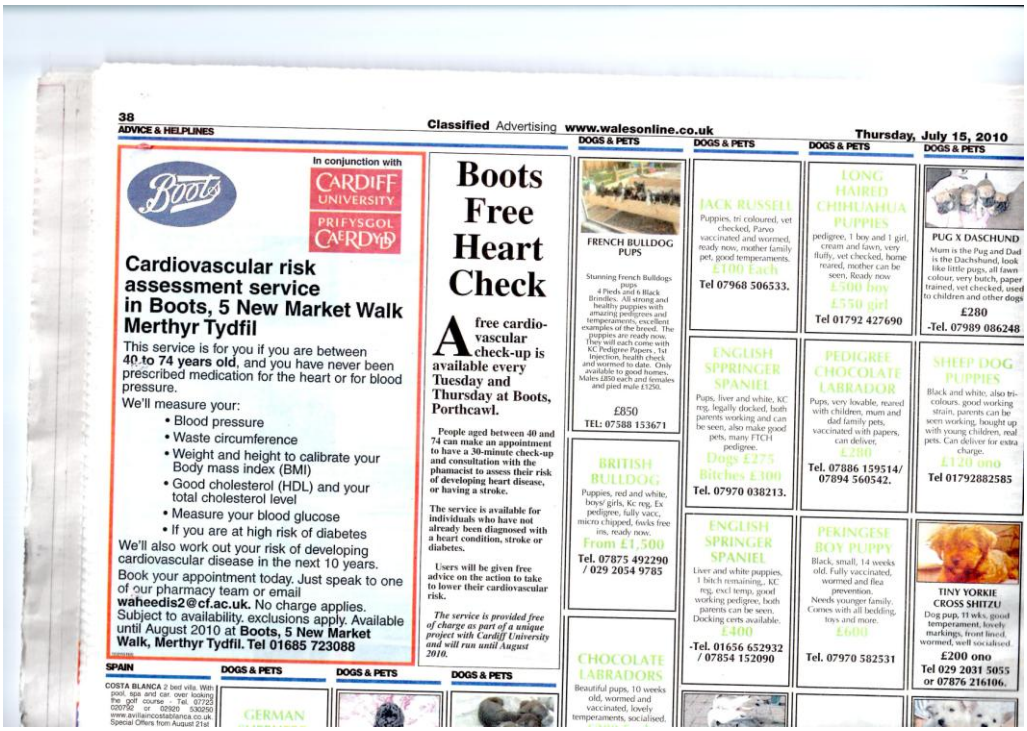
Ms Leonard, Year One teacher, said: "This has been such a wonderful experience for the children.

"We could never have facilitated this type of project as we simply don't have the specialist skills or equipment, and it is amazing that the children have worked one-to-one with an artist like this.

"The work produced is of an exceptional standard."

Beverley Owen's son is taking part in the project and she said: "A fantastic project that is really stimulating my son's creativity and we are very excited about the prospect of future projects.

"My son has thoroughly enjoyed both projects so far and we are thrilled he is a part of this."



38 ADVICE & HELPLINES Classified Advertising www.walesonline.co.uk Thursday, July 15, 2010

In conjunction with CARDIFF UNIVERSITY PRIFYSGOL CAERDYDD

Cardiovascular risk assessment service in Boots, 5 New Market Walk Merthyr Tydfil

This service is for you if you are between **40 to 74 years old**, and you have never been prescribed medication for the heart or for blood pressure.

We'll measure your:

- Blood pressure
- Waste circumference
- Weight and height to calibrate your Body mass index (BMI)
- Good cholesterol (HDL) and your total cholesterol level
- Measure your blood glucose
- If you are at high risk of diabetes

We'll also work out your risk of developing cardiovascular disease in the next 10 years.

Book your appointment today. Just speak to one of our pharmacy team or email **waheedis2@cf.ac.uk.** No charge applies. Subject to availability. exclusions apply. Available until August 2010 at **Boots, 5 New Market Walk, Merthyr Tydfil. Tel 01685 723088**

Boots Free Heart Check

A free cardiovascular check-up is available every Tuesday and Thursday at Boots, Porthcawl.

People aged between 40 and 74 can make an appointment to have a 30-minute check-up and consultation with the phamacist to assess their risk of developing heart disease, or having a stroke.

The service is available for individuals who have not already been diagnosed with a heart condition, stroke or diabetes.

Users will be given free advice on the action to take to lower their cardiovascular risk.

The service is provided free of charge as part of a unique project with Cardiff University and will run until August 2010.

DOGS & PETS

FRENCH BULLDOG PUPS
Stunning French Bulldogs pups
4 Piedi and 6 Black Brindles. All strong and healthy puppies with amazing pedigrees and temperaments, excellent examples of the breed. The puppies are ready now. They will each come with KC Pedigree Papers , 1st Injection, health check and wormed to date. Only available to good homes. Males £850 each and females and pied male £1250.
£850
TEL: 07588 153671

BRITISH BULLDOG
Puppies, red and white, boys/ girls, Kc reg, Ex pedigree, fully vacc, micro chipped, 6wks free ins, ready now.
From £1,500
Tel. 07875 492290 / 029 2054 9785

CHOCOLATE LABRADORS
Beautiful pups, 10 weeks old, wormed and vaccinated, lovely temperaments, socialised

JACK RUSSELL
Puppies, tri coloured, vet checked, Parvo vaccinated and wormed, ready now, mother family pet, good temperaments.
£100 Each
Tel 07968 506533.

LONG HAIRED CHIHUAHUA PUPPIES
pedigree, 1 boy and 1 girl, cream and fawn, very fluffy, vet checked, home reared, mother can be seen, Ready now
£500 boy
£550 girl
Tel 01792 427690

ENGLISH SPRINGER SPANIEL
Pups, liver and white, KC reg, legally docked, both parents working and can be seen, also make good pets, many FTCH pedigree.
Dogs £275
Bitches £300
Tel. 07970 038213.

ENGLISH SPRINGER SPANIEL
Liver and white puppies, 1 bitch remaining,, KC reg, excl temp, good working pedigree, both parents can be seen. Docking certs available.
£300
-Tel. 01656 652932 / 07854 152090

PEDIGREE CHOCOLATE LABRADOR
Pups, liver and white, reared with children, mum and dad family pets, vaccinated with papers, can deliver.
£300
Tel. 07886 159514/ 07894 560542.

PEKINGESE BOY PUPPY
Black, small, 14 weeks old. Fully vaccinated, wormed and flea prevention. Needs younger family. Comes with all bedding, toys and more.
£600
Tel. 07970 582531

PUG X DASCHUND
Mum is the Pug and Dad is the Dachshund, look like little pugs, all fawn colour, very butch, paper trained, vet checked, used to children and other dogs
£280
-Tel. 07989 086248

SHEEP DOG PUPPIES
Black and white, also tri-colours, good working strain, parents can be seen working, bought up with young children, real pets. Can deliver for extra charge.
£120 ono
Tel 01792882585

TINY YORKIE CROSS SHITZU
Dog pup, 11 wks, good temperament, lovely markings, front lined, wormed, well socialised
£200 ono
Tel 029 2031 5055 or 07876 216106.

SPAIN DOGS & PETS DOGS & PETS DOGS & PETS

COSTA BLANCA 2 bed villa. With pool, spa and car. over looking the golf course . Tel. 07723 020792 or 02920 530250 www.avillascostablanca.co.uk Special Offers from August 21st

GERMAN

Appendix 8: Assessment results form

PRIVATE AND CONFIDENTIAL

Health Check customer record form

Customer details

Title: Mr / Mrs / Miss / Ms / Other: _____ Surname: _____

First name: _____ Date of birth: _____

Postcode: _____

Assessment details

Date and time of consultation: _____ Store no.: _____

Pharmacist's name: _____ Does the customer have a patient medication record (PMR)? ❑ y ❑ n

Healthcare Advisor's name: _____ Relevant details: _____

Test results

Height (m): _____ Weight (kg): _____ BMI: _____

Waist circumference (cm): _____

Blood pressure (mm / Hg): Left arm ❑ SBP _____ DBP _____

Right arm ❑ SBP _____ DBP _____

(Tick box to indicate which is reference arm)

Notes: _____

(e.g. is the customer nervous, recently consumed caffeine?)

