Secondary Prevention of Cardiovascular Disease in an Australian population

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Alison Koschel

Acknowledgments

I dedicate this work to my husband my children and my mum. I especially dedicate this work to my father who left this world before I commenced this work but who I am sure has been watching over me.

This has been a long and often tedious task and I can't say a decade after it began that I am not glad to see the end of it. I have learned many things on this journey!

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To those that read this thesis, sit back enjoy a glass of red wine and happy reading!

"Get over the idea that only children should spend their time in study. Be a student so long as you still have something to learn, and this will mean all your life." ~ Henry L. Doherty

"Make every home, every shack or rickety structure a centre of learning" ~ Nelson Mandela

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Synopsis

Chapter one presents an overview of Coronary Heart Disease, Ischaemic Stroke and Secondary Prevention. A definition of disease and recurrent events addressed in this thesis is supplied along with the burden of disease in a local context which is compared to National and International burden of disease figures. Given the focus of this thesis is secondary prevention, modifiable risk factors for CHD and Stroke are identified and discussed in terms of their ability to modify CHD and Stroke if prevented. Proportions of risk factors nationally and internationally are presented to give a picture of the magnitude of the risk associated with CHD and Stroke. Management of risk factors in terms of primary and secondary prevention are presented with an emphasis on available guidelines. Proportions of secondary prevention management at national and international level are presented which highlight a gap in care which gives rise to the aim of this thesis.

Chapter two explores in the Hunter region the prevalence of risk factors and secondary prevention care in a sample of patients following discharge from hospital for either a CHD or Stroke event. The chapter concludes that there is room for improvement in this population for risk factor management in patients who have had a prior CVD event.

Chapter three describes in detail a randomised controlled trial designed to intervene with patients with existing CVD, the Prevent Another Vascular Event (PAVE) study. The chapter provides evidence of the suitability of using General Practitioners as deliverers of care and outlines the methods used in the factorial design which hypothesized an increase in risk factor management in a patient only group, a GP only group, a GP and patient intervention group compared to a usual care control group. The chapter presents recruitment and baseline risk factor prevalence results which are then compared to National and International study data.

Chapter four presents results in relation to the pharmaceutical interventions for risk factors such as high blood pressure, high cholesterol and Atrial Fibrillation. Additionally this chapter discusses the use of Aspirin and advice to take Aspirin as an outcome.

Chapter five focuses on the results relevant to behavioural risk factor modification such as advice to increase physical activity, increase smoking cessation and advice to follow a modified fat diet.

Finally chapter six presents a summary of the findings and the future directions for research and practice.

Acronyms

CHD	Coronary Heart Disease
Stroke	Cerebrovascular event
CVD	Cardiovascular disease
WHO	World Health Organization
ICD	International Classification of Disease
AMI	Acute Myocardial Infarction
UAP	Unstable Angina Pectoris
IHD	Ischaemic Heart Disease
ACE	Angiotensin-converting enzyme inhibitors
AIHW	Australian Institute of Health and Welfare
CI	Confidence Interval
AF	Atrial Fibrillation
TIA	Transient Ischaemic Attack
RR	relative risk
OR	odds ratio
BMI	body mass index
GP	General Practitioner
Statins	HMG-CoA reductase inhibitors
MI	Myocardial Infarction
CR	Cardiac Rehabilitation
AHA/ACC	American Heart Association/American College of Cardiology
AHA/ASA	American Heart Association/American Stroke Association
LDL-C	Low-density lipoprotein cholesterol
HSP	Hunter Secondary Prevention study
PAVE	Prevent Another Vascular Event study
et al.,	More than one author
mmHg	Millimeters of Mercury (blood pressure reading)

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Chapter One

Coronary Heart Disease, Ischaemic Stroke and secondary prevention

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Chapter One – Coronary Heart Disease, Ischaemic Stroke and Secondary Prevention

1.1 Overview

The purpose of this chapter is to provide an overview of the burden of disease associated with coronary heart disease (CHD) or cerebrovascular disease (stroke), and the opportunity for reducing this burden through the provision of secondary prevention care. This chapter first describes the prevalence and incidence of CHD and stroke in developed countries, the prevalence of risk factors that are precursors to these conditions and the opportunity for prevention through reducing the prevalence of risk factors. Secondly, as people who have experienced CHD or a stroke are at risk of suffering further events, opportunities for the prevention of CHD and stroke through reducing the prevalence of risk factors among people with existing CHD or stroke are described. The chapter concludes with a description of evidence regarding the provision of secondary prevention care provided to such people. The studies described in this thesis were commenced in 2000. In this context, the above overview is based primarily on reported data from mid 1990 to 2000. To demonstrate the ongoing need for action in this area, more recent data are provided where appropriate.

1.2 Coronary Heart Disease and Stroke

Cardiovascular disease (CVD) is a disease that affects the heart or blood vessels.[1] The main components of CVD are listed in Figure 1.1 defined according to the World Health Organization (WHO) International Classification of Diseases (ICD).[1] Coronary heart disease and cerebrovascular disease (stroke) are the two leading causes of cardiovascular disease in Australia and other developed countries, and are the focus of this thesis.[2]

Coronary heart disease is defined for the purposes of this thesis as any condition in which heart muscle is damaged or works inefficiently because of an absence or deficiency of its blood supply. Coronary heart disease therefore is considered to include acute myocardial

infarction (AMI), Unstable angina pectoris (UAP), and other ischaemic heart disease (IHD) (Figure 1.1).[3, 4]

Acute myocardial infarction (otherwise called 'heart attack') occurs when a coronary artery becomes completely blocked, obstructing blood flow to a section of cardiac muscle and results in 'death' of the myocardial tissue. Acute myocardial infarction most commonly results from the formation of a thrombus on atheromatous plaque.[1] A thrombus is a blood clot that is formed when platelets aggregate (i.e. stick together) and form a plug. The reason thrombi form is not clear.[5] Thrombi stick to the blood vessel wall and decrease the blood flow through the blood vessel. An atheromatous plaque is a nodular accumulation of soft flaky yellow material composed of specialised cells called macrophages and cholesterol crystals.[6] The first step in the formation of this plaque is the development of fatty streaks, which are deposits of lipids. The aetiology of this development is unknown. When a plaque in the coronary artery ruptures, the body's clotting system fills the lumen of the artery to close it. This limits the blood flow to the heart which causes ischemia (lack of oxygen in the cells). Cells that are starved of oxygen die and heart muscle is damaged.[6] Unstable angina pectoris is pain in the chest due to ischemia of the heart muscle caused by either spasm of or narrowing of the coronary arteries,[1, 4, 6] and is differentiated from a heart attack as no death to myocardial tissue results.

Figure 1.1: ICD-10 Chapter IX. Diseases of the circulatory system

I00-I99 - Diseases of the circulatory system
(I00-I02) Acute rheumatic fever
(I05-I09) Chronic rheumatic heart diseases
(I10-I15) Hypertensive diseases
(I20-I25) Ischemic heart diseases
(I26-I28) Pulmonary heart disease and diseases of pulmonary circulation
(I30-I52) Other forms of heart disease
(I60-I69) Cerebrovascular diseases
(I70-I79) Diseases of arteries, arterioles and capillaries
(I80-I89) Diseases of veins, lymphatic vessels and lymph nodes, not elsewhere classified
I95-I99 – Other and unspecified disorders of the circulatory system

Source: World Health Organisation 2009[1]

Stroke is defined as an event which results in a reduction of blood flow to a region of the brain resulting in the 'death' of brain tissue.[3, 4, 7, 8] Eighty five percent (85%) of strokes have an ischaemic origin due to obstruction in blood flow, with the remaining 15% being of haemorrhagic origin (trauma to a vessel resulting in bleeding).[5] Risk factors for ischaemic and haemorrhagic stroke are not exactly the same,[9] and management of the two main types of strokes differ.[10] Of the two forms of stroke, this thesis concentrates on ischaemic stroke as evidence suggests that it is associated with similar risk factors as exist for CHD. Like heart attack, ischemic stroke, otherwise known as an acute vascular occlusion, is often due to thromboses or emboli. These emboli break free from the vessel wall and float freely, often originating from the heart.[5]

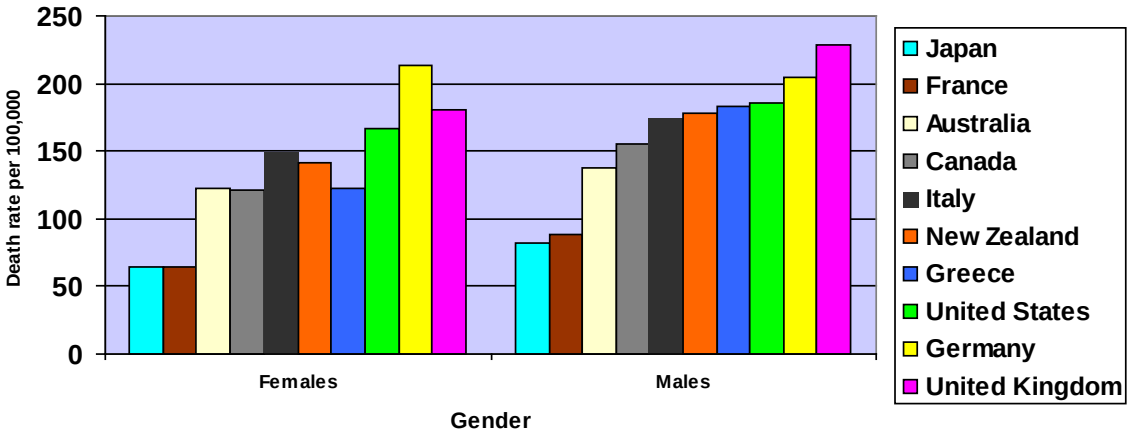
1.3 Burden of disease from CHD and Stroke

The burden of illness associated with CHD and stroke can be measured in many ways, including mortality (for example, measure of death rates),[6, 11] morbidity (for example, proportion of patients with disease during a year per unit of population)[11] or by the burden that either mortality or morbidity places on the economy of countries (economic burden), such as hospitalisations (direct costs), and economic productivity (indirect costs).[12]

Given the differences between countries with regard to access to health care and other factors, the following description of CHD and ischaemic stroke burden of illness will be confined to those countries defined as "developed" by the human development index, and gross domestic product.[13] According to the United Nations using these criteria, Japan, Canada, the United States, Australia, New Zealand and Europe are considered "developed" regions or areas.[13]

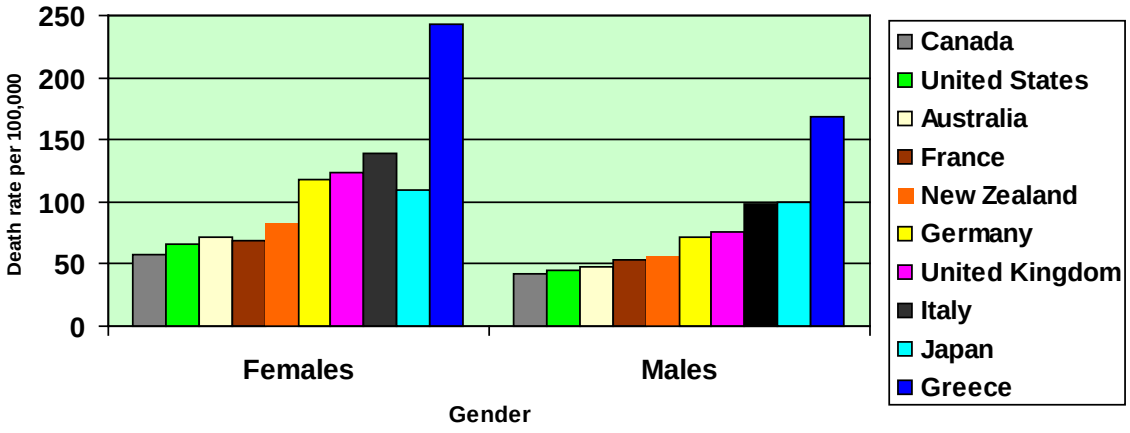
CHD and stroke mortality rates for these developed countries are shown in Figure 1.2 and Figure 1.3 for the year 2002.[14]

Figure 1.2: International age standardised 2002 CHD mortality rates by gender



Source: WHO Global InfoBase Online. 2002[14]

Figure 1.3: International age standardised 2002 Stroke mortality rates by gender



Source: WHO Global InfoBase Online. 2002[14]

The data as shown in Figures 1.2 and 1.3 indicate marked variations between countries in both CHD and stroke mortality rates. Coronary heart disease death rates per 100,000 vary from 82 to 229 for males and 65 to 214 for females across these countries. Countries such as France and Japan have much lower mortality rates of CHD than other developed

countries, including Australia, while countries such as New Zealand, Italy, Greece and the United States have higher rates.[14]

Stroke mortality rates in Australia range between 42 to 169 per 100,000 for males and between 57 to 243 per 100,000 for females. Such rates are similar to those in France and New Zealand. However, Canada and the United States have much lower rates of stroke compared to Australia while Italy, Japan, China and the United Kingdom have higher rates. The mortality rate of stroke in Greece is triple that in Australia.[14]

Stroke rates are higher than CHD rates in Japan, France, and Greece, with rates of stroke in Greece double those of CHD. Conversely rates of stroke in the United States and Canada are half that of the corresponding CHD rates.[14] Potential reasons for the difference in mortality for CHD and stroke between countries include differences in dietary patterns, physical activity profiles and access to health care services and equipment.[5]

In Australia, 45,670 deaths each year have been attributed to CVD.[15] Approximately 50% (22,983 deaths) of these are attributed to CHD. In 2006 stroke was reported to be Australia's second leading single cause of death with 8,484 deaths (19% of all CVD deaths).[16]

In 2002-2003 in Australia the second highest number of hospital separations (patient discharges with diagnoses of interest) were for patients with a diagnosis of CHD, while stroke was the seventh highest cause of such separations.[17] During this period people who had a stroke had the longest average length of stay.

The CVD burden of disease attributed to years of healthy life that is lost was 18% of the overall burden experienced by Australians in 2003. Eighty percent of this burden was made up of those with either CHD or stroke. Males were more likely to contribute to CHD morbidity and females more likely to contribute to morbidity from stroke.[18]

1.4 Trends in CHD and Stroke in developed countries

Since the 1960s, death rates for CHD have declined by about half in several countries including the United States, Canada, Japan and Italy but not in France. In the United States, mortality due to CHD fell at an annual rate of more than 3% over the decades 1970

to 1990.[19] Annual rates of decline in CHD of between 3% and 5% have been noted in a number of countries over the period of 1985 to 1993. The WHO MONICA Project (The World Health Organization's multinational Monitoring of trends and determinants in cardiovascular disease project)[20] involving 37 populations in 21 countries reported that CHD mortality rates fell by 4% annually for men [between country range -10.8% to 3.2%] and 4% for women [-2.7% to 3.0%] from 1980 to 1990.[20] A similar decline in death rates due to stroke of about one third has been reported in several countries, with a significantly lower rate of decline occurring in Greece.

Coronary heart disease death rates peaked in Australia in the 1960s and since that time have fallen by 60% – 70%.[3, 21] Between 1987 and 1998 in Australia, CHD deaths declined by about 4% per year, with a total decrease of 37% (37% for men 35% for women). During this period, cardiovascular disease deaths declined by 3.9% for men and 3.7% for women, a faster decline than death from all causes (2.3% for men and 1.9% for women).[22]

Death rates from stroke in Australia were steady over the 1950s and 60s but since have fallen by 68%.[5] Over the period 1991 to 2000 stroke death rates declined at about 3% per year for both males and females, with a total decline of approximately 28%.[3, 23]

Potential reasons for the decline in CHD and stroke death rates have been suggested to include reductions in risk factor levels and increases in the use of medical treatments such as thrombolytic therapy, heparin, and aspirin and coronary angioplasty.[24] This explanation is supported by the reduction in early mortality from AMI during the last 20 years in the United States of America being suggested to result from the use of aspirin (34% of the decrease in 30-day mortality), thrombolysis (17%), primary angioplasty (10%), beta-blockers (7%), and angiotensin-converting enzyme (ACE) inhibitors (3%).[25]

In a further study (Nurses Health study) conducted in the United States involving 85,941 women aged 34 to 59 years over two time periods, 1980–1982 and 1992–1994, a reduction in the prevalence of smoking was found to explain 13% of a decline in the incidence of coronary disease, while improvements in diet explained 16%, and an increase in postmenopausal hormone use explained 9%. In contrast, an increase in body-mass index contributed an additional 8% to the incidence of coronary disease.[26] More recent studies have cast doubt on the value of hormone replacement therapy in either primary or

secondary prevention of CVD. Authors of an American Heart Association statement recommend initiation or continuation of HRT based on established non-coronary benefits and risks and patient preference.[27]

Between 1998 and 2008 in Australia the number of hospital separations in Australia have remained relatively stable for both CHD and stroke.[17 28]

Table 1.1: Number of hospital separations for CHD and Stroke by principal diagnosis in Australia 1998-99 to 2004-05

Principal diagnosis	2000-01	2001-02	2002-03	2003-04	2004 – 05	2005-06	2006-07	2007-08
	N	N	N	N	N			
Ischaemic heart disease	158,410	159,561	161,794	164,226	162,283	161,367	162,328	161,417
Angina pectoris	88,740	87,023	83,212	81,909	80,229	77,242	75,109	71,801
Acute myocardial infarction	37,672	40,333	43,767	46,885	47,633	49,534	51,667	55,676
Subsequent MI	486	426	349	360	290	294	310	321
Cerebrovascular diseases	40,641	40,243	40,250	40,791	40,723	41,454	41,483	41,716
Cerebral infarction	14,301	14,276	14,071	14,504	14,822	15,653	16,1169	16,565
Stroke, not specified	10,595	10,215	10,107	9,813	9,589	9,339	8,592	8,667

Source: AIHW Australian Hospital Statistics[18, 27]

1.5 Risk factors for CHD and Stroke

As described above, despite significant reductions in the burden of CHD and stroke in many developed countries over time, the burden of disease for both conditions remains large. The reported declines in mortality for CHD and stroke have been attributed, in part, to enhanced prevention and management of risk factors.[29] Such a contribution suggests

that further reductions in the burden of disease may be achievable through further initiatives to reduce the prevalence of the risk factors for both conditions.

According to Last (1995),[30] a health risk factor is an aspect of personal behaviour or lifestyle, an environmental exposure or an inborn or inherited characteristic which is known to be associated with preventable health-related conditions.[30]

Risk factors associated with CHD and stroke include increasing age, being male, family history of CHD, lack of moderate or vigorous exercise, smoking, poor nutrition, hypertension, high cholesterol, obesity, diabetes, and atrial fibrillation (AF).[5, 31, 32] These major risk factors are implicated in 85% of cases of CHD.[33] Risk factors for CHD and stroke can be classified as non-modifiable or modifiable (see Table 1.2).[5]

Table 1.2: Risk factors for CHD and Stroke

Risk factor	CHD	Stroke	Modifiable
Age	♥	♥	
Sex	♥		
Family history	♥	♥	
Physical inactivity	♥	♥	✓
Smoking	♥	♥	✓
Nutrition	♥	♥	✓
High blood pressure	♥	♥	✓
High cholesterol	♥	♥	✓
Overweight	♥	♥	✓
Diabetes	♥	♥	✓
Non valvular atrial fibrillation		♥	✓

Source: AIHW Heart, Stroke and vascular disease, Australian facts 1999[3]

1.5.1 Non-modifiable risk factors

Non-modifiable risk factors are those which cannot be changed by the individual and include age, gender, or family history.[34] The impact of one such risk, gender, is illustrated by the incidence of CHD in men being triple that of women in Australia[5]. Similarly, the risk of CHD is suggested to increase with age as the result of progressive accumulation of coronary atherosclerosis.[4, 5]

In the Framingham heart study of 2,302 men and women, a United States population-based epidemiologic cohort, the association of parental cardiovascular disease with an eight-year risk of offspring cardiovascular disease, was examined. Compared with participants with no parental cardiovascular disease, those with at least one parent with premature cardiovascular disease (onset age <55 years in father, <65 years in mother) had greater risk for events, with age-adjusted odds ratios (OR) of 2.6 (95% confidence interval [CI], 1.7-4.1) for men and OR 2.3 (95%CI, 1.3-4.3) for women.[35]

Similarly, for stroke, the most notable non-modifiable risk factor is age. For every 10 years after the age of 55, stroke incidence doubles in both men and women. In terms of gender, men are 1.25 times more likely to report a stroke than women.[10, 36]

An increased risk of stroke has also been reported in those with a family history of stroke. Family history of stroke was assessed in a self reported survey of 3,168 people with stroke. The age adjusted odds ratios for paternal (OR 2.0, CI 1.1-3.5) and maternal (OR 1.4, CI 0.8–2.5) histories confirmed that there was an increased risk of stroke among persons with a positive paternal family history compared to those without a family history of stroke.[37]

1.5.2 Modifiable risk factors

Modifiable risk factors are those which, if altered, will or have the potential to reduce either the risk, progression or impact of CHD or stroke.[11] Modifiable risk factors include high blood pressure, atrial fibrillation, diabetes mellitus and insulin resistance, high cholesterol, tobacco smoking, obesity, sedentary lifestyle and absence of key dietary elements such as omega-3 fatty acids.[34, 36] The contribution of individual modifiable risk factors to CHD and stroke mortality and their prevalence in the general population are discussed below.

1.5.2.1 High Blood Pressure

High blood pressure is known in medical terms as hypertension. It is estimated that 11% of deaths from CHD in men and women are due to raised blood pressure (defined as a systolic blood pressure of 140 mmHg or over, or a diastolic blood pressure of 90 mmHg or over).[38] Five percent (5%) of deaths in men and women from stroke are attributed to high blood pressure.[38]

High blood pressure is also a major risk factor for ischaemic stroke. An estimated RR of four has been reported for stroke due to high blood pressure (defined as systolic blood pressure greater than or equal to 160 mmHg and/or diastolic blood pressure greater than or equal to 95 mmHg). A summary of seven studies reported that from the lowest to the highest level of blood pressure, risk of stroke is increased about 10-fold.[36]

The prevalence of high blood pressure in the general population in the United States between 1984 and 1998 ranged between 17% and 24%.[39] Among the older United States population, people aged 65 to 69 years, the prevalence of high blood pressure was reported to be 41%.[39] Even higher prevalence rates have been reported for people aged 65 to 74 years, with 70% of men and 67% of women reporting having high blood pressure in 1999-2000.[22]

In 1999-2000, 32% of all men and 27% of all women in Australia reported high blood pressure.[3]At this time more recent data on the prevalence of high blood pressure are not available.[16]

1.5.2.2 Diabetes

In a prospective study of non-institutionalised Australian people over 60 years of age followed up over a median of 62 months, a RR of 1.7 and 1.5 in men and women respectively was reported for CHD among those with diabetes.[40]

An independent relationship between diabetes and stroke has been reported in numerous epidemiological studies, with a RR of ischemic stroke ranging from 1.8 to 3.0. Those diagnosed with glucose intolerance in the Framingham study reported double the risk of brain infarction compared to non-diabetic persons.[36] While diabetes was associated with

an increased risk of ischaemic stroke, a decreased risk of hemorrhagic stroke has been noted in diabetics.[9]

Prevalence rates for diabetes in developed countries referred to in Figures 1.1 and 1.2 are estimated in 2010 to be between 4.9% and 12.3%. The prevalence of diabetes in Australia was estimated to be 7.2% in 2010.[41]

1.5.2.3 High Cholesterol

According to a 2002 world health report,[14] over 50% of CHD in developed countries is due to blood cholesterol levels higher than 3.8 mmol/L. It is estimated that 45% of deaths from CHD in men and 47% of deaths in women in the United Kingdom are due to high blood cholesterol.[14] The medical term for high cholesterol is hypercholesterolaemia.

Unlike CHD, the association between plasma lipoprotein concentrations and the risk of stroke is not clear.[10, 42] However studies that have specifically evaluated ischaemic strokes have shown a positive association with higher cholesterol levels.[10]

The prevalence of high blood cholesterol was reported to be between 18% and 21% in 1987–1998 in the United States.[39] In a population-based cross-sectional study of 63 general practices (sample size 378,021) in London, total cholesterol was elevated in 44% of men and 59% of women with CHD.[43] Higher rates were reported in the period before 2000 in Australia with approximately 40% of individuals reporting high cholesterol.[5, 16] More current data on the population prevalence of high cholesterol are not available.[16]

1.5.2.4 Smoking

Smokers are twice as likely to have a heart attack as non-smokers.[5] Recent studies report that 13% of CVD deaths in Australia are due to smoking.[3]Cigarette smoking predisposes the smoker to CVD in several ways, including acceleration of coronary plaque development, destabilising coronary plaques and promoting plaque rupture and coronary thrombosis.[44] In case control studies, an estimated RR for CHD of three (3) for both men and women has been associated with current smoking while for those who quit between two and three years earlier the RR was the same as that for people who never smoked.[45]

In an Australian population case-control study (5,572 cases, 6,268 controls) of men and women aged 35 to 69 years, the odds of suffering a major coronary event for men who were current cigarette smokers was 3.5 (95%CI, 3.0-4.0) times higher than for never smokers and this fell to 1.5 (95%CI, 1.1-1.9) for men who had quit for one to three years. Women who were current cigarette smokers were 4.8 (95%CI, 4.0-5.9) times more likely to suffer a major coronary event than never smokers and this fell to 1.6 (95%CI, 1.0-2.5) for women who had quit for one to three years. The odds of a major coronary event for those who had quit cigarette smoking for four to six years or more were similar to those for never smokers.[46]

Smoking increases the RR of ischemic stroke by approximately two times with a clear dose-response relationship.[36] Risk of total stroke among former smokers compared with never smokers has been reported to be 1.3 (95%CI, 1.04-1.73).[47]

In a population-based case-control study of men and women aged 35 to 69 years in Australia, and men and women aged 35 to 64 years in New Zealand, men who were current cigarette smokers had 3.5 (95%CI, 3.0-4.0) times the odds of suffering a major coronary event than never smokers. Women who were current cigarette smokers had 4.8 (95%CI, 4.0-5.9) times the odds of suffering a major coronary event than never smokers.[46]

Smoking status was reported to be 25% to 28% during the period 1984-1998 in the United States.[5, 39, 48]Smoking rates in Australia in 1995 were higher in younger cohorts with 24% of 15 year old boys and 29% of 15 year old girls smoking while those over 30 years of age reported lower smoking rates.[5, 22] In 2001, 19% of Australians were reported as smokers,[3]in 2007 approximately 16% of the population were smokers.[16]

1.5.2.5 Physical activity

A major prospective study in the United States has investigated the associations between total physical activity, walking, and vigorous exercise and the incidence of coronary events among 72,488 female nurses aged 40 to 65 years old. Following eight years of followup, a strong, graded, inverse association between level of physical activity (measured by Metabolic Equivalent (MET)) and the risk of coronary events was found with age-adjusted RRs of 0.77 (2.1–4.6 METs), 0.65 (4.7-10.4 METs), 0.54 (10.5-21.7 METs), and 0.46 (>21.7 METs) for coronary events (p=<0.001).[49]

The relationship between the level of physical activity and the incidence of CHD was similarly examined in a prospective study of men attending general practice in the United Kingdom. Among 4,311 men with no history of CHD or stroke, physical activity was associated with improved cardiovascular mortality, with an OR of 0·66 (95%CI, 0·35-1·23). The study investigators concluded that maintaining or taking up light or moderate physical activity reduces mortality and heart attacks in men with and without diagnosed CVD.[50]

When results from 23 studies (18 cohort and five case-control) were combined, highly active individuals had a 27% lower risk of stroke incidence or mortality (RR 0.73; 95%CI, 0.67-0.79) than low-active individuals.[51] In a further study, people who are physically inactive have been reported to have twice the risk of stroke than physically active individuals.[14]

In 1998 data from the 247,964 participants in the 2002 Behavioral Risk Factor Surveillance System survey conducted in the United States reported that about 29% of Americans aged 18 years or older reported no leisure-time physical activity with 44% reporting some activity but not enough to achieve recommended levels.[6] In the United Kingdom data from the sport and leisure module of the 2002 general household survey of 15,972 participants reported a prevalence of inactivity of 41% (95%CI, 40%-42%).[14]

In a 1995 study, over one third of adults in Australia reported no leisure time physical activity in the two weeks prior to interview.[5] Further, in 1999, 44% of people aged 18 to 75 years did not undertake sufficient physical activity, 15% reported no physical activity and 29% reported some physical activity, but not sufficient for health benefit. In 1999 men were more likely than women to participate in sufficient physical activity (60% versus 54% for men and women respectively).[22] In 2000, 54% of 3,841 adults who completed the national physical activity survey in Australia did not undertake sufficient activity for health benefit with 15% reporting no activity at all.[3] According to the Australian bureau of statistics in the national health surveys conducted in 2001 and 2004-05 seventy percent (70%) of Australians reported sedentary to low level physical activity.[4] Based on data from the 2007–08 national health survey's definition of 'sedentary' which states "people who reported that they did not do any, or did very low levels of exercise for recreation, sport or

fitness in the 2 weeks before interview and related to people aged 18 years and over", approximately 35% of the population are physically inactive.[28]

1.5.2.6 Diet and Obesity

A 2002 WHO report on the global burden of disease suggests that approximately 30% of CHD in developed countries is due to low fruit and vegetable consumption.[14] It is estimated that about 5% of deaths from CHD in men and 6% of deaths from CHD in women are due to obesity (a body mass index [BMI] of greater than 30 [kg/m2]).[14]

Two major studies, the Framingham heart study[36]and the Honolulu heart study[36] have identified obesity as an independent factor for stroke incidence. Increased consumption of fish, green tea, and milk have been reported to be protective of stroke, however the association between stroke and diet is inconclusive,[36] despite a WHO report that low intake of fruit and vegetables is estimated to cause about 11% of stroke worldwide.[14]

Currently more than one billion adults are overweight - and at least 300 million of them are clinically obese. Current obesity levels range from below 5% in China, Japan and certain African nations, to over 75% in urban Samoa.[14]

In the 1995 national nutrition survey in Australia, over half of males and one third of children had not eaten fruit the day before the interview while 37% of people aged 19 to 24 years reported eating fruit.[3, 5] In 1995 the recommendation for saturated fat for total energy intake was 10% but in Australia the average intake of saturated fat was reported to be 13%.[5]

In 1994, 40% of 7,160 people attending 230 general practitioners in metropolitan Brisbane and rural Toowoomba in Queensland Australia, reported a BMI of greater than 24.9 (kg/m2).[48] In a community prevalence study, the national health survey conducted in 1995, higher proportions of people were overweight (56%) (BMI greater than 25) and obese (19%) (BMI greater than 30). Men were more likely to be overweight than women (64% men, 49% women). Overweight/obesity increased with age and peaked at age 50 to 54 years for men (79%) and 55 to 64 years for women (68%).[5]According to the Australian Institute of Health and Welfare (AIHW) in 2006-07, more than 58% of Australians were overweight or obese.[16]

1.5.2.7 Atrial fibrillation – a risk factor associated with Stroke

Atrial fibrillation, defined as an abnormal irregular heart rhythm in the atria of the heart, is a major risk factor for stroke[52], and is considered to be the most treatable cardiac precursor to stroke.[36]An estimated three to fivefold increased risk of stroke associated with nonvalvular AF was reported in the Framingham study.[36]The impact of AF on the risk of stroke persists with age.[36] Atrial fibrillation accounts for one-third of strokes in people over 80 years of age with the incidence increasing markedly through the seventh, eighth and ninth decades of life.[53]

The Cardiovascular health study, a population-based study of risk factors for coronary artery disease and stroke in 5,201 men and women aged greater than or equal to 65 years reported that AF was diagnosed in 4.8% of women and in 6.2% of men and prevalence was strongly associated with advanced age in women.[54]

For each successive decade of life above age 55 years, the incidence of AF doubles with an estimated prevalence of 5.9% for those above the age of 65 years in Australians.[15]

1.5.2.8 Multiple risk factors for CHD and Stroke

The above risk factors independently increase the probability of stroke and CHD however, combinations of these risk factors are also suggested to act synergistically,[15] with risk for CHD increasing substantially with each additional reported risk factor.[55]

The tendency of risk factors to cluster in a single individual is becoming increasingly recognised.[44] In the first National Health and Nutrition Examination Survey (NHANES) in the United States,[55] the proportions of respondents with none, one, two, three or four or more risk factors were 25%, 33%, 28%, 12%, and 2.1%, respectively.[55] Relative risks for CHD associated with having one, two, three or four or more risk factors were 1.6 (95%CI, 1.4-1.9), 2.2 (95%CI, 1.9-2.6), 3.1 (95%CI, 2.6-3.6), and 5.0 (95%CI, 3.9-6.3), respectively. Relative risks for stroke associated with the same risks were 1.4 (95%CI, 1.1-1.8), 1.9 (95%CI, 1.5-2.4), 2.3 (95%CI, 1.7-3.0), and 4.3 (95%CI, 3.0-6.3), respectively.[55]

In one Australian study, for a given age and cholesterol level, CHD risk over five years doubled in the presence of antihypertensive medication or diabetes, increased by 50%

with cigarette smoking, and halved in women compared with men.[56] In a review of 16,148 general practice patients in five states of Australia 70% of patients aged 30 years or more had at least one major risk factor, with 34% having two or more.[57, 58]

1.6 Primary prevention of CHD and Stroke

Given the significant contribution of modifiable risks to the incidence and prevalence of CHD and stroke and the high prevalence of such risks, the opportunity exists to further reduce the burden of these conditions through further risk reduction initiatives. Primary prevention represents one approach to achieving this. Primary prevention has been defined as any intervention strategy, such as, screening or treatment of risk factors, that are intended to reduce the prevalence/incidence of a disease in a population.[44] The principal focus of primary prevention are those people who are yet to be diagnosed with a condition. A considerable proportion (29%) of the decline in CVD mortality in the period 1980 to 1990 in developed countries has been reported to be due to such primary prevention.[19]

As described in the previous section, the modifiable risk factors for CHD and stroke that contribute most to the incidence of CHD and stroke involve either biomedical risks, high blood pressure, high blood cholesterol and AF; or behavioural risks: physical inactivity (sedentary behaviour), nutrition and smoking.[59] As a consequence, the primary prevention of CHD and stroke has the potential to be enhanced by either pharmaceutical treatment and/or behavioural management of these risk factors.[60] In the primary prevention of CHD and stroke, the General Practitioner (GP) is suggested to have a central role, particularly in terms of the initial detection and management of modifiable risks.[19]

1.6.1 Pharmaceutical treatment

Pharmaceutical treatment of CHD risk is common and has played a significant role in the reduction of CHD mortality.[29] The role and the efficacy and effectiveness of pharmaceutical treatment in the management of risks such as high blood pressure, high cholesterol, AF and the use of antiplatelet therapy (i.e. aspirin) are described below.

1.6.1.1 Pharmaceutical treatment of high blood pressure

Evidence suggests that blood pressure reduced by five to six mmHg decreases the risk of CHD by 15% to 20% and the risk of stroke by 40%.[44] There are several different classes of

blood pressure lowering medications, known as antihypertensive medications, and these are classified according to the method of action in lowering blood pressure. The major classes of blood pressure lowering medications are discussed briefly below.