Test strip lot number: _____

Total cholesterol (mmol / L) _____ HDL (mmol / L) _____ Total cholesterol: HDL ratio _____

CVD risk assessment

Estimated 10 year CVD risk (%)

Outcomes

Diabetes test required? ❑ y ❑ n

Refer to GP? ❑ y ❑ n

Reason for referral

_____

_____

Update PMR ❑ y ❑ n

Other service / product recommendations:

Weight Loss Programme ❑ NHS Stop Smoking / Smoking Cessation ❑

BP monitor ❑

Vitamins / supplements ❑

MCU ❑ RPS ❑

Other advice and Information:

Weight loss leaflet ❑ Diabetes ❑

Targets and action plan agreed with customer:

_____

_____

97-06-623 59999/01

Appendix 9: Referral letter

Boots

Referral letter

Branch Stamp

Date:

Dear Doctor,

Your patient named below has recently used the Boots Health Check Service. The service included a private consultation with a pharmacist as well as:

- Blood pressure measurement (using a meter validated by the British Hypertension Society)
- BMI measurement
- Waist measurement
- Measurement of Total and HDL Cholesterol (using the CardioCheck PA testing device)
- Recording smoking status
- A diabetes filter, based on BMI and blood pressure measurement (at or above the Department of Health thresholds*), was used to determine whether your patient should be referred to yourself to undergo a fasting blood glucose or a HbA1c measurement.
- Calculation (where applicable) of patient's cardiovascular disease (CVD) risk

* BMI is 30 or over (or 27.5 if Indian, Pakistani, Bangladeshi, other Asian or Chinese) or BP is 140/90 or over, or where the SBP or DBP exceeds 140mmHg or 90mmHg respectively

Name:		Date of birth:		Ethnic origin:			
Address:							
Results							
BP (mmHg)	BMI	Waist measurement (cm)	Total cholesterol (mmol/L)	HDL	TC:HDL	% CVD	Smoking status
SBP:							
DBP:							

As a result of the consultation, I have advised the patient to see you because:

I provided them with the following lifestyle advice:

If you would like more information about this service, or have any questions you would like to discuss, please do not hesitate to contact me.

Yours sincerely,

Pharmacist Date

Registered Address: Boots UK Limited, 92853, Nottingham, NG2 3AA.

97-08-499 59999/10

Appendix 10: Satisfaction questionnaire

Evaluation of a cardiovascular risk assessment service

Satisfaction Questionnaire

Your opinion about the cardiovascular risk assessment service will help us to make improvements. This questionnaire will take about 5 to 10 minutes. Please complete it and return it in the pre-paid envelope provided. If you prefer to hand in the questionnaire in the pharmacy, please put it in an envelope after completion and hand it in to a member of staff.

Please answer the questions by ticking the appropriate box

1- Your gender is:

☐ Male ☐ Female

2- What age group are you in:

☐ 39 or younger ☐ 40 - 49 ☐ 50 – 59 ☐ 60 – 74 ☐ 75 or older

3- Have you had a similar health check before?

☐ Yes ☐ No
Please go to question 4

4- Where did you have the health check?

☐ GP surgery ☐ Pharmacy ☐ Other
Please specify_____

5- How long ago did you have the health check?

☐ 3 months ☐ 6 months ☐ One year
☐ 2-4 years ☐ 5 years or more

The following questions are about the cardiovascular risk assessment service you had at Boots, Porthcawl.

6- Which cardiovascular risk assessment service did you have at Boots, Porthcawl?

☐ Brief Health Check (no blood test)

☐ Cardiovascular Risk Assessment (with blood test)

Please turn over

1

7- How did you find out about this cardiovascular risk assessment service?

- ☐ Informed by partner, friend, relative, colleague
- ☐ Informed by GP
- ☐ Informed by pharmacy staff
- ☐ Leaflet. Please specify the location where you obtained the leaflet _____
  _____
- ☐ Advert. Please specify where you saw the advert _____
- ☐ Other, please state _____

8- What made you decide to have this cardiovascular risk assessment service? (Please tick all that apply)

- ☐ I was worried about my health
- ☐ I take care of my health.
- ☐ This was an opportunity to have my health checked out.
- ☐ I was encouraged by a family member or friend to have the cardiovascular risk assessment service
- ☐ The staff at Boots Porthcawl told me about it.
- ☐ The staff at another pharmacy told me about it. What is the name and location of that pharmacy_____
- ☐ I don't get to see my doctor
- ☐ It's more convenient than making an appointment with my doctor.
- ☐ To confirm the results of a similar check I had elsewhere.
- ☐ Other, please state _____

  _____

Please turn over

2

9- Please tick one box for each statement that best indicates how far you agree or disagree with the following statements with regard the cardiovascular risk assessment service you had at Boots, Porthcawl:

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree
a. I am totally satisfied with the cardiovascular risk assessment service.	☐	☐	☐	☐	☐
b. The staff were friendly.	☐	☐	☐	☐	☐
c. The staff made me feel comfortable.	☐	☐	☐	☐	☐
d. There was sufficient privacy in the consultation room.	☐	☐	☐	☐	☐
e. I found it difficult to tell the pharmacist about some private things.	☐	☐	☐	☐	☐
f. The pharmacist explained everything to me in a way I could understand.	☐	☐	☐	☐	☐
g. The pharmacist gave me sufficient opportunity to ask questions.	☐	☐	☐	☐	☐
h. I was worried about my health **BEFORE** having the cardiovascular risk assessment service.	☐	☐	☐	☐	☐
i. I am worried about my health **AFTER** having the cardiovascular risk assessment service.	☐	☐	☐	☐	☐

Question 7 continues over the page
Please turn over

	Strongly Agree	Agree	Neither agree nor disagree	Disagree	Strongly Disagree

j. The consultation time with the pharmacist should have been a little longer.	☐	☐	☐	☐	☐
k. The pharmacist informed me about the results of the tests without making me worried.	☐	☐	☐	☐	☐
l. I had trust in the pharmacist's ability to perform the cardiovascular risk assessment service before I saw him for the check.	☐	☐	☐	☐	☐
m. My trust in the pharmacist remains the same after the cardiovascular risk assessment service.	☐	☐	☐	☐	☐
n. I would rather have had this health check in my doctor's surgery.	☐	☐	☐	☐	☐
o. I would recommend the cardiovascular risk assessment service to other people.	☐	☐	☐	☐	☐
p. Some things about the cardiovascular risk assessment service could have been better.	☐	☐	☐	☐	☐
If you ticked Strongly Agree or Agree, please specify in the box what it was that could have been better:					

10- Are there any other comments you would like to make? Please specify here:

Please put the questionnaire in the pre-paid envelope provided and send it by post or hand it in to a member of staff.

Thank you very much for your time.

4

Appendix 11a: Interview schedule for two-week follow-up

Interview conducted over the phone by an independent researcher

- Hello. May I speak to _____ please?
-
    - Hello my name is _____ from Cardiff University. I am phoning to see if it is convenient to ask some questions about the cardiovascular risk assessment service you had at Boots Porthcawl recently
    - Is now a good time to talk? If they hesitate or aren't sure then say ' If it is more convenient I can call back" and ask 'what day and time suits you'
      Date/Time_____

- Before we start we would like to record the interview so that we don't miss anything you say. We won't be asking sensitive questions. Is this OK?

The interview

- How did you find out about the cardiovascular risk assessment service at Boots, Porthcawl?

- Can you remember the reasons you decided to have the cardiovascular assessment service at Boots on this occasion?

- Have you had any similar checks in the past either in the surgery or pharmacy or elsewhere?

If YES, can you remember when it was and what the results were?

- Is there anyone in your family who had or has heart disease?

- Do you know any friends, neighbors or colleagues who have had heart disease?

I am now going to ask a few questions about what happened at Boots

- Did the pharmacist say if you were at high, low or moderate risk of cardiovascular disease?

The consent form will state if risk assessment performed **If NO, go to next page**

- At that time what did being at _____* risk mean to you? [*they may give a %]

- How was it useful to be told of your individual risk by the pharmacist?

- How did you feel when the pharmacist told you what your risk was?

(If they're not sure, ask Did the cardiovascular risk assessment service make you reassured, concerned or something else ?)

- Have you talked to your doctor or nurse about the results of the Boots check?

Do you remember what they said?

- Have you discussed the Boots results with anybody else? (Prompt only: spouse, friend, relatives)

- How do you feel NOW that is today about your _____ * risk ? *[they may give a %]

- I am now going to ask some questions about the advice you and the pharmacist discussed

Did the pharmacist mention anything about _____? Do you remember what was discussed? Ask for each section one by one

- diet,

- weight,

- exercise,

- smoking,

- alcohol

- anything else

- Have you recommended this Boots service to anyone else?

If NO, have you mentioned it to anybody or would you?

- Is there anything you would like to say about the actual cardiovascular risk assessment service you had at Boots, Porthcawl?

Thank you very much for your time.

Appendix 11b: Example Interview Transcript (with subject 104)

Subject 104: Hello

Interviewer: oh hello can I speak to Mr [ ] please?

Subject 104: Speaking

Interviewer: oh hello Mr [ ] my names Dai John from Cardiff University I was hoping to ask a few questions about your Boots health check

Subject 104: Yes

Interviewer: But I know it's about tea time so you may be having your tea at the moment?

Subject 104: Right if I just finish my mouthful I'll be fine actually.

Interviewer: Are you sure I tried to call in the day but of course I realised that people don't sit at home waiting for me to ring.

Subject 104: ah yeh no no its fine now

Interviewer: ah right thank you I'm just wondering if it's ok to record the conversation please there's nothing...

Subject 104: Yes that's fine.

Interviewer: Thank you thank you, so first of all Sir how did you find out about the service down at Boots?

Subject 104: I saw it in the local paper

Interviewer: ah right thank you and can you remember the reasons you decided to have the tests done at Boots on this occasion?

Subject 104: Well just to see what my blood pressure and cholesterol was like really.

Interviewer: OK thank you have you had similar checks in the past please sir?

Subject 104: um I've had my blood pressure checked.

Interviewer: OK

Subject 104: Before

Interviewer: Right and do you remember what the results were?

Subject 104: um not exactly no

Interviewer: OK no that's fine that's fine is there anybody in your family who's got heart disease?

Subject 104: um no.

Interviewer: OK and do you know any friends neighbours or colleagues who've got heart disease or may have had it?

Subject 104: uh no not really no

Interviewer: OK thank you now were going to take you to the actual visit that you had with the pharmacist.

Subject 104: Yes sure.

Interviewer: Do you remember if he said to you if you were a high low or moderate risk of cardiovascular disease?

Subject 104: He said I was let me think moderate I think

Interviewer: Moderate?

Subject 104: Yes

Interviewer: And at the time what did being at moderate risk mean to you do you remember?

Subject 104: uh it was something like it was under 20% chance that I would have a heart attack or a stroke within the next 10 years I think

Interviewer: OK thank you and was it useful for you to be told your individual risk do you think

Subject 104: uh well it was useful to have uh to know the results of the blood pressure and uh cholesterol yes

Interviewer: OK and what about the risk itself was it useful to know your individual risk or not useful

Subject 104: um I suppose it was yes yes

Interviewer: OK and how did you feel when the pharmacist told you what your risk was when he said to you are less than 20%

Subject 104: I suppose that was a bit disconcerting really obviously a low would have been a lot better

Interviewer: Right, OK yeh have you spoke to your doctor or nurse about the results of the Boots check?

Subject 104: No I haven't no

Interviewer: OK is it something that you might do you won't do or have you not bothered about it?

Subject 104: Well I rarely go to a doctor so um I probably wouldn't mention it you know.

Interviewer: Right, yeh... and have you talked to anybody else about the results of this test maybe friends or family?

Subject 104: um friends yes yes

Interviewer: OK thank you and finally it's been two and a half weeks since you had the test..

Subject 104: Yes

Interviewer: Nearly three weeks now how do you feel today about your moderate risk is there any change?

Subject 104: um no I think what it's made me do I think is think about the amount of exercise I have and what I'm eating you know.

Interviewer: yeh...

Subject 104: So I think it'll probably um amend the way that I do things over the next year.

Interviewer: OK did the pharmacist and you discuss the types of foods you eat when he met with you?

Subject 104: Yes he did yes yes

Interviewer: OK

Subject 104: And he suggested that I eat less salt

Interviewer: Yeh

Subject 104: Well I've taken less salt

Interviewer: Yeh.. anything else you can remember not the detail just broadly really

Subject 104: um no all he said was perhaps get a bit more exercise

Interviewer: Yeh OK

Subject 104: And be careful what I'm eating have lots of fresh fruit and veg you know.

Interviewer: Yeh... thank you and what about weight I don't need to know how much you are but did you discuss with the pharmacist?

Subject 104: My weight was fine.

Interviewer: OK thank you and about alcohol intake did you and the pharmacist discuss alcohol?

Subject 104: We did and that was fine as well yeh.

Interviewer: Fine OK and smoking did that come up?

Subject 104: uh it did but I don't smoke.

Interviewer: You don't smoke right?

Subject 104: No

Interviewer: Thank you and was there anything else you and the pharmacist talked about in terms of lifestyle advice if you like?

Subject 104: uh no I don't think so. I think the two things were exercise and diet really.

Interviewer: OK thank you have you recommended the service to anybody else sir?

Subject 104: uh I've mentioned it to some other people.

Interviewer: Right

Subject 104: Who for whatever reason didn't seem that keen on going but yes

Interviewer: OK thank you and finally I've been asking you questions for the past 5 minutes is there anything you'd like to say about the risk assessment you had at Boots in Porthcawl that I've not asked you about this evening

Subject 104: No not really it was fine it was yeh it was quite useful I think

Interviewer: OK and I noticed you live in Pencoed so

Subject 104: Yeh

Interviewer: Did you go all the way over to Porthcawl to have the test or do you go to Porthcawl?

Subject 104: Yes we did go there although we often go to Porthcawl anyway

Interviewer: ah right ok ok well thank you very much indeed for your time Mr [ ]

Subject 104: OK that's fine

Interviewer: Sorry to have troubled you thank you

Subject 104: No problem

Interviewer: Bye bye

Appendix 11c: Questionnaire for two-week follow-up

Covering letter:

Date

Dear

Evaluation of a cardiovascular risk assessment service

We are writing to you as you had a health check at Boots pharmacy in Porthcawl recently. We have tried contacting by telephone but we have not been able to speak to you. Therefore, we are writing to you to ask if you would be kind enough to answer the questions enclosed and return to us in the next 5 days if possible. We have enclosed a Freepost envelope, so no stamp is required.

If you have any questions please do contact me on 029 2087 5804, or if you prefer you can e-mail me at JohnDN@cardiff.ac.uk.

Thank you very much in anticipation of your help.

Yours sincerely

Dr DN John

Questionnaire:

Evaluation of a cardiovascular risk assessment service

Follow-up Questionnaire

Q1. How did you find out about the cardiovascular risk assessment service at Boots, Porthcawl?

Q2. What was the reason you decided to have the cardiovascular assessment service at Boots on this particular occasion?

Q3. Have you had any similar checks in the past either in the surgery or pharmacy or elsewhere ? Please tick one box.

Yes ☐ No ☐ Can't remember ☐

The following questions ask about your health check at Boots.

Q4. Did the pharmacist say if you were at high, low or moderate risk of cardiovascular disease? Please tick one box.

High ☐ Moderate ☐ Low ☐ He did not say ☐ Can't remember ☐

Q5. In what way/s was it useful for the pharmacist to tell you what your individual risk was?

Q6. How did you feel **at the time** of the health check when the pharmacist told you what your risk was?

Q7. How did you feel about the risk **today**, some weeks after the health check ?

Q8. Have you talked to anyone about the results of the Boots health check yet? Please tick all boxes that apply.

Doctor☐ Nurse ☐ Other health professional ☐ (please state) _____

Family ☐ Friend/s ☐ Other ☐ (please state) _____

Please turn over

The following questions ask about the advice you and the pharmacist discussed. There is no need to write a lot of detail, please just mention the main points.

Q9. What things did you discuss about your **diet**, that is, the types of food you eat?

Q10. What things did you discuss about your **weight**?

Q11. What things did you discuss about **exercise**?

Q12. What things did you discuss about **smoking**?

Q13. What things did you discuss about **alcohol**?

Q14. Did you and the pharmacist discuss anything else? If Yes, please list.

Q15. Have you recommended this Boots service to anyone else? Please tick one box.

Yes ☐ Not yet, but I would recommend it ☐ No, I would NOT recommend it ☐

Q16. Is there anything you would like to say about the actual cardiovascular risk assessment service you had at Boots, Porthcawl? If so, please write in the box below.

Q17. If you have any comments on the questionnaire, please would you write them in this box.