A meta analysis of clinical trial evidence concerning the safety and efficacy of various antihypertensive therapies used as first-line agents recommended that thiazide diuretics should be the first line of therapy for lowering high blood pressure if another medication was not indicated for a different purpose (for example, beta-blockers to reduce CVD mortality additionally to lowering blood pressure).[61] The action by which thiazide diuretics lower blood pressure is related to the ability of the drug to cause vasodilation (widening) of blood vessels.[44]

In a study conducted in 1,623 medical centres in the United Kingdom, 58% of people taking a thiazide were able to achieve the target goal of 140/90mmHg at one year post treatment, compared to 51% of those not taking thiazide medication at baseline. The study suggested that an 11% reduction in AMI was attributable to thiazide use.[62]

Angiotensin-converting enzyme inhibitors are a class of medications used in the treatment of high blood pressure and congestive heart failure. Angiotensin-converting enzyme inhibitors inhibit the activity of the angiotensin-converting enzyme, an enzyme responsible for the conversion of angiotensin I into angiotensin II, a vasoconstrictor (narrows arteries).[44] An overview of four trials reported reductions in incidence of stroke of 30% (95%CI, 15%-43%) and CHD of 20% (95%CI, 11%-28%) associated with the use of angiotensin-converting enzyme inhibitors for the treatment of high blood pressure.[63]

Angiotensin II receptor antagonists, also known as angiotensin receptor blockers, modulate the renin-angiotensin-aldosterone system and are used in the treatment of high blood pressure, diabetic nephropathy (kidney damage due to diabetes) and congestive heart failure. Such medications block the activation of angiotensin II receptors which cause vasodilation and reduce secretion of vasopressin, which then reduce production and secretion of aldosterone, the combined effect of which is reduction of blood pressure.[44] The Effectiveness of Enalapril was measured in the SOLVD study conducted in a double-bind trial of placebo (n = 2,077) or Enalapril (n = 2,068) in normotensive subjects with

heart failure. Total mortality was reduced by 21% in the Enalapril group compared to 24% in the placebo group (p= 0.006).[64]

Another class of antihypertensive medications is adrenergic receptor antagonists, more commonly known as beta-blockers (β-blockers). Beta-blockers are used for the management of angina and cardiac arrhythmias.[44] Evidence suggests that an estimated RR of 0.62 (95%CI, 0.39-0.99) for non fatal infarctions is associated with beta-blocker use in people with high blood pressure from a group health cooperative in Seattle USA.[65]

Calcium channel blockers are a class of drugs which affect the muscle of the heart and smooth muscles of blood vessels, they decrease the force of contraction of the myocardium (muscle of the heart) and hence aid the reduction in blood pressure.[44,63] Two trials of 5,520 patients mostly with high blood pressure showed reductions in stroke of 39% (95%CI, 15%-56%) and CHD of 28% (95%CI, 13%-41%) in those taking calcium channel blockers.[63]

1.6.1.2 Pharmaceutical treatment of high cholesterol

Statins (or HMG-CoA reductase inhibitors) are a class of hypolipidemic agents used to lower cholesterol levels. They lower cholesterol by inhibiting the enzyme HMG-CoA reductase, which controls the rate of the enzyme required for cholesterol synthesis in the liver. Inhibition of this enzyme stimulates low-density lipoprotein receptors to increase clearance of low-density lipoprotein from the bloodstream and decrease blood cholesterol levels.[44]

Although clinical trials of the early lipid-lowering therapies did not demonstrate a reduction in the rate of stroke, data from statin trials strongly suggest such a benefit.[66] A review of the literature covering 16 trials of statin use (29,000 subjects) demonstrated significant reductions in the risk of CHD of 28% (95%CI, 16%-37%) and of stroke of 29% (95%CI, 14%-41%).[67]

1.6.1.3 Pharmaceutical treatment with Aspirin

Aspirin or acetylsalicylic acid is a salicylate drug with analgesic, antipyretic, anti-inflammatory and antiplatelet actions. Aspirin decreases platelet aggregation and inhibits thrombus formation and hence is used long-term in low doses to prevent heart attacks and

blood clot formation in people who are at high risk of a coronary event.[44] Meta-analysis of four randomised controlled trials demonstrated that aspirin taken as a primary prevention strategy significantly reduced all cardiovascular events by 15% (95%CI, 6%-22%) and AMI by 30% (95%CI, 21%-38%).[68]

A review of six randomized controlled trials of aspirin therapy in participants without cardiovascular disease reported data on myocardial infarction (MI), stroke, and cardiovascular mortality in a total of 95,456 individuals and found that aspirin therapy was associated with a significant 12% reduction in cardiovascular events (OR 0.88; 95%CI, 0.79-0.99) and a 17% reduction in stroke (OR 0.83; 95% CI, 0.70-0.97) which was a reflection of reduced rates of ischemic stroke (OR 0.76; 95% CI, 0.63-0.93).[69]

1.6.1.4 Pharmaceutical treatment of atrial fibrillation

The risk of forming a cardiac embolus with AF depends on underlying structural problems (for example, mitral valve stenosis) and on the presence of other risk factors, such as diabetes and high blood pressure. Those with a high risk of stroke derive most benefit from anticoagulant treatment, such as warfarin. An anticoagulant is a substance that prevents blood from clotting.[44] In a pooled analysis of trials for anticoagulant use in patients with AF the risk of stroke was reduced by 68% (95%CI, 50%-79%).[36, 53, 70]

1.6.1.5 Pharmaceutical treatment of diabetes

The American association of clinical endocrinologists developed medical guidelines for clinical practice for the management of diabetes mellitus in 2007. These guidelines recommend aggressive management of diabetes to decrease the progression of chronic complications. New generation pharmacologic therapies and technologies such as “smart” insulin pumps provide clinicians and patients with the ability to adjust treatment regiments to effect near normal glycaemic control.[71] Greater glycaemic control lowers the risk of CVD by 50% in patients with type 1 diabetes.[72]

1.6.2 Management of behavioural risk factors

Interventions to reduce behavioural risk factors have also proven to be beneficial in the primary prevention of CHD and stroke and are summarized below.

1.6.2.1 Smoking cessation

An analysis of 37 controlled trials of smoking cessation in community interventions reported a non statistically significant effect on the lowering of prevalence of smoking with an estimated net change ranging from -1.0% to +3.0% for men and women who ceased smoking in eleven relevant studies.[73]

1.6.2.2 Management of physical inactivity

A Cochrane review of the effectiveness of interventions designed to promote physical activity in adults found 11 studies with 2,195 participants and reported that cardio-respiratory fitness (pooled standardized mean difference random effects model 0.52; 95%CI, 0.14-0.90) was improved following such interventions. The authors concluded that physical activity interventions have a moderate effect on self-reported physical activity and on achieving a predetermined level of physical activity and cardio-respiratory fitness.[74]

1.6.2.3 Management of diet

A meta-analysis of 27 randomised controlled trials, including 30,902 person years of observation in healthy adults demonstrated a reduction in cardiovascular mortality of 9% (Hazard Ratio 0.91; 95%CI, 0.77-1.07) and cardiovascular events of 16% (Hazard Ratio 0.84; 95%CI, 0.72-0.99) associated with reduced or modified dietary fat or cholesterol intake.[75]

1.6.2.4 Multiple risk factor interventions for primary prevention of CHD

In addition to evidence of the efficacy or effectiveness of interventions to reduce the prevalence of single risk factors, a number of studies have assessed the ability of interventions to reduce the prevalence of a number of risks in a comprehensive intervention. In a meta-analysis of 14 randomised controlled trials of such multiple risk factor interventions that involved education and counseling targeted towards diet, exercise, weight loss, smoking cessation, diabetes management and use of medication, statistically significant decreases in blood pressure, smoking and cholesterol levels were reported,

however there was a non statistically significant reduction in CHD mortality (OR 0.96; 95%CI, 0.88–1.04).[76]

1.7 Management of patients following a CHD or Stroke event

In addition to the opportunity for reducing the prevalence and incidence of CHD and stroke through primary prevention, a further opportunity for reducing the prevalence of CHD and stroke events exists through the prevention of modifiable risk factors in people following an initial event.

There are three phases to recovery after a CHD or a stroke event. These phases include immediate acute management on presentation to hospital, early recovery management, and long term management.[21]

In the acute management phase of a CHD event, if cardiac arrest occurs rapid transmission to hospital for external shock is essential, although this may not be sufficiently timely to be effective.[21] Treatment with medications to dissolve clots and remove blockages to blood flow is recommended.[21] For patients who present to hospital with signs and symptoms of blockage to the coronary arteries revascularisation may be recommended.[21] The two most common procedures are percutaneous coronary intervention and coronary artery bypass grafting.[21] Percutaneous coronary intervention (eg angioplasty or stenting) involves a catheter being introduced into a coronary artery and a balloon being inflated to reduce the obstruction. A stent is commonly put in place to hold the artery open. Coronary artery bypass grafting involves opening the patient's chest cavity and grafting other blood vessels (usually from the upper leg) in place of those that are blocked.[21]

In the acute management phase of a stroke, airway support and ventilation for those compromised is essential as is oxygen therapy.[77] Symptomatic treatment such as reduction of fever and gradual lowering of blood pressure should be undertaken with appropriate medications, together with cardiac monitoring to determine AF and treatment. Re-perfusion is a key therapeutic strategy.[77] Additional management in the acute management phase concentrates on complications such as pain, spasticity, affective

disorder, and the availability of support services including those to support caregiver stress.[7]

The second phase of recovery, early recovery management, involves optimising physical recovery and identification of risk factors and opportunities for lifestyle change following discharge from hospital. The third phase of recovery, long term management of patients, focuses on maintenance of lifestyle changes and on prevention of recurrent events and is discussed further in the following sections.[78]

1.8 Recurrent events in those with CHD and Stroke

Once an individual has survived a cardiovascular event, such as a CHD event or stroke they are at increased risk of a further event.[79] Several studies have reported that the rate of CHD and stroke events in the United States and the United Kingdom is between three to six times greater for those people with a previous history of such events compared to those without a history.[80,81,82, 83]

For example, the WHO-PREMISE study (prevention of recurrences of myocardial infarction and stroke), involved a descriptive cross-sectional study in three low-income and seven middle-income countries (Brazil, Egypt, India, Indonesia, Islamic Republic of Iran, Pakistan, Russian Federation, Sri Lanka, Tunisia and Turkey) of people with previous MI, stable angina, unstable angina, percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG), stroke, transient ischaemic attack (TIA) or carotid endarterectomy more than one month previously and not later than three years ago. The study found that such people had an annual death rate six times that of their age counterparts who did not have coronary heart disease [13]

A further United States study identified different rates of recurrent stroke and AMI in two large managed care populations of patients aged 40 years who had been previously admitted with stroke or AMI. In one “commercial” cohort of 1,631 patients, cumulative occurrence of subsequent stroke events was 4.2%, 6.5%, 9.8%, and 12% at six months and one, two and three years respectively. The cumulative occurrence of subsequent AMI events (6,458 patients) was 3.5%, 4.8%, 7.3%, and 8.5% for these time periods respectively. In contrast, in a second “medicare” agency cohort, cumulative secondary event occurrences were found to be higher for recurrent stroke (1,518, 18%) and AMI

(2,197, 17%) at three years. More than 75% of the secondary events in the stroke cohorts were strokes and more than 75% of the secondary events in the AMI cohort were AMI.[81]

The risk of a recurrent ischaemic stroke has similarly been reported to be 30% higher among people with a previous history of a stroke event in the United Kingdom and Canada[84] with long-term stroke recurrence rates ranging from 4% to 14% annually,[34] the highest rates occurring early after the first stroke.[85] Similarly, in a two year observational study of a sample of 288 hospitalised patients with stroke and AF in southeastern England, a recurrent stroke rate of 3.6% was found compared to the eastern atrial fibrillation trial in Europe of 5.1% over a two year period.[86]

In the United Kingdom, the Oxfordshire community stroke project, a community-based study of 675 unselected patients after a first acute stroke[85] sought to develop precise estimates of the absolute and RR of stroke recurrence. One hundred and thirty five first recurrences out of 180 recurrent episodes of stroke were identified over a six year period. The risk of suffering a recurrent event was highest in the first year after the first stroke: 13% (95%CI, 10%-16%), 15 times the risk in the general population. The risk over five years was 30% (95%CI, 20%-39%) about nine times the risk of stroke in the general population.[85]

Despite the greater risk of another CHD event, surveillance of hospital admissions for myocardial infarction due to CHD among 35-to-74-year-old residents of four communities in the United States (a total of 352,481 persons) showed that rates of recurrent myocardial infarction had declined by a significant 19% among men (2.6% per year) and a non significant 15% among women (1.9% per year) between 1987 and 1994.[87]

1.8.1 Recurrent events in those with CHD and Stroke in Australia

Limited data are available with regard to rates of recurrent CHD events in the Australian setting. In the MONICA study,[88] average annual rates of non fatal AMI in patients with previous AMI aged 35 to 64 years were calculated for the period between 1985 and 1993. Thirty percent (30%) of men during 1985 to 1990 and 25% during the period 1991 to 1993 reported previous AMI events when a probable non fatal AMI was diagnosed. Corresponding rates for women were 19% during 1985 to 1987, 22% during 1988 to 1990 and 19% during the 1991 to 1993 period.[88]

In the Dubbo community study, population rates of recurrent AMI and stroke in non-institutionalised people over 60 years of age were calculated. The study reported that among 1,236 men and 1,569 women, recurrent rates were three times greater than population rates for first events.[40] In the same study, significant predictors of recurrent CHD were found to be: advancing age, prior CHD (RR 2.50 for men and 2.15 for women), use of anti-hypertensive medication (RR 1.92 for men and 1.75 for women) and diabetes (RR 1.67 for men and 1.53 for women).[40]

In a further study conducted between 1989 and 1990 in Perth, Australia, of all people with a suspected acute stroke or TIA, the five-year cumulative risk of recurrent stroke was 15%. The risk of recurrent stroke was greatest in the first six months after stroke, at 8.8% (95%CI, 5.4%-12.1%).[89]

In the same location a further prospective study of all individuals with suspected acute stroke or TIA was undertaken. Patients with a definite first-ever stroke were followed up 10 years after the index event in 1989. The cumulative risk of a first recurrent stroke was reported to be 43% (95%CI, 34%-51%) with the average annual risk of recurrent stroke approximately 4%.[90]

1.9 Secondary prevention of CHD and Stroke

Given the greater risk of recurrent CHD and stroke events for people with a first AMI or stroke event, considerable opportunities exist for the prevention of further events, through the provision of risk reduction treatments. The provision of risk reduction treatments in individuals with existing disease is known as secondary prevention[91] [59] and refers to treatment and management intended to reduce the risk of recurrent events and to decrease cardiovascular mortality in patients with CHD and stroke.[92]

Secondary prevention commonly encompasses rehabilitation programs that involve comprehensive risk factor interventions to extend survival, improve quality of life, decrease the need for surgical procedures and reduce the incidence of recurrent events.[93] To be most effective secondary prevention is suggested to be initiated during hospitalisation and continued after discharge from hospital for several years,[94] hence is suggested to occur throughout all three phases of recovery after an event.[85]

The National Heart Foundation of Australia recommends that cardiac rehabilitation and secondary prevention programs should be available and routinely offered to all patients with CVD.[95] Such programs are recommended to address identification and modification of risk factors, and enhance compliance with medical therapies.[95] Further, and more specifically, Bradley et al., and others suggest that to reduce the risk of recurrent CHD events, stopping smoking; eating a "Mediterranean diet"; participating in exercise; and taking appropriate drug treatment with Aspirin, angiotensin-converting enzyme inhibitors, beta-adrenergic blocking agents, acetylsalicylic acid and statins are essential elements for the effective secondary prevention of CHD events.[96,97] Similarly, long-term management of high blood pressure using both nonpharmacological interventions, such as salt reduction, exercise, and weight control, and pharmaceutical interventions has been suggested to form the basis of secondary prevention of stroke.[7]

1.9.1 Pharmacological interventions for secondary prevention for CHD and Stroke

Many of the risk factor interventions previously described as appropriate for the primary prevention of CVD are also suggested to be suitable for the secondary prevention of CHD and stroke. These interventions include the use of pharmaceutical agents such as angiotensin-converting enzyme inhibitors, beta-blockers, other blood pressure lowering agents, statins, aspirin and anticoagulants. The reported effectiveness of these medications in preventing recurrent events among people with previous CHD or stroke is discussed below.

In a review of four studies with 12,124 patients following a CHD event, reductions of approximately 20% (95%CI, 11%–28%) in CHD events were reported following the use of angiotensin-converting enzyme inhibitors.[63] In a systematic review of 35,000 patients who had survived AMI, beta-blockers were found to be beneficial in reducing overall CHD mortality by 20%, with a reduction in sudden cardiac death of 34%.[79]

A review of 34 randomised controlled trials involving 24,968 individuals with existing CHD reported 12% CHD mortality in the group allocated to receive active statin intervention as compared to 17% CHD mortality in the control group (risk reduction 13%; 95%CI, -19% to -6%).[98] A meta-analysis of 25 randomised trials published between January 1966 and

December 2002 regarding the effectiveness of statin therapy in the secondary prevention of CHD demonstrated that such therapy reduced CHD mortality or nonfatal AMI by 25% (RR 0.75; 95%CI, 0.71-0.79), and CHD mortality by 23% (RR 0.77; 95%CI, 0.71-0.83).[99]

In a review of four studies with 12,124 patients following a stroke event, reductions of 30% in stroke events (95%CI, 15%–43%) were reported following the use of angiotensin-converting enzyme inhibitors.[63]

A systematic review of seven randomised controlled trials of patients with prior ischemic or hemorrhagic stroke, or TIA, reported the effects of treating high blood pressure with a variety of blood pressure lowering agents. Reduction in further stroke events of 24% (OR 0.76; 95%CI, 0.63-0.92), of nonfatal stroke by 21% (OR 0.79; 95%CI, 0.65-0.95), and AMI by 21% (OR 0.79; 95%CI, 0.63-0.98) were found.[100] A further review of 28 trials with 7,521 patients with previous stroke reported no effect of calcium antagonists on recurrent events at the end of follow-up (OR 1.07; 95%CI, 0.97-1.18), or on death at the end of follow-up (OR 1.10; 95%CI, 0.98-1.24).[101]

Reductions in fatal or nonfatal AMI of 62% (p=0.001) have been reported in reviews of four atherosclerosis trials of 1,891 participants who had evidence of atherosclerosis and treatment with pravastatin. A 62% reduction in the risk of fatal or nonfatal stroke associated with this statin treatment was also achieved, although this did not quite reach statistical significance (p=0.054).[102]

Two secondary prevention trials, Cholesterol And Recurrent Events[66] and Long-term Intervention with Pravastatin in Ischemic Disease[66] involving a total of 13,173 patients reported a 22% reduction in total strokes (95%CI, 7%-35%, p=0.01) and a 25% reduction in nonfatal stroke (95%CI, 10%-38%) for those patients with a previous stroke who were prescribed statins relative to those that were not.[66]

Similarly a meta-analysis of five randomised controlled trials with 11,459 patients with stroke demonstrated reduced odds of recurrent stroke for dipyridamole as compared with control (OR 0.82; 95%CI, 0.68-1.00), and by combined aspirin and dipyridamole versus aspirin alone (OR 0.78; 95%CI, 0.65-0.93), dipyridamole alone (OR 0.74; 95%CI, 0.60-0.90), or control (OR 0.61; 95%CI, 0.51- 0.71).[103]

Six randomised controlled trials of 2,900 people with AF and stroke demonstrated that adjusted-dose warfarin reduced recurrent stroke by 62% (95%CI, 48%-72%). Adjusted-dose warfarin from five trials of 2,837 participants was found to be more efficacious than aspirin (RR reduction, 36% (95%CI, 14%- 52%) in reducing recurrent stroke.[104]

Similarly, Wolf et al., reported from observational epidemiological studies and clinical trials that recurrent ischemic stroke can be prevented. The mainstay treatment strategies to prevent recurrent stroke included warfarin for patients with TIA or mild ischemic stroke and AF, carotid endartectomy for patients with TIA or mild stroke without AF or moderate-to-severe carotid stenosis, and treatment daily with aspirin. Other antiplatelet agents, including clopidogrel, extended-release dipyridamole plus aspirin, and ticlopidine, may be used.[34]

1.9.2 Behavioural interventions for secondary prevention of CHD and Stroke

Reviews of cohort studies that addressed the secondary prevention of smoking cessation and physical activity were found in the literature and these are presented below. In addition, evidence is also cited from cohort studies to further demonstrate the benefits of secondary prevention of behavioural risk factors.

The effect of quitting smoking on the risk of CHD mortality was assessed in a review of 20 prospective cohort studies where a large RR reduction in CHD mortality of 36% was reported for smokers who had quit smoking relative to those who continued to smoke (RR 0.64; 95%CI, 0.58-0.71).[105]

Similarly, a review of 12 cohort studies containing data on 5,878 patients after a CHD event in six countries between 1949 and 1988 found a halving of the likelihood of death after AMI for those who quit smoking, relative to those who continued to smoke (OR; 0.54: 95%; CI, 0.46-0.62). Relative risk reductions across studies ranged from 15% to 61%.[106]

In terms of the benefits of increased physical activity a 31% reduction in cardiac mortality (random effects model OR 0.69; 95%CI, 0.51-0.94) was reported by patients in an exercise only group and a 26% reduction (random effects model OR 0.74; 95%CI, 0.57-

0.96) among those in a comprehensive cardiac rehabilitation group compared to a usual care group. These findings were obtained from a large meta-analysis of randomized controlled trials of 7,683 patients with CHD.[107]

In terms of the secondary prevention of patient dietary behaviours, a review of a prospective cohort of 54,506 patients with stroke in Denmark demonstrated that a diet high in fruit and vegetables reduced the odds of ischaemic stroke by nearly 28% (RR 0.72; 95%CI, 0.47-1.1) compared with a lower intake of fruit and vegetables.[108]

1.9.3 Effectiveness of comprehensive secondary prevention and rehabilitation programs

A number of reviews of the effectiveness of comprehensive CHD and stroke secondary prevention and rehabilitation programs have been undertaken.[109] Such studies concluded that these programs have a beneficial impact on reducing the number of recurrent events and mortality. For example, in a meta-analysis of the effectiveness of 63 secondary prevention programs between 1966 and 2004 involving 21,205 patients with CHD, a positive risk reduction in CHD mortality and reduction of recurrent CHD events was reported. Across all studies, an overall RR of CHD mortality of 0.85 (95%CI, 0.77-0.94) was found for those patients who participated in a secondary prevention program at 24 and 60 months, relative to those did not.[109]

Over 150 randomized controlled trials confirm the effectiveness of antiplatelet therapy for both primary prevention of stroke and the substantial long-term protection against subsequent stroke. A European trial of carotid endartectomy calculated the absolute benefit from surgery as 11.6%. Additional management to reduce recurrent stroke events include long-term management of high blood pressure using both non-pharmacological interventions, such as salt reduction, exercise, and weight control, as well as pharmaceutical interventions. Anticoagulation is essential for patients with AF following stroke and there is now a place for the use of statins in the secondary prevention of stroke. Behavioural interventions that are effective in primary prevention, such as cessation of smoking and increased physical activity, remain important in secondary prevention. Case-control and cohort studies demonstrate that exercise is beneficial in primary prevention of stroke, and despite evidence that exercise programs improve balance, strength, and

endurance after stroke, there is little evidence of the effect of exercise on recurrent stroke rates.[7]

For CHD and stroke patients secondary prevention optimally includes outpatient rehabilitation. stroke and CHD rehabilitation is a patient centered process commonly involving the use of multidisciplinary teams to provide education/information and training, early mobilisation and support to patients.[78] According to Leon et al., (2005) the term cardiac rehabilitation refers to "coordinated, multifaceted interventions designed to optimise a cardiac patient's physical, psychological, and social functioning, in addition to stabilizing, slowing, or even reversing the progression of the underlying atherosclerotic processes, thereby reducing morbidity and mortality."[110] Since 1994, cardiac rehabilitation programs have included baseline patient assessments, nutritional counseling, risk factor management, psychosocial and vocational counseling, and the appropriate use of cardio protective drugs.[110]

The cost-effectiveness of cardiac rehabilitation was assessed by combining published results of randomized trials of cardiac rehabilitation. Cardiac rehabilitation participants experienced an incremental life expectancy of 0.2 years during a 15-year period. Compared with other post-MI treatment interventions, cardiac rehabilitation is more cost-effective than thrombolytic therapy, coronary bypass surgery, and cholesterol lowering drugs, though less cost-effective than smoking cessation programs.[111]

A review of cardiac rehabilitation studies was conducted by Lear et al., which found that numerous studies investigating exercise therapy and cardiac rehabilitation have each demonstrated some beneficial effect. Limitations of current cardiac rehabilitation research include the lack of large randomized trials and inconsistent interventions (duration and methodology). In spite of these limitations, evidence strongly supports the use of exercise therapy and cardiac rehabilitation for the treatment of men and women with ischemic heart disease.[112]

1.10 Guidelines for secondary prevention

Based on the previously described evidence regarding the efficacy of both pharmaceutical and behavioural interventions in reducing CHD and stroke risks, recurrent CHD and stroke events, and CHD and stroke mortality through secondary prevention interventions,

guidelines for the provision of such interventions to individuals with CHD or stroke have been developed in several countries.

According to Woolf et al., (1999) clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances."[113] They are designed to close the gap between what clinicians do and the care that is supported by scientific evidence.[113] The use of clinical guidelines is one strategy intended to improve health care quality, rein in costs, and standardize medical practice.[114]

In 1995, the American Heart Association published a secondary prevention guideline titled "AHA/ACC Guidelines for Secondary Prevention for Patients with Coronary and Other Atherosclerotic Vascular Disease".[115] This guideline was updated in 2006.[116] Recommendations for the secondary preventative care of patients with AMI include the use of aspirin, beta-blockers, angiotensin-converting enzyme inhibitors, diet counseling (low saturated fat diet), lipid lowering agents, smoking cessation and all discharged patients being referred to outpatient cardiac rehabilitation.[115, 116]

In the United Kingdom the guideline "Management of patients with stroke" has been available since 1999.[78] In terms of United Kingdom guidelines for prevention of cardiovascular disease, the first national health service guideline "Risk estimation and the prevention of cardiovascular disease. A national clinical guideline" was published in 2007.[117]

Similar guidelines focusing on stroke were released in 2006 in the United States by the AHA/ASA "Guidelines for Prevention of stroke in Patients with Ischemic stroke or Transient Ischemic Attack".[34] The aim of these guidelines was to provide comprehensive evidence-based recommendations for the secondary prevention of ischemic stroke. The recommendations included control of risk factors, interventional approaches for atherosclerotic disease, antithrombotic treatments for cardioembolism, and the use of antiplatelet agents for noncardioembolic stroke.[118]

In the Australian setting, the National Heart Foundation produced guidelines for patients with CVD in 2000: "Guide to risk reduction for patients with/or 'at risk' of Cardiovascular disease (CVD)". These guidelines have been updated a number of times.[119]

At the commencement of this thesis there were no guidelines for the secondary prevention of stroke in Australia. Subsequently, in 2008 The Stroke Foundation of Australia developed and published a guide for general practice for stroke "Clinical Guidelines for Stroke and TIA management. A guide for general practice".[120]

In all available guidelines, the recommendations for the secondary prevention of either stroke or cardiovascular prevention are similar. To illustrate the content of such guidelines, the components of the "AHA/ACC Guidelines for Secondary Prevention for Patients With Coronary and Other Atherosclerotic Vascular Disease: 2006 Update" are summarised below in Table 1.3.[116]

Table 1.3: AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease

Risk Factor	Goal	Recommended Interventions
High blood pressure	<140/90 mmHg exception <130/85 mmHg for patients with heart failure or renal insufficiency or <130/80 mmHg for patients with diabetes	Lifestyle modification, such as weight control, physical activity, moderation of alcohol, moderate sodium restriction and high fruit and vegetable, low fat dairy products, in all patients with a blood pressure reading of ≥ 130 mmHg systolic or 80 mmHg diastolic. Blood pressure medication should be added if blood pressure is greater than the above readings and there are other patient risk factors such as age and race.

Risk Factor	Goal	Recommended Interventions
High cholesterol	Primary Goal: Serum low density lipoprotein (LDL) reading of <100 mg/dL. Secondary goal: Serum triglyceride (TG) of <200 mg/dL (non high density lipoprotein (HDL) should be <130 mg/dL).	Dietary therapy, promotion of physical activity and weight management should be advised. Increased consumption of omega-3 fatty acids should also be encouraged. Drug therapy should be added if LDL is < 100 mg/dL and additional therapies should be added as required. If TG ≥150 mg/dL or HDL <40 mg/dL, lifestyle advice on weight management and physical activity and smoking cessation should be provided. Medication should be considered in addition to omega-3 fatty acids as an adjunct.
Diabetes	The goal for diabetes is to report a HbA1c <7%.	Lifestyle advice and appropriate hypoglycemic therapy to maintain fasting plasma glucose level.
Smoking	The goal for smoking is complete cessation.	Assess tobacco use and encourage the patient and family to stop smoking. Provision of counseling, pharmacological therapy including nicotine replacement therapy and formal smoking cessation programs should be offered.
Physical inactivity	Minimum goal is 30 minutes of moderate physical activity per day on three to four days of the week.	Encouragement of physical activity of 30 to 60 minutes daily should then be advised. Assess risk with an exercise test prior to prescription.
Obesity	Ideal BMI of 18.5 – 24.9 kg/m2.	Weight management includes calculation of BMI and waist circumference prior to therapy and starting weight management and physical activity programs.

Risk Factor	Goal	Recommended Interventions
Antiplatelet/Anticoagulant agents	Daily Aspirin of 75 to 325 mg/d if not contraindicated. If Aspirin/Warfarin contraindicated Clopidogrel 75 mg per day considered.	For those on Warfarin, management to the international normalised ratio in post myocardial infarction patients is essential.
ACE inhibitors		Treat all patients post myocardial infarction.
Beta-blockers		Specific use beta-blockers to manage angina, rhythm or blood pressure, post myocardial infarction and acute ischaemic syndrome patients recommended.

Source: AHA/ACC Guidelines for Preventing Heart Attack and Death in Patients With Atherosclerotic Cardiovascular disease: 2001 Update. A Statement for Healthcare Professionals From the American Heart Association and the American College of Cardiology.[116]

1.11 Prevalence of risk factors in those with existing CHD and Stroke

Despite the recognised importance of secondary prevention and risk factor management in patients with CHD or stroke, and the development and promotion of secondary prevention guidelines to support such care, several studies have demonstrated an ongoing high prevalence of risk factors among such people.[121]

For example, studies in United Kingdom, United States of America, Asia and Europe have shown that the prevalence of high blood pressure in patients with CHD or stroke over the period 1995 to 2000 varied from 43% to 90%.[122-128] High cholesterol has been reported in several studies in patients with CHD or stroke in United Kingdom, Europe and Asia between 1995 and 2000 with rates varying between 25% and 99%.[122-125, 127, 129, 130]

Rates of smoking in CHD or stroke patients in United Kingdom and Europe were reported to range between 6.7% and 34% in 1995 to 2000.[122-125, 131, 132]

For lifestyle variables such as physical inactivity, 11% to 51% of CHD patients in studies conducted in United Kingdom in 1997 to 1999 were reported to undertake little or no exercise. [131, 132] In terms of the prevalence of overweight and obesity, between 18% and 81% of CHD or stroke patients in United Kingdom, United States of America and Europe in 1995 to 2000 were reported to be overweight or obese.[121-125, 127, 131, 132]

In Australia data from the 1995 national health survey reported that people with heart disease were more likely to report high blood pressure (48%) compared to those without CHD (10%).[21] High cholesterol rates were reported by 47% of people with CHD in Australia in 1998.[5] Rates of smoking in CHD patients in Australia were reported to range between 12% and 15% in 1995 to 2003.[4, 21]

Sixty four percent (64%) of 4,112 CHD patients report being smokers in an Asia Pacific study in 1999.[133] In an Australian study in 1995, people with heart disease were more likely to report being physically inactive (58%) compared to those without heart disease (52%).[21] In the 1995 national health survey of Australia, the proportion of people with CHD who were overweight or obese was 47% compared to 30% of those without CHD who were overweight or obese.[21] Similar prevalence patterns apply to the reported prevalence of dietary intake of fat above recommended levels. In one study conducted in the United Kingdom in 1997 52% of CHD patients reported that they ate more fat than recommended and only 47% ate fruit and vegetables at recommended levels.[132]

In Australia for the period 1997 to 2004 50% of stroke patients report high blood pressure.[134] In a study conducted in the United Kingdom between 1994 and 1996 AF was reported by 18% of individuals pre stroke and 26% post stroke.[126] The estimated prevalence of AF was 5.9% for those above the age of 65 years in Australia.[15] In stroke patients in Australia between 1997 and 2004 high cholesterol has been reported by up to 31% of patients.[134]

In stroke patients in Australia in 1997 to 2004, 18% were reported to be smokers.[134] In a study of stroke patients in Australia between 1997 and 2004 insufficient physical activity was reported by up to 77% of patients.[134] In stroke patients the prevalence of overweight and obesity has been reported to be 53% in Australia between 1997 and 2004.[134] In stroke

patients in Australia in 2001, low fruit consumption was reported by 64% and low vegetable consumption was reported by 87%.[134]

A pattern of high levels of risk factor prevalence in patients with CHD or stroke have also been reported in Australia. For example, 88% of Australians with CHD reported having at least one CHD risk factor for CHD in 1995,[21] with 84% of men and 74% of women reporting at least one major risk factor and 12% of men and 9% of women reporting three or more risk factors.[5] In stroke patients participating in the national health survey in 2001 in Australia, 62% reported four or more risk factors, 34% reported two to three risk factors, and 4% reported less than two risk factors.[134]

1.12 Provision of secondary prevention care and adherence to guidelines for management of individuals with CHD and Stroke

Despite the existence of care guidelines, the high prevalence of risk factors among people with a history of CHD or stroke suggests that secondary prevention care may not be provided in an optimal manner to those people in need. To assess the extent to which this may be the case the following section reviews available data regarding the provision of secondary prevention to people following a CHD or stroke event.

A study in the northern region of the United Kingdom reported that on discharge from hospital, 16% of patients with CHD were treated sub optimally in that they did not receive a secondary prophylactic drug to which they had no contraindication.[135] In a study in the Grampian region of United Kingdom, of 1,921 patients aged under 80 years with CHD, half had at least two aspects of their medical management that were suboptimal and nearly two thirds had at least two aspects of their health behaviour that would benefit from change.

A prospective cohort study in Victoria, Australia, assessed gaps in care from 1996 to 1998 and 1999 to 2000. This study confirmed substantial treatment gaps exist in the Australian setting.[136] The majority of studies that have looked at compliance or adherence to guidelines for secondary prevention of CVD have focused on high blood pressure and high

blood cholesterol. Given such findings there seems to be considerable potential to increase secondary prevention of CHD in general practice.[132]

1.12.1 Prevalence of use of blood pressure lowering medication

Between 1996 and 2000 in the United Kingdom and Asia the use of blood pressure lowering medication was reported by 39% - 96% of patients with CHD or stroke.[126, 128, 131, 132, 137]

Similarly, the prevalence of treatment with beta-blockers in patients with CHD was reported to be approximately 14% to 39% in the United Kingdom and Asia between 1996 and 2000.[43, 122, 128, 132] While among AMI patients treatment with beta-blockers was reported to be between 24% and 70% between 1986 and 1997 in people in the United Kingdom, Germany and Europe.[124, 125, 127, 137] Treatment with ACE inhibitors for patients with CHD was reported to range between 24% and 55% between 1995 and 2000 in the United Kingdom and Asia.[43, 124, 125, 127, 128, 132, 137]

In Australia blood pressure lowering medications for stroke patients was reported by 69% in the period 1997 to 2004. In the early part of the 2000 decade 34% of Australians with CHD reported taking an ace inhibitor.[4, 134]

In a random sample of 1,921 general practice patients aged less than 80 years identified from pre-existing registers of CHD, blood pressure was managed according to current guidelines for 1,566 (82%) patients.[132] In another study, 44% of 644 women participating in a randomized trial of estrogen for secondary prevention of stroke had blood pressure values within national guidelines (less than 140/90 mmHg).[138] In a study by Yamamoto et al., despite high rates of therapy, in more than half (58%) of all hypertensive patients blood pressure failed to fall below 140/90 mmHg.[128]

1.12.2 Prevalence of lipid lowering medication use

The use of lipid lowering medication was reported by between 12% and 62% of patients with CHD in several studies between 1995 and 2000 in the United Kingdom.[43, 124, 125, 127, 137] [132]

In a prospective cohort study in six university teaching hospitals in Melbourne, Australia, 460 patients who completed follow-up in the control groups of two randomised controlled trials of a coaching intervention in patients with established CHD were provided with lipid lowering medication. Rates of lipid lowering medication ranged from 60% to 87% between 1996 and 2000.[136] Between 21% and 32% of patients with stroke in Australia between 1997 and 2000 reported receiving lipid lowering medication.[134, 139]

The appropriateness of statin therapy compared with recommendations of the national cholesterol education program II guidelines in patients at a tertiary medical centre with established CHD or cardiac risk factors was assessed. Patients with identified CHD from general practice reported lipid concentrations in accordance with current guidelines for only 133 (17%) patients.[140]

To determine adherence to the national cholesterol education program II guidelines for the secondary prevention of CHD using lipid lowering drugs, a study of 622 eligible patients recently hospitalised with AMI was conducted in the US. Only 230 (37%) patients received lipid lowering drugs and only 15% achieved the recommended goal of a total cholesterol below 160 mg/dL.[141] Of 48,586 patients with CHD in a retrospective outpatient chart audit, 44% had annual diagnostic testing of low-density lipoprotein (LDL) cholesterol. However only 25% of these patients reached the target LDL cholesterol level of less than or equal to 100 mg/dl, and only 39% were taking lipid lowering therapy.[142] In the McBride et al., study of CVD patients 14% had achieved the recommended LDL level of less than 2.58 mmol/L (100 mg/dL) and 302 (50%) had triglyceride levels lower than 2.26 mmol/L (200 mg/dL).[143] In a multicentre study in Germany, only 176 (6.2%) of 2,856 CHD patients were found to meet the target LDL level of less than 15 mg/dl and at week six, only 76 (2.7%) patients had LDL levels less than 100 mg/dl, and 363 (12.7%) patients had LDL-C levels less than 130 mg/dl.[144]

1.12.3 Prevalence of Aspirin / anticoagulant use

Patients with CHD reported aspirin use ranging between 47% and 90% between 1995 and 2000, in the United Kingdom and Europe.[43, 122, 124-127, 131, 132] Anticoagulants were reported by 6.9% to 7.5% of patients with stroke in Europe between 1995 and 2000[124, 125] In Australia 10.3% of patients with stroke reported taking warfarin in the period 1997 to 2004.[134]

1.12.4 Prevalence of behavioural risk factor management

In the mid 1990s in the United Kingdom, a study of patients hospitalized with AMI, reported that 82% of continuing smokers were documented to have received smoking cessation advice.[137]In the Wessex research network study in the mid 1990s, of 266 AMI survivors, smoking cessation advice was given to 75% of smokers and 42% of ex smokers.[137] Eighty eight percent (88%) of patients in Europe between 1999 and 2000 with CHD reported receiving smoking cessation advice.[123]

In a study by Bradley et al., in the mid 1990s in the United Kingdom, 53% reported receiving exercise advice.[137] In patients with CHD in Europe between 1999 and 2000, 67% reported receiving physical activity advice.[123, 137]

Fifty two percent (52%) of patients with AMI were given diet advice in the United Kingdom in the mid 1990s.[137] CHD patients between 1999 and 2000 in Europe reported receiving advice regarding the need to lose weight (57%), following a special diet to lower blood pressure (33%) and following a special diet to lower blood cholesterol (62%).[123]

Data regarding the provision of advice for physical activity, for dietary intervention and smoking cessation in stroke patients were not found in any published study from Australia.