Thank you very much for your time.

Please return in the Freepost envelope, **no stamp is required.**

Appendix 12a: Reminder letter for twelve-month follow-up

Evaluation of a cardiovascular risk assessment service

Date

Dear Mr [ ]

It is about a year since we asked you to participate in a study to help us evaluate a cardiovascular risk assessment service. You received the cardiovascular risk assessment service on 5th August 2010 at Boots, 5 New Market Walk, Merthyr Tydfil. At that time you gave permission for us to contact you to check out your progress.

I am writing to invite you for a follow-up consultation with me as part of the study. This consultation may include a repeat of the tests you had about 11 months ago. I will try to contact you in about a week to see if you are still interested in participating and to answer any questions you may have. If you are interested in participating then we can arrange a mutually convenient time for the follow-up consultation to take place in Boots.

In addition to offering the follow-up at the New Market Walk branch we are also able to offer this service at Boots, Cyfartha Retail Park. When I speak with you I will ask you to specify whether you prefer to have this follow-up at:

1- Boots, 5 New Market Walk, Merthyr Tydfil
2- Boots, Cyfarthfa Retail Park, Merthyr Tydfil

If you would prefer to contact me feel free to do so. You can contact me by telephone, email, or by return of the enclosed slip in the Freepost envelope provided.

Thank you very much for your help with this study.

Yours sincerely

Salah Waheedi

WaheediS2@cf.ac.uk
07765596906

Appendix 12b: Withdrawal form to accompany reminder letter for twelve-month follow-up

Name _____

Please do not complete and return this form if you wish to be contacted by the research pharmacist to arrange the appointment.

If applicable, please tick one of the following boxes and return in the Freepost envelope provided as soon as possible.

- I would prefer NOT to be contacted by anyone from the research team for the follow up consultation.* ☐
- I do not want to be contacted but I may contact you to arrange for the appointment myself ☐

Please write the date of completing this form here: _____

* If you do not wish to have a follow-up consultation it would be very helpful to us to hear any reasons you may have. Please note that you do not have to give any reasons, it is entirely up to you. If you are willing, please use the following box to provide any information you would like to share with us.

Appendix 13: Questionnaire for twelve-month follow-up

Evaluation of a cardiovascular risk assessment service
Twelve-month follow-up questionnaire

Name_____ **Date** _____

Please answer the questions below. Please ask the pharmacist if there is anything you wish to clarify.

1- On average, how many units of alcohol do you drink per week? ☐

Note: 1 unit = approx. ½ pint of beer/ lager/ cider, a small glass of wine, a single measure of spirits.

2- Do you smoke?

☐ Yes ☐ No

If yes: How many cigarettes do you smoke per day? ☐

If no

☐ Never smoked ☐ Quit within the last 5 years ☐ Quit more than 5 years ago

3- How often do you eat vegetables, fruit or berries?

☐ Every day ☐ Not every day

Please state on average how many portions of fruits and vegetables you eat per day ☐

4- **In the past 7 days**, on how many days have you exercised for at least 30 minutes, such as brisk walking, cycling or active recreation? Please circle one number (0 to 7) in the box.

0 (none)	1 (One day per week)	2	3	4	5	6	7 (Every day)

5- This question asks about any cardiovascular risk assessment tests you have had in the past 12 months or so.
Have you had a similar test to the Boots cardiovascular risk assessment about one year ago?

☐ Yes, at my GP practice

☐ Yes, at a community pharmacy

☐ Yes, somewhere else. Pease state _____

☐ No

Please turn over

6- Please tick the box that **OVERALL** best describes the change or otherwise in the types of food in your diet between having the cardiovascular risk assessment in Boots **about 12 months ago and today**. If for example you have never eaten a certain type of food eg red meat please tick the 'No Change' box.

	Much increased	Increased	No change	Decreased	Much decreased	Unsure
Red meat	☐	☐	☐	☐	☐	☐
Dairy products	☐	☐	☐	☐	☐	☐
Oily fish	☐	☐	☐	☐	☐	☐
Salt	☐	☐	☐	☐	☐	☐
Fruits and vegetables	☐	☐	☐	☐	☐	☐

7- Please tick the box that **OVERALL** best describes the change or otherwise in each lifestyle factor between having the cardiovascular risk assessment in Boots **about 12 months ago and today**.
If for example you have never smoked, please tick the 'No Change' box.

	Started	Increased	No change	Decreased	Stopped	Unsure
Exercise	☐	☐	☐	☐	☐	☐
Smoking	☐	☐	☐	☐	☐	☐
Alcohol	☐	☐	☐	☐	☐	☐

V1.6

Appendix 14: List of subjects who accessed the VRA service

P = Porthcawl. MT = Merthyr Tydfil. ¥ data collected at 12 month follow-up. Q subject completed a questionnaire at the 2 week follow-up instead of a telephone interview

Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
1 (P)	21	12.6	74	Male	26.9	26.3	109	106	138/91	131/80	4.3	4.87	1.05	1.32	4.1	3.7	25.8	
2 (P)	19		66	Female	23.9		77		162/95		5.8		1.83		3.2		19.5	
3 (P)	16		74	Female	25.6		80		184/98		3.93		1.56		2.5			
4 (P)	15		59	Male	25.5		101		122/88		4.27		0.91		4.7		21.0	
5 (MT)	25		62	Female	23.7		81.5		135/81		5.42		1.39		3.9		9.2	
6 (P)	20		67	Male	29		100		132/83		4.44		0.75		5.9		37.0	
7 (MT)	16	12.0	54	Female	26.7	27.1	95	87	116/77	106/71	5.23	5.56	1.43	2.09	3.7	2.7	4.4	2.3
8 (MT)	14	11.7	55	Female	36.4	35.7	114	114	126/84	107/72	5.42	5.87	0.83	0.96	6.5	6.1	17.1	12.1
9 (MT)	15	12.4	59	Female	26.6	26.7	100	100	125/80	112/69	4.18	4.56	1.19	1.41	3.5	3.2	10.9	8.1
10 (P)	14	14.0	70	Male	27.8	27			161/104	138/87								
11 (P)	19	12.6	52	Female	23.7	24.2	85.5	81	116/85	109/77	5.88	5.32	1.71	1.73	3.4	3.1	3.6	2.7
12 (P)	40		62	Female	26.7		88		132/89		5.52		1.31		4.2		9.5	
13 (MT)	14		41	Female	30.2		96.5		124/84		5.07		1.19		4.3		3.2	
14 (P)	20	12.1	68	Male	26.4	26.6	90	91	135/88	129/80	4.7	5.15	2.19	1.4	2.1	3.7	16.8	26.3
15 (MT)	20	12.4	47	Female	30.1	31	94.5	94	121/87	129/87	5.27	6.59	2.41	2.59	2.2	2.5	4.3	3.4

Appendix 14: List of subjects who accessed the VRA service

P = Porthcawl. MT = Merthyr Tydfil. ¥ data collected at 12 month follow-up. Q subject completed a questionnaire at the 2 week follow-up instead of a telephone interview

Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
16 (P)	20		49	Female	28.8		84.5		113/75		4.05		1.32		3		3.4	
17 (MT)	15	12.1	50	Male	28	28.5	102	101	170/100	139/87	4.57	5.98	0.97	1.11	4.7	5.4	16.1	13.3
18 (P)	28	13.1	56	Female	31.5	31.9	107	99	125/84	113/77	4.93	5.2	1.07	1.18	4.6	4.4	7.7	6.1
19 (MT)	22		47	Male	30.3		100.5		109/79		4.53		0.69		6.6		13.0	
20 (P)	20	12.8	71	Female	30.6	33.6		108	141/94	142/80	3.98	3.92	1.14	0.96	3.5	4.1	11.3	13.6
21 (MT)	15	12.1	64	Female	25.1	23.8	78	79.5	118/87	118/79	5.44	5.38	1.21	1.25	4.5	4.3	12.7	12.4
22 (P)	19	14.8	55	Male	26.9	26.7	108.5	96	132/80	131/80	5.75	8.11	1.41	1.82	4.1	4.5	11.0	12.5
23 (P)	15		78	Male	27.6		99		143/83		3.43		1.06		3.2			
24 (P)	15		72	Female	26.9		79		120/85		3.62		1.78		2		6.7	
25 (P)		12.1	79	Female	26.7	26.5	97	90	113/68	104/68	4.97	3.26	1.27	1.09	3.9	3		
26 (MT)	21		61	Male	25		92		158/102		5.8		1.46		4		20.2	
27 (MT)	15	11.9	55	Female	23.4	23.5	82.5	81.5	160/104	145/93	4.01	6.32	0.9	0.96	4.5	6.6	11.9	15.3
28 (P)	19	12.1	62	Male	30.8	29.7	108	102	141/90	117/76								
29 (P)	19	12.4	43	Female	23.9	22.6	74.5	73	126/85	116/81	4.34	4.51	2.34	2.18	1.9	2.1	0.8	0.8
30 (MT)	24		72	Female	27.3		87		144/89		6.68		1.16		5.8		18.9	
31 (MT)	14		60	Female	36.9		106.5		161/104		3.84		0.8		4.8		15.6	
32 (MT)	17	12.1	57	Female	26.9	27.5	90	93	157/91	125/76	4.89	5.86	1.37	1.3	3.6	4.5	14.9	12.1
33 (P)	19	13.8	69	Female	26.2	26.2	87	96	123/83	122/83	6.51	5.82	1.19	1.56	5.5	3.7	12.6	8.4
34 (P)	15	13.8	65	Male	29.2	28	99	98	170/102	142/85	5.31	4.2	2.02	1.05	2.6	4		

Appendix 14: List of subjects who accessed the VRA service

P = Porthcawl. MT = Merthyr Tydfil. ¥ data collected at 12 month follow-up. Q subject completed a questionnaire at the 2 week follow-up instead of a telephone interview

Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
35 (MT)	14	11.4	67	Female	28.8	27.7	94.5	80.5	123/80	109/74	4.92	5.93	1.04	1.19	4.7	5	10.5	8.8
36 (MT)	15		40	Female	21		77		115/70		5.38		2.36		2.3		0.5	
37 (P)	16	11.9	66	Female	28.7	28	100	95	120/73	120/81	5.52	6.64	2.16	2	2.6	3.3	7.2	9.9
38 (P)	19	13.3	59	Female	28.1	27.2	89.5	87	116/85	117/82	6.76	5.92	2.11	1.24	3.2	4.8	4.6	8.0
39 (MT)	32	12.6	42	Female	26.4	29.7	85	89	105/68	122/61	4.97	5.15	1.29	1.29	3.8	4	1.3	2.3
40 (MT)	15	11.7	49	Female	26	25.7	86	81	104/69	99/69	4.4	4.59	1.18	1.34	3.7	3.4	2.5	2.1
41 (P)	23	14.7	56	Female	27	26.8	94.5	92	120/111	111/79	4.06	3.82	1.36	1.44	2.99	2.7	5.6	4.2
42 (P)	14		59	Male	32.6		107		142/85		5.06		0.74		6.9		24.5	
43 (P)	19	13.5	56	Female	27.7	27	90	81	127/83	99/68	6.17	5.95	1.77	2.24	3.5	2.7	5.6	2.1
44 (P)	19	12.1	46	Male	27.5	27.3	104.5	102	122/89	129/85	5.33	5.07	1.06	0.83	5	6.1	10.7	16.2
45 (MT)	21	11.7	43	Female	28.8	28.1	91	92	128/80	114/70	5.34	6.94	1.3	1.37	4.1	5.1	7.9	9.0
46 (P)	22	12.9	47	Male	30.7	29.6	107	108	114/84	109/71	4.27	4.37	1.04	1.09	4.1	4	5.0	4.7
47 (MT)	16	11.7	65	Male	25.6	24	92	85	128/71	115/59	3.08	2.59	0.71	0.59	4.3	4.4	25.9	
48 (P)	50	11.4	66	Female	22.8	22.8	71	71	153/99	164/99	4.91	5.37	1.09	1.36	4.5	3.9	15.5	16.5
49 (MT)	44		58	Female	31.4		103		177/121		5.29		1.26		4.2		15.8	
50 (MT)	16	12	50	Female	33.6	32.9	116	112	127/92	130/84	4.17	3.75	1.18	1.53	3.5	2.5	4.1	2.8
51 (P)	19		70	Female	33.6		106		133/73		4.48		1.57		2.9		7.9	
52 (P)	33		71	Male	27.3		100.5		122/82		4.84		1.4		3.4		16.0	
53 (P)	41	13.9	61	Female	31.5	26.1	95.5	84	146/103	107/76	3.71	4.14	1.24	2.18	3	1.9	8.1	2.1

Appendix 14: List of subjects who accessed the VRA service

P = Porthcawl. MT = Merthyr Tydfil. ¥ data collected at 12 month follow-up. Q subject completed a questionnaire at the 2 week follow-up instead of a telephone interview

Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
54 (P)	21	13.1	64	Male	30	29.3	104	102	146/94	121/88	4.37	4.94	1.41	1.2	3.1	4.1	23.6	22.2
55 (P)	21	13.1	63	Female	29.5	28.3	100	100	153/88	136/91	5.3	6.04	1.15	1.2	4.6	5	14.7	12.9
56 (P)	27	12.6	62	Female	24.2	24.3	81.5	87	108/73	92/69	4.13	5.29	0.87	1.15	4.7	4.6	10.7	7.5
57 (P)	20		55	Female	28.8		97.5		127/84		4.86		0.9		5.4		13.9	
58 (P)	26	12.8	56	Female	26.6	27.3	86.5	92	158/108	155/95	5.94	6.96	1.68	1.05	3.5	6.6	14.3	26.9
59 (P)	16		72	Male	26.3		96		137/77		4.35		1.04		4.2		24.3	
60 (P)	22	13.1	57	Male	32.1	31.7	108.5	109	119/78	107/75	4.82	4.84	0.82	0.95	5.9	5.1	22.3	16.5
61 (P)	28	13.6	72	Male	29.7	29.6	102	103	142/86	156/80	3.83	3.91	0.63	0.88	6	4.5		
62 (P)	19		58	Female	24.3		78.5		140/95		5.81		2.11		2.8		5.9	
63 (P)	22		61	Female	32.8				141/76		4.4		0.74		5.9			
64 (P)	20	12.1	67	Male	36.5	36.8	124	120	137/98	128/84	3.12	3.88	0.96	0.97	3.3	4	16.3	18.0
65 (P)	20	12.1	50	Female	20.4	20.4	71	70	130/78	151/87	6.26	7.08	1.91	2.2	3.3	3.2	3.9	5.9
66 (P)	20	12.6	52	Male	25.2	24.7	88	80	147/84	133/75	4.47	4.75	1.38	1.59	3.2	3	9.0	7.0
67 (MT)	17	12.6	62	Male	30.5	30.4	111	113	161/94	132/88	4.52	4.2	0.71	0.69	6.4	6.5	31.3	23.0
68 (MT)	16	12.7	65	Female	28.2	26	94	84	143/86	118/73	6.45	5.8	1.88	1.75	3.4	3.3	10.0	6.2
69 (P)	16	11.7	67	Male	24.3	24.3	90.5	91	146/82	130/75	4.27	5.46	0.83	0.76	5.1	7.2	40.5	45.1
70 (P)	16	11.7	65	Female	21.6	21.4	71.5	70	189/98	134/74	4.84	4.79	1.32	1.06	3.7	4.5	31.1	17.5
71 (MT)	17	12.4	74	Female	27.8	28.1	89	86	142/79	119/71	5.78	5.07	1.32	1.37	4.4	3.7	14.9	
72 (P)	15	11.9	53	Female	22.8	22.5	77	71	100/69	111/71	4.93	4.81	1.51	1.63	3.3	3	3.6	4.3

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P = Porthcawl. MT = Merthyr Tydfil. ¥ data collected at 12 month follow-up. Q subject completed a questionnaire at the 2 week follow-up instead of a telephone interview

Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
73 (P)	23	11.4	65	Male	24.1	23.6	91.5	88	125/81	109/73	3.55	4.15	0.82	1.12	4.4	3.7	24.8	17.0
74 (P)	21	13.8	71	Female	29.9	28	89	87	153/97	135/86	7	5.53	1.49	1.75	4.7	3.2		
75 (MT)	28	12.3	68	Female	21.6	21.3	75	70	119/74	122/74	5.59	5.98	1.6	1.72	3.5	3.5	7.0	7.6
76 (P)	23	12.7	67	Male	30.5	29.9	105	100	121/84	104/70	4.02	3.16	0.89	1.07	4.5	2.9	26.3	13.0
77 (MT)	17	12.2	55	Female	28.9	28.2	86	84	112/74	122/77	5.52	4.63	0.98	0.76	5.6	6.1	7.6	10.3
78 (P)	33	12.6	47	Female	26.5	26.4	93.5	93	126/63	108/77	4.54	5.08		2.11	0	2.4	1.2	1.3
79 (MT)	16	12.9	48	Female	29.1	27.9	94	84	123/71	110/67	5.8	3.83	0.99	1.1	5.8	3.5	6.6	2.6
80 (P)	17	12.8	62	Female	19.3	19.3	73	68	120/83	109/74	3.83	4.15	1.45	1.98	2.6	2.1	6.6	3.9
81 (P)	20		57	Male	26.5		99		127/78		3.85		0.62		6.2		26.2	
82 (P)	19		61	Male	33				144/82		4.4		0.9		4.9		30.5	
83 (P)	15	13.1	56	Male	28.7	26.7	97	98	134/81	134/66	5.14	4.6	1.92	1.96	2.7	2.3	7.5	6.8
84 (P)	34	13.5	45	Male	27.5	26.5	94	94	136/87	133/74	4.06	3.42	0.88	0.85	4.6	4	19.0	16.7
85 (P)	14		51	Female	27.9		85		108/74		4.12		1.4		2.9		3.3	
86 (P)	30	13.3	53	Male	34.4	33.1	114	116	126/89	120/62	4.98	4.29	1.03	0.89	4.8	4.8	16.4	15.7
87 (P)	34		56	Female	25.2		84		124/81		5.18		1.58		3.3		4.9	
88 (P)	91	17.5	72	Male	23.2	22.3			170/89	163/89	3.22	4.12	1.14	1.39	2.8	3	28.2	27.5
89 (P)	91	17.5	67	Female	25.2	25.5	74	86	122/82	112/72	4.05	3.77	1.28	1.27	3.2	3	6.5	5.0
90 (P)	16	13.8	67	Male	30	31.4	110	120	161/90	180/99	4.38	4.11	1.19	0.95	3.7	4.3		
91 (P)	20	13.5	69	Male	27	27.3	99	101	186/101	152/93	4.94	3.71	1.3	1.26	3.8	2.9		

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P = Porthcawl. MT = Merthyr Tydfil. ¥ data collected at 12 month follow-up. Q subject completed a questionnaire at the 2 week follow-up instead of a telephone interview

Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
92 (P)	20		83	Female	24.9		85		149/84		3.77		1.73		2.2			
93 (P)	21		69	Female	22.6		85		130/80		5.48		1.13		4.8		12.5	
94 (P)	19		67	Female	24.1		69		123/75		3.34		1.69		2			
95 (MT)	16	12.9	48	Female	37.2	28.4	110	82	130/98	112/68	5.05	4.12	1.71	1.51	2.9	2.7	8.3	5.5
96 (P)	20	12.8	42	Female	24.4	24	71.5	71	95/68	93/63	3.85	3.72	1.9	2.25	2	1.7	0.3	0.2
97 (P)	15		57	Female	36.4		106		127/87		5.07		0.96		5.3		9.7	
98 (P)	28	12.8	65	Female	33	32	94	98	117/91	114/72	3.15	3.02	1.21	1.31	2.6	2.3		
99 (P)	20		71	Female	23.1		74		136/85		5.1		0.98		5.2		15.2	
100 (P)	20		63	Female	32		94		118/82		3.53		1.13		3.1		5.3	
101 (MT)	14	11.4	68	Male	24.2	22.8	88	83	129/93	110/72	5.22	5.05	1.17	1.14	4.5	4.4	20.1	15.7
102 (P)	28	14.5	58	Male	18.9	17.7	79	76	120/76	118/72	3.15	3.32	1.18	1.64	2.7	2	6.4	4.7
103 (P)	28	14.5	54	Female	27.9	26.9	88	86	131/98	109/76	4.64	5.92	1.71	1.91	2.7	3.1	7.4	3.1
104 (P)	19	13.3	64	Male	23.3	22.8	83	80	136/92	136/84	6	5.84	1.34	1.14	4.5	5.1	19.1	22.3
105 (MT)			48	Female	24.1		79		129/84		4.21		1.64		2.6		2.3	
106 (MT)		11.7	48	Male	24.5	25.6	82	89	122/69	115/73	4.42	5.88	1.26	1.34	3.5	4.4	5.0	6.4
107 (P)	27Q		71	Female	29.3		95.5		128/76		6.05		0.81		7.4		18.9	
108 (P)	27Q	12.1	64	Female	21.5	21.1	79	78	135/93	125/85	5.14	6.76	1.2	1.66	4.3	4.1	16.1	13.2
109 (P)	29Q		71	Female	25.9		72		194/113		5.58		1.51		3.7		26.2	
110 (P)	28	13.8	54	Male	33.9	34.5		120	123/84	147/88	2.86	2.73	1.21	1.05	2.4	2.6		

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P = Porthcawl. MT = Merthyr Tydfil. ¥ data collected at 12 month follow-up. Q subject completed a questionnaire at the 2 week follow-up instead of a telephone interview

Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
111 (P)	26		44	Male	24.4		78		116/80									
112 (P)	27		54	Female	23		89.5		115/80		4.97		2.06		2.4		2.4	
113 (P)	21	12.4	67	Male	32.9	32.7	117.5	116	151/97	144/90	4.31	4.74	0.89	1.11	4.8	4.3	27.3	23.6
114 (P)	21		55	Male	32.6		111		153/93		5.25		0.83		6.4		22.1	
115 (P)	37	14.2	60	Male	27	26.5	89	94	148/95	146/99	5.35	5.13	0.9	0.78	5.9	6.6	36.3	39.9
116 (P)	28	14.9	67	Female	28.1	27.6	89	89	150/98	128/81	6.28	5.77	1.23	1.68	5.1	3.4	17.0	8.2
117 (P)	35	13.8	65	Female	35	36.3	103	107	114/79	113/77	4.84	3.54	1.12	0.89	4.3	4	7.7	7.0
118 (P)	35	13.8	68	Male	23.6	24	87	92	150/83	144/85	4.53	3.83	1.2	1.26	3.8	3		
119 (P)	35	14.5	69	Male	27.5	27.7	96	98	147/85	136/75	3.69	4.39	0.75	0.75	4.9	5.8	28.2	29.2
120 (P)	35	14.5	63	Female	24.5	24.1	79	76	124/82	128/84	4.7	4.91	1.52	2.59	3.1	1.9	5.9	3.9
121 (P)	35	13.8	68	Male	28	27.5	99	105	150/97	158/98	5.18	5.79	1.56	1.46	3.3	4	20.8	27.4
122 (P)	19		57	Male	25.8		90		174/100		4.74		1.31		3.6		19.0	
123 (P)	19		55	Female	19		74		137/79		5.64		2.17		2.6		4.5	
124 (P)	26	16.2	49	Male	30.1	29.6	94	99	141/87	133/85	7.28	6.45	0.98	1.03	7.5	6.3	17.3	13.8
125 (P)	20	13.8	42	Male	24.8	25.3	92	92	147/93	143/91	4.66	4.2	1.08	1.01	4.3	3.9	6.5	6.3
126 (P)	18	13.8	38	Female	30.3	30.2	91.5	101	120/89	109/82	4.47	3.68	1.41	1.51	3.2	2.4	0.7	0.4
127 (P)	35		68	Male	28		104		141/95		5.06		2.47		2		18.0	
128 (P)	37	14.2	64	Male	29.2	27.7	110	102	138/83	119/78	2.75	2.81	0.66	0.71	4.1	4	27.5	20.7
129 (P)	15		40	Male	30.3		105		128/63		3.93		0.98		4		3.6	