1.13 Aims of thesis

The review of evidence described in this chapter has demonstrated a continuing high CHD and stroke disease burden despite a decline in CVD mortality overall.[60, 145] The review also demonstrated a high prevalence of modifiable risk factors among people who have had a CHD or stroke event, and reported evidence that the provision of secondary prevention care designed to reduce recurrent events is less than optimal, despite the existence of evidence and supportive secondary prevention care clinical guidelines.[43, 48, 84, 92, 126, 137,91]

Given these levels of care provision, desired reductions in the prevalence of risk factors are unlikely to be achieved.[121] Such findings suggest that both an opportunity and a need exist to develop new approaches to enhancing the provision of secondary prevention to people who have had a CHD or stroke event.

Based on this evidence, this thesis seeks to determine the need for an enhancement of secondary prevention care delivery to individuals with CHD or stroke in the Australian context, and to determine the efficacy of an intervention to enhance the delivery of secondary prevention care.

Specifically, the aims of this thesis are to:

- Describe the prevalence of risk factors for CHD and stroke and the treatment of these risk factors in an Australian population, and
- Design, implement and evaluate a secondary prevention intervention to improve general practitioner provision of secondary prevention care to people who have had a recent CHD or stroke event.

To address the first aim, Chapter 2 describes the prevalence of risk factors for CHD and stroke and secondary prevention care in patients following recent discharge from hospital for either a CHD or stroke event, in the Hunter region of Australia.

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Chapter Two

Prevalence of risk factors and secondary prevention care following hospitalisation for Coronary Heart Disease or Ischaemic Stroke in the Hunter Region, Australia

Tables

Figures

Chapter Two – Prevalence of risk factors and secondary prevention care following hospitalisation for Coronary Heart Disease or Ischaemic Stroke in the Hunter Region, Australia

2.1 Introduction

In Chapter One, the problem of recurrent events in patients with CHD or stroke was discussed, and the effectiveness and importance of secondary prevention in this population highlighted. Based on such evidence, guidelines have been developed to assist practitioners' use of efficacious interventions for secondary prevention.[1] Despite this, some studies suggest that the prevalence of secondary prevention care is less than optimal. A study by Girot et al., conducted in France, involving 107 cerebral ischemia and 85 heart disease patients, found that 71% of cerebral ischemia patients and 86% of heart disease patients did not receive appropriate secondary prevention care. The study also reported that the identification of risk factors, such as high cholesterol, diabetes and smoking, did not differ between heart disease and stroke groups, but high blood pressure was more frequently identified in heart disease than stroke patients. High blood pressure and high cholesterol were the two risk factors that were least likely to be treated among heart disease patients.[2]

Given these findings and that no Australian studies have reported the prevalence of risk factors and associated secondary prevention care among both heart disease and stroke patients within the same sample, a study involving data collected in the Hunter region of New South Wales, Australia, was undertaken. This study will herein be referred to as the Hunter Secondary Prevention (HSP) study.

2.2 Aims

The aims of the HSP study were to:

1) Determine the prevalence of CVD risk factors of high blood pressure, high cholesterol and smoking in patients discharged from hospital with heart disease or stroke;

2) Compare the prevalence of these CVD risk factors in patients discharged from hospital with heart disease to those discharged with stroke;

3) Determine the prevalence of secondary prevention care, measured as: use of medication for high blood pressure and high cholesterol in patients reporting these risk factors; use of aspirin; and receipt of advice to change risk behaviours in patients following discharge from hospital with heart disease or stroke; and

4) Compare the prevalence of secondary prevention care as described in 3) between patients discharged from hospital with heart disease or stroke.

2.3 Methods

The HSP study involved a secondary analysis of data obtained from the Hunter Area Heart and Stroke Register between 1997 and 1999.

2.3.1 Hunter Area Heart and Stroke Register

The Hunter Area Heart and Stroke Register (herein referred to as the Register, now known as the Hunter New England Heart and Stroke Register) collect routine data for surveillance and research purposes. The Register was established by the Hunter Area Health Service in July 1995 to monitor the incidence and prevalence of heart disease and stroke in the Hunter region. The Hunter region of New South Wales, located on the mid-north coast on the eastern side of Australia had a population of 603,367 in 2004.[3] Socio-demographic characteristics of the Newcastle statistical subdivision in 2006, for the major city of the region, included an unemployment rate of 5.9%, an average wage and salary income of $39,392 with 53% of those being males and the majority aged between 15 and 54 years of age.[3]

Australia has a universal health care system which provides access to public health care for everyone while allowing choice for individuals through private sector involvement in delivery and financing.

Ambulatory care sensitive conditions requiring hospitalization in the Hunter & New England health region for the period 2004-05 to 2006-07 combined were highest for diabetes complications (323 per 100,00); specifically CVD conditions such as angina rated 4th (199 per 100,000).[4] Chronic disease and conditions managed in general practice during 2003-04 for Australia included high blood pressure (10 per 100 encounters, ranked first), high blood cholesterol (2 per 100 encounters, ranked 6th), and coronary heart disease (2 per 100 encounters, ranked 7th).[5] Specific general practice service utilization for the Hunter & New England health region could not be located.

The Register collects data for all public hospital admissions for heart disease or stroke involving residents in the Hunter region aged 20 to 85 years. The upper age limit was removed in January 2002, with data for everyone over 20 years being collected since that time.

At the time of the study the aims of the Register were:

1) Monitoring health outcomes such as mortality rates, admission rates, readmission rates and procedure rates for persons living in the Hunter region with heart disease or stroke;

2) Providing a sampling frame for surveys of patient satisfaction, quality of life, rehabilitation and validation of diagnostic classification and coding which can be used to assess the physical, social and functional recovery of people with heart disease or stroke; and

3) Assisting with the evaluation of services provided by the Hunter Area Health Service in meeting the requirements of people with heart disease and stroke.

Computerised data were obtained by the Register from the local area health service on a regular monthly basis. Demographic and clinical data (admission and separation dates, diagnoses and mode of separation) regarding hospitalisations with a diagnostic code for either heart disease or stroke were encrypted to maintain confidentiality and transferred by secure system to the Register. At approximately two months following discharge from hospital, patients were sent a standard letter by the Register office requesting permission to retain their identifying and medical details on the Register. In addition, at this time patients were routinely sent a secondary prevention survey together with a reply paid

envelope. Non responding patients were sent a reminder letter at three separate time points: 10 days, four weeks and six weeks later. A repeat survey was sent to such patients with the four week reminder. Each patient was required to complete and return a consent form. Patient anonymity was ensured and all data was kept in accordance with the Federal Privacy Act.[6] Data were stored electronically in password protected databases and hardcopy surveys were stored in locked filing cabinets in the Centre for Clinical Epidemiology and Biostatistics, University of Newcastle, Australia. Data were all de-identified using assignation of a specific unique identifying number.

Information on date of death was obtained by the Register from the State Registry of Births, Deaths and Marriages on a monthly basis. Hospital separation data were linked to death data prior to contact with patients. Coded cause of death was obtained annually from the Australian Bureau of Statistics.

2.3.2 Study population

The HSP study extracted data from the Register for the period between August 1st 1997 and December 31st 1999. This period of time was chosen as the reference period as the content of the routine register secondary prevention survey remained consistent during this period.

For those patients who may have had multiple admissions during the study period, data presented in this study reflects their most recent admission. The denominator in this study therefore reflects the number of patients rather than the number of admissions during this period.

While the Register collects information on all patients hospitalised with a heart disease or stroke diagnosis, for this study specific diagnostic codes within these broad categories were included where there was strong evidence of the benefit of secondary prevention. These codes were: International Disease Classification system version 9 (ICD9) code for Ischaemic Heart Disease (410-414) (referred to as CHD throughout this chapter), and the ischaemic components of Cerebrovascular disease (433-438) (referred to as stroke throughout this chapter).[7]

Ineligibility criteria for the study included the following ICD9 codes included in the Register:

Acute rheumatic fever (390-392)

Chronic rheumatic heart disease (393-398)

Hypertensive disease (401-405)

Diseases of pulmonary circulation (415-417)

Other forms of heart disease (420-429)

Diseases of arteries, arterioles, and capillaries (440-448)

Diseases of veins and lymphatics, and other diseases of circulatory system (451-459)

Subarachnoid hemorrhage (430)

Intracerebral hemorrhage (431)

Other and unspecified intracranial hemorrhage (432)

2.3.3 Secondary Prevention measure

Data regarding the risk and secondary prevention care characteristics of patients were obtained from the existing secondary prevention survey routinely administered by the Register. The survey contained seven questions, described in more detail below. Two of the questions had multiple items within them resulting in 19 items in total which required a response. Refer to Appendix 2.1 for a copy of the survey items.†

The survey questions had dichotomous response categories, either “yes” or “no”. One question asked patients to report if they had ever been told by a doctor or other medical person that they had high blood pressure, diabetes or high cholesterol. For each of these risk factors additional information on treatment was requested. Those who reported high blood pressure and high cholesterol were asked whether they had been prescribed medication for their condition(s). All patients reporting high blood pressure, high cholesterol and diabetes were asked if they had been advised by a doctor to follow a special diet.

A further question asked patients if they had smoked any cigarettes, cigars or a pipe in the three months prior to their hospital admission and since their discharge. Patients were also asked whether, since their recent hospital admission, they had been advised to increase

† This survey has not been validated.

physical activity, follow a special diet or give up smoking. These behavioural advice questions were directed at all patients regardless of any risk factor(s) being reported.

Further questions asked patients about their taking of aspirin both prior to and after discharge and if they had ever received medical advice not to take aspirin. Survey responders were also asked to record the date they completed the questionnaire.

Clinical and demographic data used to describe the sample were obtained from the register and included gender, age, length of hospital stay, ICD coded diagnosis, marital status, origin of admission and residential location measured by local government area.

2.3.4 Statistical methods

Statistical analyses were undertaken using the Stata Version 8 statistical software package.[8] Prior to analysis the variables of age and length of stay were transformed to categorical variables. Date of birth was used to calculate age in years at December 31st 1998, which was then categorised into four groups of 59 years or less, 60 to 69 years, 70 to 79 years, and 80 years of age and over. This enabled classification as 'younger people', 'those in the early and post retirement phase' and 'the elderly'. Length of hospital stay was calculated by subtracting date of hospital admission from date of hospital discharge and categorised into 'zero days', 'between one and two days', 'between three and five days' and 'six days or more'. There were no Stroke patients with 0 days of stay therefore the first two groups were combined into one length of stay category of '0-2 days' for some analyses. Length of stay was categorised in this way as a de-facto measure of disease severity.

The ICD diagnostic categories used by the health system (described in Section 2.3.2) were classified into four diagnostic groups reflecting the major categories of CHD and stroke. ICD codes were classified as follows:

Acute Myocardial Infarction (AMI)	ICD9 code 410
Unstable Angina Pectoris (UAP)	ICD9 code 413
Other Ischaemic Heart Disease (IHD)	ICD9 code 414
Stroke	ICD9 code 430-438

Characteristics of those who completed the survey were compared to those who elected not to, or who preferred not to have their details retained on the Register, using Pearson chi-square tests for categorical variables. Sociodemographic and hospitalisation characteristics were compared between those with a diagnosis of CHD and those with a diagnosis of stroke using the Pearson chi-square statistic.

The outcomes of interest for the study were prevalence of the self reported risk factors of high blood pressure, high cholesterol and smoking status prior to and after hospitalisation; the use of aspirin as a secondary prevention measure before and after hospitalisation, receiving advice to increase physical activity, to follow a special diet and to give up smoking as well as being prescribed medication for the management of high blood pressure or high cholesterol.

The proportion of individuals with each risk factor of interest (Aim 1), and the proportion of individuals reporting receiving secondary prevention care (Aim 3) are presented with corresponding 95% confidence intervals. These confidence intervals were obtained using the normal approximation of the binomial distribution. Pearson chi-square tests were undertaken to compare the prevalence of risk factors (Aim 2) and the proportion receiving secondary prevention care (Aim 4) between CHD and Stroke patients. Multiple logistic regression analyses were undertaken to examine the relationship between outcomes and diagnosis (CHD versus Stroke) while adjusting for potential confounders such as sociodemographic and hospitalisation characteristics. Backward stepwise regression was undertaken with all sociodemographic and hospitalisation variables included in the model and removed if they had a p value of 0.1 or more on likelihood ratio tests. Adjusted odds ratios and 95% confidence intervals are reported from the final model. A significance level of 0.05 was used for all analyses.

Based on prior Register data, there are approximately 335 patients registered per month and it was estimated that 65% of patients registered would have a CHD or stroke discharge diagnosis suitable for the HSP study. Therefore, over a 28 month period it was estimated that there would be a total of approximately 9,380 people eligible for inclusion in the register with 6,100 of these (65%) eligible for the HSP study. An anticipated Register consent rate of 65% was estimated to result in 4,270 potential participants. Further information from the Register estimated that 60% would return the secondary prevention

survey resulting in a sample of 2,560 participants. Of these it was estimated that 80% would have a diagnosis of CHD and 20% a diagnosis of stroke.

This expected sample would allow for an estimate of the prevalence of risk factors and secondary prevention care (Aims 1 and 3), with 95% confidence intervals within ± 2% for CHD and within ± 5% for stroke. This sample size would also enable detection of differences in outcomes between CHD and stroke patients (Aims 2 and 4) of 7%, with 80% power and a 5% significance level.[9]

2.3.5 Ethical approval

Ethical approval to undertake the secondary data analysis was granted on March 21st 2001, by the University of Newcastle Human Research Ethics Committee and the Hunter Area Health Service, Hunter Area Research Ethics Committee.

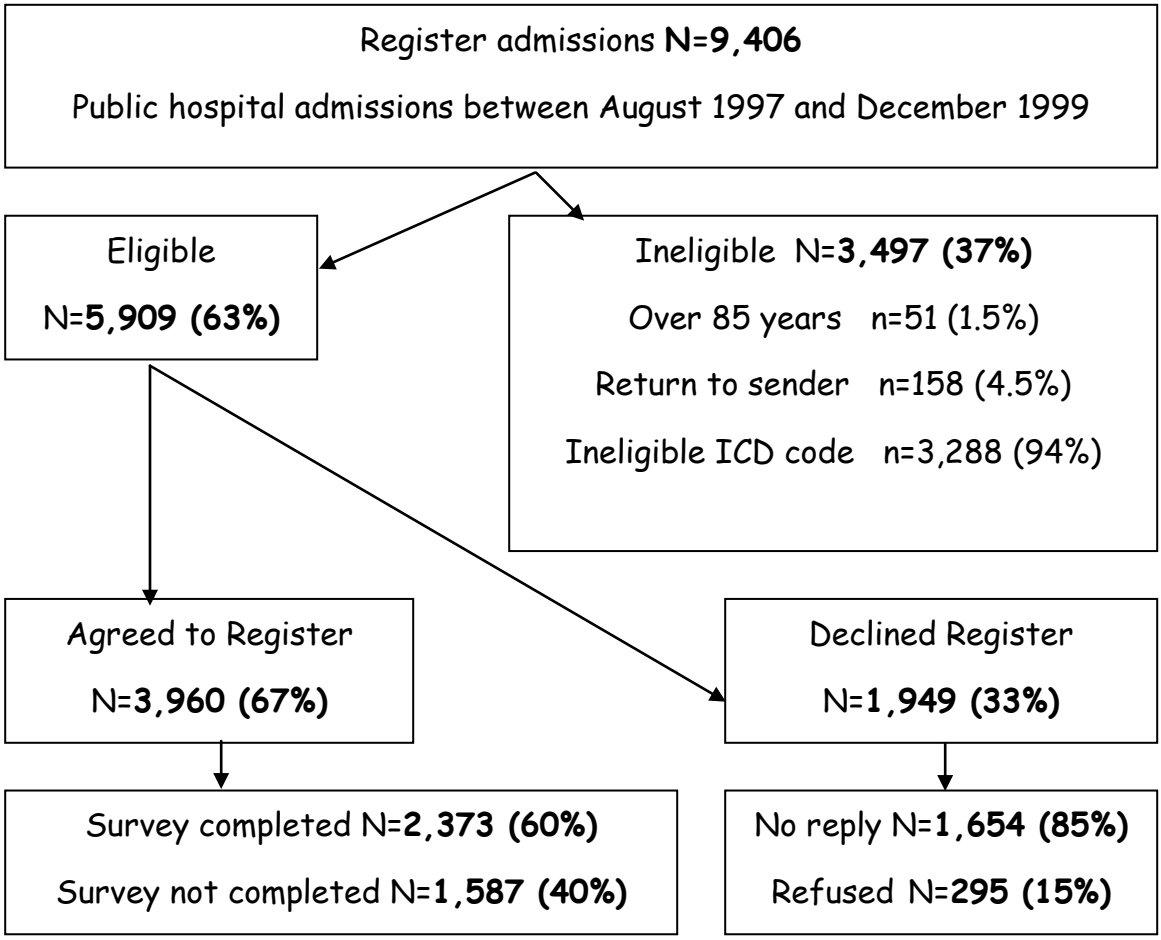
2.4 Results

2.4.1 Sample

During the study period August 1st 1997 and December 31st 1999, 9,406 individuals residing in the Hunter region were discharged alive from a public hospital in the study area (see Figure 2.1 for study flow chart). Of these, 63% (n=5,909) were eligible for inclusion in the study with the remaining 3,497 patients (37%) being ineligible due to being over 85 years of age (n=51, 1.5%), having not received an invitation to the Register (n=158, 4.5%) or having an ICD code that was ineligible for inclusion (n=3,288, 94%).

Of the remaining 5,909 patients eligible for inclusion in the study, 67% (n=3,960) agreed to have their details kept on the Register and of these 2,373 (60%) completed the secondary prevention care survey (refer to Appendix 2.1 for a copy of the survey).

Figure 2.1: Study flow chart for the HSP study



2.4.2 Sample characteristics

Table 2.1 compares the characteristics of study participants who completed the secondary prevention survey and those who did not (including those who declined to have their information retained on the Register). Those who completed the survey were more likely to be male, to be younger than 80 years of age, to have a shorter length of stay, to have a diagnosis of UAP or Ischaemic Heart Disease IHD, and married, relative to those who did not complete the survey. However differences were of minimal clinical importance; because of the large sample size there was sufficient power to detect small differences between groups. The smaller proportion of stroke patients who completed the survey relative to those who did not may have resulted in the stroke sample being less representative than ideal. This is most likely due to higher physical disability among stroke patients. There was no difference between those who completed the survey and those

who did not in terms of origin of admission (booked or emergency) and local government area.

Table 2.1: Characteristics of eligible patients who completed the survey in the HSP study

characteristic	survey complete N=2,373	survey not complete N=3,536	test statistic		
	n (%)	n (%)	$\chi 2$	df	p-value
Gender	**N=2,373**	**N=3,536**			
Male	1,545 (65%)	2,192 (62%)			
Female	828 (35%)	1,344 (38%)	5.93	1	0.01
Age group	**N=2,373**	**N=3,536**			
≤ 59 years	676 (28%)	1,019 (29%)			
≥ 60 & ≤ 69	705 (30%)	929 (26%)			
≥ 70 & ≤ 79	786 (33%)	1,183 (33%)			
≥ 80 years	206 (8.7%)	405 (11%)	16.7	3	0.001
Length of stay	**N=2,373**	**N=3,536**			
0 days	347 (15%)	441 (12%)			
≥ 1 & ≤ 2	663 (28%)	1,207 (34%)			
≥ 3 & ≤ 5	454 (19%)	653 (18%)			
≥ 6	909 (38%)	1,235 (35%)	26.9	3	<0.001
Diagnosis	**N=2,373**	**N=3,536**			
UAP	989 (42%)	1,308 (37%)			
AMI	287 (12%)	563 (16%)			
Other IHD	831 (35%)	1,055 (30%)			
Stroke	266 (11%)	610 (17%)	69.4	3	<0.001

characteristic	survey complete N=2,373	survey not complete N=3,536	test statistic		
	n (%)	n (%)	$\chi 2$	df	p-value
Marital status	**N=2,043**	**N=3,282**			
Married	1,497 (73%)	2,246 (68%)			
Never Married	112 (5.5%)	208 (6.3%)			
Widowed	305 (15%)	583 (18%)			
Divorced/Separated	129 (6.3%)	245 (7.5%)	14.17	3	0.003
Origin of admission	**N=2,368**	**N=3,525**			
Emergency	1,069 (45%)	1,587 (45%)			
Booked	1,299 (55%)	1,938 (55%)	0.0086	1	0.92
Local government area	**N=2,373**	**N=3,536**			
Newcastle	703 (30%)	1,024 (29%)			
Lake Macquarie	793 (33%)	1,163 (33%)			
Cessnock	219 (9.2%)	329 (9.3%)			
Maitland	220 (9.3%)	328 (9.3%)			
Port Stephens	274 (12%)	402 (11%)			
Upper Hunter/ Dungog/Singleton	164 (6.9%)	290 (8.2%)	3.46	5	0.63

UAP *Unstable Angina Pectoris*

AMI *Acute Myocardial Infarction*

IHD *Ischaemic Heart Disease*

Table 2.2 compares the sociodemographic and hospitalisation characteristics of study participants with a diagnosis of CHD and those with a diagnosis of stroke. Relative to participants with a stroke diagnosis, those with CHD were significantly more likely to be male and significantly less likely to be over 70 years of age, with the difference even greater for those over 80 years of age. Stroke participants were less likely to have a

shorter length of stay (less than 3 days) compared to CHD participants. Participants with a diagnosis of CHD were more likely to be married and less likely to be widowed compared to participants with a diagnosis of stroke. CHD patients were more likely to have a booked admission relative to stroke participants; but local government area was similar for CHD and stroke participants.

Table 2.2: Characteristics of Coronary Heart Disease and Stroke patients in the HSP study

characteristic	**CHD** N=2,107	**Stroke** N=266	**test statistic**		
	n (%)	n (%)	$\chi 2$	df	p-value
Gender	**N=2,107**	**N=266**			
Male	1,399 (66%)	146 (55%)			
Female	708 (34%)	120 (45%)	13.77	1	0.001
Age group	**N=2,107**	**N=266**			
≤ 59 years	630 (30%)	46 (17%)			
≥ 60 & ≤ 69	642 (30%)	63 (24%)			
≥ 70 & ≤ 79	682 (32%)	104 (39%)			
≥ 80 years	153 (7.3%)	53 (20%)	63.69	3	<0.001
Length of stay	**N=2,107**	**N=266**			
0 days	347 (16%)	0			
≥ 1 & ≤ 2	631 (30%)	32 (12%)			
≥ 3 & ≤ 5	382 (18%)	72 (27%)			
≥ 6	747 (35%)	162 (61%)	120.7	3	<0.001
Marital status	**N=1,786**	**N=257**			
Married	1,339 (75%)	158 (61%)			
Never Married	92 (5.1%)	20 (7.8%)			
Widowed	245 (14%)	60 (23%)			
Divorced/Separated	110(6.2%)	19 (7.4%)	22.91	3	<0.001

characteristic	CHD N=2,066	Stroke N=256	test statistic		
	n (%)	n (%)	$\chi 2$	df	p-value
Origin of admission	**N=2,105**	**N=263**			
Emergency	856 (41%)	213 (81%)			
Booked	1,249 (59%)	50 (19%)	153.5	1	<0.001
Local government area	**N=2,107**	**N=266**			
Newcastle	622 (30%)	81 (30%)			
Lake Macquarie	715 (34%)	78 (29%)			
Cessnock	185 (8.8%)	34 (13%)			
Maitland	199 (9.4%)	21 (7.9%)			
Port Stephens	244 (12%)	30 (11%)			
Upper Hunter/ Dungog/ Singleton	142 (6.7%)	22 (8.3%)	7.10	5	0.21

The first aim of this study was to report the prevalence of specific risk factors in people recently hospitalised for CHD disease or stroke in the Hunter. For the total study population, the prevalence of both high blood pressure and high cholesterol was 60%. Eighteen percent (18%) of study participants reported smoking in the three months prior to admission and 9.4% reported smoking since discharge. Table 2.3 details the self reported prevalence of high blood pressure, high cholesterol and smoking.

Table 2.3: Self reported risk factors by CHD and Stroke diagnosis in the HSP study sample

	All patients N=2,322	**CHD patients** N=2,067	**Stroke patients** N=256	**test Statistic**			
	n (%) [95%CI]	n (%) [95%CI]	n (%) [95%CI]	$\chi 2$	df	p-value	†Adjusted OR (95%CI)
High Blood Pressure	**N=2,322**	**N=2,066**	**N=256**				
	1,402 (60%) [58,62]	1,227 (59%) [57,61]	175 (68%) [63,74]	7.65	1	0.006	1.3 (1.02-1.8)
High Cholesterol	**N=2,097**	**N=1,880**	**N=217**				
	1,262 (60%) [58,62]	1,179 (63%) [60,65]	83 (38%) [32,45]	48.58	1	<0.001	0.48 (0.35-0.66)
Smoking 3 months prior to admit	**N=2,270**	**N=2,023**	**N=247**				
	409 (18%) [16,19]	368 (18%) [16, 20]	41 (17%) [12, 21]	0.37	1	0.54	0.94 (0.64-1.4)
Smoking since discharge	**N=2,243**	**N=1,996**	**N=247**				
	212 (9.4%) [8.2,10]	189 (9.5%) [8.2,10.7]	23 (9.3%) [5.7,13]	0.006	1	0.93	0.98 (0.57-1.7)

† adjusted OR from parsimonious logistic regression model; details of final models provided in Appendix 2.2

Self reported high blood pressure was statistically significantly higher in patients with stroke compared to patients with CHD (68% and 59% respectively, p=0.006). The odds of high blood pressure adjusted for gender and age in stroke patients, was 1.3 times that of CHD patients (95%CI, 1.02-1.8). Conversely, self reported high cholesterol was statistically significantly higher in patients with CHD compared to patients with stroke (63%

and 38% respectively, p<0.0001). The odds of high cholesterol, adjusted for gender, age and emergency admission, in stroke patients was 0.48 times that of CHD patients (95%CI 0.35-0.66). Similar rates of smoking were reported for CHD and stroke prior to admission (18% and 17%, OR adjusted for gender age, marital status, emergency admission and local government area 0.94; 95%CI, 0.64-1.4) and following discharge (9.5% and 9.3%; OR adjusted for gender, age, length of stay, marital status, emergency admission and local government area 0.98; 95% CI, 0.57-1.7).

Ninety five percent (95%) of all patients surveyed reported taking a blood pressure lowering medication and 86% reported taking medication for high cholesterol. Nearly half of the sample (49%) reported taking aspirin regularly prior to their recent hospital admission and this increased to 82% post discharge. Thirteen percent (13%) of patients reported being advised not to take aspirin (Table 2.4).

There was no statistically significant difference in self report of prescribed blood pressure lowering medication between patients with CHD and stroke (96% and 95% respectively). The odds of self report of taking blood pressure lowering medication in stroke patients, adjusted for age, was 0.8 times that of CHD patients (95%CI, 0.38-1.8). Significantly fewer patients were treated with medication for high cholesterol if they had a stroke diagnosis (70%) compared to patients with CHD (88%, p<0.001). After adjusting for emergency admission, the odds of self reported cholesterol lowering medication in stroke patients was 0.35 times that of CHD patients (95%CI, 0.22-0.56).

There were no significant differences in the use of aspirin prior to admission between those with CHD and stroke (46% and 52% respectively, p=0.07). The odds of aspirin prior to admission, adjusted for age and emergency admission, were 0.77 (95%CI, 0.58-1.03) for the stroke group relative to those with a diagnosis of CHD. After discharge from hospital, significantly more CHD patients reported taking aspirin than stroke patients (84% and 71% respectively, p<0.001). The odds of reported aspirin use after discharge in stroke patients were 0.45 times that of CHD patients, after adjusting for gender, age, length of stay, marital status and emergency admission (95%CI, 0.32-0.63). Significantly more patients reported being advised not to take aspirin following a stroke (20%) compared with patients following a CHD event (12%, p<0.001). The odds of being advised not to take

aspirin, adjusted for age, were 1.6 higher for stroke patients compared to CHD patients (95%CI, 1.1-2.3).

Table 2.4: Self report of pharmaceutical treatment of risk factors by heart disease and Stroke diagnosis in the HSP study

	All patients N=2,322	**CHD patients** N=2,067	**Stroke patients** N=256	**test Statistic**			
	n (%) [95%CI]	n (%) [95%CI]	n (%) [95%CI]	$\chi 2$	df	P value	†Adjusted OR (95%CI)
Taking medication for high blood pressure*	**N=1,383**	**N=1,208**	**N=175**				
	1,322 (95%) [94,97]	1,155 (96%) [94,97]	167 (95%) [92,98]	0.01	1	0.91	0.8 (0.38-1.8)
Taking medication for high cholesterol*	**N=1,389**	**N=1,284**	**N=105**				
	1,202 (86%) [85,88]	1,129 (88%) [86,89]	73 (70%) [61,78]	28.2	1	<0.001	0.35 (0.22-0.56)
Taking Aspirin before admission	**N=2,254**	**N=2,011**	**N=243**				
	1,153 (49%) [49,53]	1,042 (52%) [50,54]	111 (46%) [39,52]	3.26	1	0.07	0.77 (0.58-1.03)
Now taking Aspirin	**N=2,234**	**N=1,999**	**N=235**				
	2,234 (82%) [81,84]	1,674 (84%) [82,85]	166 (71%) [65,76]	24.85	1	<0.001	0.45 (0.32-0.63)

	All patients N=2,322	CHD patients N=2,067	Stroke patients N=256	test Statistic			
	n (%) [95%CI]	n (%) [95%CI]	n (%) [95%CI]	$\chi 2$	df	P value	†Adjusted OR (95%CI)
Advised NOT to take Aspirin	**N=2,235**	**N=1,994**	**N=241**				
	291 (13%) [12,14]	242 (12%) [11,13]	49 (20%) [15,25]	12.75	1	<0.001	1.6 (1.1-2.3)

** Response based on a question defining a history of risk factor and recording of an anti-hypertensive medication for blood pressure or lipid lowering medication for high cholesterol*

† adjusted OR from parsimonious logistic regression model; details of final models provided in Appendix 2.2

Sixty one percent (61%) of patients reported being advised to increase their physical activity, half reported being advised to give up smoking and approximately half reported being advised to follow a special diet. The results are presented in Table 2.5.

Table 2.5: Self report of management of lifestyle risk factors by heart disease and Stroke diagnosis in the HSP study

	All patients N=2,322	**CHD patients** N=2,067	**Stroke patients** N=256	**test Statistic**			
	n (%) [95%CI]	n (%) [95%CI]	n (%) [95%CI]	$\chi 2$	df	p-value	†Adjusted OR (95%CI)
Advised to give up smoking*	**N=947**	**N=827**	**N=120**				
	470 (50%) [46,53]	424 (51%) [49,55]	46 (38%) [29,47]	7.01	1	0.008	0.60 (0.38-0.95)
Advised to increase physical activity*	**N=2,082**	**N=1,866**	**N=216**				
	1,279 (61%) [59,64]	1195 (64%) [62,66]	84 (39%) [32,45]	51.68	1	<0.001	0.32 (0.23-0.45)
Advised to follow special diet*	**N=1,959**	**N=1,755**	**N=204**				
	1,027 (52%) [50,55]	979 (56%) [53,58]	48 (24%) [18,29]	76.22	1	<0.001	0.28 (0.19-0.41)

** Advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian)*

† adjusted OR from parsimonious logistic regression model; details of final models provided in Appendix 2.2

Patients with CHD were statistically significantly more likely than patients with stroke to report receiving advice for smoking cessation, 51% vs 38% (p=0.008), increasing physical activity 64% vs 39% (p<0.001) and following a special diet 56% vs 24% (p<0.001). The odds of these outcomes for stroke patients relative to CHD patients were 0.60 (95%CI, 0.38-0.95) for giving up smoking (adjusted for gender, age, length of stay, marital status), 0.32 (95%CI, 0.23-0.45) for increasing physical activity (adjusted for gender, age, length of stay, marital status) and 0.28 (95% CI, 0.19-0.41) for following a special diet (adjusted for age, length of stay and emergency admission).

2.5 Discussion

Aims 1 and 2 of the HSP study were to report the prevalence of high blood pressure, high cholesterol and smoking status among people with CHD and stroke, and to compare the prevalence of these risks between patients with CHD and stroke.

In the previous chapter the prevalence of risk factors in people with existing CHD was shown to vary from 50% to 82%.[10-18] In an Australian setting high blood pressure was reported to be approximately 50% in people discharged with CHD and those discharged with stroke.[19] In contrast, the prevalence of high blood pressure between 1980–2004 in the general Australian population has been reported to range between 17% and 32%.[19-21] As Australians age, the reported rates of high blood pressure also increase (65 to 69 years, 41%)[22, 23] (65 to 74 years, 70%).[24]

In comparison to these previous studies, the prevalence of high blood pressure in the HSP study was slightly higher, with 59% of those participants with CHD and 68% of those with stroke reporting high blood pressure. Given the age of this study population (median 70 years) these findings are consistent with the prevalence of older Australian's self-reported blood pressure readings.[22-24]

The higher prevalence of high blood pressure in stroke patients compared to CHD patients observed in this study suggests a need to ensure that models of care for stroke patients have a greater emphasis on the assessment, treatment and monitoring of blood pressure.