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Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
130 (P)	28	13.8	69	Female	26.3	29.6	86	94	153/91	162/107	5.56	6.41	1.47	1.5	3.8	4.3	21.3	27.6
131 (P)	28	13.8	69	Male	25.9	24.9	91	95	150/88	150/89	6.89	5.83	1.11	0.99	6.2	5.9	34.3	34.1
132 (P)	35		53	Male	31.8		104		159/98		6.11		0.94		6.5		22.1	
133 (P)	44		52	Female	19.4		65		82/59		3.48		1.38		2.5		0.8	
134 (P)	21		61	Female	27.4		79		150/97		5		1.97		2.5		7.4	
135 (P)	15	13.8	49	Male	27.6	26	95	93	155/90	145/80	3.91	3.24	1.63	1.49	2.4	2.2	6.1	4.9
136 (P)	22	14.2	72	Male	29.1	29.5	107	114	135/85	117/82	5.25	4.94	1.14	1.01	4.6	4.9	25.5	21.8
137 (P)	21	13.5	72	Female	26.6	27.5	79	80	130/83	123/76	4.92	6.08		2.27		2.7	5.4	6.4
138 (P)	19	14.5	62	Female	25.3	25.4	81		129/78	119/77	4.15	5.06	1.22	1.91	3.4	2.7	7.1	4.4
139 (P)	35	13.7	67	Male	30	30.4	106	107	168/93	168/91	4.56	3.93	1.4	1.24	3.3	3.2	37.5	38.3
140 (P)	28	14.9	69	Male	29.7	29.8	100	105	139/90	129/78		3.55		1.38		2.6		
141 (P)	21	13.5	65	Female	29.1	28.4	82	83	122/86	119/76	6.41	4.52	1.8	2.1	3.6	2.2	7.1	3.9
142 (P)	15		61	Female	34		98		143/98		6.21		1.49		4.2		16.3	
143 (P)	20	13.8	71	Female	23.2	24.4	79	84	153/95	146/88	3.93	3.92	0.91	1.44	4.3	2.7	16.6	10.2
144 (P)	21		46	Female	20.9		71		123/82		4.41		1.09		4		9.3	
145 (P)	26		62	Female	40.4		116		143/109		6.19		1.12		5.6		14.9	
146 (P)	19		71	Male	29.9		97		148/79		4.62		0.8		5.8		33.9	
147 (P)	19		55	Female	44.9				125/83		4.51		1.31		3.5		5.1	
148 (P)	19	11.9	53	Male	23.9	22.2	89.5	83	173/112	152/101	3.95	4.59	2.04	2.22	1.9	2.1	8.7	6.9

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P = Porthcawl. MT = Merthyr Tydfil. ¥ data collected at 12 month follow-up. Q subject completed a questionnaire at the 2 week follow-up instead of a telephone interview

Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
149 (P)	21	12.8	67	Female	31	33.2	88	98	135/88	123/75	5.97	5.91	1.41	1.35	4.2	4.4		9.8
150 (P)	15	12.1	63	Female	27.1	22.2	89	78	137/93	126/78	5.71	3.64	1.61	1.44	3.5	2.5		
151 (MT)	15	11.8	56	Male	31.8	31	109.5	106	140/92	140/89	5.44	5.77	0.69	0.67	7.8	8.6	24.3	27.0
152 (P)	14		70	Female	25.2		67		150/93		4.11		2.49		1.7			
153 (P)	20		43	Male	28.4		96.5		125/49		5.36		0.92		5.9		12.5	
154 (MT)	16	11.7	43	Male	29	29.9	99.5	103	137/86	127/72	7.15	7.28	1.3	1.33	5.5	5.5	8.3	7.6
155 (P)	16	12.6	87	Male	23.9	21.3			135/71	154/98								
156 (P)	19		54	Female	48.5				131/97									
157 (P)	20	13.1	74	Female	18.4	18.1	67	66	167/74	171/77	4.9	5.71	1.82	2.06	2.7	2.8	15.6	
158 (MT)	14		51	Female	22.7		79		112/73		4.74		1.91		2.5		5.6	
159 (MT)			48	Female	26.7		89		114/80		6.17		1.29		4.8		11.4	
160 (MT)			49	Female	25.8		85.5		141/96		4.46		1.09		4.1		15.6	
161 (P)			71	Female	33.8				140/90		4.85		1.54		3.1		10.1	
162 (MT)			74	Male	31.5		115		155/91		4.56		0.78		5.9		40.0	
163 (P)			72	Male	27.9		101		165/94		4.7		1.24		3.8		32.1	
164 (P)			65	Male	34.6		122		134/79		4.6		0.73		6.3		55.7	
165 (P)			72	Male	35.8		119.5		142/88		3.73		0.95		3.9		24.7	
166 (P)			55	Female	31.2		97.5		137/98		4.53		1.82		2.5		4.3	
167 (P)			19	Female	38				108/83									

Appendix 14: List of subjects who accessed the VRA service

P = Porthcawl. MT = Merthyr Tydfil. ¥ data collected at 12 month follow-up. Q subject completed a questionnaire at the 2 week follow-up instead of a telephone interview

Subject	Time to 2wk follow-up (days)	Time to 12mnth follow-up (mnths)	Age (yrs)	Sex	BMI	BMI¥	Waist	Waist¥	BP	BP¥	TC	TC¥	HDL	HDL¥	TC: HDL ratio	TC: HDL ratio¥	Risk	Risk¥
168 (P)			73	Female	29.3				125/75									
169 (P)			62	Female	20.8		72		156/82									
170 (P)	35	14.2	41	Female	31.2	27.1	86	86	117/79	124/76	4.24	4.4	1.07	1.83	4	2.4	1.6	1.0
171 (P)			68	Male	25.2		101		134/89		4.72		0.83		5.7		38.0	
172 (MT)	21Q	12.0	63	Male	25.2	25.2	97	96	155/98	129/78	4.21	3.6	0.76	1.61	5.5	2.2	27.5	

Appendix 15: Diabetes risk score

The Diabetes risk score was developed by:

University of Leicester

University Hospitals of Leicester NHS NHS Trust

Diabetes UK

Diabetes risk score

Questions

1 How old are you?

A 49 or younger	[0]
B 50–59	[5]
C 60–69	[9]
D 70 or older	[13]

2 Are you female or male?

A Female	[0]
B Male	[1]

3 What is your ethnic background?

A Only white European	[0]
B Other ethnic group	[6]

4 Do you have a father, mother, brother, sister and/or own child with Type 1 or Type 2 diabetes?

A Yes	[5]
B No	[0]

5 Measure the person's waist circumference and choose the range:

A Less than 90cm (35.3in)	[0]
B 90–99.9cm (35.4–39.3in)	[4]
C 100–109.9cm (39.4–42.9in)	[6]
D 110cm (43in) or above	[9]

6 Calculate the person's Body Mass Index (BMI) and choose the range (a BMI chart can be used).

A Less than 25	[0]
B 25–29.9	[3]
C 30–34.9	[5]
D 35 or above	[8]

7 Have you been given medicine for high blood pressure OR told that you have high blood pressure, by your doctor?

A Yes	[5]
B No	[0]

Your score is: _____ points

Risk level	Chances of having Type 2 diabetes now	Chance of high blood glucose now, meaning risk of Type 2 in 10 years	What you need to do
0–6 points (Low risk)	1 in 200	1 in 20	Keep up the good work, make lifestyle adjustments to further reduce risk.
7–15 points (Increased risk)	1 in 50	1 in 10	Make lifestyle changes.
16–24 points (Moderate risk)	1 in 33	1 in 7	See your GP to discuss your risk and how to reduce it.
25 or more points (High risk)	1 in 14	1 in 3	See your GP **as soon as possible** for a blood test.

Appendix 16: Data collection tool used in the retrospective study of a non-NHS VRA service

Patient: ☐ Date of assessment:_____

Age: ☐

Sex: ☐ Male ☐ Female

Ethnicity: ☐ White ☐ South Asian ☐ Other_____

Postcode: ☐

Clinical information:

- □ Diabetic?
- □ Had a heart attack, angina, stroke or TIA?
- □ Angina or heart attack in a 1st degree relative < 60?
- □ Current smoker?
- □ Chronic kidney disease?
- □ Atrial fibrillation?
- □ On blood pressure treatment?
- □ Rheumatoid arthritis?