The prevalence of high cholesterol in patients with CHD in the United Kingdom, Europe and the Asia Pacific region has been reported in several studies to vary between 33% and 99%.[10-14, 17, 22, 25] In contrast to the Australian National Health Survey of 2001, the prevalence of high cholesterol for people with a diagnosis of stroke was estimated to be 31%.[19]

In the context of these previously reported findings, the prevalence of high cholesterol observed in this study is consistent with rates reported in other national and international studies although there is a large range in these values. In the HSP study there was a significant difference between self reported rates of high cholesterol for patients with

stroke (38%) and CHD (63%) and this difference persisted when adjusted for socio-demographic and hospitalisation factors. The evidence for high cholesterol as a risk factor for CHD is stronger and less contradictory than for stroke.[26-28] However Girot et al.'s study did not report any difference in self report of high cholesterol between those with CHD and stroke.[2]

Smoking rates of 19% to 28% in the general population in Australia have been reported,[19-21, 29] with such rates being lower than in European countries such as Greece, Japan and Spain (34% - 37%).[22] Studies from the United Kingdom and Europe report rates of smoking between 10% and 64%.[10-12, 30] In the Australian setting, smoking was reported by 12% of those with heart disease[16] and by 18% of people with a diagnosis of stroke.[19]

In the HSP study rates of smoking prior to hospitalisation were similar for patients with CHD and stroke at 18% and this rate was nearly halved after discharge, with 9.4% of both CHD and stroke patients reporting smoking since discharge from hospital. Similar results for smoking in stroke patients were noted in a study by Girot et al.[2] While optimally all patients should quit smoking following diagnosis with CHD or stroke, it is pleasing to note that rates have reduced to almost half the pre-event rates.

The third and fourth aims of the HSP study were to describe the prevalence of secondary prevention care in CHD and stroke patients and investigate any potential differences in these between the two CVD diagnoses.

The self-reported rates of prescribed medication use for high blood pressure in the HSP study were high for both CHD and stroke patients (95% for both). These rates of high blood pressure medication use compare favourably with rates of between 14% and 89% [10, 11-15, 17, 18, 31-37] in CHD patients shown in studies from the United Kingdom and Europe, and with rates of 69% reported for stroke patients.[19] While the high percentage of patients with such medication (95%) leaves little room for improvement in management of high blood pressure, it is important to ensure that this high rate of treatment is sustained.

It should be noted that treatment with a blood pressure medication in itself does not infer that high blood pressure is adequately controlled and therefore minimized as a risk factor. In the presence of medication, high blood pressure that is not at optimal levels remains a

risk. This study did not have the capacity to determine adequacy of treatment prescribed and can make no comment on the room for improvement that may exist in relation to adequate control.

There are several potential reasons why the rates of medication use for high blood pressure are so varied in the literature and higher in this study, including possible differences in characteristics of study samples, such as age, gender, diagnosis, time of study. In addition, the prevalence of medication use may depend on whether the denominator used in these calculations is the total study population or just those who report having high blood pressure. Medication use would be expected to be higher among those with high blood pressure than among all patients with CHD or stroke.

The higher prevalence of both blood pressure as a risk factor and medication use for high blood pressure may be as a results of a recent acute event requiring hospitalization. Patients during their hospital stay are likely to have been informed of their high blood pressure and medication may have been commenced or altered by a cardiac specialist during this hospitalisation. The likelihood that appropriate use of medications was maximized during hospitalisation and the recency and repercussions of the hospitalisation may contribute to patient's recall of risk factors and management of the same.

Other methodological differences such as the source of information, for example patient self report[38] versus medical record audit[39], may also help explain differences in prevalence of outcomes across studies. Studies using a more objective measure such as medical record audit may be more likely to report higher use of blood pressure medication given the possibility of recall problems in self report identified in specific populations such as those older than 65 years of age and those with a lower education.[40]

Medication use for lowering high cholesterol has been reported by 16% to 62% of patients with CHD [31, 34, 11-13, 17, 25, 32, 37, 41] and between 17% and 21% of patients with stroke.[19, 42] Higher rates of cholesterol medication use in Australia have been reported with 87% in CHD patients in 1999-2000.[43] In the HSP study the reported use of cholesterol lowering medication by individuals with a diagnosis of CHD (88%) was similar to those previously reported in Australia.[43] Higher rates of cholesterol lowering medication use were reported by those with a diagnosis of stroke (70%) compared to the available international literature.

The implications of this are that only minimal improvements in care may be possible for CHD patients with more potential for improvement in management of high cholesterol in stroke patients, given the lower prevalence of cholesterol lowering medication in this group. However it is difficult to estimate if 70% of the stroke cohort taking medication for high cholesterol is already the optimal number of patients able to be treated, given the reduced evidence for benefit of this treatment in this patient population.[44]

In the HSP study, as in international studies, patients with CHD were significantly more likely to report being prescribed cholesterol lowering medication compared to those with stroke (88% vs 70%). This may be because there is better evidence for treating cholesterol to prevent recurrent CHD events compared to the evidence for treating cholesterol to prevent recurrent stroke.[45] While in the HSP study high rates of cholesterol lowering medication were reported, there still exists opportunities for improvements in these rates in patients with CHD and stroke.

In the HSP study patients were asked to report if they had been advised not to take aspirin. Significantly more stroke (20%) than CHD (12%) patients had been advised not to take aspirin. While aspirin is a relatively safe and effective prophylactic medication for secondary events, it is not always tolerated by patients or may be contraindicated and therefore may not be recommended.[46] Aspirin is beneficial and recommended for patients with ischaemic stroke, however it is not recommended for patients with haemorrhagic stroke (who were not eligible for the HSP study).[47] Aspirin is generally contraindicated for a patient taking anti-coagulant therapy, such as warfarin[47] as the combination of both warfarin and aspirin increases the risk of bleeding.[47] Stroke patients are more likely to be prescribed warfarin than patients with CHD due to the increased risk of AF following a stroke. The HSP study did not collect data on actual prescribed medications and therefore cannot cross-check individuals who reported being advised not to take aspirin with those reporting taking medications such as warfarin.

Aspirin use ranging between 28% and 92% has been reported by patients following AMI in studies undertaken in the United Kingdom and Europe.[10-15, 17, 31-36, 48] The prevalence of aspirin use of 84% post event in CHD patients observed in the HSP compares favourably to such international and national rates reported above. Although it is not clear though why there is such a large variation in International rates for aspirin use, this may be due to

differences in population demographics or the timing of data collection; the prevalence may be higher in more recent years due to the increasing evidence for the effectiveness of this for secondary prevention of CVD.

The observed prevalence of aspirin use in stroke patients in the HSP study (71%) is also consistent with the international literature with 72% of patients with stroke reportedly receiving either aspirin or anticoagulant therapy in a European study.[49] Although aspirin use would not be expected to be 100% due to contraindications, there may still be opportunities to increase aspirin use in both CHD and stroke patients, given that this medication is recommended as a secondary prevention measure in all CHD and stroke patients. However, particularly for stroke patients, the optimal rate of aspirin use is unknown.

International rates of advice for physical activity in CHD and stroke patients have been reported to be between approximately 53% and 67% in the United States of America and Europe.[11, 31, 33] The Euroaspire II study reported similar rates of such advice to that observed in the HSP study for those with CHD (64%).[11]

There was a significant difference in self reported physical activity advice between CHD and stroke patients in the HSP study with only 39% of patients with a stroke being advised to increase physical activity as compared to 64% for CHD patients. The reasons for these differences between CHD and stroke patients are not clear. Patients with stroke could be perceived to benefit less from, and be less able to participate in, physical activity due to a residual partial paralysis compared to those with CHD.[50] There may also be a perception that those with severe deficit following stroke would not respond to, or benefit from, secondary prevention, so risk factor identification and management is not seen as a priority especially if intensive physical rehabilitation is still required.[50] The HSP study did not assess the patient's state of health in terms of physical measures of functioning and ability post event, so can only postulate this as an explanation.

In the United States and Europe, rates of provision of dietary advice to patients following a cardiac event were between 33% and 62%.[11, 31, 33, 51] In the HSP study 56% of CHD patients reported receiving advice to follow a special diet, which is comparable with International data but indicating room for improvement.

Only 24% of patients with stroke in the HSP study were advised to follow a special diet. One potential reason why stroke patients were less likely than CHD patients to receive dietary advice could be that there is little evidence that dietary advice following stroke provides a benefit. These findings suggest that further initiatives are required to provide evidence for the role of dietary advice in secondary prevention, particularly for stroke patients.

Provision of smoking cessation advice in the United Kingdom and Europe has been reported to be quite high for CHD patients with values of 82% to 88%.[11, 31, 33] In the HSP study smoking cessation advice was found to be lower than these studies, with approximately 51% of CHD patients and 38% of stroke patients who were current smokers reporting receipt of smoking cessation advice. In addition to actual differences in management of patients with CHD and stroke because of physician behavior and beliefs, factors which may impact on these rates include potential recall bias, sample characteristics and timing of the study. Patients with CHD may have been more likely to be given advice on smoking cessation than patients with stroke because of the stronger evidence for the benefit of smoking cessation in this group. This difference in provision of smoking cessation advice for CHD and stroke patients was also reported in a study by Girot et al.[2] A more rigorous application of existing guidelines regarding the provision of smoking cessation care to CHD and stroke patients is therefore required.

The opportunity to improve secondary prevention care for CHD and stroke patients is substantial. An increase in advice regarding physical activity of 36% could be made for CHD patients and 61% for stroke patients. Gaps that have the potential to be filled in secondary prevention care in terms of dietary advice are 44% for those with CHD and 76% for stroke patients. Secondary care provision of smoking cessation advice could similarly be improved by 49% and 62% respectively for CHD and stroke patients.

A significant strength of this study is that it examines risk factor prevalence and management in both CHD and stroke patients, and demonstrates that there are differences in care depending on diagnosis of stroke and CHD. This study did not seek to determine why there may be a difference in care, however it does challenge clinicians to ensure, that regardless of diagnosis, risk should be appropriately treated.

The main limitations of this study include the low response rate, self report of information and missing data. Overall, 67% of people agreed to have their details kept on the Register, and 2,373 patients (60%) provided data for this study, however this reflects less than 40% of those eligible to be part of the study (n=5,909).

Patients who completed the secondary prevention survey were statistically significantly more likely to be male, younger, have a shorter length of stay, have a diagnosis of UAP or IHD and be married relative to those who were not included in the study. The generalisablity of the results to the wider population of CHD and stroke patients could be questioned and it may be that the healthier patients were the respondents. It is reasonable to assume that patients who are sicker have more risk factors and an underestimate of secondary prevention care could exist and thus gaps in care provision could be higher than reported. Additionally it should be borne in mind when considering the results of this study that patients older than 80 years of age, females and those with a diagnosis of stroke are under represented. However, due to the large sample size there was power to detect small differences between groups. Thus the differences in sociodemographic characteristics may not necessarily be clinically important.

It has been suggested that the validity of self reported CVD risk factors is low especially for both high blood pressure and high cholesterol.[52] Some authors have suggested that due to low sensitivity, self reported high cholesterol in particular should be interpreted with caution.[20, 21, 38] To ensure valid measurements are made and to avoid misclassification, methods such as physiological assessment should be undertaken where possible.[53]

This study did not have the capacity or resources to perform biological testing or to fully audit hospital records. The implications for this research are that self reported risk factors may be under or over stated, although prevalence of high blood pressure, high cholesterol and smoking status rates were similar to those reported in the literature. This would imply that although there are potential problems with self report of risk status, the effect on this study was likely to be low.

A further consideration for data that relies on self report is the assumptions made, in this case, related to the provider of medical advice. This study did not seek to qualify who gave

this advice. This study did not audit secondary prevention services at the time of data collection in an attempt to determine from where advice was being delivered. At the time of the study secondary prevention advice was provided by health professionals, including medical specialists in acute settings such as hospitals and in sub acute services such as general practice. Patients could also have used services offered in the community such as physical activity programs and quit smoking programs offered by peak bodies, for example the National Heart Foundation of Australia.

Further advice may have been delivered to the patients who undertook cardiac rehabilitation after discharge compared with stroke rehabilitation. One of the functions of cardiac rehabilitation is to provide lifestyle advice to reduce risk factors. A cross sectional study conducted in the same population as this study reported that referral to cardiac rehabilitation between 2002 and 2007 had remained stable with approximately half of all eligible patients being referred.[54] Uptake data in Australia is available however this study was chosen to address CR as it was of the same population.

Lifestyle variables also suffer from potential misclassification with the suggestion that self report may underestimate smoking prevalence by 4% and overestimate the amount of physical activity undertaken.[55, 56] It is difficult to ascertain if advice was actually provided by a health care professional based on self report and it has been suggested that under reporting of advice for lifestyle risk factors occurs because patients either forget the advice or are unaware that they are being given advice to reduce lifestyle risk factors.[57]

Missing data is a potential limitation of the HSP study. There was very little missing data for high blood pressure (2.1%) or smoking (5.5%), although 12% failed to respond to the question asking if they had ever been told by a doctor or other medical person that they had high cholesterol. Likely reasons for missing data include that patients may be unaware whether they had cholesterol levels measured; or that routine cholesterol measurements did not necessarily occur during hospitalisation.

Lifestyle variables also had greater than 10% missing data for receipt of advice from a medical person (eg. doctor, nurse, physiotherapist, dietitian) for physical activity (12%), following a special diet (17%) and smoking cessation (17%). This amount of missing data

may reflect a lack of recall in terms of receiving the advice, or it may be that those who did not make any change to these behavioural risks were loathe to report this information.

2.6 Conclusion

The aims of this study were to determine the prevalence of risk factors and secondary prevention care of risk factors for CHD and stroke in the Hunter region that may be amenable to further intervention to reduce recurrent CVD events.

The key findings of this study suggest disparities in secondary prevention care exist between patients with CHD and stroke, particularly for factors amenable to behavioural interventions, such as smoking cessation, increasing physical activity and following a special diet. Also, there is room for improvement in the use of cholesterol lowering medication and the use of prophylactic aspirin. While use of blood pressure lowering and cholesterol lowering medication was generally high; these were measured in patients with self reported high blood pressure and high cholesterol. More recent evidence demonstrates that these medications have secondary prevention benefits in all patients with CHD, and to a lesser extent Stroke. It is therefore important to examine the use of these medications in patients with CHD or stroke managed following more recent guidelines for pharmacological treatment.

Evidence suggests from past research, in addition to this study, that there are gaps in the provision of secondary prevention care in patient with CHD and stroke. Therefore an intervention study was designed and undertaken in the Hunter region. Chapter Three describes the methods used to conduct this study and Chapters Four and Five present the results of the intervention.

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Chapter Three

Prevent Another Vascular Event (PAVE) study rationale, methods, measures, and recruitment outcomes

Tables

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Chapter Three - Prevent Another Vascular Event (PAVE) study rationale, methods, measures, and recruitment outcomes

3.1 Introduction

Data in the previous chapter demonstrated that the prevalence of preventable risks among individuals discharged from hospital with CHD or stroke is currently less than optimal. This was particularly the case for risks which are amenable to behavioural interventions such as smoking cessation, increasing physical activity and modifying fat in the diet. Additionally, the data suggested that there was room for further improvement in the use of prophylactic aspirin and the use of cholesterol lowering medication.

Given this, a study was undertaken to determine the effectiveness of an intervention to increase GP provision of care designed to reduce the prevalence of risks factors among CHD and stroke patients. Description of the study design, implementation and findings are presented in three chapters. This current chapter will describe the background, design, methods and recruitment of the study participants and the demographic and risk factor characteristics of the sample. The next chapter (Chapter Four) will describe the effectiveness of the intervention on the use of medications designed to reduce high blood pressure and high cholesterol, to improve control of AF and prophylactic management of CVD by the use of aspirin. The following chapter (Chapter Five) describes the effect of the intervention on the reported provision of advice by GPs regarding smoking cessation, increasing physical activity and improving diet.

3.2 Rationale for utilising General Practitioners to provide secondary prevention

Provision of secondary prevention care in Australia is commonly undertaken in general practice. General practitioners (GPs) are often the first place a person visits for a health problem, particularly following hospitalization.[1] According to the Royal Australian College of General Practitioners' (RACGP), general practitioners provide a comprehensive service to patients incorporating a holistic approach. General practitioners provide preventative,

curative and rehabilitative care on a continuous and long term basis to all members of the community. The RACGP highlights the need for general practitioners to be the "gatekeepers" of patients care with the ability to refer to medical specialist care as required.[2] General practitioners are in a unique position to provide preventative care to patients with CHD or stroke[2-11] particularly given their strategic role in detection of health risks[12-14] and in providing long term medical management.[3] Most Australian patients will visit their GP following hospital discharge after CHD or stroke.[4] Patients with CHD and stroke are advised to consult with their GP within four to five days after discharge from hospital and GPs are recommended to continue to followup patients for another six to eight weeks.[3] In this period GPs have the capacity to monitor patient medication commenced in hospital, including secondary prevention prophylactic medications[1, 16]and to advocate for lifestyle changes and compliance with drug therapy.[5] Physician counseling combined with other interventions often involves repeated advice, followup visits and referral.[6]

General practitioners perceive themselves to be effective in identifying patients at high risk of further CHD or stroke events,[7] although they have expressed concern about their effectiveness in relation to prevention activities.[8] In addition to the favorable characteristics of general practice as a setting for the provision of secondary prevention care as described above, research has further demonstrated that patients perceive that GPs have a role in the provision of secondary prevention care and are an important source of advice about risk factor management.[9, 10]

Patients perceive their GPs as authoritative sources of information and suggest that they would alter risky behaviour on the advice of their GP[11] and that this advice should be addressed as part of routine medical consultation.[12] General practitioners are a large pool of professionals that have credibility regarding health recommendations, with patients respecting GP advice and wanting to receive counseling from their GP. Succinct messages from GPs are a potent catalyst in motivating change in health behaviours.[13] However, practitioners have been reported to respond primarily to patients' presenting problems rather than initiating risk factor change. It has been suggested that both the patient and the physician need to be cued to change high risk behaviour.[14]

3.3 Effectiveness of secondary prevention interventions

There is good evidence, including two meta-analyses, of the effectiveness of secondary prevention interventions in improving outcomes and management of patients with CHD. The first of these meta-analyses examined 63 randomised controlled trials of 21,205 patients with CHD, examining the benefit of secondary prevention programs in terms of mortality and recurrent MI. Secondary prevention studies involved a range of interventions including different combinations of risk factor education, counseling and exercise components. There was no improvement in all cause mortality at 12 months post discharge in 20 trials of 9,462 patients (RR 0.97; 95%CI, 0.82-1.14); however there were statistically significant reductions in mortality at 24 months in six trials of 1,780 patients (RR 0.53; 95%CI, 0.35-0.81) and 60 months in seven trials of 2,477 patients (RR 0.77; 95%CI, 0.63-0.93). There was a statistically significant reduction in recurrent MI over a median of 24 months of followup: RR 0.83; 95%CI, 0.74-0.94.[15]

The second meta-analysis included 12 trials (9,803 patients with CHD) of multidisciplinary chronic disease management programs including various components of exercise rehabilitation, psychological support, health education phone and clinic visits, counseling, relaxation and stress management, medical and lifestyle advice and a personal health record with prompts. Patients randomised to these programs were more likely to be prescribed cholesterol lowering medication (RR 2.14; 95%CI, 1.92-2.38), beta-blockers (RR 1.19; 95%CI, 1.07-1.32) and antiplatelet agents (RR 1.07; 95%CI; 1.03-1.11) relative to those in the control groups.[16]

3.4 GP-based interventions to increase provision of secondary prevention care

There is no level one evidence on the effectiveness of secondary prevention interventions in stroke patients, and neither of the meta-analyses discussed above specifically evaluated the effectiveness of GP based interventions. Given that health care providers are an important source of preventative health information and the characteristics of general practice being amenable to the provision of secondary prevention care, a literature search was conducted to identify intervention studies undertaken within the general practice

setting shown to be effective in improving secondary prevention care for individuals with CHD or stroke.

The literature review was undertaken using health related electronic databases in the University of Newcastle library. Search terms included intervention studies, general practice, secondary prevention, CHD and stroke. Searches were limited to english language and full text with a ten year limit from the date of search. Additionally when studies were located the reference lists of each paper were interrogated to ensure that relevant studies had not been missed.

The review specifically sought to identify interventions designed to improve use of medications to treat high blood pressure, high cholesterol and AF; increase in routine prophylactic use of aspirin, and to increase advice about lifestyle risk factors such as physical inactivity, diet and smoking cessation. Eight relevant articles describing six different studies were identified. Details of the sample characteristics and sizes, country and length of followup of the various studies are provided in Table 3.1.

Table 3.1: Secondary prevention studies for CHD or Stroke in General Practice

Study	Recruitment rate	Follow up	Diagnosis/Age range	Countries	Sample sizes
Campbell[17] *Murchie[18]	68% 1 year followup 82% 4 year followup 91%	1 year 4 years	CHD under 80 yrs	Northeast Scotland	19 general practices, 1,343 patients (673 intervention and 670 control)
Cupples[19]	48%, followup 94%	2 years	Angina for at least six months under 75 yrs	Belfast	18 practices, 688 patients (342 education, 346 no education)
Feder[20]	95%, followup 78%	1 year	Myocardial Infarction or Unstable Angina Pectoris	East London	52 general practices, 328 patients admitted to hospital

Study	Recruitment rate	Follow up	Diagnosis/Age range	Countries	Sample sizes
Heller[21]	71%	6-months	suspected heart attack < 70 years	Newcastle, Australia	635 patients
Jolly[22, 23]	87% 90%	1 month, 4 months	MI, angina adults	Southampton and South-West Hampshire, England	67 practices, 597 patients
Moher[24]	Followup 75%	18 months	CHD 55-75 years	Warwickshire	21 general practices, 1,906 patients

* This study was a followup to Campbell et al.'s study

High intensity interventions used in four of the studies included nurse[17, 18] or specialised health worker[19] involvement in personalised health education and followup; practice audit and feedback; patient register and recall systems[24] and enhanced hospital-GP liaison.[22] Low intensity mail-out interventions were undertaken by two of the studies. Heller et al., evaluated a low cost mail out intervention consisting of a letter to GPs informing them of the benefit of secondary prevention and three mailed packages plus supplementary telephone contact by nurses to patients.[21] The POST study involved mailing patients general risk reduction information and a prompt for the patient to raise such information with their GP or practice nurse. In addition, this study also included a letter sent to the patient's GP reminding them about effective secondary prevention interventions and the existence of local CHD care guidelines.[20]

The outcomes in the studies included indicators of secondary prevention care, such as blood pressure management, cholesterol management, aspirin use, advice to quit smoking, exercise and follow a healthy diet. Such outcome measures were obtained at a variety of time points, including one and four months,[22] six months,[21] 12 months,[25 20] 12 months and 4 years,[18] 18 months[24] and two years after discharge.[19]

All studies reported that their interventions had some degree of effectiveness on study outcomes. Of the five studies that reported blood pressure management as an outcome measure, only the study by Campbell et al., reported a significant impact on care delivery. Blood pressure management in the Intervention group at one year followup was 96% versus 88% in the control group (OR 5.32; 95%CI, 3.01-9.41),[25] although this difference was not sustained four years after the intervention, with blood pressure management reported by 94% of the intervention group compared to 92% of the control group.[18]

Of the five studies that reported cholesterol management as an outcome measure, only one reported a significant intervention effect. In Campbell et al.'s study at one year followup 41% of the intervention group compared to 22% of the control group (OR 3.19; 95%CI, 2.39-4.26) reported a positive change in cholesterol lowering medication.[17] All other studies reported no significant differences.

Five studies investigated aspirin (or antiplatelet) use as an outcome measure, and only two demonstrated a significant difference between intervention groups. Campbell et al., reported a higher aspirin use in the intervention relative to control group at one year (OR 3.22; 95%CI, 2.15-4.80)[17] but not at four years followup 1.02 (0.71 to 1.47).[18] Prescription of antiplatelet drugs differed significantly (p-value 0.017) among the nurse recall (85%), the GP recall (80%) and audit groups (74%) in Moher et al.'s study.[24]

Of the three studies that reported GP advice regarding smoking cessation as an outcome measure, Feder et al.'s study reported more advice in the intervention group (68%) compared to control group (44%; OR 2.8; 95%CI, 1.1-6.8).[20] While there were no differences between intervention and control groups for other studies, smoking rates were generally low and thus small numbers may have been an issue.[17]

Only one study investigated GP advice regarding physical activity as an outcome and reported a significant intervention effect for this measure. Receipt of exercise advice was 30% in the intervention group versus 7% in the control group in Feder et al.'s study (OR 5.7; 95%CI, 2.0-16.3).[20]

Of the two studies that reported GP advice regarding diet as an outcome, both reported a significant difference in provision of such advice between intervention groups. Campbell et

al., reported significant differences in diet advice at one year followup (56% versus 49% for intervention and control groups respectively; OR=1.47; 95%CI; 1.10-1.96).[25] In the five year followup of this sample the effect was not sustained (OR 0.74; 95%CI, 0.5-1.02).[18] Feder et al.'s study reported provision of diet advice in 27% of the intervention group compared to the 14% in the control group; (OR 2.4; 95%CI, 1.2-4.7).[20]

The high intensity intervention studies demonstrated improvements in medication use and behavioural advice with the exception of smoking cessation advice.[17 19, 24] However in a followup of Campbell et al.'s study these results were not sustained five years later. This may be related to the effort required to remain in contact with patients to reinforce the messages of secondary prevention.[18] Some of the disadvantages of high intensity strategies are the cost of establishing and maintaining resource intensive interventions and the long term sustainability and the transferability to other locations.

In the two lower intensity interventions, while Heller et al.'s study did not demonstrate any improvements in care (only in quality of life), Feder et al.'s study of postal prompts did show marginal improvements in GP advice to patients to reduce risk factors.[20] Heller et al., suggest that the intensity of their intervention may have been too low to be effective.[21] Feder et al.'s intervention included a leaflet to patients recommending reducing risk factors and suggesting discussion with their GP. Generic information on recommendations for secondary prevention was sent to patients and GPs; the intervention was not specifically targeted to the patients' individual risk factors. The lower intensity interventions were effective in improving GP recording of risk factors and lifestyle advice but had no impact on patient behaviour or clinician prescribing behaviour.

3.5 Prevalence of GP provision of secondary prevention care to patients with CHD and Stroke

Despite the suggestion that general practice is an appropriate setting for the provision of secondary prevention care, and the evidence of such care can be effective in reducing the prevalence of preventable risks, a number of studies have reported that there is room for improvement in the delivery of such care by GPs.[9, 12, 25-33]

For example, a review of general practice records of 266 patients who survived a myocardial infarction in southern England demonstrated variable levels of secondary prevention care, with the provision of smoking cessation advice recorded for 75% of smokers and 42% of ex smokers. Fifty two percent (52%) of participants were given dietary advice and 53% exercise advice. Blood pressure lowering medication use was recorded by 39% of participants, with 55% taking a beta-blocker or angiotensin-converting enzyme inhibitors, and 18% taking cholesterol lowering medication.[26]

The need for enhanced provision of secondary prevention care is further demonstrated by a review of a random sample of medical records of 1,921 GP patients with CHD in the United Kingdom. The review demonstrated that 64% of patients were taking aspirin, 31% of the 414 patients with a myocardial infarction were taking beta-blockers and 40% of the 257 patients with heart failure were taking angiotensin-converting enzyme inhibitors.[34]

Aspirin use was reported by 57% of a sample of 722 patients with CHD who attended education sessions in primary care.[35] In another cross sectional study of 2,676 GP patients with high blood pressure only 71% recalled receiving lifestyle advice, with 60% receiving advice about weight.[36] In an observational study conducted in 603 GP patients with CVD, 45% of participants did not receive dietary advice while 67% were not receiving medication for high cholesterol.[37]

3.6 Predictors of provision of secondary prevention by GPs

Studies of secondary prevention care in other settings have indicated that factors such as diagnosis, length of stay in hospital, urban/rural location, gender and age can have an impact on care. Shorter length of stay has been suggested to reduce the opportunity to counsel inpatients about risk reduction.[1] Increased aspirin use has been reported to be associated with shorter length of stay.[38]

A study by Carroll et al., of CHD patients in general practice, reported more men than women were treated with aspirin and statins, even though women had higher cholesterol levels than men.[22] In a multivariable analysis the prescribing of angiotensin-converting enzyme inhibitors was higher with female gender and previous myocardial infarction.[39]

Males were more likely to be hospitalised for CHD than females, and hospitalization increased with age.[44]

Many studies have assessed the relationship between age and prescription of medications (particularly beta-blockers[39] and cholesterol lowering medication)[40, 41] and have reported that the more elderly patients often receive suboptimal care compared to their younger counterparts.

Significant predictors of medication prescription for adult outpatients from medical practice in the United States of America with diagnoses of coronary artery disease and/or congestive heart failure are reported to include diagnostic testing, younger age, history of myocardial infarction or coronary artery bypass grafting, high blood pressure, cardiology specialty, and geographic region. Patient age, diagnostic testing, and practice environment influence medication prescription for patients with CHD.[42]

Not all studies have reported a negative age bias, however and Silagy et al., reported that the rate of receiving lifestyle advice for improving diet and physical activity and reducing smoking was unaffected by age, marital status, or social class.[43]

3.7 Barriers to, and strategies to increase, GP delivery of secondary prevention care

Various studies have been conducted to determine barriers to the provision of secondary prevention care in patients in general practice. Reported barriers to provision of secondary prevention care include lack of institutional support[3, 4, 10, 21, 49, 50] and referral options,[44] time pressures[1, 2, 21] lack of training, [1, 24, 52, 53] little or no reimbursement for preventive care[12, 45, 46] and lack of patient interest.[52, 53, 55]

Further reasons for the gaps in secondary prevention care may in part be attributable to patients' failure to seek preventive services.[28] It has been noted by Campbell et al., that a comprehensive package of secondary prevention is a considerable undertaking for the elderly and patients with other health priorities.[47] In addition, patients suggest that a reason for not attending cardiac rehabilitation, a key component of secondary prevention care,[3] is a lack of referral from a physician.[1, 35, 51] Further, if communication between the

cardiologist (who has managed the patient in hospital) and the GP does not occur, the primary care physician may not continue with treatment commenced in hospital.[48]

Although GPs perceive that their role is to advise patients about high risk health behaviours, many express a lack of confidence in their ability to provide such care with the increased workload.[9, 17] GPs' provision of secondary prevention care has also been reported to be low as a consequence of a lack of knowledge regarding qualified professionals to whom they can refer patients for weight loss and physical activity programs.[49] Other reasons identified for non use of anticoagulants such as warfarin include the lack of confidence in the ability of the medication to prevent stroke, difficulty in managing anti-coagulant drug treatment and the notion that risk of harm from taking anticoagulants outweighs the benefit.[50]

Past research and theories of clinical practice change suggest that a number of factors may facilitate behaviour change among health care providers. For example, providing clinicians with performance-related feedback has been shown to be effective as a behaviour changing strategy,[51] particularly if the feedback is specific, personalised and immediate. A review of meta-analyses of interventions to improve physician performance in primary care settings in the United States has found that interventions which include multiple components such as education, prompts and reminders, audit and feedback, and guidelines yielded better results.[52] A meta analysis of 12 trials (9,803 patients with CHD) of multidisciplinary chronic disease management programs including a personal health record with prompts demonstrated that patients randomised to these programs were more likely to be prescribed pharmaceutical interventions relative to those in the control groups.[16] The use of clinical guidelines is one strategy intended to improve health care quality, rein in costs, and standardize medical practice.[53] As a consequence, it is suggested that if GP provision of secondary prevention care is to increase, strategies that address identified barriers to the provision of such care are required particularly those that involve change to general practice organizational conditions.[54]

3.8 Study Aims

The above review of the literature suggests that GPs occupy a position that is central to the provision of appropriate secondary prevention care to patients following their discharge from hospital after a CHD or stroke event. Despite this, there is evidence that there is room

for improvement in provision of secondary prevention by GPs. Although various studies have evaluated strategies to improve GP provision of secondary prevention care to patients with CHD or stroke, no such studies have been reported in the Australian setting. Given the differences in health care settings among countries, the effectiveness of secondary prevention strategies conducted elsewhere may not necessarily translate to the Australian environment. Therefore a study was undertaken to develop, implement and evaluate an intervention to improve GP provision of secondary prevention care to patients following their discharge from hospital with CHD or stroke.

The specific aim of this intervention study, known as Prevent Another Vascular Event (PAVE), was to test, using a randomized controlled trial design, the individual and combined effect of separate secondary prevention interventions sent via mail from a disease register to a patient and to their GP.

A secondary aim of this study was to describe factors associated with the appropriate use of medical therapy for high blood pressure and high cholesterol, the appropriate use of prophylactic aspirin and advice to use regular aspirin, and the receipt of lifestyle advice to take regular physical activity, cease smoking and follow a modified fat diet.[47]

3.9 Hypotheses

There are three primary hypotheses for the PAVE study.

3.9.1 GP Intervention

That patients of GPs who received a mailed intervention that involved feedback regarding the patient's risk factor status, credible risk reduction guidelines and identified local risk reduction referral options will report:

- 10% higher use of cholesterol lowering medication, blood pressure lowering medications and prophylactic aspirin;
- 10% higher rate of GP advice for behaviour on regular physical activity, and a modified fat diet; and
- 20% higher rate of advice on smoking cessation or nicotine replacement therapy six months post discharge,

relative to patients of GP's who did not receive the GP intervention (i.e. the 'no GP intervention' group).

3.9.2 Patient Intervention

That patients who received a mailed intervention that involved feedback regarding their risk factor status and receipt of secondary prevention care, guidelines regarding best practice secondary prevention care, and information regarding locally available lifestyle change programs will report:

- 10% higher use of cholesterol lowering medication, blood pressure lowering medications and prophylactic aspirin;
- 10% higher rate of GP advice for regular physical activity, and modified fat diet; and
- 20% higher rate of GP advice on smoking cessation or use of nicotine replacement therapy six months post discharge,

relative to those patients that did not receive the patient intervention (i.e. the 'no patient intervention' group).

3.9.3 GP and patient Intervention

That patients who received the patient intervention and whose GP's received the GP intervention will report:

- 15% higher use of cholesterol lowering medication, blood pressure lowering medications and prophylactic aspirin;
- 15% higher rate of GP advice on regular physical activity, and modified fat diet; and
- 25% higher rate of GP advice on smoking cessation or use of nicotine replacement therapy six months post discharge,

relative to those patients that did not receive the patient intervention and whose GP did not receive the GP intervention (i.e. the 'usual care' group).

3.9.4 Patient characteristics associated with provision of secondary prevention care

The secondary hypothesis is

that those patients who were provided with each of the elements of secondary prevention care were more likely to be male, younger (less than 59 years of age), to have a shorter length of stay in hospital (between zero (0) and three (3) days), or to have a specific CVD diagnosis relative to those not provided such secondary prevention care.

3.10 Methods

3.10.1 Design

A two by two factorial randomised controlled trial was considered the most appropriate study design as it would allow evaluation of the individual effect of the GP intervention, the patient intervention as well as the combined effect of these two interventions. Patients were assigned to one of four intervention groups based on the patient's stated GP. The four groups were: GP only intervention group, both GP and patient intervention group, patient only intervention group and a usual care group. The groups were combined as appropriate for evaluation of GP, patient and combined intervention effects.

3.10.2 Sample selection and patient recruitment

Patients for this study were recruited through the Hunter Area Heart and Stroke Register. This Register, described in Chapter Two, is a register of all patients discharged from hospital with heart disease or stroke in the Hunter region of New South Wales, Australia. It has been reported that development of registers is the first step in the process of improving outcomes in secondary prevention of CHD.[22] Individuals were eligible for inclusion in the PAVE study if they were discharged alive from one of 15 Hunter area hospitals, between August 2002 and August 2003, with CHD or ischaemic stroke as identified by one of the ICD-10 diagnostic or procedure codes.[55] These diagnoses were included as there is strong evidence that secondary prevention is beneficial to patients with CHD or ischaemic stroke.[56] For the purpose of analysis the codes of interest have been categorized into one of four diagnostic categories, shown in Table 3.2. Exclusion criteria were related to diagnoses where there is no evidence for the benefit of secondary prevention measures or where treatment would be contraindicated (for example, aspirin therapy following haemorrhagic stroke).

Table 3.2: ICD 10 Codes and Diagnostic Categories used in PAVE study

ICD 10	Diagnosis	Diagnosis Category
I20	Unstable Angina Pectoris	UAP
I21	Acute Myocardial Infarction	AMI
I22	Subsequent Myocardial Infarction	AMI
I23	Complications following Acute Myocardial Infarction	AMI
I24	Acute Ischaemic Heart Disease	IHD
I25	Chronic Ischaemic Heart Disease	IHD
38497, 385, 90201	Coronary Artery Bypass Surgery	IHD
353	Coronary Angioplasty	IHD
382, 59903	Coronary Angiography	IHD
I61	Intracerebral Haemorrhage (up to and including 161.4)	Stroke
I63	Cerebral Infarction (exclusive of I63.6 due to blood dyscrasia)	Stroke
I64	Stroke not specified as haemorrhage or infarction	Stroke
335	Carotid endarterectomy	Stroke
37215	Carotid stent	Stroke

Sources: Australian Bureau of Statistics 2004[55] World Health Organisation 2009[57]

Approximately two months following discharge from hospital, eligible patients with a first hospital admission for CHD or stroke since inception of the Register were mailed a study information package, which included a study information letter, an invitation to participate in PAVE and a secondary prevention survey, along with their initial contact/invitation to participate in the Hunter Area Heart and Stroke Register. Patients who had a prior hospital admission for CHD or stroke, who were already on the Register and who had agreed to being approached for future studies were sent a study information letter, survey and an invitation to be part of the PAVE study. The invitation included a request for the name of their GP and for permission to provide their GP with information from the Register. Refer to Appendix 3.1 for examples of all recruitment materials.

Prior to the mailing of the recruitment letters, information regarding the death of patients post discharge from hospital was obtained from the Australian Bureau of Statistics1 and the State Registry of Births, Deaths and Marriages2. The details of those patients who had died were removed from the list of eligible patients. Non-responding individuals were sent a reminder letter on three subsequent occasions, as per standard Register protocol.

3.10.3 Data collection procedures

The secondary prevention survey included baseline information on socio-demographic characteristics, medication use, risk status and lifestyle risk factor management provided by their GP and can be found in Appendix 3.2. The survey used was not a validated instrument. The Register had been using a survey purpose designed to collect information on risk factors prior to this study. To maintain continuity of this data collection for comparison over a longer timeframe the decision was made bys study investigators for this study to use this survey. Consideration was given to amendments, with none recommended.

Self report medications were assessed by way of an open ended question “Please list all the medications that you are currently taking. (Please copy the names as written on the container). Include herbal preparations and vitamins.” Medications were classified according to their primary actions, i.e. angiotensin-converting enzyme inhibitors, beta-blockers, calcium channel blockers, angiotensin II receptors, and other anti-hypertensive medications by project officers according to the Anatomical, Therapeutic, Chemical Classification System.[57]

Six months post randomisation, study participants were sent the same survey, but with additional items requesting information about GP advice for reducing risk factors and the current medications they were taking. Further information requested at six month followup for those patients receiving the intervention included specific information about the

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[1] *Australian Bureau of Statistics – National statistics*

[2] *State Registry of Births, Deaths and Marriages - The Births, Deaths and Marriages Registration Office is responsible for maintaining registers of births, deaths, marriages, changes of name, adoption of children and reassignments of sex that occur in Australia.*

acceptability of the intervention. The survey items relevant to the PAVE Study are summarised in Tables 3.3 and 3.4.

Table 3.3: Survey items on self report of risk factors and medication use and Aspirin advice

Question	Response
"Have you ever been told by a doctor that you had any of the following conditions?"	
"High blood pressure"	"yes" or "no"
"High cholesterol"	"yes" or "no"
"Atrial Fibrillation (irregular heartbeat)"	"yes" or "no"
Since your most recent hospital admission have you been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to take Aspirin on a regular basis, that is everyday or almost everyday?	"yes" or "no"
Are you currently taking Aspirin on a regular basis, that is every day or almost every day?	"yes" or "no"
Have you been told by a medical person (eg doctor, nurse) that you should not currently be taking Aspirin?	"yes" or "no"
Please list all the medications that you are currently taking. (Please copy the names as written on the container). Include herbal preparations and vitamins.	

Table 3.4: Survey items on self report of Behavioural risk and advice

Question	Response
Have you smoked more than 100 cigarettes in your entire life?	"yes" or "no"
Have you smoked any cigarettes in the last 6 months?	"yes" or "no"
Have you smoked any cigarettes in the last week?	"yes" or "no"
Since your hospital admission, in an average week, on how many days of the week would you do at least 30 minutes of physical activity? Physical activity can be walking, swimming, gentle cycling etc. Physical activity can be done in 2 lots of 15 minutes or 3 lots of 10 minutes each day	circle no. days 0 - 7 days
Since your hospital admission are you currently following a modified fat diet?	"yes" or "no"
If you have smoked in the last 6 months	
Since your admission to hospital have you been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to stop smoking?	"yes" or "no"

Question	Response
Since your admission to hospital have you been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to do any physical activity?	"yes" or "no"
Since your admission to hospital have you been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to follow a modified fat diet?	"yes" or "no"

3.10.4 Randomisation

Randomisation of patients to intervention groups was on the basis of patient nominated GP. Given that GPs could work in small or large practices and therefore have exposure to few or many patients with CHD or stroke, past details of nominated GPs obtained in a previous study was used to determine a potential number of study subjects per practice. Practices were then stratified into small or large practices for purposes of randomisation.

GPs are often employed in more than one practice, particularly part time GPs. To minimize the resultant risk of intervention contamination, clusters of practices were created to ensure that any GP in a cluster would be randomised to the same intervention group.

Clusters of GP practices were randomly assigned to one of the four intervention groups within six strata based on location (urban versus rural) and size (one, two to five, and greater than six study participants). The complete GP randomisation protocol is described in Appendix 3.3.

The randomisation code assigned to the GP cluster was generated by a computer program in an Access database operated by the research assistant. General practitioners, study participants and study investigators were all blind to the unit of randomization. The study project manager and research assistant were not blind to the GP cluster randomisation. Provision for GPs who may have left one practice of GPs and joined another practice within a different cluster was made in the randomization protocol. Study investigators were not notified of any breaches to the randomisation due to GPs moving practices.

General Practitioners were not formally recruited into the study as they were not required to provide any information directly or via medical records.

3.10.5 Intervention

The interventions were designed using evidence from the literature as outlined in section 3.4, and from behaviour theory.[54] The evidence suggested that high intensity interventions can be beneficial in improving secondary prevention, however there are concerns about the long term feasibility and sustainability of these. Lower intensity interventions demonstrated some degree of success but this was limited by their general rather than specific nature. The barriers reported in section 3.7 indicate that patient interest, GP confidence, and GP knowledge of referral options and tailoring by use of postal prompts could be successful in changing patient and clinician behaviour. Therefore the interventions in this study sought to provide secondary prevention information to patients and GPs tailored to the patients' reported risk. The interventions also provided national guidelines and a list of possible referral options for GPs to assist with management of risk factors.

The intervention included recommendations for the secondary prevention care based on responses from the baseline secondary prevention survey consolidated into a patient report card specifically designed for the study. The report card highlighted potentially untreated risk factors. The report cards are described in more detail below.

For those with a CHD diagnosis, the report card targeted risk factors included high blood pressure, high cholesterol, diabetes, physical inactivity, smoking, overweight; and information on cardiac rehabilitation attendance and aspirin/antiplatelet therapy was also provided. The stroke report card was similar to the CHD report card and included AF as a risk factor and excluded mention of rehabilitation.

Intervention materials were posted to the GP and/or patient depending on the patient's allocated intervention group. Patients allocated to the GP intervention group received no information and their GPs received the GP intervention package. Patients allocated to the GP and patient intervention group received the patient intervention package and their GPs received the GP intervention package. Patients in the patient intervention group received the patient intervention package and patients in the usual care group received no intervention from the study team. Table 3.5 describes the intervention components sent to each of the different intervention groups. Appendix 3.4 includes a copy of the letters and report cards for CHD and stroke patient groups.

To address a potential lack of knowledge about local opportunities to assist with risk factor management, a local resource/referral map was included in the patient and GP intervention packages (see Appendix 3.5). The maps were developed separately for urban and rural areas and listed services for diabetes care, dietitians, physical therapists, community based physical activities and exercise classes, for example, Heartmoves3, and smoking cessation help such as Quitline4

Table 3.5: Intervention Components by groups

	GP group	GP & patient group	Patient group	usual care group
Patient Report		Yes	Yes	
Patient Letter		Yes	Yes	
GP report	Yes	Yes		
GP Letter	Yes	Yes		
Resource Map	Yes	Yes	Yes	
Stroke Guideline	Yes	Yes		
Heart Guideline	Yes	Yes		

3.10.6 GP intervention

The GP intervention package included a letter, a tailored report card, a resource/referral map and relevant disease specific practice guidelines. The GP letter consisted of information outlining local current Register statistics regarding GP secondary prevention practices in the Hunter area, and informed the GP that their patient had consented to sharing his/her information with them. Information regarding performance incentive payments5 available for secondary prevention activities was also provided as part of the GP intervention package.

3 Heartmoves – Heartmoves is a low to moderate exercise program managed by the Heart Foundation

4 Quitline – Quitline is a confidential telephone service providing information, support and advice for quitting. A local call in Australia.

5 *Performance Incentive Payments – Enhanced Primary care items were recommended to GPs. The enhanced Primary Care program is a government program to provide more preventive care for*

The main focus of the patient's secondary prevention summary report card was to provide the GP with participants self reported responses (from the baseline survey results) and to highlight potential areas of concern. The report card referred GPs to a copy of disease specific guidelines that were also included in the package. Separate report card templates were used for CHD and stroke patients.

3.10.7 Patient intervention

The patient intervention package included a letter, a tailored patient report card and a resource map. The tailored patient report card provided a brief summary of risks that were important for secondary prevention, the study participant's reported risk factor status (based on his/her survey responses), the likely benefits of secondary prevention and current recommendations for risk reduction. The report card was formatted in such a way that where a study participant's self reported risk status was potentially problematic, a recommendation to discuss this with their GP was displayed. The report card emphasised the importance of the patient working with the GP to develop a risk reduction plan.

The letter summarised potential gaps in care, listing those areas that were identified in the accompanying report card, and included a recommendation that patients discuss secondary prevention care with their GP.

3.10.8 Guidelines for CHD and Stroke

Guidelines from the National Heart Foundation of Australia "Guide to risk reduction for patients with/or at risk of Cardiovascular Disease–2004"[58] were used as the basis for this study given their extensive development and endorsement for use in the Australian context.

No nationally accepted or endorsed guidelines for stroke were identified for use by Australian GPs at the time this study was undertaken. Given this, stroke guidelines for GPs were developed using a modified version of the National Heart Foundation CVD guideline. Consultation with appropriate bodies such as the National Health and Medical

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older Australians and improve coordination of care for people with chronic conditions and complex needs.

Research Council was undertaken to determine the information that should be included in reference to the management of AF. Local and national experts in the field were approached for comment and as a result the guideline was further modified to differentiate treatments for different types of stroke (ischaemic or haemorrhagic) (see Appendix 3.6).

3.10.9 Tailored report card recommendations

For each risk factor the patient's response from the baseline secondary prevention survey was inserted into a column on the report card. Depending on the patient's response a recommendation was made for secondary prevention care. A generic example for each of the risk factors that respond to medication intervention is reported in Table 3.6. Appendix 3.7 provides a copy of all responses and recommendations.

Table 3.6: Example of study participant response and recommendation for appropriate management

Response	Recommendation
a history of risk factor OR a history of risk factor and reported taking (listed medications here) OR no history of risk factor but reported taking (listed medications here) OR * no report of history of risk factor but reported taking (listed medications here) OR * no report of history of risk factor	Appropriate version for each of the possible responses was included here (Appendix 3.7 includes the links for each risk factor and the appropriate recommendations for each)

For each risk factor identified as treatable by medication such as high blood pressure, high cholesterol and AF, treatment by medications and behaviour change was recommended.

3.10.10 Pre-testing of intervention materials

Pre-testing of intervention materials was conducted with three focus groups: a group of patients participating in outpatient cardiac rehabilitation, a group of people attending a

diabetes education service and a group of patients attending a stroke recovery group. In total 48 people participated in the focus groups with an overall consent rate of 87%. Ages of participants ranged from 37 to 94 years, and 68% were male. See Appendix 3.8 for protocols and materials used during pre-testing.

The majority of focus group participants reported that they would have read the information (patient letter, report card and resource map) if it was sent to them in the mail. Most participants thought that there was sufficient information in the patient letter, report card and resource map, and the majority reported that the materials were easy to understand. Very few participants reported that there was too much information in the report card and few thought that there was too little information. A very small number of participants reported that the patient letter, resource map and the report card were difficult to understand. “Atrial Fibrillation” was identified as difficult to understand and subsequently a description was added to the information.

Most participants reported that the print size and colour of the letter, report card and map were suitable. All study participants were able to correctly report that the aim of the letter was to inform people how to prevent having another event. Pre-test participants were able to indicate that the purpose of the report card was to plan to improve health.

The only change therefore made to the intervention materials was to add further detail to the question on AF in the baseline secondary prevention survey.

3.10.11 Outcome measures

Two types of outcome measure were the focus of the study: self report of medications used and aspirin advice received, and receipt of advice for behavioural risk factors.

In terms of self reported medication use and aspirin advice, the measures were:

- The proportion of patients taking blood pressure lowering medication;
- The proportion of patients taking cholesterol lowering medication;
- The proportion of patients reporting having been advised to take regular aspirin;
- The proportion of patients reporting taking regular aspirin; and
- The proportion of patients with a history of AF taking warfarin.

In terms of self reported behavioural risk factor advice, the measures were;

- The proportion of current smokers who reported receiving GP advice to stop smoking;
- The proportion of patients reporting GP advice to undertake regular physical activity and;
- The proportion of patients reporting GP advice to follow a modified fat diet.

Baseline prevalence of risk factors such as high blood pressure, high cholesterol and AF are reported in this thesis to contextualize risk in this group of participants.

3.10.12 Process measures

For individuals who received the patient intervention, intervention acceptability was measured as part of the follow-up survey. For those in the GP intervention group and the usual care group a shortened version of the follow-up survey (see Appendix 3.9) was used without the process measure questions.

The follow-up questionnaire sent to participants who received the patient intervention included items that assessed the participant's recall of the intervention, receipt of the various intervention components, and the reported usefulness and acceptability of those components.

In particular, patients were asked to report if they remembered receiving the letter and information pack in the mail. Specific questions asked if the patient remembered receiving the report card, reading the information in the report card, whether they found the information useful, and easy to understand, whether they kept the report card or whether they took the report card to their doctor and if they left a copy of the report card with their doctor.

As previously described, a part of the intervention involved development of a resource map which highlighted local exercise programs, smoking cessation programs and dietary advice (refer to Appendix 3.5). Participants were asked if they remembered receiving the resource map and reading the included information, whether they found the information useful and easy to understand, whether they kept the resource map and whether they had

made contact with any of the services on the resource map. Open ended questions invited patients to make comments about the information mailed to them and asked them to describe which treatment or event had helped them the most.

General practitioners were not surveyed to determine their acceptability of the intervention. General practitioners were not recruited to the study and were approached by their patients or had information forwarded to them with their patients consent. Given that the general practitioner did not consent to take part in the study contacting them for their opinions would have been problematic. No comments or complaints were received by general practitioners throughout the study period.

3.11 Data management and statistical methods

Replies to the PAVE study surveys were entered into databases, created using Access.[59] Monitoring of progress and the target response rate were recorded on log sheets. Appendix 3.10 details the database process instructions.

To ensure that data entry remained consistent across each survey, a small sub sample was reviewed against coding manuals to determine accuracy of coding. This same sample was then double-entered by two research assistants and the inter-rater reliability compared using the Kappa statistic.

3.11.1 Data management

Date of birth was used to calculate age in years. Age was categorised into age groups of less than 59, 60 to 69, 70 to 79 and over 80 years of age. These age groups were chosen to reflect those who were younger, those in pre and post retirement phase and the elderly. Length of hospital stay was calculated by subtracting date of hospital admission from date of hospital discharge. These were also categorised into zero days, one to three days, four to six days and seven days or more. Length of stay was categorised in this way as a de-facto measure of disease severity.[1]

Given the range of diagnostic codes included, diagnoses were combined to form four discrete categories: Ischaemic Heart Disease (IHD), Unstable Angina Pectoris (UAP), Acute Myocardial Infarction (AMI) and Stroke. Status of admission to the Register was recorded as either new to the Register or previous admission to the Register. Height and

weight were used to calculate body mass index (BMI), calculated as weight in kilograms divided by height in metres squared and categorised as healthy weight (BMI up to and including 25) or overweight/obese (BMI greater than 25). These BMI cutpoints were derived from evidence of the association between BMI and mortality.[60]

Cardiovascular medications were classified according to their primary actions, i.e. as either blood pressure lowering or cholesterol lowering or anti-coagulant medications using the International Anatomical Therapeutic Chemical Classification System.[57]

Study subjects were asked to report by way of circling a number between zero (0) and seven (7), "on how many days of the week would you do at least 30 minutes of physical activity?" According to the National Heart Foundation guidelines sufficient physical activity is categorised as five or more days of the week.[58]Individual data were therefore categorised into sufficient (greater than or equal to five days per week) or insufficient (four or less days per week).

3.11.2 Data analysis

3.11.2.1 Sample characteristics

Characteristics of eligible individuals who agreed to participate in the study were compared with those who did not agree, using the chi-square test for categorical variables, and t-test (or the non-parametric rank sum test) for continuous variables. Descriptive baseline socio-demographic, clinical, risk factor, cardiovascular medication use, and CVD behavioural risk advice characteristics of those participants who received each particular intervention and those who did not are presented. As is standard practice for clinical trials no statistical tests were undertaken to compare baseline characteristics between intervention groups.

3.11.2.2 Effect of the Intervention

The outcomes of interest were the proportions of participants who reported the use of each cardiovascular medication category and the proportions who reported the receipt of advice regarding aspirin use, smoking cessation, physical activity and diet from their GP at the six month followup. Missing values were not included in the denominators in calculation of percentages.

Each outcome was compared between intervention and control group using the chi square test from the "survey" (svy) commands in Stata[61] which adjusts for the effect of clustering of patients within GPs. In addition the intervention effect was also assessed using logistic regression analyses (using the svy commands in Stata) which included intervention group and adjusted for baseline values of the outcome of interest. Main results are presented from chi-square tests, with odds ratios and 95% confidence intervals adjusted for baseline values of outcomes and for clustering of patients within GPs also reported. With the exception of smoking advice, the denominator in these analyses included all participants. For smoking advice, the denominator used was all smokers.

Separate analyses were conducted to assess the individual effects of the patient and GP interventions, and the combined effect of both interventions on each specific medication and behavioural risk advice outcome. To assess the individual effect of the patient intervention, all participants that received the intervention (i.e. participants in the patient group plus those in the GP and patient group) were compared to all participants that did not (i.e. participants in the GP group plus those in the usual care group). The effect of the GP intervention was similarly assessed. All study participants were included in both analyses.

To assess the combined effect of both the GP and patient interventions, participants who received both interventions (i.e. those in the GP and patient group) were compared to those who received neither intervention (i.e. those in the usual care group, thus involving a subset (approximately half) of all study participants).

3.11.2.3 Predictors

Multiple logistic regression was undertaken to examine patient characteristics associated with self reported medication use and self reported receipt of aspirin and behavioural risk advice. The variables of interest; gender, diagnosis, age group, length of hospital stay, and intervention group (ie GP group, GP and patient group, patient group and usual care group) were included in the initial model and backward stepwise methods were used to exclude variables. Analyses were adjusted for clustering of patients within GPs using the cluster option in Stata.[61] Variables were removed if they had a p-value greater than 0.10 for the Wald test.

3.11.3 Sample size

It was estimated that there would be approximately 2,250 patients per year recorded on the Register with discharge diagnoses codes of interest. Assuming a 65% consent rate (10% lower than current Register consent rates to allow some non-consent for provision of secondary prevention data), 1,460 patients were estimated to be recruited to the PAVE study during a twelve month period. Allowing for an 80% return rate at six month follow-up (including a 10% death rate) it was estimated that there would be approximately 1,170 patients for followup analysis. This would provide 580 participants who would receive a particular intervention, and 580 who would not, sample sizes sufficient to detect a 10% difference between intervention groups in cardiovascular medication use, advice to undertake regular physical activity and modify fat in the diet, and a 20% difference in quitting smoking, assuming 80% power, a 5% significance level and allowance of 30% for adjustment of confounders (10%) and clustering (20%). For the third primary hypotheses, the study would have 290 participants with both interventions and 290 with neither. This would allow detection of effect sizes of 15% for cardiovascular medication use, advice to undertake regular physical activity and modify fat in the diet, and a 25% effect size for smoking cessation, with 80% power, 5% significance level, 10% adjustment for confounders and 20% clustering effect. These effect sizes are based on similar numbers of patients with and without the outcomes of interest. Assuming that a maximum of 80% of study participants had the outcome of interest, a sample of 1,170 would allow detection of differences in characteristics of those with and without medication use and advice outcomes of interest of 12%, with 80% power, 5% significance level, 10% adjustment for confounders and 20% clustering effect.

It was expected that the effect of clustering of patients within GPs would be limited as the number of GPs was large and the number of patients per GP was expected to be small. For a six month period prior to the study, over 400 GPs were linked to Register participants, 50% of whom had between one and three patients admitted, and 80% of whom had less than 15 patients admitted. Assuming an average of five patients per GP, and an intra-class correlation coefficient of 0.05, the design effect was estimated to be 1.2.

3.11.4 Quality Assurance

A data entry check was performed on 122 randomly selected baseline surveys (approximately 10% of the study sample) for potential coding and data entry errors.

Overall, 233 (4.8%) potential coding problems (inconsistencies in the way 'skip' questions were answered) were noted in the 40 variables addressed by the 122 surveys (total possible data entry points 4,880). Ninety three percent (93%) of the 4,880 data entry points were coded correctly with the remaining 7% of the sample coded incorrectly (based on the coding manual rules).

The same random sample of 122 surveys was double entered and analysed using Stata[61] for inter-rater agreement using the Kappa statistic. The majority of variables had a Kappa agreement of 1.00, with other variables with a Kappa greater than 0.95 with the exception of exercise advice (Kappa 0.91) and smoking advice (Kappa 0.39). On manual examination of the smoking advice variable the observed proportion of agreement was 85%.

3.11.5 Project Advisory Group

A project advisory group was formed to oversee the development of the intervention materials. It included the chief executive officer or nominated representative from the urban and rural divisions of general practice, a neurologist, a rehabilitation specialist, a cardiologist, a senior area health director, study investigators, the project manager and consumer representatives from the Australian Cardiac Association and the Stroke Foundation.

3.11.6 Ethical approval

Ethical approval was granted on the 21st March 2001 by the University of Newcastle Human Research Ethics Committee and the Hunter Area Health service, Hunter Area Research Ethics Committee.

3.12 Sample and Recruitment Results

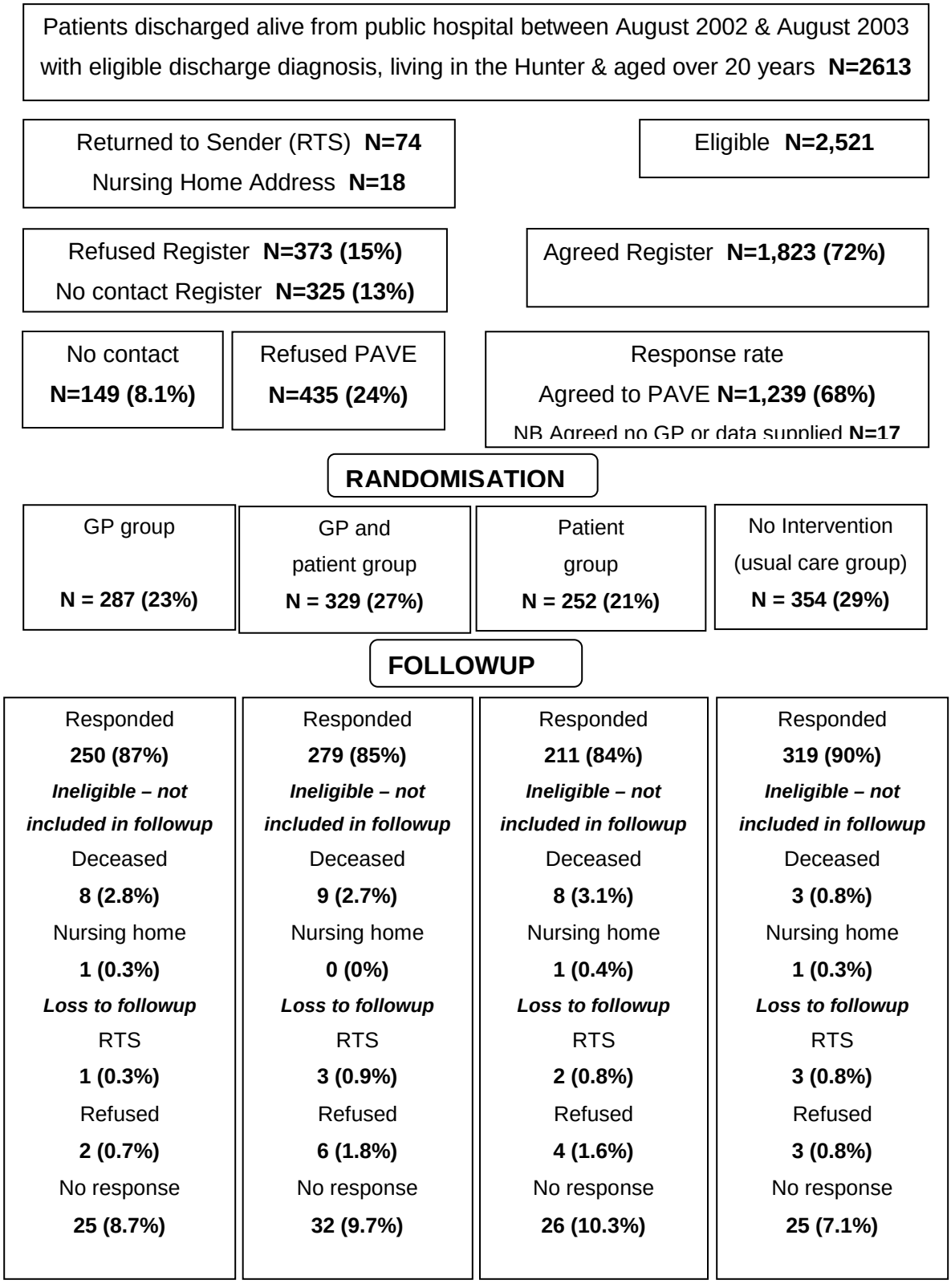
The sample and recruitment results, including response rates, baseline risk factor and socio-demographic characteristics are reported in the following section. Chapter Four details the effect of the intervention in terms of pharmaceutical management of risks, and Chapter Five details the effect of the intervention in terms of behavioural risk reduction advice.

3.12.1 Recruitment and consent

During the period of the study, 2,613 patients were discharged alive from a public hospital in the study region, who were residents of the region, and were over 20 years of age. Of these, 18 were living in a nursing home and were thus ineligible for the study. Of the remaining 2,595 individuals, 74 could not be contacted (mail was returned to sender). This left 2,521 individuals, from whom 1,823 (72%) agreed to have their details held by the Register, 1,239 of whom consented to participate in the study (68% of Register participants and 49% of eligible individuals). Randomisation of these patients based on their nominated GP cluster resulted in 23% (n=287) being allocated to the GP intervention group, 27% (n=329) to the GP and patient group, 21% (n=252) to the patient intervention group and 29% (n=354) to the usual care group (neither GP nor patient intervention).

For the purposes of assessing the effectiveness of the interventions, the four intervention groups were classified as receiving the GP intervention or not receiving the GP intervention (50% in each), receiving the patient intervention or not receiving the patient intervention (46% and 54% respectively) or in the GP and patient group or the usual care group (27% and 29% respectively).

Figure 3.1: Recruitment flow chart for PAVE study



In this study we used an estimate of 0.05 for the ICC and an average of 5 patients per GP which produced a design effect of 1.2. Results indicated that the average number of patients per GP was less, with an average of 3 patients per GP. Table 3.7 provides the design effects and ICC for each of the outcomes of interest. The design effects were less than 1.2 for all outcomes with the exception of aspirin advice (1.23) and exercise advice (1.24). Given that these design effects were only marginally greater than estimated, it is unlikely that clustering would have more than a trivial impact on power.

Table 3.7: Intracluster Correlation Coefficients

	Design effect	ICC
Blood pressure lowering medication	1.011958	0.005979
Cholesterol lowering medication	0.9408374	-0.029581
Aspirin use	0.9676196	-0.01619
Aspirin advice	1.230519	0.1152595
Anti-coagulant medication	0.9590304	-0.020485
Smoking cessation advice	1.237554	0.118777
Physical activity advice	1.094593	0.0472965
Modifying fat in the diet	0.9371259	-0.031437

Table 3.8 presents details on those who agreed to participate in the study and those who did not. Those who did not agree to participate were significantly more likely to be older and female, to have a longer length of stay in hospital and to have a diagnosis of stroke relative to non-consenters ($p<0.0001$ for age, length of stay, gender and diagnosis category).

Table 3.8: Characteristics of consenters and non-consenters for PAVE study

	consented to participate		test statistic		
	Yes	No	$\chi 2$	df	p-value
	N=1,239	N=1,282			
Age – years	**N=1,239**	**N=1,282**			
Mean (SD)	68.0 (0.33)	69.7 (0.39)	-3.29	2519	<0.001 **a**
Length of stay - days	**N=1,239**	**N=1,282**			
Median (min-max)	3 (1–6)	4 (1–7)	-3.44	2521	<0.0006 **b**
Gender	**N=1,239**	**N=1,282**			
Male	824 (67%)	700 (55%)			
Female	415 (33%)	582 (45%)	37.3	1	<0.001 **c**
Diagnosis	**N=1,236**	**N=1,280**			
AMI	313 (25%)	314 (25%)			
UAP	509 (41%)	516 (40%)			
IHD	235 (19%)	171 (13%)			
Stroke	179 (15%)	279 (22%)	31.2	3	<0.001 **c**

a students t-test b ranksum c chi square

AMI – Acute Myocardial Infarction

UAP – Unstable Angina Pectoris

IHD - Ischaemic Heart Disease

3.12.2 General Practitioners

Overall 151 practices and 356 different GPs were involved in the study. The number of participants seen by each GP was categorised into one study participant (n=129 GPs, 12%), two to five study participants (n=48 GPs, n=564 patients, 53%) or more than six study participants (n=179 GPs, n=365 patients, 33%). Overall there were 332 (31%) rural patients and 727 (69%) urban patients.

3.12.3 Time between agreement, intervention and followup

On average the time between discharge from hospital and agreement to be part of the PAVE study was 100 days (15 weeks). From date of consent to the PAVE study to when the intervention materials were mailed out, a median of two weeks elapsed. Completion of six month followup surveys was approximately one week after the survey was mailed to the study participant.

3.12.4 Six month followup data

Of the 1,239 study participants at baseline, 28 had died before follow-up (2.3%). Of the remaining participants, nine had their followup questionnaire 'returned to sender', 15 refused to provide data and 108 did not respond to contact. Thus 1,059 (85%) of initial participants provided baseline and follow-up data. The followup response rates varied from 84% to 90% between intervention groups. All subsequent analyses include only these 1,059 participants providing both baseline and followup data. See Figure 3.1 for recruitment and followup data.

3.12.5 Participant characteristics by receipt of GP intervention

Table 3.9a presents baseline characteristics of those participants who received the GP intervention compared with those who did not. Characteristics were similar for both intervention groups, except that the proportion participants receiving the GP intervention living in an urban location (72%) was higher than those not receiving the GP intervention (65%), although this difference was not large. The proportion of individuals in the GP intervention group with a diagnosis of stroke was minimally higher than in the no GP intervention group.

3.12.6 Participant characteristics by receipt of patient intervention

Diagnosis category, age, location, admission status, gender or length of stay were similar for study participants who received the patient intervention and those who did not (see Table 3.9b).

3.12.7 Participant characteristics for the GP and patient group compared to the usual care group

Characteristics of those in the GP and patient group compared to those who received usual care are also presented in Table 3.9c. Participants receiving both GP and patient interventions were similar to those receiving no intervention except that the combined intervention group appears to have more participants living in an urban location (75%) than the group receiving no intervention (64%). There also appeared to be a higher proportion of intervention than control participants who were new admission to the Register (72% versus 65% for intervention and control groups respectively).

Table 3.9a: Characteristics of study participants by GP intervention

	GP intervention N=529 (50%)	No GP intervention N=530 (50%)
	n (%)	n (%)
Diagnosis	**N=529**	**N=530**
AMI	135 (26%)	133 (25%)
UAP	220 (42%)	217 (41%)
IHD	88 (17%)	114 (22%)
Stroke	86 (16%)	66 (12%)
Age group	**N=529**	**N=530**
≤ 59 yrs	122 (23%)	126 (24%)
60 – 69	136 (26%)	145 (27%)
70 – 79	188 (36%)	187 (35%)
≥ 80 yrs	83 (16%)	72 (14%)
Length of stay	**N=529**	**N=530**
4 days or less	341 (64%)	349 (66%)
5 – 7 days	104 (20%)	95 (18%)
8 days or more	84 (16%)	86 (16%)
Location	**N=529**	**N=530**
Urban location	382 (72%)	345 (65%)
Admission status	**N=529**	**N=530**
New admission	369 (70%)	343 (65%)
Gender	**N=529**	**N=530**
Male	355 (67%)	350 (66%)

AMI – Acute Myocardial Infarction

UAP – Unstable Angina Pectoris

IHD - Ischaemic Heart Disease

Table 3.9b: Characteristics of study participants by patient intervention

	Patient intervention N=490 (46%)	No patient intervention N=569 (54%)
	n (%)	n (%)
Diagnosis	**N=490**	**N=569**
AMI	124 (25%)	144 (25%)
UAP	198 (40%)	239 (42%)
IHD	92 (19%)	110 (19%)
Stroke	76 (16%)	76 (14%)
Age group	**N=490**	**N=569**
≤ 59 yrs	105 (21%)	143 (25%)
60 – 69	134 (27%)	147 (26%)
70 – 79	182 (37%)	193 (34%)
≥ 80 yrs	69 (14%)	86 (15%)
Length of stay	**N=490**	**N=569**
4 days or less	320 (65%)	370 (65%)
5 – 7 days	93 (19%)	106 (19%)
8 days or more	77 (16%)	93 (16%)
Location	**N=490**	**N=569**
Urban location	348 (71%)	379 (67%)
Admission status	**N=490**	**N=569**
New admission	338 (69%)	374 (66%)
Gender	**N=490**	**N=569**
Male	335 (68%)	370 (65%)

AMI – Acute Myocardial Infarction

UAP – Unstable Angina Pectoris

IHD - Ischaemic Heart Disease

Table 3.9c: Characteristics of study participants by GP and patient group compared to the usual care group

	GP & patient group N=279 (47%)	**usual care group** N=319 (53%)
	n (%)	n (%)
Diagnosis	**N=279**	**N=319**
AMI	71 (25%)	80 (25%)
UAP	111 (40%)	130 (41%)
IHD	48 (17%)	70 (22%)
Stroke	49 (18%)	39 (12%)
Age group	**N=279**	**N=319**
≤ 59 yrs	59 (21%)	80 (25%)
60 – 69	70 (25%)	81 (25%)
70 – 79	106 (38%)	111 (35%)
≥ 80 yrs	44 (16%)	47 (15%)
Length of stay	**N=279**	**N=319**
4 days or less	176 (63%)	205 (64%)
5 – 7 days	58 (21%)	60 (19%)
8 days or more	45 (16%)	54 (17%)
Location	**N=279**	**N=319**
Urban location	208 (75%)	205 (64%)
Admission status	**N=279**	**N=319**
New admission	202 (72%)	207 (65%)
Gender	**N=279**	**N=319**
Male	194 (70%)	209 (66%)

AMI – Acute Myocardial Infarction

UAP – Unstable Angina Pectoris

IHD - Ischaemic Heart Disease

3.12.8 Intervention delivery

The following results are relevant to those participants in the patient intervention group and those in the GP and patient intervention group. Table 3.10 demonstrates participant feedback regarding the receipt and utilization of the patient report card and the resource map.