Cholesterol/HDL ratio ☐

BMI ☐

Systolic BP ☐

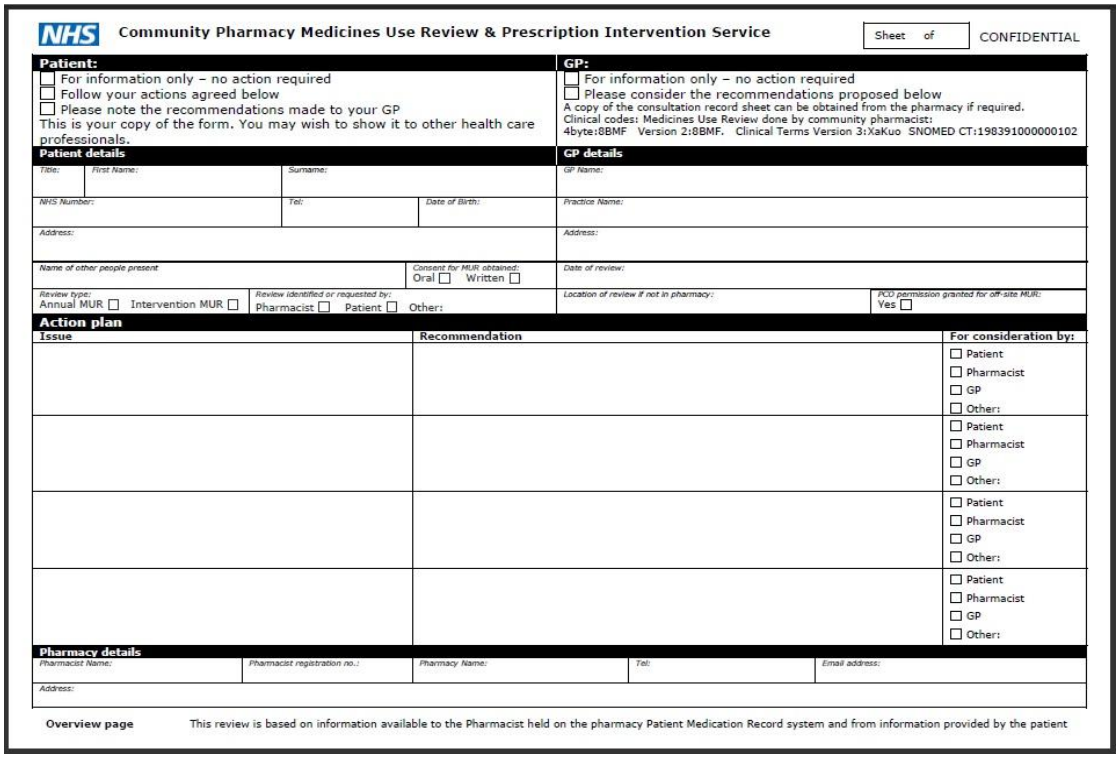
Other info:_ _

Alcohol	Exercise	Waist	TC	HDL	Glucose	Fasting G	Risk

Referred to GP? ☐ Yes ☐ No if yes the reason of referral is:_____

QRisk2 ☐

Appendix 17: The MUR form used in practice as per NHS Pharmacy Contract



NHS Community Pharmacy Medicines Use Review & Prescription Intervention Service

Sheet of CONFIDENTIAL

Patient:
- ☐ For information only – no action required
- ☐ Follow your actions agreed below
- ☐ Please note the recommendations made to your GP

This is your copy of the form. You may wish to show it to other health care professionals.

GP:
- ☐ For information only – no action required
- ☐ Please consider the recommendations proposed below

A copy of the consultation record sheet can be obtained from the pharmacy if required.
Clinical codes: Medicines Use Review done by community pharmacist:
4byte:8BMF Version 2:8BMF. Clinical Terms Version 3:XaKuo SNOMED CT:198391000000102

Patient details

Title: | First Name: | Surname:

NHS Number: | Tel: | Date of Birth:

Address:

Name of other people present | Consent for MUR obtained: Oral ☐ Written ☐ | Date of review:

Review type: Annual MUR ☐ Intervention MUR ☐ | Review identified or requested by: Pharmacist ☐ Patient ☐ Other: | Location of review if not in pharmacy: | PCO permission granted for off-site MUR: Yes ☐

GP details

GP Name:

Practice Name:

Address:

Date of review:

Action plan

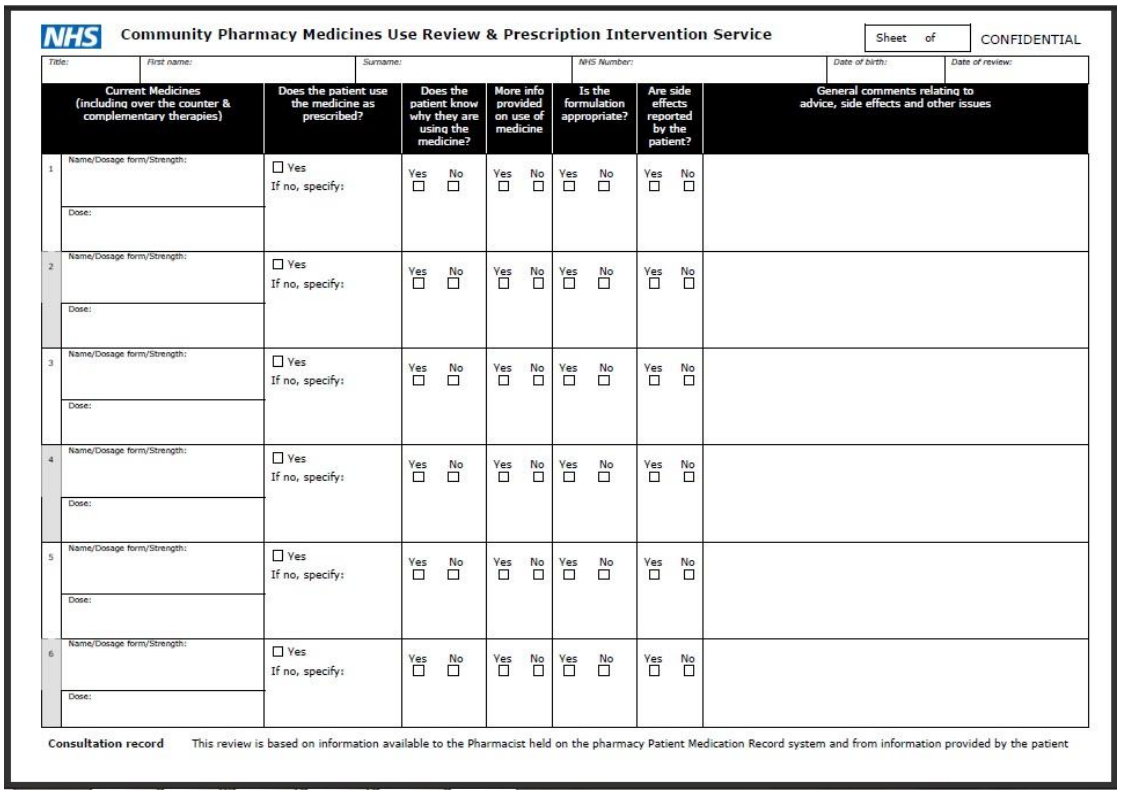
Issue	Recommendation	For consideration by:
		☐ Patient ☐ Pharmacist ☐ GP ☐ Other:
		☐ Patient ☐ Pharmacist ☐ GP ☐ Other:
		☐ Patient ☐ Pharmacist ☐ GP ☐ Other:
		☐ Patient ☐ Pharmacist ☐ GP ☐ Other:

Pharmacy details

Pharmacist Name: | Pharmacist registration no.: | Pharmacy Name: | Tel: | Email address:

Address:

Overview page This review is based on information available to the Pharmacist held on the pharmacy Patient Medication Record system and from information provided by the patient



NHS Community Pharmacy Medicines Use Review & Prescription Intervention Service

Sheet of CONFIDENTIAL

Title: | First name: | Surname: | NHS Number: | Date of birth: | Date of review:

	Current Medicines (including over the counter & complementary therapies)	Does the patient use the medicine as prescribed?	Does the patient know why they are using the medicine?	More info provided on use of medicine	Is the formulation appropriate?	Are side effects reported by the patient?	General comments relating to advice, side effects and other issues
1	Name/Dosage form/Strength: / Dose:	☐ Yes If no, specify:	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	
2	Name/Dosage form/Strength: / Dose:	☐ Yes If no, specify:	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	
3	Name/Dosage form/Strength: / Dose:	☐ Yes If no, specify:	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	
4	Name/Dosage form/Strength: / Dose:	☐ Yes If no, specify:	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	
5	Name/Dosage form/Strength: / Dose:	☐ Yes If no, specify:	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	
6	Name/Dosage form/Strength: / Dose:	☐ Yes If no, specify:	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	Yes ☐ No ☐	

Consultation record This review is based on information available to the Pharmacist held on the pharmacy Patient Medication Record system and from information provided by the patient

Appendix 18: Microsoft Access files used to collect data for the MUR study