Three quarters of participants reported receiving the intervention pack, 61% stated that they received the report card, with most indicating that they had read, used and understood it. Less than 20% of participants reported taking the report card to their GP. While almost half of the participants reported receiving and using the resource map, only 11% contacted providers identified on the map.

Table 3.10: Intervention Process Measures

Intervention process	N	(%)
Received pack N=470	357	76%
Read report card N=430	262	61%
Used report card N=407	236	58%
Understood report card N=398	243	61%
Kept report card N=400	156	39%
Took report card to GP N=394	71	18%
Left report card copy with GP N=398	39	9.8%
Read Map N=402	201	50%
Used Map N=400	180	45%
Understood Map N=394	193	49%
Kept Map N=391	133	34%
Make contact with provider on Map N=391	43	11%

3.12.9 Baseline risk factors

At baseline 66% of the study participants in all intervention groups reported having ever been told they had high blood pressure (Table 3.11).

Overall 59% of patients reported at baseline that they had ever been told they have high cholesterol, and this was similar for all intervention groups, ranging between 57% and 60% (Table 3.11).

Between 27% and 32% of participants in each intervention group, approximately 30% of patients overall reported having AF at baseline. Of those reporting AF, 19% had a diagnosis of IHD, 45% a diagnosis of UAP, 19% AMI and 17% a diagnosis of stroke (Table 3.11).

Table 3.11: Self report of high blood pressure, high cholesterol and atrial fibrillation by groups at baseline

	GP intervention group N=529 (50%)	**No GP intervention group** N=530 (50%)
	n (%)	n (%)
High Blood Pressure	**N=529**	**N=520**
	350 (66%)	343 (66%)
High Cholesterol	**N=521**	**N=520**
	297 (57%)	312 (60%)
Atrial Fibrillation	**N=511**	**N=503**
	143 (28%)	161 (32%)

	Patient intervention group N=490 (46%)	No patient intervention group N=569 (54%)
	n (%)	n (%)
High Blood Pressure	**N=483**	**N=567**
	319 (66%)	374 (66%)
High Cholesterol	**N=481**	**N=559**
	279 (58%)	330 (59%)
Atrial Fibrillation	**N=476**	**N=553**
	138 (29%)	166 (30%)
	GP & patient group N=279 (47%)	**usual care group** N=319 (53%)
	n (%)	n (%)
High Blood Pressure	**N=277**	**N=314**
	183 (66%)	207 (66%)
High Cholesterol	**N=272**	**N=313**
	155 (57%)	188 (60%)
Atrial Fibrillation	**N=274**	**N=303**
	74 (27%)	97 (32%)

At baseline 39% of study subjects reported never smoking, 47% reported smoking previously but not in the last six months, while 7.4% reported having smoked in the last week. Table 3.11 presents the comparisons between groups for smoking in the last week and within the last six months. Slightly more participants in the GP intervention than the no GP intervention groups reported smoking in the last week, although the absolute difference was not large (9.0% compared to 5.8% for GP and no GP intervention groups respectively).

Approximately 50% of the study participants reported undertaking sufficient physical activity at baseline, and this was similar for all three group comparisons (see Table 3.12).

A high proportion of study participants (approximately 81%) reporting following a modified fat diet at baseline, and this was consistent across intervention groups (Table 3.11).

Table 3.12: Self report of smoking status, physical activity and diet by groups at baseline

	GP intervention group N=529 (50%)	**No GP intervention group** N=530 (50%)
	n (%)	n (%)
Smoking In last week	**N=522**	**N=517**
	47 (9.0%)	30 (5.8%)
Smoking in the last six months	**N=527**	**N=523**
	79 (15%)	68 (13%)
Physical activity (sufficient >=5 days per week)	**N=482**	**N=490**
	241 (50%)	240 (49%)
Following modified fat diet	**N=420**	**N=436**
	340 (81%)	353 (81%)

	Patient intervention group N=490 (46%)	No patient intervention group N=569 (54%)
	n (%)	n (%)
Smoking In last week	**N=484**	**N=560**
	30 (6.2%)	47 (8.4%)
Smoking in the last six months	**N=490**	**N=550**
	59 (12%)	88 (16%)
Physical activity (sufficient >=5 days per week)	**N=447**	**N=516**
	228 (51%)	253 (49%)
Following modified fat diet	**N=395**	**N=456**
	324 (82%)	369 (81%)
	GP & patient group N=279 (47%)	**usual care group** N=319 (53%)
	n (%)	n (%)
Smoking In last week	**N=278**	**N=314**
	22 (7.9%)	22 (7.0%)
Smoking in the last six months	**N=269**	**N=314**
	35 (13%)	44 (14%)
Physical activity (sufficient >=5 days per week)	**N=260**	**N=294**
	135 (52%)	147 (50%)
Following modified fat diet	**N=220**	**N=258**
	180 (82%)	209 (81%)

3.13 Discussion

Consent rates to the PAVE study were less than optimal, with 68% of those agreeing to the Register also agreeing to be part of the PAVE study, representing 49% of all patients discharged from hospital during the study period, August 2002 to August 2003. Similar studies of secondary prevention care have reported participation rates between 48% and 95%.[25, 27-30]

Low response rates are a problem in studies seeking to determine prevalence, as this may lead to potentially biased results if responders and non-responders differ. However, low response rates are less problematic in studies which evaluate the effect of an intervention, given that patients are randomised and then followed up over time. When conducted appropriately, randomised controlled trials have high internal validity. Thus while estimates of the prevalence of risk factors and of secondary prevention care need to be interpreted with caution, the low response rates should not have major implications for the interpretation of the effect of the intervention on the outcomes of interest.

As indicated above, individuals who did not agree to take part in the PAVE study were significantly more likely to be older and female, to have a longer length of stay in hospital and to have a diagnosis of stroke, relative to participants. It is possible that this reflects that non-consenters had poorer health status than consenters.[62] There were no other measures of general health status, disability or disease severity available to us so we are unable to examine this further. The implications of this are that risk factors may be worse and secondary prevention care potentially higher, for individuals not included in the study. These differences will not impact on the validity of the evaluation of the PAVE intervention, but may mean that the intervention effect could vary in a population which is different to that included in the PAVE study. For example, in a population with worse health status than those included in PAVE, the intervention may be more, or less, effective. Due to their strict eligibility criteria, a common criticism of randomised controlled trials is that the intervention impact is often diluted when applied to the general population.

A strength of the PAVE study was the high retention rate of patients at six month followup. Approximately 95% of patients were still available at six month followup, and of these 87% responded to the secondary prevention followup survey. These followup rates for the PAVE study were similar (75% - 95%)[19, 20, 22, 24] to other randomised controlled trials of

secondary prevention care. This high rate of retention and response of patients at six months suggests that the impact of loss to followup will be minimal.

The intervention groups were well balanced for all socio-demographic characteristics except for some minor differences in residence (urban versus rural) and type of admission (first admission versus having a prior admission). A greater proportion of individuals in the GP intervention and the combined GP and patient intervention group, relative to the control groups were living in an urban location. While the actual difference in urban location between intervention groups was not substantial (7% to 9%), the possible implication of this is that those in the GP group or the GP and patient group may have had better access to health services including GPs, given that these services are generally more difficult to access in rural areas.[63] Patients receiving the GP intervention may report more secondary prevention care than the no GP group because of this potential disparity in access to health care.

Additionally, participants in the combined GP and patient intervention group, relative to those who received usual care, appeared slightly more likely to be patients with a first registration on the Register rather than those with multiple admissions within the study period. Because the actual difference is less than 10% it is unlikely to have any major impact on the results.

Prevalence rates for high blood pressure at baseline were 66% across all intervention groups. Somewhat lower rates have been reported in CHD populations in other Australian settings (48% to 50%)[64, 65] and some international settings (41% to 56%).[36, 55, 73, 74] Although some previous research on secondary prevention in CHD and stroke patients, particularly the Asia Pacific, have reported higher rates (58% to 82%)[75-77] the majority of these studies used a different methodology, such as medical record review and hospital audit, which may impact on the prevalence estimates. Okurra et al., report there is little difference between self report and medical record data particularly for patients with hypertension. This study also suggested that the factors associated with agreement between self report and medical record data were being female, less than 65 years and having a higher education.[66] Since the average age for PAVE study participants was 68, and only one third were female, different methods of obtaining data could still be responsible for some of the variation in prevalence of high blood pressure among studies.

Future studies should beware of the limitations of self report of high blood pressure; it may be that the results of our study over or under estimate high blood pressure. Our question may have been ambiguous given it asked if they had ever been diagnosed with high blood pressure. Patients may have responded in the affirmative because they considered they had a diagnosis of hypertension when they may have had a short term condition with raised blood pressure that was resolved. Alternatively, this prevalence could even be an underestimate if patients believe that they no longer have hypertension because they are on treatment or they may be unaware that they have been diagnosed with hypertension.

The overall prevalence of self reported high cholesterol at baseline was approximately 60%. This falls within the range of results from international studies in patients with CHD. Estimates of the prevalence of high cholesterol appear far more variable than those for high blood pressure, with values ranging from 42% in Taiwan[67] to 75% in the United Kingdom[76, 81] to 99% in Japan[67]. Similar rates of 44% to 58% were reported by other European studies.[33, 55, 73, 74, 76] The prevalence of high cholesterol in stroke patients has been estimated at 51%.[65]. As for hypertension discussed above, validity and reliability may be of concern for self reported data.

The prevalence of AF in this study (30%) was higher than the Kalra et al., study.[30] While higher rates of AF are reported in older populations, the PAVE population was a relatively young group (average age 68 years) compared to Kalra et al.'s study, which had an average age of 76.4 years in females and 74.6 years in males, and would therefore be expected to have lower rates. In addition initial pre-testing of survey questions in this study suggested that the question on AF was not well understood. A further clarification was made to this item; the term "irregular heartbeat" was added to the question to clarify the meaning of atrial fibrillation. It is possible that this clarification resulted in higher rates being reported. Without further research or validation by electrocardiograph (ECG) it is impossible to know if PAVE results reflect the true rate of AF, or are an over estimation, given the lower rates reported elsewhere.

The PAVE study reported participants' smoking in the last week and in the last six months. The prevalence of smoking in the last week was less than 10% in all groups. Internationally, rates of smoking ranged between 10% and 27% in CHD patients.[13, 39, 55, 73-

[75] Higher rates were reported in two studies - between 23% and 64% in males and 0% and 25% in females in the Asia Pacific study[68] and 39% patients smoked at the beginning of a cardiac rehabilitation study.[69] Although Willich et al.'s study of cardiac rehabilitation patients reported initially high smoking rates at the start of the rehabilitation program, these were much less at the end of the program (5%) and 12 months (10%) after the program.[68, 69]

Current smoking was reported in 12% of individuals with heart disease in Australia in the 1995 National Health Survey.[64] In a National Health Survey of Australians conducted in 2001, the prevalence of smoking in individuals with a diagnosis of stroke was 18%.[65] These rates are slightly higher than the proportion of participants in the PAVE study reporting smoking in the past week (7.4%). Potential reasons for the range in smoking rates may be attributed to inconsistency of the wording of questions assessing smoking status. For example the timeframe for smoking, such as the last few days or last few weeks, could potentially yield different results. Additionally the length of time between the event and being asked may result in different rates being reported.

The prevalence of smoking in the last week was similar for the patient intervention group versus no patient intervention group; as well as for the GP and patient group versus usual care groups. Although the prevalence of smoking in the last week was slightly higher in the GP intervention group compared to the no GP intervention group, this difference was small and unlikely to be clinically important.

According to the National Heart Foundation of Australia recommendation of physical activity on five or more days of the week, half (50%) of the PAVE participants were insufficiently active at baseline, and this was similar for all intervention groups. Similar estimates of physical inactivity were noted in other studies of CHD patients with around 51% of individuals reporting little or no exercise.[34] Even lower rates were noted by Flanagan et al.'s cross-sectional study of 1,015 patients aged less than 75 years with documented CHD (11% to 17%).[35] In one Australian report on the 'Epidemic of coronary heart disease and its treatment in Australia', 58% of people with CHD were reported to be physically inactive,[64] while in the Australian National Health Survey of 2001, the prevalence of physical inactivity for patients with stroke was estimated to be 77%.[65] It is not surprising that physical inactivity may be higher in stroke than CHD patients as

residual effects of the stroke may limit the ability and confidence of people to be physically active. Additionally measurement of physical activity by self report can be difficult to interpret with people possibly perceiving incidental activity as negligible and underreporting physical activity or overstating their physical activity in an effort to please the researchers.[70]

Self report of following a modified fat diet was similar for all the intervention groups (approximately 80%). In a study by Campbell et al., 52% of 1,173 patients (685 men and 488 women) under 80 years with diagnoses of coronary heart disease reported that they ate more fat than recommended and only 47% reported that they ate fruit and vegetables at the recommended levels.[34] In an Australian stroke study report 'How we manage Stroke in Australia', 64% of individuals reported low vegetable consumption and 87% reported low fruit consumption.[65] The gold standard for assessing diet is the three day food diary.[71] We did not use food diaries to assess diet in the PAVE Study due to the intensive nature of this method of data collection. The use of a self report measure may have resulted in an under or over reporting of the amount of fruit and vegetables consumed and the fat content of a person's diet.

In summary, the estimated prevalence of baseline risk factors in the PAVE study is high, but generally similar to International and other national study results. Given this, the risk of another event remains high for PAVE respondents, a level of risk that provides an opportunity to develop and evaluate additional risk reduction interventions.

Intervention process measures were obtained from individuals in the patient group and GP and patient group. At six month followup approximately three quarters of those in the patient group remembered receiving the intervention, and more than half reported reading, understanding and using the report card. One of the important aspects of the intervention was the emphasis that the patient should take the report card to their GP. Less than one-fifth of the sample reported doing this. Similar process measures were reported for the resource map, with even fewer patients contacting the identified providers on the resource map. The finding of a limited discussion of the intervention materials with GPs, and limited utilisation of the referral programs listed on the map may have been a result of the timing of the distribution of this information. Given that the average time between recruitment and intervention mail-out was 15 weeks (almost four months), it may be that patients were well

into their recovery stage when they received the intervention package and perhaps less concerned about their health if no further events or complications had arisen during this time. Patients may have already discussed many secondary prevention issues with their GP, given that they are advised to make an appointment with their GP after discharge from hospital and this is very likely to have occurred prior to receipt of the intervention.

The following chapters report on the effects of the PAVE randomised controlled trial. Chapter Four reports on the results of the effect of the intervention on risk factors that can be treated with pharmaceutical agents and Chapter Five reports on the results of the intervention effectiveness in terms of GP provision of risk reduction advice.

3.14 References

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Chapter Four

Effectiveness of a register-based intervention on increasing general practitioner provision of secondary prevention care: Effect on medication use and advice

Tables

Chapter Four – Effectiveness of a register-based intervention on increasing general practitioner provision of secondary prevention care: Effect on medication use and advice

4.1 Introduction

Chapter Three reviewed the evidence regarding the effectiveness of interventions to increase general practitioner provision of secondary prevention care and outlined the rationale and methods for an intervention study designed to improve GP secondary prevention care (the PAVE Study). This chapter presents the study results of the PAVE study for the medication outcomes. Firstly, self reported medication use at baseline is reported, as is followup medication use. The extent of any differences in such use between intervention groups at followup is then presented. The chapter concludes with an analysis of patient characteristics associated with GP provision of medication treatment for risk factor management. Details of the rationale, methods, measures and the analytical approach that underpins this chapter are described in detail in Chapter Three.

4.2 Results

4.2.1 Baseline Self report of medication use and Aspirin advice

At baseline, 85% of participants reported using blood pressure lowering medication and this was similar for all intervention groups as shown in Table 4.1.

Self reported cholesterol lowering medication use was 73% at baseline. While this was similar for the patient intervention group (74%) and the no patient intervention group (72%), self reported use of cholesterol lowering medication was slightly higher in the no GP intervention group (76%) compared to the GP intervention group (69%) and the combined GP and patient intervention group (76%) versus the usual care group (71%) at baseline for cholesterol lowering medication. These results are shown in Table 4.1.

Baseline reported aspirin use was 80% overall and this was similar for all intervention groups (see Table 4.1).

At baseline 81% of participants reported receiving advice to take regular aspirin and this was similar for the GP intervention group (82%) and the no GP intervention group (81%) but slightly higher for the patient intervention group (84%) and the GP and patient intervention group (85%) relative to their respective comparison groups (79%) (see Table 4.1).

Self reported use of anticoagulant therapy at baseline was similar for all intervention groups, at around 10% (see Table 4.1).

Table 4.1: Self report of medication use and advice at baseline

	GP intervention group N=529 (50%)	**No GP intervention group** N=530 (50%)
Medication	n (%)	n (%)
Blood pressure lowering medication	**N=527**	**N=530**
	448 (85%)	457 (86%)
Cholesterol lowering medication	**N=529**	**N=530**
	367 (69%)	404 (76%)
Aspirin use	**N=512**	**N=521**
	430 (84%)	422 (81%)
Aspirin advice	**N=502**	**N=514**
	412 (82%)	416 (81%)
Anti-coagulant medication	**N=528**	**N=518**
	47 (8.9%)	57 (11%)

	Patient intervention group N=490 (46%)	**No patient intervention group** N=569 (54%)
Medication	n (%)	n (%)
Blood pressure lowering medication	**N=490**	**N=567**
	417 (85%)	488 (86%)
Cholesterol lowering medication	**N=489**	**N=568**
	362 (74%)	409 (72%)
Aspirin use	**N=478**	**N=562**
	397 (83%)	455 (81%)
Aspirin advice	**N=471**	**N=547**
	396 (84%)	432 (79%)
Anti-coagulant medication	**N=490**	**N=569**
	44 (8.9%)	60 (11%)
	GP and patient intervention group N=279 (47%)	**usual care group** N=319 (53%)
Medication	n (%)	n (%)
Blood pressure lowering medication	**N=279**	**N=319**
	232 (83%)	272 (85%)
Cholesterol lowering medication	**N=279**	**N=317**
	199 (71%)	241 (76%)
Aspirin use	**N=269**	**N=316**
	231 (86%)	256 (81%)
Aspirin advice	**N=267**	**N=313**
	227 (85%)	247 (79%)
Anti-coagulant medication	**N=279**	**N=309**
	21 (7.5%)	34 (11%)

4.2.2 Comparison of followup self report of medication use and Aspirin advice

At six month followup self reported blood pressure lowering medication use was 86%. There was no significant difference in the use of blood pressure lowering medication between the GP intervention group (85%) versus no GP intervention group (87%), the patient intervention group (85%) and the no patient intervention group (87%) or combined GP and patient intervention group (84%) compared with the usual care group (88%) at six month followup as shown in Table 4.2. Adjustment for baseline self report of blood pressure lowering medication also did not demonstrate any differences between intervention groups in six month self reported blood pressure lowering medication use.

Self reported cholesterol lowering medication use was 75% at six month followup. There was no statistically significant difference in this outcome for the patient intervention group (76%) versus the no patient intervention group (75%), the GP intervention group (73%) versus the no GP intervention group (77%) or the GP and patient intervention group (74%) compared to the usual care group (77%) (see Table 4.2). These results are confirmed after adjustment for baseline self report of cholesterol lowering medication.

Eighty-one percent (81%) of participants reported using aspirin at the six month followup. There were no statistically significant differences in self reported current aspirin use in the GP intervention group (79%) versus the no GP intervention group (80%), the patient intervention group (80%) versus the no patient intervention group (79%), or GP and patient intervention group (80%) versus usual care group (79%) at six month followup (see Table 4.2). The odds of self reported aspirin use adjusted for baseline values were similar for all three group comparisons.

At followup 89% of participants reported receiving advice to take regular aspirin. There were no significant differences in receipt of aspirin advice in the GP intervention group (90%) versus the no GP intervention group (87%), the patient intervention group (89%) versus the no patient intervention group (89%) or the GP and patient intervention group (90%) versus the usual care group (88%) (Table 4.2) on analyses which are unadjusted or adjusted for baseline aspirin use advice.

Eleven percent (11%) of patients reported taking anti-coagulant therapy at six month followup. There were no significant differences in the GP intervention group (10%) versus the no GP intervention group (12%), the patient intervention group (10%) versus the no patient intervention group (12%) or the GP and patient intervention group (8.6%) versus the usual care group (12%) for anticoagulant medication use at six month followup, as summarized in Table 4.2. Odds ratios for all three comparisons, adjusted for baseline self reported anti-coagulant therapy, were approximately one.

Table 4.2: Self report of medication use and Aspirin advice at six month followup

	GP intervention group N=529 (50%)	**No GP intervention group** N=530 (50%)	**test statistic**			
Medication	n (%)	n (%)	$\chi 2$	df	P-value	†Adjusted OR (95% CI)
Blood pressure lowering medication	**N=529** 450 (85%)	**N=530** 462 (87%)	0.98	1	0.32	0.8 (0.5-1.3)
Cholesterol lowering medication	**N=527** 385 (73%)	**N=530** 409 (77%)	2.72	1	0.09	1.0 (0.7-1.5)
Aspirin use	**N=515** 407 (79%)	**N=519** 415 (80%)	0.09	1	0.77	0.8 (0.5-1.2)
Aspirin advice	**N=516** 464 (90%)	**N=521** 453 (87%)	2.04	1	0.15	1.4 (0.9-2.4)
Anti-coagulant medication	**N=529** 53 (10%)	**N=530** 64 (12%)	1.14	1	0.29	0.9 (0.4-1.8)

	Patient intervention group N=490 (46%)	**No patient intervention Group** N=569 (54%)	**test statistic**			
Medication	n (%)	n (%)	$\chi 2$	df	P-value	†Adjusted OR (95% CI)
Blood pressure lowering medication	**N=488** 415 (85%)	**N=569** 497 (87%)	1.55	1	0.21	0.7 (0.4-1.1)
Cholesterol lowering medication	**N=487** 370 (76%)	**N=565** 424 (75%)	0.14	1	0.71	0.9 (0.7-1.4)
Aspirin use	**N=482** 386 (80%)	**N=552** 436 (79%)	0.96	1	0.32	1.0 (0.7-1.5)
Aspirin advice	**N=471** 419 (89%)	**N=560** 498 (89%)	0.009	1	0.93	0.7 (0.4-1.2)
Anti-coagulant medication	**N=490** 51 (10%)	**N=550** 66 (12%)	0.38	1	0.54	1.1 (0.5-2.3)

	GP and patient intervention group N=279 (47%)	**usual care group** N=319 (53%)	**test statistic**			
Medication	n (%)	n (%)	$\chi 2$	df	P-value	†Adjusted OR (95%CI)
Blood pressure lowering medication	**N=277** 233 (84%)	**N=318** 280 (88%)	2.22	1	0.14	0.6 (0.3-1.2)
Cholesterol lowering medication	**N=278** 206 (74%)	**N=318** 245 (77%)	0.70	1	0.40	0.9 (0.6-1.5)
Aspirin use	**N=275** 220 (80%)	**N=315** 249 (79%)	0.76	1	0.38	0.8 (0.5-1.4)
Aspirin advice	**N=271** 244 (90%)	**N=316** 278 (88%)	0.80	1	0.37	1.0 (0.5-1.9)
Anti-coagulant medication	**N=279** 24 (8.6%)	**N=308** 37 (12%)	1.46	1	0.23	0.9 (0.3-2.8)

† OR from logistic regression model adjusting for, baseline values of outcome and clustering of patients within GPs

4.2.3 Patient Characteristics associated with six month medication use and Aspirin advice

The variables included in the initial multivariable logistic regression analysis for all outcomes were gender, diagnosis, age, length of stay and intervention group. Due to the small numbers of patients reporting warfarin, there was no examination of factors associated with this outcome measure.

In logistic regression analysis, gender and intervention group were not statistically significantly associated with self reported blood pressure lowering medication use at followup (Table 4.3). Diagnosis, age group and length of stay were significantly associated with blood pressure medication use at followup. Compared to patients with a diagnosis of Ischaemic Heart Disease (IHD), the odds of patients with stroke reporting blood pressure lowering medication use at 6 month followup were significantly lower (OR 0.24; 95%CI, 0.12-0.44) (see Table 4.3). The odds of self reported use of blood pressure lowering medication was marginally higher for patients with UAP than those with IHD, but this was not significant at the 5% level (OR 0.59; 95%CI, 0.34-1.01).

Compared to patients with a length of stay less than 4 days, patients with a length of stay 5 – 7 days had a 1.9 times higher odds of receiving blood pressure lowering medication (OR 1.9; 95%CI, 1.1-3.2). Patients with a length of stay 8 days or more had a 1.8 times higher odds of reporting blood pressure lowering medication (OR 1.8; 95%CI, 0.99-3.2) compared to those with a length of stay less than four days (see Table 4.3), however this was only significant at the 10% level.

While patients aged between 70 and 79 years had 1.7 times higher odds of receiving medication for high blood pressure compared to those less than 59 years of age (OR 1.7; 95%CI, 0.99-2.8), this was not statistically significant at the 5% level (see Table 4.3).

Table 4.3: Results of multiple logistic regression to investigate factors associated with self reported Blood pressure lowering medication use

	Blood pressure lowering medication N=1,059					
				Wald test		
	OR	SE (OR)	95%CI	Z	df	P-value
Diagnosis						
IHD	1.0					
UAP	0.59	0.16	0.34, 1.01	-1.91	3	0.06
AMI	0.83	0.27	0.44, 1.6	-0.58	3	0.56
Stroke	0.24	0.07	0.12, 0.44	-4.47	3	< 0.001
Age group						
< = 59 years	1.0					
60 – 69 years	1.3	0.32	0.79, 2.1	1.03	3	0.30
70 – 79 years	1.7	0.44	0.99, 2.8	1.95	3	0.05
> 80 years	1.00	0.29	0.58, 1.8	0.03	3	0.98
Length of Stay						
Less than 4 days	1.0					
5 – 7 days	1.9	0.51	1.1, 3.2	2.35	2	0.02
More than 8 days	1.8	0.53	0.99, 3.2	1.96	2	0.05

For the outcome of cholesterol lowering medication, intervention group, length of stay and gender were not statistically significantly associated with self report of cholesterol lowering medication (see Table 4.4), while diagnosis and age group were associated with this outcome.

Compared to patients with a diagnosis of IHD, patients with a diagnosis of stroke had statistically significantly lower odds of self reported cholesterol lowering medication use (OR 0.23; 95%CI, 0.14-0.38). Patients with UAP had a 0.69 time the odds of reporting cholesterol lowering medication compared to those with IHD (OR 0.69; 95%CI, 0.47-1.03) (see Table 4.4) which was not significant at the 5% level.

Compared to patients aged less than or equal to 59 years, patients over 80 years of age had statistically significantly lower odds of reporting cholesterol lowering medication use (OR 0.34; 95%CI, 0.21-0.57) (see Table 4.4).

Table 4.4: Results of multiple logistic regression to investigate factors associated with self reported Cholesterol lowering medication use

	Cholesterol lowering medication N=1,059					
				Wald test		
	OR	SE (OR)	95%CI	Z	df	P-value
Diagnosis						
IHD	1.0					
UAP	0.69	0.14	0.47, 1.03	-1.78	3	0.07
AMI	1.2	0.31	0.75, 2.0	0.81	3	0.42
Stroke	0.23	0.06	0.14, 0.38	-5.79	3	< 0.001
Age group						
< = 59 years	1.0					
60 – 69 years	0.96	0.23	0.60, 1. 6	-0.15	3	0.88
70 – 79 years	0.95	0.20	0.62, 1.5	-0.23	3	0.82
> 80 years	0.34	0.09	0.21, 0.57	-4.26	3	< 0.001

Age and intervention group were not statistically significantly associated with six month self-reported aspirin use. Gender, length of stay and diagnosis were significantly associated with self reported aspirin use as summarised in Table 4.5. Compared to males, female patients had lower odds of reporting regular aspirin use (OR 0.60; 95%CI, 0.44-0.87). Compared to patients with IHD, patients with AMI had 1.8 times higher odds of reporting regular aspirin use (OR 1.8; 95%CI, 1.00-3.3) and patients with stroke had lower odds (OR 0.27; 95%CI, 0.19-0.56). Patients who were in hospital longer than eight days had 0.68 lower odds of report aspirin use than those with a length of stay less than four days (OR 0.68; 95%CI, 0.44-1.06) (see Table 4.5) which was only significant at the 10% level.

Table 4.5: Results of multiple logistic regression to investigate factors associated with self reported Aspirin use

Aspirin use N=1,037						
				Wald test		
	OR	SE (OR)	95%CI	Z	df	P-value
Gender						
male	1.0					
female	0.60	0.10	0.44, 0.87	-2.75	1	0.006
Diagnosis						
IHD	1.0					
UAP	0.94	0.24	0.60, 167	-0.12	3	0.91
AMI	1.8	0.55	1.00, 3.3	1.97	3	0.049
Stroke	0.27	0.09	0.19, 0.56	-4.02	3	<0.0001
Length of Stay						
Less than 4 days	1.0					
5 – 7 days	0.97	0.21	0.64, 1.5	-0.12	2	0.9
More than 8 days	0.68	0.15	0.44, 1.06	-1.66	2	0.09

Gender, diagnosis and length of stay were significantly associated with six month self reported aspirin advice, while intervention group and age were not significant (see Table 4.6). Compared with males, females had 0.57 times the odds of reporting aspirin advice (OR 0.57; 95%CI, 0.37-0.87). Relative to patients with IHD, patients with stroke had statistically significantly lower odds of reporting aspirin advice (OR 0.33; 95%CI, 0.17-0.63) (see Table 4.6). Patients who had a length of stay longer than eight days had significantly lower odds of having aspirin advice (OR 0.52; 95%CI, 0.32-0.87) (see Table 4.6).

Table 4.6: Results of multiple logistic regression to investigate factors associated with self reported Aspirin advice

Aspirin advice N=1,034						
				Wald test		
	OR	SE (OR)	95%CI	Z	df	P-value
Gender						
male	1.0					
female	0.57	0.12	0.37, 0.87	-2.62	1	0.009
Diagnosis						
IHD	1.0					
UAP	1.05	0.35	0.55, 2.0	0.16	3	0.87
AMI	1.4	0.52	0.66-2.9	0.87	3	0.38
Stroke	0.33	0.11	0.17, 0.63	-3.32	3	0.001
Length of Stay						
Less than 4 days	1.0					
5 – 7 days	0.77	0.21	0.45, 1.3	-0.91	2	0.36
More than 8 days	0.52	0.13	0.32, 0.87	-2.50	2	0.01

4.3 Discussion

The aim of the PAVE study was to determine if an intervention sent to GPs and/or patients would increase the delivery of secondary prevention care by GPs according to guidelines for secondary prevention of CHD or stroke. In summary, with respect to self reported medication use and aspirin advice the results suggest that the interventions were ineffective in increasing medication use or receipt of advice to take aspirin.

The PAVE study aimed to increase blood pressure lowering medication use by 10% in the GP and patient intervention groups and 15% in the combined GP and patient group compared to usual care groups. Self report of blood pressure lowering medication use was similar for all intervention groups at baseline (83% to 86%) and followup (84% to 88%). Baseline use of blood pressure lowering medication was higher than anticipated based on

previous data from the Hunter Area Heart and Stroke Register and other sources and may have limited the opportunity for further improvement following the intervention.[1, 2]

Several studies have reported proportions of use of blood pressure lowering medication in CHD patients, with large variation ranging from 20%[3-9] to 89%.[10-14] Proportions of blood pressure lowering medications in stroke patients are somewhat more consistent, ranging between 60%[15] and 86%.[1, 2] Blood pressure lowering medication use in the PAVE study was at the upper limit of previous research. Potential reasons for this include firstly, there may be high proportions of blood pressure lowering medication use in individuals attending a general practice that provides systematic blood pressure screening at every practice visit,[16] although there is no local information to support or refute this hypothesis.

Secondly, knowledge of disorders and treatments has increased over time, and guidelines for specific risk factors and for chronic disease management for CHD have become more easily accessible to general practitioners.[17] Initiatives such as the enhanced primary care program funded by the Australian government provides benefits which allow GPs to claim for provision of secondary prevention care using multidisciplinary care plans.[17] The Enhanced Primary Care (EPC) program provides more preventive care for older Australians and improves coordination of care for people with chronic conditions and complex care needs.[16] These initiatives are an example of activities that may have resulted in higher proportions of secondary prevention care currently being reported.[17]

Although the high reported use of blood pressure lowering medication at baseline limited the potential for an intervention effect, previous research has demonstrated improvements in blood pressure medication in other populations with high baseline use. Campbell et al.'s study reported baseline medication use of 87% and 88% in intervention and control groups respectively, with one year followup of 96% and 88% respectively (OR 5.32; 95%CI, 3.01-9.41).[13] Although there were some similarities to the aims of the PAVE study, the more intensive methodologies used in these studies may explain why these interventions were more effective than PAVE. Campbell et al.'s study used nurses to successfully deliver secondary prevention advice while the PAVE study mailed a tailored report card.

We anticipated a 10% increase in the use of cholesterol lowering medication in the GP intervention group and in the patient intervention group, and a 15% increase in the

combined GP and patient intervention group compared to the usual care groups. At baseline, reported proportions of cholesterol lowering medication were approximately 73%, and at six month followup around 75%. These values are in the upper range of estimates from international studies, where there was wide variation from 18%[3, 5-8, 10, 11, 13, 18] to 87%[19] similar to that found for blood pressure lowering medication use. As for blood pressure lowering medication, estimates for medication treatment of cholesterol varied less for stroke than CHD patients, with estimates ranging between 17%[2, 20] and 42%.[1]

PAVE and the baseline prevalence proportions reported in the Hunter Secondary Prevention study in Chapter 2 were both higher than expected. The reasons why patients with CHD in this study reported higher proportions of cholesterol medication use than previously reported have not been explored in this study. However this may reflect the results of major clinical trials demonstrating a benefit for patients with CHD taking cholesterol lowering medication.[21-23]

Significantly lower proportions in baseline cholesterol lowering medication were demonstrated in the GP intervention group (69%) relative to the no GP intervention group (76%). In addition, while followup proportions were similar in the two groups, there was no change over time in medication use in any of the groups.

In regard to cholesterol lowering medication there is still potential for improvement in this outcome. The higher baseline proportions of cholesterol lowering medication reported in the PAVE study relative to other studies could be related to the cut points used to detect and diagnose high cholesterol.[24] It may be that patients in this study with no recorded cholesterol levels, or levels that were not high based on objective cut points for treatment were not treated. Different cut points used for diagnosis of abnormal cholesterol compared with treatment cut points in people with existing heart disease may also explain some of the differences between the International literature and the PAVE study data.[25]

Previous studies undertaken to improve management of cholesterol have had mixed success. Campbell et al.'s more intensive intervention using nurses to deliver secondary prevention care demonstrated an improvement in cholesterol management (baseline 12%, one year followup 41% in the intervention group compared to 14% and 22% in the control group for baseline and followup respectively, OR 3.19; 95%CI, 2.39-4.26).[13] Similarly in a

meta analysis conducted using a total of 12 trials (9,803 patients with CHD) focusing on the impacts on processes of care in disease management programs, patients randomised to these programs were more likely to be prescribed cholesterol lowering drugs than those in the comparison group, (RR 2.14; 95%CI, 1.92-2.38).[26] These studies demonstrate that more intensive interventions, such as nurse led clinics, can be used to successfully deliver secondary prevention care although in relation to the PAVE study delivery of care was different to these studies possibly explaining the null result in the PAVE study.

Feder et al., conducted a randomised controlled trial in 52 general practices in east London to determine whether postal prompts to patients who have survived an acute coronary event and to their general practitioners improved prescribing of cholesterol lowering drugs and reported no difference between intervention and control groups (intervention 28%, control 19%, OR 1.7; 95%CI, 0.8-3.4, p>0.05) at six month followup.[27] It is important to note that Feder et al.'s study did not recruit the targeted sample and may have been underpowered to detect a difference. This study used a methodology very similar to the PAVE study with the intervention consisting of a postal prompt recommending that patients discuss issues with their GP. Therefore it would seem that postal prompts are not effective in terms of cholesterol medication and other, more intensive interventions such as nurse led clinics, should be used to enhance the prescription of lipid lowering medications to reduce high cholesterol levels.

Aspirin use was reported by 80% of patients at baseline, with similar use among all intervention groups. No significant differences were observed at six month followup (average 81%) between any of the groups. The prevalence of aspirin use has been reported in International studies to range between 56%[3, 9, 11, 13-15, 28-31] and 88%.[5 1, 4, 7, 8] The PAVE study reported aspirin proportions at the higher end of the spectrum of International results. Despite this, there is still potential for improvement: secondary prevention guidelines recommend that "Daily aspirin of 75 to 325 mg/d be prescribed if not contraindicated. If aspirin/warfarin is contraindicated clopidogrel 75 mg per day should be considered".[32]

There have been some interventions which have successfully increased the use of aspirin in secondary prevention for patients with CHD and stroke. In a meta analysis conducted using a total of 12 trials (9,803 patients with CHD), patients allocated to interventions that

involved mainly intensive nurse led clinics were more likely to be prescribed antiplatelet agents than those not allocated to intervention groups (RR 1.07; 95%CI, 1.03-1.11).[26] For example, Campbell et al., reported significant improvements in aspirin management following a nurse led clinic of secondary prevention care (baseline 69%, one year followup 81% compared to 63% and 66% for baseline and followup respectively in the comparison groups, (OR 3.22; 95%CI, 2.15-4.80).[13] Moher et al., demonstrated that prescribing of antiplatelet drugs was higher in a nurse recall group (85%) than in GP recall or audit groups (80%, 74% respectively).[33]

On the other hand, there was no improvement in Aspirin use associated with CHD patients in a randomised controlled trial of postal prompts containing recommendations for lowering risk of another coronary event sent to patients after discharge from hospital in general practice in East London (followup Aspirin use was 90% in the intervention group and 91% in the control group at 12 months).[27] An earlier study of Heller et al.'s using a low cost mail out program for intervention groups of patients aged less than 70 years, admitted to hospitals in and around Newcastle, Australia with a suspected heart attack demonstrated no intervention effect on receipt of aspirin with 67% of the intervention group and 71% of the control reporting aspirin use at followup.[34] Jolly and colleagues undertook a randomized controlled trial to assess the effectiveness of a nurse-led programme to ensure that follow-up care is provided in general practice after hospital diagnosis of myocardial infarction or angina pectoris. Levels of prescribing of preventive medication were similar in both intervention (77%) and control groups (74%) at followup.[35]

The studies which demonstrated an effective intervention were all using a nurse to deliver the intervention; while those which did not show an intervention effect, had either a similar population to that of the PAVE study and/or a similar intervention for example, the use of postal prompts. Therefore, when planning future studies to intervene to reduce recurrent cardiovascular disease risk, this study recommends that postal prompts should not be used in preference to nurse led clinics, however there is no evidence that postal prompts in synergy with nurse led clinics, would not be a suitable intervention for this at risk population.

At baseline 81% of participants reported receiving aspirin advice and this had increased to 89% at followup. A significant difference was seen between the patient intervention group

and the no patient intervention groups and the GP and patient intervention group compared to the usual care group at baseline however this disappeared at six month followup. A similar report of aspirin advice was reported by Brown et al., in their study with 81% reporting advice to take aspirin.[30] Given that an initial response to increase aspirin was noted in the patient intervention group using this single postal prompt it could be suggested that the effect may have been sustained if further interventions using either postal prompts or nurse led clinic appointments were considered for this intervention.

Anti-coagulant medication (warfarin) use was reported by 9.8% of patients at baseline and 11% at six month followup. There were no significant differences between groups at either baseline or six month followup in any of the three groups. The observed prevalence proportions are consistent with national reported proportions of warfarin use in Australian stroke patients (10.3%).[2] European studies have demonstrated higher proportions of warfarin use ranging from 6.9%[7, 8] to 45% in patients with AF.[15] In another specialized stroke clinic warfarin was reported by 25% of the sample at baseline with a reduction to 20% two years later at followup.[1]

Low proportions of warfarin use in the PAVE study could be attributed to GPs being reticent to commence or continue warfarin therapy with patients due to the potential risks of excess bleeding[36] or due to the intensity of monitoring required with regular blood testing of the International Normalised Ratio to titrate the drug to safe therapeutic levels.[37]

A secondary hypothesis of this study was to determine which patient characteristics may be associated with the self reported medication use and aspirin use advice as discussed above. Potential explanatory factors were chosen based on known biological relationships and on previous literature and included age, gender, diagnosis and length of hospital stay. Factors associated with the use of anti-coagulation therapy were not explored due to the small numbers of patients reporting anti-coagulation therapy to manage AF.

Diagnostic category was associated with all outcomes, with stroke patients having statistically significantly lower odds of blood pressure lowering medication (OR 0.24; 95%CI, 0.12-0.44), cholesterol lowering medication (OR 0.23; 95%CI, 0.14-0.38) aspirin use (OR 0.27; 95%CI, 0.19-0.56) or aspirin advice (OR 0.33; 95%CI, 0.17-0.63) than IHD patients (the reference group). The UAP group had marginally non significantly lower odds

of self reported medication use for high blood pressure and high cholesterol (OR 0.69; 95%CI, 0.47-1.03), while patients with AMI had significantly higher odds of aspirin use (OR 1.8; 95%CI, 1.00-3.3) than the reference group. These associations likely reflect the strength of evidence for secondary prevention for different medications across the different diagnostic groups.[21, 38-40] In general the evidence for the effectiveness of medication use is not as strong for stroke patients as for those with CHD. Girot et.al., has also demonstrated variation in secondary prevention care among different diagnostic groups. They reported that inappropriate management of risk factors was more frequent in patients with angina pectoris than myocardial infarction.[41]

Age was associated with self reported blood pressure and cholesterol lowering medication use; although there was no consistent relationship. Patients 70 to 79 years of age had higher odds of blood pressure medication relative to those aged 59 years or less (OR 1.7; 95%CI, 0.99-2.8). Patients over 80 years of age (OR 0.34; 95%CI, 0.21-0.57) had reduced odds of reporting cholesterol lowering medication compared to those less than 59 years of age. In a study by Majumdar et al., older patients and younger patients were both less likely to report cholesterol lowering medication relative to those in middle age.[42] Bandyopadhvay et al., found that older patients from secondary prevention of CVD trials were less likely to receive treatment or interventions than younger patients.[43] Advancing age may be perceived to be a barrier to survival and therefore prescription of any medication, including Statins and blood pressure lowering medication, to treat CHD or stroke risk may decline with increasing age.[44]

Increasing length of stay was generally associated with a higher odds of self-reported use of blood pressure lowering medication (five to seven days: OR 1.9; 95%CI, 1.1-3.2, eight days or more: (OR 1.8; 95%CI, 0.99-3.2) and a lower odds of aspirin use (OR 068; 95%CI, 0.44-1.06) and receipt of advice to take aspirin (OR 0.52; 95%CI, 0.32-0.87), although aspirin use was only significant at the 10% level and for the longest length of stay group. It is possible that length of stay is a marker for severity and/or comorbidity. An admission of more than eight days may reflect patients with more complex care needs, co-morbidity and chronic disease and those potentially more at risk of adverse side effects such as bleeding from aspirin.[45]

Females had significantly lower odds of self reported aspirin use (OR 0.60; 95%CI, 0.44-0.87) and advice to take aspirin relative to males (OR 0.57; 95%CI, 0.37-0.87). Although age was not statistically significantly associated with aspirin use, there is a tendency for females in the population with cardiovascular disease to be older than males; as above older patients are more likely to have chronic conditions, complex care needs and to be at a higher risk of bleeding.[45]

In terms of the association between patient characteristics and reported medication use, it is clear that secondary prevention care could be improved and should be directed at specific groups of patients where care is currently less than optimal, recognizing that this study did not explore the reason for these differences. Specifically secondary prevention care could be improved for females who had lower odds of reporting aspirin use or aspirin advice than males, the elderly where patients aged over 80 years had lower odds of reporting cholesterol lowering medication than those less than 59 years of age, and those with stroke who had lower odds of reporting blood pressure lowering medication, cholesterol lowering medication and aspirin use or aspirin advice compared to those with IHD. Patients with a length of stay in hospital of more than eight days had lower odds of reporting either aspirin use or aspirin advice compared to those having a length of stay of less than four days. Factors potentially associated with outcomes of interest were limited in PAVE to those available from patient self report and excluded objective and clinical measures which may have been important.

Reasons for less than optimal provision of care to females, those over 80 years of age, those with a diagnosis of stroke and those with a length of stay longer than eight days needs to be explored further and could potentially be used to explain and reduce barriers to appropriate care provision. One of the potential disparities in secondary prevention care in relation to diagnosis may be explained in part by access to rehabilitation and delivery of the prevention message. Patients with CHD who have access to cardiac rehabilitation undergo sessions where the preventative message is delivered as a core component. Patients with a diagnosis of stroke undergoing rehabilitation may have a greater focus on physical recovery and management of deficits as opposed to prevention of recurrent events.

There were limitations in the study recruitment and delivery of the intervention which will be discussed in detail in Chapter Six as they are relevant to both the results in this chapter and the following chapter.

4.4 Conclusion

The key finding of this study is that the tailored intervention delivered via a specific disease register failed to increase self-reported secondary care in terms of the appropriate use of medical therapy to manage the risk factors of high blood pressure, high cholesterol, and AF in a secondary prevention setting for people immediately following hospitalisation for CHD or stroke. The study also failed to report an increase in aspirin use or aspirin advice. None of the hypothesised effect sizes were reached for any of the primary medication use outcomes in this study, suggesting that this intervention to increase secondary prevention care was not successful.

Another key finding is that baseline secondary prevention care from hospital discharge and early post discharge is relatively good. Proportions of reported medication use for high blood pressure and high cholesterol were higher at baseline than expected, indicating good quality of care at and following hospital discharge, and demonstrating a limited opportunity to improve secondary prevention care. These high proportions may be explained by an increasing trend over time in regard to provision of ACE inhibitors and statins as prophylactic treatment of CVD regardless of a history of individual risk factors.[32, 46]

The findings also suggest that the elderly and people following stroke receive less than optimal secondary prevention care for reasons that cannot be explained from this work.

4.5 References

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Chapter Five

Effectiveness of a register-based intervention on increasing general practitioner provision of secondary prevention care: Effect on behavioural risk advice

Tables

Chapter Five - Effectiveness of a register-based intervention on increasing general practitioner provision of secondary prevention care: Effect on behavioural risk advice

5.1 Introduction

The previous chapter presented results of the evaluation of the effectiveness of the PAVE study interventions on medication use outcomes. The aim of this chapter is to describe the effectiveness of the PAVE study interventions on general practitioner provision of behavioural risk advice regarding smoking cessation, increasing physical activity and modifying fat in the diet. This chapter firstly describes the proportion of participants who reported receiving advice for behavioural risk factors at baseline and then describes the proportion who reported receiving advice for behavioural risk factors at six-month follow up. Differences in proportions between intervention groups at follow up are described. A secondary aim of the chapter is to determine the extent to which patient characteristics were associated with general practitioner provision of such behaviour risk reduction advice. Details of the rationale, methods, measures and the analytical approach that underpin this chapter are described in Chapter 3.

5.2 Results

5.2.1 Baseline Self Report of behavioural risk advice

At baseline 90% of participants reported having received advice for smoking cessation and this did not differ between groups (Table 5.1). The prevalence of self-reported receipt of advice for physical activity was 78% at baseline and this was similar for all intervention groups. At baseline, 67% of participants reported having received advice to follow a modified fat diet, and this was reasonably consistent across groups, varying from 65% to 70%.

Table 5.1: Self report of behaviour risk advice at baseline

	GP intervention group 529 (50%)	**No GP intervention group** 530 (50%)
	n (%)	n (%)
#Smoking cessation advice	**N=78**	**N=65**
	73 (94%)	56 (86%)
Physical activity advice	**N=501**	**N=505**
	391 (78%)	389 (77%)
Modifying fat in the diet	**N=421**	**N=437**
	295 (70%)	284 (65%)
	Patient intervention group 490 (46%)	**No patient intervention group** 569 (54%)
	n (%)	n (%)
#Smoking cessation advice	**N=57**	**N=86**
	51 (89%)	78 (91%)
Physical activity advice	**N=462**	**N=539**
	370 (80%)	410 (76%)
Modifying fat in the diet	**N=394**	**N=464**
	268 (68%)	311 (67%)

	GP & patient intervention group 279 (47%)	**usual care group** 319 (53%)
	n (%)	n (%)
#Smoking cessation advice	**N=34**	**N=42**
	32 (94%)	37 (88%)
Physical activity advice	**N=265**	**N=308**
	212 (80%)	231 (75%)
Modifying fat in the diet	**N=220**	**N=262**
	154 (70%)	170 (65%)

self reported smokers only

5.2.2 Comparison of follow up self report of behavioural risk advice

At six month follow up 92% of smokers reported receiving smoking cessation advice. There were no statistically significant differences in self reported receipt of smoking cessation advice between the GP intervention and the no GP intervention groups, between the patient intervention and no patient intervention groups, or between the GP and patient intervention group and the usual care group at six month follow-up (Table 5.2) adjusted ORs were similar for all group comparisons.

Overall prevalence of receipt of physical activity advice was 83% at six-month follow up. A statistically significantly higher proportion of participants in the patient intervention group, relative to the no patient intervention group reported receiving such advice (patient intervention 86%, no patient intervention 81%, p=0.04). However after adjustment for baseline values of receipt of physical activity advice, there was no statistically significant difference in six month outcomes (adjusted OR 0.7; 95%CI, 0.5-1.2). There was no significant difference in other group comparisons in the reported receipt of such advice (Table 5.2) unadjusted or adjusted for baseline values.

At six month follow up 80% of all participants reported being advised to follow a modified fat diet. There were no statistically significant difference in self reported receipt of dietary advice for all group comparisons (Table 5.2) as demonstrated by chi-square test and adjusted odds ratios.

Table 5.2: Self report of behavioural risk advice at six month follow up

	GP intervention group 529 (50%)	**No GP intervention group** 530 (50%)			**test statistic**	
	n (%)	n (%)	$\chi 2$	df	P-value	†Adjusted OR 95%CI)
#Smoking cessation advice	**N=56** 53 (95%)	**N=50** 44 (88%)	1.50	1	0.22	2.0 (0.5-8.8)
Physical activity advice	**N=511** 429 (84%)	**N=518** 430 (83%)	0.38	1	0.54	1.0 (0.7-1.6)
Modifying fat in the diet	**N=425** 344 (81%)	**N=445** 347 (78%)	1.04	1	0.31	1.2 (0.8-1.8)
	Patient intervention group 490 (46%)	**No patient intervention group** 569 (54%)			**test statistic**	
	n (%)	n (%)	$\chi 2$	df	P-value	†Adjusted OR 95%CI)
#Smoking cessation advice	**N=43** 40 (93%)	**N=63** 57 (90%)	0.21	1	0.64	1.1 (0.2-5.2)
Physical activity advice	**N=472** 406 (86%)	**N=559** 453 (81%)	4.32	1	0.04	1.3 (0.8-2.0)
Modifying fat in the diet	**N=395** 324 (82%)	**N=471** 367 (78%)	2.37	1	0.12	1.3 (0.8-1.9)

	GP & patient intervention group 279 (47%)	usual care group 319 (53%)	test statistic			
	n (%)	n (%)	$\chi 2$	df	P-value	†Adjusted OR 95%CI)
#Smoking cessation advice	**N=26** 24 (92%)	**N=33** 28 (85%)	0.77	1	0.38	1.6 (0.3-10.0)
Physical activity advice	**N=264** 230 (87%)	**N=314** 254 (81%)	3.35	1	0.07	1.4 (0.8-2.5)
Modifying fat in the diet	**N=224** 184 (82%)	**N=272** 207 (76%)	2.68	1	0.10	1.4 (0.8-2.4)

self reported smokers only GP intervention group

† adjusted OR for baseline and clustered GP from parsimonious logistic regression model

5.2.3 Patient characteristics associated with GP provision of risk reduction advice

To determine the patient characteristics associated with GP provision of risk reduction advice, separate logistic regression models were developed to assess the association between the independent variables of patient age, gender, diagnosis, length of stay and intervention group, and reported advice for physical activity and modified diet behaviours. Smoking cessation advice was not analysed using logistic regression due to the small number of smokers.

With respect to the provision of physical activity advice, gender, intervention group and length of stay were not associated with self report of such advice. Diagnosis and age were significantly associated with self-reported receipt of such advice (Table 5.3). Patients with stroke had significantly lower odds of reporting receipt of such advice compared to those with IHD (OR 0.43; 95%CI, 0.24-0.76). Compared to patients aged less than 59 years of age, patients aged over 80 years had significantly lower odds of reporting having received

physical activity advice (OR 0.29; 95%CI, 0.17-0.52). Patients who were aged 70 to 79 years also reported lower odds of physical activity advice compared to those less than 59 years of age (OR 0.66; 95%CI, 0.40-1.08) although this was not significant at the 5% level.

Table 5.3: Results of multiple logistic regression to investigate factors associated with Self Reported physical activity advice

Physical activity advice N=1,030						
				Wald test		
	OR	SE (OR)	95% CI	t	df	P-value
Diagnosis						
IHD	1.0					
AMI	0.93	0.23	0.58, 1.5	-0.29	3	0.77
UAP	1.6	0.49	0.86, 2.9	1.49	3	0.13
Stroke	0.43	0.12	0.24, 0.76	-2.90	3	0.004
Agegroup						
< = 59 years	1.0					
60 - 69 years	1.3	0.39	0.69, 2.3	0.76	3	0.48
70 - 79 years	0.66	0.16	0.40, 1.08	-1.65	3	0.09
> 80 years	0.29	0.09	0.17, 0.52	-4.17	3	> 0.001

Diagnosis group, gender and intervention group were not associated with self-reported of advice to modify dietary fat. Age and length of stay were significantly associated with self-reported receipt of such advice as shown in Table 5.4. Compared to patients aged less than 59 years, patients over 80 years of age had significantly lower odds of self report of modified fat diet advice (OR 0.31; 95%CI, 0.18-0.53). Patients aged between 70 and 79 years had lower odds of reporting modified fat diet advice (OR 0.69; 95%CI, 0.45-1.07) although not at the 5% level. Patients with a length of stay of between five and seven days had higher odds of receiving modified fat dietary advice compared to patients with a length of stay of less than 4 days (OR 1.5; 95%CI, 0.95-2.4).

Table 5.4: Results of multiple logistic regression to investigate patient characteristics associated with Self Reported modified fat diet advice

Modified fat diet advice N=869						
				Wald test		
	OR	SE (OR)	95% CI	t	df	P-value
Agegroup						
< = 59 years	1.0					
60 - 69 years	0.87	0.23	0.52, 1.5	-0.51	3	0.61
70 – 79 years	0.69	0.15	0.45, 1.07	-1.66	3	0.09
> 80 years	0.31	0.08	0.18, 0.53	-4.21	3	> 0.001
Length of Stay						
Less than 4 days	1.0					
Between 5 & 7 days	1.5	0.35	0.95, 2.4	1.74	2	0.08
> 8 days	1.4	0.34	0.85, 2.3	1.31	2	0.19

5.3 Discussion

A primary aim of this chapter was to assess if a GP intervention, a patient intervention or both interventions combined increased GP delivery of behavioural risk advice regarding physical activity, smoking cessation, and intake of fat in the diet. The results suggested that overall the interventions were not effective in improving the provision of such advice.

The study aimed to increase the provision of behavioural risk advice by 10% in the patient and GP intervention groups, and 15% in the combined intervention group compared to usual care. Smoking cessation advice at baseline was reported to have been received by approximately 90% of participants and at six months follow up by 92% of participants.

Smoking cessation advice in other studies was much lower than the PAVE study results. In a postal survey of general practice (73% response rate) in New South Wales, Australia, 34% of GP's reported providing cessation advice during every routine consultation with a smoker.[1] In the north east of England (64% response rate) patients were sent a postal

questionnaire asking them to recall lifestyle advice received. Of the 25% of identified smokers, 4% recalled being advised to stop smoking.[2] A cross sectional study in the Netherlands of GP provision of smoking cessation revealed that 54% of patients were given advice to stop smoking. These results were based on self report by GP's completing a form recording their performance with patients.[3]

A study that was similar to the PAVE study in terms of results was a structured review of general practice records following a myocardial infarction (MI) in southern England. Provision of advice on smoking cessation was documented for 27 of 33 continuing smokers (81.8%; 64.5-93.0).[4]

The high rates of provision of smoking cessation in the PAVE study are promising for secondary prevention. In the HPS study approximately 50% of patients received smoking cessation advice. In the HPS study smoking cessation was asked of all respondents, however in the PAVE study only smokers were asked about smoking cessation advice. This difference in study sample responding could explain the difference in proportions of people reporting smoking cessation advice. Another reason for the higher rates in the PAVE study is possibly due to GP's exposure to guidelines that espouse the benefits of smoking cessation for patients with existing CVD.

Steptoe et al., suggest that risk factors such as cigarette smoking, physical inactivity and obesity are difficult to change.[5, 6] Reasons for the differences between the high rates in the PAVE study and the lower rates in other studies could be a perception that GP's may not be able to provide opportunistic screening due to high workloads.[7] Young et al., suggest that a lack of patient motivation and disinterest was the most important barrier to smoking cessation advice in their study of general practice, and that a lack of reimbursement or lack of knowledge of effective smoking cessation strategies were not potential barriers to smoking cessation.[1]

Finally from a patient's perspective there may be under reporting of receipt of behaviour change advice because patients may forget that advice was given or fail to recognize the GP intervention as advice. For example, a statement made to a patient by the GP about behavioural change may not be perceived as advice by the patient.[8] However it should be noted that apart from one postal study conducted in Australia that used a similar

methodology to the PAVE study, all other studies were audits or self report data from GPs. This differing methodology could explain the lower results obtained in these other studies compared to the PAVE study.

The PAVE study aimed to increase the provision of physical activity advice by 10% in the patient and GP intervention groups and 15% in the combined group compared to usual care groups. Physical activity advice was reported at baseline by approximately 78% of the study population and at six months followup by 83% of participants.

While there were no differences in self reported receipt of advice on physical activity at followup between the GP intervention versus the No GP intervention and the combined GP and patient group compared to the usual care group, individuals in the patient intervention were significantly more likely to report receipt of physical activity advice at six month follow up compared to those in the no patient intervention group (patient intervention 86% versus no patient intervention 81%). However this difference was likely due to a slightly higher prevalence of physical activity advice reported at baseline in the intervention group relative to the comparison group; adjusted analyses did not demonstrate a significant difference in self report receipt of physical activity advice at six month followup.

Self report of receiving advice to increase physical activity in the PAVE study (78%) was generally higher than several international studies where proportions between 4% and 64% were reported. In a cross-sectional survey of 2,676 men and women with mild to moderate hypertension recruited from general practices throughout the UK found that 38% had received advice on exercise.[9] In a cross-sectional descriptive survey using a postal questionnaire, of the 44% who exercised occasionally, advice on exercise was received by 4%.[2] Data are from 51,193 participants in the 1999 Behavioral Risk Factor Surveillance System, a state-based telephone survey in the US, 2.4% of the participants reported a history of Stroke. Almost 64% of those who reported a stroke had been advised to exercise more.[10] The study by Feder et al., of 328 patients with a history of hospitalisation for MI or unstable angina and attending one of 52 general practices in east London, found receipt of risk factor advice via a postal prompt was reported by 30% of individuals in the intervention group for exercise advice versus seven percent (7%) in the control group.[11]

In a study of GP self-report of patients counseled on physical activity GPs reported that they counseled approximately 30% of their patients about physical activity in a week (range 0% to 80%).[12] The studies discussed above included different populations and risk profiles, which may help explain the differences in prevalence estimates.

Accuracy of recall of physical activity advice is not likely to be an issue for the difference in reported rates given that Lewis et al., measured reliability of self report of exercise advice with 80% of participants accurately recalling receiving advice and 91% correctly recalling not receiving advice.[13]

The PAVE study aimed to increase diet advice by 10% in the patient and GP intervention groups and 15% in the combined group compared to usual care groups. Sixty seven percent (67%) of subjects reported having been advised to follow a modified fat diet at baseline with an overall increase to 80% reported at six month follow up.

Self report of receipt of advice for modifying diet in the PAVE study was similar to or higher than other studies. Of 51,193 participants in the telephone based survey in the 1999 Behavioral Risk Factor Surveillance System, 2.4% of participants reported a history of stroke. Sixty-one percent (61%) of those who reported a history of stroke had been advised to eat fewer high fat/high cholesterol foods.[10] In a cross-sectional survey of 2,676 men and women with mild to moderate hypertension recruited from 1,044 general practices throughout the United Kingdom, 60% of the sample had received advice on weight control and 47% hard received advice on diet.[9]

A health survey in 1987 of 484 persons was conducted in Sydney's western suburbs, few respondents reported receiving any lifestyle-related advice at their most recent doctor visit and 77% said that the food they ate was rarely or never discussed with their doctor.[14] A cross-sectional descriptive survey of 512 patients (64% response rate) in a general practice in the north-east of England were sent a postal questionnaire about recall of counselling received from practice nurses. Forty percent (40%) of the sample had a body mass index greater than25kg/m2 and advice received on diet was reported by 6% of patients.[2] In a face to face survey on a representative sample of 2,947 South Australian residents 41% of males and 25% of females were overweight and 19% of males and 20%

of females were obese. Twenty-seven percent (27%) of overweight/obese respondents reported receiving lifestyle advice for weight loss purposes.[15]

From the perspective of the GP giving advice, in a self-completed questionnaire in New South Wales, Australia of 399 GPs in 2004 (50% response rate), 97% of GPs reported that they provided some nutrition counseling, with 66% reporting 'often' assessing the patients diet.[16] In another GP report study relying on the prospective recording of patient encounters by GPs, 195 GPs completed 5,330 encounter forms. Conversely to the Australian study low levels of performance were found with regard to advice on weight reduction for patients with hypertension.[3]

Some of the reasons for the differences in report of advice are likely to be due to the interpretation of the term “modified fat diet”; this term is not specific and as such is more difficult to interpret and quantify for comparison to other studies.

The intervention used in this study was an individually tailored report card for patients to take to their general practitioners in the patient intervention group and the GP and patient intervention group. Additionally to identifying risk, the report card had advice on minimization of risk such as taking medications or undertaking quit smoking programs. This study did not seek to determine if this advice was taken however given the results with no difference between groups this knowledge would not have changed the outcome.

Our intervention used a theoretical framework based on a multi faceted approach. Wensing et al., conducted a systematic literature review of interventions in general practice and concluded that while all theoretical based interventions demonstrate varying effectiveness the combination of interventions based on theoretical frameworks such as information transfer and learning through social influence, management support, reminders and feedback can all be effective.[17]

The key conceptual elements of the intervention in respect of theoretical aspects of behaviour change interventions included information transfer, information linked to performance, learning through social influence and management support. For example information transfer was achieved by providing patient education material, the report cards sent to patients provided information about the patients risk and advice for change along

with advice to consult their GP and discuss their risk management. Management support for patients was also achieved by including resource maps and encouragement for patients to attend physical activity classes or consult a dietician or attend a quit smoking program if required. Process measures in this study suggest a very modest uptake of the intervention by patients in terms of reading, understanding and using the report card and resource map. These results also indicate that very few patients took advice and took the report card to their GP to discuss risk factor management and this may explain some of the results.

Apart from an approach using information transfer and management support which were applied to the patient intervention, this study used a theoretical approach to GP interventions using key conceptual elements of information linked to performance, learning through social influence and management support. The GP intervention included patient feedback on risk factors through reports (information linked to performance, learning through social influence) and a resource map (management support). In this study, the GP was sent information after the patient was recruited and consented for this to occur. The GP was not the focus of the study and was not contacted for follow up. It is therefore not possible to determine the uptake of the intervention by GP's. However it is likely that the uptake was not maximized due to the non significant differences between the GP and no GP groups for all risk factor management.

The secondary aim of this study was to determine factors associated with providing secondary prevention behavioural advice. For each outcome except smoking cessation in the PAVE study stepwise logistic regressions models were developed based on patient characteristics suggested in the literature to be potentially associated with the outcomes of interest.

Assessment of patient characteristics found to be associated with the provision of smoking cessation advice were not analysed in this study due to the small number of self reported smokers (N=143 at baseline, N=106 at followup). Although this study could not investigate factors associated with smoking cessation advice, previous literature by Young et al., in a national random sample of Australian GPs (67% response rate) demonstrated that significantly more GPs reported that they would be "highly likely" to initiate an opportunistic discussion about smoking with a male smoker (48%; 95%CI, 44-51) than a female smoker

(36%; 95%CI, 33-39).[18] In a prospective study by Wilson et al., comparing the characteristics of smokers who do and do not receive smoking cessation treatment in primary care in 2001-2003 in the UK, the opposite was found for males, where smokers were less likely to receive smoking cessation treatment if they were male (adjusted OR 0.68; 95%CI, 0.62-0.75). Smokers were more likely to receive smoking cessation treatment if they lived in the most deprived areas, if they were aged 25–74 years compared to 18–24 years or 75 and over and if they reported co-morbidities.[19]

In the PAVE study patients with Stroke had significantly lower odds of reporting physical activity advice compared to those with IHD (OR 0.43; 95%CI, 0.24-0.76). Differences in the management of risk factors in patients with CHD and stroke were reported in Girot et al.,'s study, although this study did not specifically address behavioural risk factors other than smoking.[20] The potential reason for this difference could be due to residual effects of stroke on the physical ability of a patient compared to patients after AMI who are less likely to have a physical disability.

Patients over 80 years of age had lower odds of reporting physical activity advice compared to patients younger than 59 years of age (OR 0.29; 95%CI, 0.17-0.52). Patients aged 70 years or over had significantly lower odds of reporting modified fat diet advice compared to those less than 59 years of age (70 – 79 years, OR 0.69; 95%CI, 0.45-1.07; (80 years and over, OR 0.31; 95%CI, 0.18-0.53). Similar relationships between age and provision of behavioural advice have been demonstrated in another study from two contrasting UK practices where 370 patients were sent a postal questionnaire (77% response rate) assessing recall of lifestyle advice. Advice was less likely in older than younger age groups (age < or = 64 years (reference group) OR 1.00; 65-74 years OR 0.47; 95%CI, 0.27-0.81; 75+ years OR 0.34; 95%CI, 0.20-0.60).[21] The authors of this study report that patients with dementia or from nursing homes were excluded to minimise the impact of recall advice as an explanation for lack of advice. The findings in Little et al.'s study suggest that although advice is not reported it is not due to a lack of memory of the advice but rather due to a lack of delivery of advice.[21]

Increasing evidence suggests that even elderly individuals with CHD can benefit greatly from exercise and secondary prevention.[22] Traditionally, secondary prevention (including exercise) has been provided by the clinician or through cardiac rehabilitation programs but

unfortunately, many older patients who would derive benefit from these interventions do not participate because of lack of referral or a variety of other barriers such as history of depression, cognitive ability to recognise the severity of "illness" and time.[22] Campbell et al., suggest that interventions related to improving physical activity and diet may be considered to be a large undertaking for elderly patients with other health priorities.[23]

Patients with a length of stay between five and seven days reported higher odds of having received modified fat diet advice compared to those with a length of stay less than four days (OR 1.5; 95%CI, 0.95-2.4). One possible reason for the association between receipt of dietary advice and a mid-term length of stay compared to a short term length of stay is severity of disease or the difficulty in achieving optimal management of the disease while in hospital. Ades et al., suggest that advice opportunities may be missed in hospital due to shorter length of stays .[24]

There were no reported gender characteristics with either physical activity or dietary outcomes in the PAVE study however in a study of 370 patients (77% response rate) from two contrasting UK practices sent a postal questionnaire assessing recall of lifestyle advice, the odds of receiving advice was higher in men compared to women (OR 1.64; 95%CI, 1.07-2.52).[21]

Similar to the results for high blood pressure, high cholesterol and aspirin use, baseline proportions of behavioural advice were also high. While this is very encouraging for secondary prevention in general, there was a change in report of advice for a modified fat diet across all groups suggesting that although the intervention may not have been effective, there was a general improvement in this outcome at a population level and even small gains at this level may be worthwhile.

Limiting factors in the study recruitment and with the delivery of the intervention, specifically the low consent rate and the time of delivery of the intervention may have contributed to this and are discussed in Chapter six.

5.4 Conclusion

The hypothesised intervention effects of increasing GP provision of advice for lifestyle behaviors were not achieved for any of the primary behavioural outcomes in this study:

smoking cessation advice, physical activity advice and dietary advice, suggesting that this intervention was not effective. The results previously described in Chapter 4 suggest that the intervention was also not effective in increasing the provision of aspirin advice or medication use in any of the intervention groups.

The key finding of the PAVE study is that the tailored intervention delivered via a specific disease register failed to increase the appropriate use of GP advice for smoking cessation, physical activity or a modified fat diet in a secondary prevention setting for people following hospitalisation for CHD or stroke.

The observed baseline prevalence of secondary prevention care for these behavioural risk factors was observed to be higher compared to the HSP study and international studies than was anticipated. These findings also suggest that for behavioural managed risk factors, the elderly and people following stroke receive less than optimal secondary prevention care, and this warrants further investigation.

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Chapter Six

A summary of findings and future directions for research and practice

Chapter 6 – A summary of findings and future directions for research and practice

6.1 Introduction

This thesis explored the burden of CHD and stroke, including the recurrent nature of CVD, the association of preventable risk factors with CVD mortality and the prevalence of secondary prevention treatment of CVD risk factors in an Australian population. From this exploration an intervention designed to increase secondary prevention care of CVD through enhanced GP provision of pharmaceutical and behavioural interventions was developed and implemented. This chapter summarises the major findings of these studies and their implications for further research and practice.

There is a significant burden of illness associated with CHD and stroke in Australia.[1, 2] Despite this there has been a noted improvement in premature mortality due to CHD and stroke over the last few decades.[3-5, 6] Potential reasons for the decline in CHD and stroke mortality rates are partly attributed to both the use of effective treatments known to improve survival[7, 8] and better treatment of risk factors.[9]

Secondary prevention, or the prevention of further events in individuals who have already had a cardiovascular event is the major focus of the studies reported in this thesis.[10] Once an individual has survived a cardiovascular event, they are at increased risk of a further event.[11,12] Given this, considerable opportunities exist for the prevention of such further CHD or stroke events. The cumulative effects of secondary prevention have been reported by McAlister et al., (2001) who conducted a systematic review of randomised controlled trials of disease management programs in patients with CHD and found that disease management programs including secondary prevention programs improve

processes of care, reduce admissions to hospital, and enhance the quality of life in patients with CHD.[13]

Although an abundance of information regarding the prevalence of risk factors and secondary prevention among people who have had a CVD or stroke event is available in the international literature, there is limited such information for the Australian setting.[14,15,16,17,18,10, 19,20,21,22,23,24,25,26,27,28,29,30,31,32,33, 34,35,36,37] To redress this lack of knowledge, this thesis explored the prevalence of risk and secondary prevention care among such people in the Hunter region of Australia. Given the opportunity to use a purposeful sample of people with existing CVD, the aim of the study described in Chapter 2 was to determine the prevalence of risk factors for CHD and stroke and the management of such risks in an Australian population. Given that evidence suggested that such risk factors were prevalent and not optimally managed in this population group, an intervention study was also undertaken to increase the provision of GP advice for behavioural risk factors and to increase the use of pharmaceutical agents to reduce physiological risk factors for CHD and stroke (Chapters 3, 4 and 5).

6.2 Prevalence of secondary prevention care - the HSP study

To determine prevalence rates of risk factors for CVD and their management in people with CVD, a secondary data analysis of CVD register data was conducted in the Hunter region of Australia for the period 1997 and 1999. The methodology of the study (known as the Hunter Secondary Prevention study (HSP)) using self report data was described in Chapter 2. Results of the study confirmed that in this 'at risk' population, rates of high blood pressure and high blood cholesterol were elevated, as were behavioural risks, for example 20% continued to smoke cigarettes. In terms of the prevalence of secondary prevention care, the HSP study found that management of high blood pressure by medication was almost universal with 95% of participants reporting taking medication for high blood pressure. A slightly lower prevalence of pharmaceutical management of cholesterol was evident with 86% of participants taking cholesterol lowering medication. The provision of behavioural interventions aimed at improving physical activity and reducing fat in the diet

was less prevalent with only half of the sample reporting receiving advice to change physical activity or dietary practices.

In comparison to international and national studies, the findings of the HSP study were similar to those previously reported for high blood pressure, high cholesterol and smoking in patients with CHD.[16,18,19,20,38] Such findings of the HSP study indicated that opportunities existed to improve the provision of secondary prevention care for patients with CHD and stroke in the Hunter Region. For example, use of cholesterol lowering medications and aspirin had the potential to be improved. Similarly, the potential for improvement in the provision of advice regarding physical activity existed for patients with CHD (64%) and those with stroke (39%). Similar potential existed for the provision of dietary advice for those with CHD (44%) and stroke (76%) and smoking cessation advice, 49% and 62% for patients with CHD and stroke respectively.

6.2.1 HSP study Methodological strengths

The major strength of the HSP study given the absence of data in the Australian setting was that an existing population based disease register, the Hunter area health service Heart and Stroke Register, was able to be used to access patients recently hospitalized for an acute cardiovascular event and therefore at risk of further CVD events. Patients already enrolled on the register had completed a secondary prevention survey listing the relevant risk factors. The Register, in this instance, was designed to provide feedback to health service managers to help streamline service provision. An extension of Register activities to provide feedback to participants was demonstrated in this study with the provision of information direct to participants considered acceptable by participants. This study sought to use only a part of the information available from the Register however data from the Register could be used to link to medical records where the definitive diagnosis of risk factors such as AF, high blood pressure, high cholesterol, smoking status and medications would be stored.

6.2.2 HSP study Methodological limitations

Information reported in Chapter 1 suggested there were modifiable risk factors for future cardiovascular events that the Heart and Stroke Register did not routinely collect data for that may have added to our understanding of the adequacy of secondary prevention care, including diabetes and depression.

Additionally the use of self report data to determine prevalence of risk factors is a limitation of the HSP study. In a study from the United States of America describing trends for risk factors of CVD, the authors report higher proportions of risk factors using self reported data in the Centers for Disease Control and Prevention's Behavioral Risk Factor Surveillance System (BRFSS) compared to data from the National Health and Nutrition Examination Survey (NHANES). The authors suggest that the measurement techniques, self report in the BRFSS and objective measures in the NHANES study were likely to explain the differences reported, indicating that self report can overestimate CVD risk factors.[39]

A third limitation of the HSP study is the observed prevalence of missing data. As missing data, in particular for the behavioural risks, could lead to an underestimation of the prevalence of such risks, the identified "gaps" in secondary prevention care provision may be potentially larger than reported in the HSP study. Missing data may have been minimised by piloting questions to ensure relevant and meaningful answers that can be appropriately interpreted.

6.3 Preventing further vascular events - the PAVE study

Based on the literature review described in Chapter 1 and findings of the HSP study, a general practitioner based intervention to improve secondary prevention care delivery to people who have had a recent cardiovascular or stroke event (PAVE) was developed and evaluated and is reported in Chapters 4 and 5.

The results of the study suggested that the intervention was not effective in increasing the use of medications for high blood pressure, high cholesterol, AF

or aspirin, or in increasing the provision of aspirin advice. Baseline rates of blood pressure lowering medication use, cholesterol lowering medication use and aspirin use were found to be high; over 70% for all three types of medication, suggesting only modest room for improvement. These results were reported in Chapter 4.

Multivariate analysis of factors associated with the provision of advice for pharmaceutical use found that diagnosis, age and length of hospital stay were independently associated with blood pressure lowering medication use, that diagnosis and age were independently associated with cholesterol lowering medication use, and that gender and diagnosis were independently associated with aspirin use. Gender, diagnosis and length of hospital stay were also independently associated with receipt of aspirin advice.

Patients recently hospitalized for stroke had reduced odds of reporting blood pressure lowering and cholesterol lowering medication use and reduced odds of reporting aspirin use and receipt of aspirin advice compared to patients with IHD. After adjusting for age and diagnosis, female patients had reduced odds of using aspirin and receiving aspirin advice.

Compared with younger patients with either stroke or CHD those aged between 70 and 79 years with high blood pressure had higher odds of reporting use of anti hypertensive medication and patients aged older than 80 years had reduced odds of reporting cholesterol lowering medication use.

The results of the PAVE intervention study with respect to the provision of secondary prevention care regarding risk behaviours similarly suggested the intervention was not effective in terms of increasing GP provision of advice regarding physical activity, smoking, or modifying the intake of fat in the diet (as reported in Chapter 5). Baseline rates of such care provision suggested limited room for improvement (78%, 67% and 90% respectively).

Multivariate analysis of the factors associated with the provision of advice for the behavioural risk factors for patients with stroke or CHD found that diagnosis and age were independently associated with receipt of physical activity advice and that age and length of hospital stay were associated with receipt of advice to modify fat in the diet. Patients recently hospitalised with a diagnosis of stroke had reduced odds of receiving physical activity advice compared to those with IHD. Patients aged 80 years and over had reduced odds of receiving both physical activity advice and advice to modify fat in the diet.

6.3.1 PAVE study Methodological strengths

6.3.1.1 Study design

A major strength of this study was the use of a two by two factorial cluster randomized controlled trial design that enabled the rigorous and concurrent analysis of a number of interventions, both singularly and in combination. The study design enabled the effectiveness of the intervention to be efficiently assessed across a range of relevant outcomes measures and had the capacity to measure the effectiveness of a GP intervention compared to a no GP intervention, to measure a patient intervention compared to a no patient intervention and to measure a combined GP and patient intervention compared to no intervention at all. The design of the intervention study was sound and based on previous studies that had demonstrated successful outcomes[40, 41]

Implementation of the study design was successful in terms of practitioner/participant randomisation, and the limited loss of participants at six-month follow–up. The randomisation process was robust and is described in detail in chapter 3 including an explanation of minor variations in socio-demographic variables.

6.3.1.2 Intervention

A further strength of the PAVE study was the utilization of an existing resource, the Register, which provided readily accessible and complete data enabling investigators to produce a tailored report card including risk factor information

for each patient in the intervention groups. Based on similar CVD intervention studies, the PAVE study hypothesized that using a report card to highlight areas of concern would improve care.[42]

Assessment of the acceptability of the intervention at baseline was measured with most of the patients who received the intervention (76%) reporting having read and having understood it (61%). Approximately 40% reported keeping the report card for future reference. At six month follow up approximately three quarters of those in the intervention group recalled receiving the intervention, and more than half reported reading, understanding and using the report card. The retention rate, a measure of the acceptability of the intervention, was high with 87% of the sample being available at six month follow up.

As a consequence of these design and implementation characteristics, the consistent finding of no intervention effect across the intervention types and across the multiple and diverse outcome measures strengthens the overall study conclusion that the interventions, as delivered in this study, were not effective in changing general practitioner provision of secondary prevention care. Despite this conclusion, the impact of a number of additional study design and study implementation factors need to be considered when interpreting the results of the PAVE study.

6.3.2 PAVE study Methodological limitations

The main limitations for the PAVE study included the magnitude of the problem, the use of the intervention, change in treatment over time, and measurement of outcomes using self-report. These limitations have a bearing on the interpretation and generalisability of the results as summarised below.

6.3.2.1 Magnitude of the problem

Data from previous studies[4, 5, 10,14,15,16,18,21,24,25,26,28,30,31,32,33,43,44] and early data from the Hunter Register itself suggested that not all individuals were receiving recommended secondary prevention care following discharge from hospital. In contrast to these previous reports, a large proportion of participants in this study

reported receiving advice regarding physical activity, smoking and diet (83%, 92% and 80% respectively). Although such findings suggest an opportunity continues to exist to further enhance these forms of care, particularly anti-coagulant use and dietary advice, the higher than expected prevalence of secondary prevention care for some aspects, such as blood pressure and cholesterol, may have limited the capacity of the study to achieve its stated outcomes.

6.3.2.2 Reach of the Intervention

Of those patients that agreed to participate in the Hunter Heart and Stroke Register 68% agreed to participate in the PAVE study. Consent rates to the PAVE study were not optimal, given that when all eligible patients were considered the consent rate was 49%. This raises the possibility that those patients who participated may have been least likely to respond positively to the intervention as they may have been already motivated to make behavioural changes to prevent further events. Using additional follow up measures such as phone call reminders may have improved the response rate.

In the analysis of the characteristics of study responders and non-responders differences between the two groups in terms of age, gender, length of stay and diagnosis were identified. The potential exists for these and other unmeasured characteristics, to have contributed to the observed pattern of findings. For example, the finding that older patients, and those with a longer length of stay, and those with stroke were less likely to participate, may have contributed to a bias towards participants with less severe disease being more likely to participate in the study. The impact of this participant response bias to the intervention on practitioner delivery of secondary prevention care is unknown.[45]

An element to consider is the health literacy and socioeconomic status of the participant. In this study intervention materials were pre tested to determine their suitability. Only one minor change was required, this suggests that health literacy while known as a potential barrier to uptake of such an intervention was not in this study an obvious limiting factor.

Additionally socioeconomic status is known as a potential barrier to patients accessing the services of general practice. However the Australian Medicare system, a universal health care system, provides free access to healthcare for those with lower socioeconomic status. There is no evidence in this study that patients did not receive follow up by their GP, although it is acknowledged that this study did not seek to specifically qualify if GP follow up did occur.

Timely delivery of the intervention to study participants was not achieved due to the constraints of retrieving data from the local area health service. There was a median difference of 116 days between the discharge date and the date of intervention delivery. The intention was to provide feedback and prompts to the general practitioner regarding the potential care needs of recently discharged CHD and stroke patients in terms of relevant risk factors and medication. Existing evidence of the effectiveness of feedback in improving practitioner delivery of care indicates that feedback needs to be specific, personalised and immediate.[46] In many instances evidence has involved the provision of feedback and/or prompts, often in computerised form, in the context of a specific patient consultation.[47] Immediate delivery of prevention advice closer to the precipitating event was a key element in the proposed effectiveness of the intervention. The delayed patient receipt of feedback information in this study did not meet these criteria and hence may explain the absence of an intervention effect.

In addition to the above, an important aspect of the intervention was the emphasis that the patient should take the report card to their GP acting as their own directors of care and as a prompt to their GP. Unfortunately, less than one-fifth (18%) of the sample reported doing this. The reasons why patients did not take the information to their GP were not explored in this study. Similar results were reported for the resource map, with even fewer patients reported contacting any of the identified providers on the resource map. Based on these data, it is unlikely that the intended purpose of the patient intervention, to empower participants to facilitate the delivery of secondary prevention care by their GP, was achieved at a level sufficient to result in a positive outcome. We hypothesise that participants may believe their GP was already providing the

best care for them or they may have found it uncomfortable to question existing care. Such intervention reach outcomes are considered to have contributed strongly to the absence of an intervention effect.

6.3.2.3 Change in treatment over time

During the study period and after completion of the intervention, recommendations for secondary prevention care underwent major changes in line with new evidence for the effectiveness of pharmaceutical management of CVD. Early in the study period guideline recommendations for those with previous AMI indicated that aspirin and beta blockers be prescribed routinely, unless contraindicated, and statins and ACE inhibitors be used for specific indications only.[48] During the study period ACE inhibitors were recommended more widely for people following AMI and statins were recommended to be routinely prescribed for patients with CHD.[48] The implications for the PAVE study is that the prevalence of anti-hypertensive medication use, such as ACE inhibitors and beta blockers, and cholesterol lowering medication use may have increased among GPs as a result of changes in care guidelines reducing the effect of the intervention.

In line with this it is acknowledged that there may be a proportion of participants in this study with high blood pressure or high cholesterol who were initially treated with lifestyle interventions, including diet and physical activity, as first line management. Given the patients in the PAVE study were recently hospitalized with a CHD or stroke event and with an increased risk of further CVD events the likelihood of this occurring is considered to be low however it may have occurred due to limited evidence for the effectiveness of cholesterol lowering medications in the early part of the study or due to medication intolerance or contraindications.[49,50]

6.3.2.4 Measurement of the outcome

The use of patient self report data as the outcome measure raises the possibility that limitations in participant knowledge, recall, or preparedness to respond accurately may have resulted in inaccurate reporting of medication

use, or receipt of advice.[40] The extent to which this occurred, and resulted in the prevalence of these outcomes being either an under or over estimate of actual care provision is unknown. Given the successful randomisation of participants to groups in the study, it is considered unlikely that any such inaccuracy in the reporting of the outcome measures would have varied systematically between groups, and hence resulted in biased study results.

Wiggers et al., suggest that the most frequently used methodology for measuring care is self report, which when compared to observational data tends to overestimate prevalence.[51] For example, Wilson et al., compared self report to audiotape and found an over estimate of care provision for behavioural risk factors. In contrast, they reported that such an effect did not apply for the recording of blood pressure, a difference that suggests that practitioners fail to record preventive care discussions but are more likely to report procedural care.[51]

A potential limitation when assessing risk factors as an outcome measurement relates to the denominator used. When evaluating management of risk factors, particularly if evidencing gaps in provision of care, it is important to ensure that the denominator is that of the population with the risk factor in question. Although it is acknowledged that this is a potential limitation, the PAVE study ensured that risk factors and their respective management were cross referenced correctly to ensure that gaps in care were reported as accurately as possible.

A further limitation to the study was the inability to confirm self reported risk factors. This was evidenced by the higher rates of AF reported than indicated by previous research.[52] Definitive diagnosis of AF could have occurred if the patients had undergone a recent ECG, or were able to undergo ECG as a component of this study. Financial constraints partly explain the lack of provision of ECG as a diagnostic tool in addition to the added burden placed on study participants to participate in diagnostic testing. Investigators need to weigh up the benefits of more precise diagnosis compared to the costs.

All outcome analyses in the PAVE study included all participants in the denominator, rather than only those participants with the relevant risk factor, with the exception of smoking advice. This design was selected to ensure the feasibility of obtaining a sufficiently large sample of participants in the study period and because the validity of self-reported risk factor status was uncertain. The possibility exists that, as a consequence of this approach, any effect of the interventions on those most 'at risk' may have been masked.

6.4 Implications

6.4.1 For future research

The findings of the PAVE study described above provide an insight into the types of factors that need to be considered when designing an intervention study. It is essential to determine from the literature and from key stakeholders the potential barriers to uptake of the planned intervention. In particular, the results of this study demonstrate the need for further research to identify possible barriers to patients not being able to advocate for their own health needs with a general practitioner.

Any future research into the effectiveness of register-based interventions should also ensure an adequate level of public and practitioner awareness of the register and its purposes. The PAVE study interventions were founded on the assumption that the information provided would be perceived as coming from a credible source, although the Register may not have been sufficiently well recognised by GPs or members of the public for it to facilitate the required level of response. At the time this intervention was implemented, the Register was an internal health service unit jointly managed by the University of Newcastle and the Area Health Service, with its activity overseen by an advisory committee that included general practitioner and consumer representatives, among others. The primary role of the Register was to collate epidemiological and health service data for use by the health service, other interested health care providers, and by researchers. Its role in proactively disseminating information

to the public, or directly influencing care delivery practices or policies, was limited.

6.4.2 For clinical practice

A focus of this intervention was the perceived need for enhanced communication of patient information between hospital care and GP care. Implicit in the design of the intervention was an expectation that the mailed delivery of tailored patient information to a GP and the patient would be sufficient to alter the clinical behaviour of GPs and to change patient's behavior to be more involved in their own care. However, evidence has been published in the last decade that suggests that changing the clinical practice of health care providers requires a more complex array of determinants to be addressed, and hence may require a more comprehensive intervention approach than the provision of information alone.[53] The determinants suggested to be important to the achievement of clinical practice change include the development of professional support for the changed practice within the clinical environment, the development of infrastructure and systems that enable the routine implementation of best practice, the training of health care providers in the rationale for, and skills required to undertake the changed practice, and the ongoing monitoring and feedback to clinicians of their delivery of best practice.[53] In short, initiatives to increase secondary prevention care by GPs need to focus on both the information needs of GPs and their organisational capacity to respond. In comparison to this prescription, the PAVE study interventions only partially addressed a number of these determinants, and importantly did not address the professional support, training, or system aspects of delivering secondary prevention care at the practice level.

With regard to the timing of the information package being delivered to the GP, the average period of at least three months between hospital discharge and mailing of the intervention did not meet the requirement for immediacy of feedback. The potential exists, for example, for the Register data to be disseminated electronically to the GP in much the same way as electronic discharge summaries are currently forwarded to practitioners following a

patient's discharge from hospital. In future register-based interventions, more efficient data dissemination systems need to closely align the provision of information with a specific occasion of care delivery.

During this study general practice in Australia continued to change in response to needs placed by communities for preventative care. The role of the general practice nurse, now established, was emerging and while not a focus of this study is ideally situated to provide secondary prevention care to those identified with prior CVD events at risk of recurrent events. Furthermore many general practices are participating in projects to develop sharing of electronic medical records. This study used integrated information in electronic format to produce report cards to highlight areas of concern for patients and could easily be incorporated in any electronic medical record sharing program.

Further this study concentrated on the management of CHD and stroke combined and separately. Management of the two main elements of CVD in this study were similar in many respects but had some obvious differences. In particular those with CHD have better access to cardiac rehabilitation with a focus on prevention, while those with stroke have access to rehabilitation with a greater focus on improving functional capacity. Given the similar elements that both disorders share, for example a similar underlying disease process, and similar risk factors such as high blood pressure, there appears to be an opportunity to take a more holistic perspective to work with patients proactively in reducing risk factors.

Given the potential inaccuracy in the self report of study outcomes, caution should be exercised in generalizing the observed prevalence of secondary prevention care in this study sample to other clinical populations. With regard to the significance of these prevalence estimates for the Hunter region population itself, an assessment of validity of the self report data routinely collected by the Register may be warranted. In the event that such an assessment indicates that the levels observed in this study reflect actual levels of care provision, an opportunity exists for the development of targeted interventions that add value to existing levels of clinical care.

6.5 Recommendations

1. That measurement of risk factor prevalence is undertaken using validated physiological instruments where possible.

To ensure that studies in the future are focused on valid and reliable data, methods of determining the true prevalence of risk factors should be assessed using physiological measures that are less open to misclassification.

2. That the feasibility of utilising disease registers to evaluate effectiveness of interventions to improve clinical practice and processes and ultimately improve health care outcomes be further explored.

The development and evaluation of alternative, more comprehensive intervention approaches to improving delivery of secondary prevention care could be considered using existing disease registers. The conduct of this study has demonstrated the feasibility of the Register, and CVD registers more generally, of adopting a more proactive approach to their operations. The ongoing surveillance function of the Register provides a valuable platform upon which such interventions could be evaluated over an extended period of time, thereby addressing some of the limitations of the study described in this report.

3. That disease registers be utilised to establish validity of using self-reported data

Given that the findings of the HSP and PAVE studies are based on self reported data, the opportunity exists for the Hunter Heart and Stroke Register to assess the validity of these findings using coded data. The Register could provide, with participant approval, linkage to individual patient's hospital medical records to enable validation of self reported risk factors such as AF and hypertension that are coded routinely using the International Classification of Diseases as part of a hospital stay. In conducting such a study, the Register would identify, with more certainty, whether further interventions are required, either across all

forms of secondary prevention care, or if more targeted interventions are required.

6.6 Conclusion

The aim of the HSP study was to determine the prevalence of risk factors and secondary prevention care of patients recently hospitalized with CHD and stroke in the Hunter Region. This confirmed the need for the PAVE study which aimed to develop and test a multifactorial intervention to increase the appropriate provision of secondary prevention care by GPs to patients with CVD using a randomized controlled trial design. The baseline results of the PAVE study suggested an existing high level of provision of some elements of secondary prevention care for patients recently hospitalized for CHD or stroke. The stated hypotheses in terms of use of pharmaceutical agents and receipt of advice for behavioural interventions were not reached for any of the primary outcomes in this study, suggesting that this intervention was not effective in improving the delivery of secondary prevention care in general practice.

Gaps in secondary prevention care remain given that every person with CHD or stroke is recommended to take prophylactic medication according to current guidelines, unless contraindicated, and to receive appropriate advice relating to increasing physical activity, reducing fat in the diet and stopping smoking completely. The study design used here and subsequent findings may help inform the development of a more appropriate and effective intervention.

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Appendix 2.1

Heart & Stroke Register survey

The UNIVERSITY of NEWCASTLE
AUSTRALIA

HUNTER HEALTH
Improving Health in the Hunter

We are interested in how lifestyle habits and health conditions are related to heart disease and stroke. To help with this we would be grateful if you would answer the following questions for us.

1	In general would you say your health is (please circle one number only)	
	Excellent	1
	Very Good	2
	Good	3
	Fair	4
	Poor	5

In the remaining questions, please circle 'Yes' or 'No" as apply

2	Have you ever been told by a doctor or other medical person that you had any of the following conditions?			
	High Blood Pressure		Yes	No
	If 'Yes' Have you been:			
	a)	Prescribed medication for high blood pressure?	Yes	No
	b)	Advised by a doctor to follow a special diet?	Yes	No
	Diabetes		Yes	No
	If 'Yes' Have you been:			
	a)	Prescribed tablets to control your diabetes?	Yes	No
	b)	Prescribed insulin injections?	Yes	No
	c)	Advised by a doctor to follow a special diet?		
	High cholesterol		Yes	No
	If 'Yes' Have you been:			
	a)	Prescribed medication for high cholesterol?	Yes	No
	b)	Advised by a doctor to follow a special diet?	Yes	No

Please turn over

3a	In the three (3) months prior to your hospital admission, had you smoked ANY cigarettes, cigars or a pipe?	Yes	No
3b	Have you smoked ANY cigarettes, cigars or pipe since your discharge from hospital?	Yes	No

4	Since your recent hospital admission have you been advised to			
	a	Increase physical activity	Yes	No
	b	Follow a special diet	Yes	No
	c	Give up smoking	Yes	No

5	Before your recent hospital admission were you taking ASPIRIN on a regular basis, that is every day or almost every day? (Some of the more common medications that include ASPIRIN are: Aspalgin, Aspro, Astrix, Bex, Cardiprin, Cartia, Decrin, Disprin, Ecotrin, Solprin, Vincents)	Yes	No

6	Are you NOW taking ASPIRIN on a regular basis, that is every day or almost every day?	Yes	No

7	Have you ever been told by a doctor or medical person that you should not take ASPRIN?	Yes	No

Date of completing questionnaire ……/……/……

Thank you for taking time to answer this questionnaire

Heart and Stroke Health Outcomes Council
Mrs Janet Fisher
Data Manager (02) 4923 6313

Appendix 2.2

Parsimonious logistic regression model results

1) High Blood Pressure

```
. xi:logit  bp i.diag i.sex i.agecat,or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.sex             _Isex_1-2           (naturally coded; _Isex_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)

Iteration 0:   log likelihood = -1559.0954
Iteration 1:   log likelihood =   -1531.65
Iteration 2:   log likelihood = -1531.5861
Iteration 3:   log likelihood = -1531.5861

Logit estimates                                   Number of obs   =       2322
                                                  LR chi2(5)      =      55.02
                                                  Prob > chi2     =     0.0000
Log likelihood = -1531.5861                       Pseudo R2       =     0.0176

------------------------------------------------------------------------------
          bp | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |   1.354985   .1960432     2.10   0.036     1.020423    1.799239
     _Isex_2 |   1.715498    .160166     5.78   0.000     1.428626    2.059975
  _Iagecat_2 |   1.382279   .1544822     2.90   0.004     1.110366    1.720779
  _Iagecat_3 |   1.261775   .1376502     2.13   0.033     1.018878    1.562577
  _Iagecat_4 |   1.309748   .2260139     1.56   0.118     .9339032    1.836849
------------------------------------------------------------------------------
```

2) High Cholesterol

```
. xi:logit  hc i.diag i.sex i.agecat  i.emergst,or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.sex             _Isex_1-2           (naturally coded; _Isex_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)
i.emergst         _Iemergst_1-2       (naturally coded; _Iemergst_1 omitted)

Iteration 0:   log likelihood = -1407.9072
Iteration 1:   log likelihood = -1335.2875
Iteration 2:   log likelihood = -1335.0994
Iteration 3:   log likelihood = -1335.0994

Logit estimates                                   Number of obs   =       2095
                                                  LR chi2(6)      =     145.62
                                                  Prob > chi2     =     0.0000
Log likelihood = -1335.0994                       Pseudo R2       =     0.0517

------------------------------------------------------------------------------
          hc | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |   .4865026   .0761406    -4.60   0.000     .3579868     .661155
     _Isex_2 |   1.467968   .1475802     3.82   0.000     1.205431    1.787685
  _Iagecat_2 |   .7840502     .09617    -1.98   0.047     .6165058    .9971271
  _Iagecat_3 |   .5372184   .0637076    -5.24   0.000      .425803    .6777867
  _Iagecat_4 |    .272893   .0525279    -6.75   0.000     .1871323     .397957
 _Iemergst_2 |   1.576772   .1524819     4.71   0.000     1.304528    1.905831
------------------------------------------------------------------------------
```

3) Smoking 3 months prior to admit

```
. xi:logit  smk3m i.diag i.sex i.agecat i.marstat i.emergst i.lga, or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.sex             _Isex_1-2           (naturally coded; _Isex_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)
i.marstat         _Imarstat_1-4       (naturally coded; _Imarstat_1 omitted)
i.emergst         _Iemergst_1-2       (naturally coded; _Iemergst_1 omitted)
i.lga             _Ilga_1-6           (naturally coded; _Ilga_1 omitted)

Iteration 0:   log likelihood = -919.01879
Iteration 1:   log likelihood = -846.08392
Iteration 2:   log likelihood = -840.36303
Iteration 3:   log likelihood = -840.33901
Iteration 4:   log likelihood =   -840.339

Logit estimates                                   Number of obs   =       1949
                                                  LR chi2(14)     =     157.36
                                                  Prob > chi2     =     0.0000
Log likelihood =   -840.339                       Pseudo R2       =     0.0856

------------------------------------------------------------------------------
       smk3m | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |    .949725   .1930689    -0.25   0.800     .6376138    1.414614
     _Isex_2 |   .7886596   .1111423    -1.68   0.092       .59832    1.039551
  _Iagecat_2 |   .3861385   .0595239    -6.17   0.000     .2854492    .5223447
  _Iagecat_3 |   .2691428   .0442751    -7.98   0.000      .194965    .3715427
  _Iagecat_4 |   .1400164   .0455915    -6.04   0.000     .0739629    .2650596
 _Imarstat_2 |   1.747532   .4177168     2.34   0.020     1.093856    2.791836
 _Imarstat_3 |   1.451886    .319132     1.70   0.090     .9437004    2.233732
 _Imarstat_4 |   2.255727    .483053     3.80   0.000     1.482538    3.432158
 _Iemergst_2 |   .7782147   .1005562    -1.94   0.052     .6041049    1.002505
     _Ilga_2 |   1.264456   .2038929     1.46   0.146     .9218241    1.734441
     _Ilga_3 |   2.076512   .4277328     3.55   0.000     1.386752    3.109354
     _Ilga_4 |   .8649701   .2198254    -0.57   0.568     .5256237    1.423401
     _Ilga_5 |   1.075733   .2410837     0.33   0.745     .6933313    1.669046
     _Ilga_6 |    1.23357   .3156051     0.82   0.412     .7471129    2.036766
------------------------------------------------------------------------------
```

4) Smoking since discharge

```
. xi:logit  smk i.diag i.sex i.agecat i.los3cat i.marstat i.emergst i.lga, or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.sex             _Isex_1-2           (naturally coded; _Isex_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)
i.los3cat         _Ilos3cat_1-3       (naturally coded; _Ilos3cat_1 omitted)
i.marstat         _Imarstat_1-4       (naturally coded; _Imarstat_1 omitted)
i.emergst         _Iemergst_1-2       (naturally coded; _Iemergst_1 omitted)
i.lga             _Ilga_1-6           (naturally coded; _Ilga_1 omitted)

Iteration 0:   log likelihood = -593.49805
Iteration 1:   log likelihood = -526.97431
Iteration 2:   log likelihood = -498.57329
Iteration 3:   log likelihood = -498.13311
Iteration 4:   log likelihood = -498.13149
Iteration 5:   log likelihood = -498.13149

Logit estimates                                   Number of obs   =       1927
                                                  LR chi2(16)     =     190.73
                                                  Prob > chi2     =     0.0000
Log likelihood = -498.13149                       Pseudo R2       =     0.1607

------------------------------------------------------------------------------
         smk | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |   .9872729   .2764715    -0.05   0.964     .5702569    1.709243
     _Isex_2 |   .6908413   .1358307    -1.88   0.060     .4699138    1.015637
  _Iagecat_2 |    .333802   .0695427    -5.27   0.000     .2218982    .5021391
  _Iagecat_3 |   .1779494    .044041    -6.98   0.000     .1095547    .2890426
  _Iagecat_4 |   .1168868   .0581151    -4.32   0.000     .0441119    .3097242
 _Ilos3cat_2 |   .6053136   .1464063    -2.08   0.038      .376792    .9724321
```

```
 _Ilos3cat_3 |   .5530087   .1141456    -2.87   0.004      .369009    .8287566
 _Imarstat_2 |    3.01272   .8205853     4.05   0.000     1.766502    5.138112
 _Imarstat_3 |    .996483   .3646068    -0.01   0.992     .4864304    2.041358
 _Imarstat_4 |   2.964913   .7537459     4.28   0.000     1.801432    4.879846
 _Iemergst_2 |   .3852014   .0757622    -4.85   0.000     .2619821    .5663749
     _Ilga_2 |   .9360752    .211585    -0.29   0.770     .6010492    1.457845
     _Ilga_3 |    1.96592   .5214765     2.55   0.011       1.1689     3.30639
     _Ilga_4 |   .6047371   .2268512    -1.34   0.180     .2899084    1.261457
     _Ilga_5 |   1.575603   .4394854     1.63   0.103     .9120529    2.721911
     _Ilga_6 |     .88946   .3215391    -0.32   0.746     .4379431    1.806488
------------------------------------------------------------------------------
```

5) Taking medication for high blood pressure

```
. xi:logit   bpmed i.diag i.agecat,or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)

Iteration 0:   log likelihood = -250.02383
Iteration 1:   log likelihood = -245.31882
Iteration 2:   log likelihood = -244.99106
Iteration 3:   log likelihood = -244.99005

Logit estimates                                   Number of obs   =       1383
                                                  LR chi2(4)      =      10.07
                                                  Prob > chi2     =     0.0393
Log likelihood = -244.99005                       Pseudo R2       =     0.0201

------------------------------------------------------------------------------
       bpmed | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |   .8338591   .3316446    -0.46   0.648     .3824289    1.818171
  _Iagecat_2 |    1.68046   .5265412     1.66   0.098     .9093267    3.105536
  _Iagecat_3 |   2.978696   1.073025     3.03   0.002     1.470264    6.034721
  _Iagecat_4 |   2.004096   1.022271     1.36   0.173     .7374429    5.446387
------------------------------------------------------------------------------
```

6) Taking medication for high cholesterol

```
. xi:logit    hcmed i.diag i.emergst,or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.emergst         _Iemergst_1-2       (naturally coded; _Iemergst_1 omitted)

Iteration 0:   log likelihood = -546.77646
Iteration 1:   log likelihood = -534.33427
Iteration 2:   log likelihood = -532.08645
Iteration 3:   log likelihood = -532.08022
Iteration 4:   log likelihood = -532.08022

Logit estimates                                   Number of obs   =       1388
                                                  LR chi2(2)      =      29.39
                                                  Prob > chi2     =     0.0000
Log likelihood = -532.08022                       Pseudo R2       =     0.0269

------------------------------------------------------------------------------
       hcmed | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |    .358384   .0842873    -4.36   0.000     .2260253    .5682509
 _Iemergst_2 |   1.527966   .2501035     2.59   0.010     1.108628     2.10592
------------------------------------------------------------------------------
```

7) Taking Aspirin before admission

```
. xi:logit   aspbef i.diag  i.agecat i.emergst,or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)
i.emergst         _Iemergst_1-2       (naturally coded; _Iemergst_1 omitted)

Iteration 0:   log likelihood = -1558.2635
Iteration 1:   log likelihood = -1508.2822
Iteration 2:   log likelihood = -1508.2312
Iteration 3:   log likelihood = -1508.2312

Logit estimates                                   Number of obs   =       2249
                                                  LR chi2(5)      =     100.06
                                                  Prob > chi2     =     0.0000
Log likelihood = -1508.2312                       Pseudo R2       =     0.0321

------------------------------------------------------------------------------
      aspbef | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |   .7741587   .1128638    -1.76   0.079      .581747     1.03021
  _Iagecat_2 |   1.634062    .184065     4.36   0.000     1.310349    2.037746
  _Iagecat_3 |   2.616535   .2935812     8.57   0.000     2.100002    3.260118
  _Iagecat_4 |   2.801103   .4807668     6.00   0.000     2.000936    3.921253
 _Iemergst_2 |    1.49255   .1369473     4.36   0.000     1.246889     1.78661
------------------------------------------------------------------------------
```

8) Now taking Aspirin

```
. xi:logit    aspnow i.diag i.sex i.agecat i.los3cat i.marstat i.emergst,or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.sex             _Isex_1-2           (naturally coded; _Isex_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)
i.los3cat         _Ilos3cat_1-3       (naturally coded; _Ilos3cat_1 omitted)
i.marstat         _Imarstat_1-4       (naturally coded; _Imarstat_1 omitted)
i.emergst         _Iemergst_1-2       (naturally coded; _Iemergst_1 omitted)

Iteration 0:   log likelihood = -868.28891
Iteration 1:   log likelihood = -838.94018
Iteration 2:   log likelihood = -837.45258
Iteration 3:   log likelihood =  -837.4512

Logit estimates                                   Number of obs   =       1920
                                                  LR chi2(11)     =      61.68
                                                  Prob > chi2     =     0.0000
Log likelihood =  -837.4512                       Pseudo R2       =     0.0355

------------------------------------------------------------------------------
      aspnow | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |   .4524437   .0789453    -4.55   0.000     .3213967    .6369242
     _Isex_2 |   .7247194   .0978802    -2.38   0.017     .5561694    .9443494
  _Iagecat_2 |    1.18632   .2088229     0.97   0.332     .8401726    1.675079
  _Iagecat_3 |   .8820305   .1477091    -0.75   0.454     .6352391    1.224701
  _Iagecat_4 |   .6841689   .1609663    -1.61   0.107     .4314186    1.084995
 _Ilos3cat_2 |   1.928044   .3660651     3.46   0.001     1.328939    2.797235
 _Ilos3cat_3 |   1.474043   .2177048     2.63   0.009     1.103555     1.96891
 _Imarstat_2 |   .5068789   .1246153    -2.76   0.006     .3130674    .8206739
 _Imarstat_3 |    1.00627   .1911673     0.03   0.974     .6934366    1.460235
 _Imarstat_4 |   1.019231   .2687685     0.07   0.942     .6078734    1.708961
 _Iemergst_2 |   1.313449   .1868509     1.92   0.055     .9938511    1.735821
------------------------------------------------------------------------------
```

9) Advised NOT to take Aspirin

```
. xi:logit  aspnot i.diag i.agecat,or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)

Iteration 0:   log likelihood = -864.42932
Iteration 1:   log likelihood = -848.51582
Iteration 2:   log likelihood = -847.72184
Iteration 3:   log likelihood = -847.72064
```

```
Logit estimates                                   Number of obs   =       2235
                                                  LR chi2(4)      =      33.42
                                                  Prob > chi2     =     0.0000
Log likelihood = -847.72064                       Pseudo R2       =     0.0193

------------------------------------------------------------------------------
      aspnot | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |   1.622144   .2892714     2.71   0.007     1.143662    2.300813
  _Iagecat_2 |   1.694222   .3112206     2.87   0.004     1.181976    2.428466
  _Iagecat_3 |   1.876077   .3339235     3.53   0.000     1.323564    2.659232
  _Iagecat_4 |   2.687057   .6153765     4.32   0.000     1.715296    4.209348
------------------------------------------------------------------------------
```

10) Advised to give up smoking

```
. xi:logit smkquit i.diag i.sex i.agecat i.los3cat i.marstat, or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.sex             _Isex_1-2           (naturally coded; _Isex_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)
i.los3cat         _Ilos3cat_1-3       (naturally coded; _Ilos3cat_1 omitted)
i.marstat         _Imarstat_1-4       (naturally coded; _Imarstat_1 omitted)

Iteration 0:   log likelihood = -555.90155
Iteration 1:   log likelihood = -496.86785
Iteration 2:   log likelihood = -496.02573
Iteration 3:   log likelihood = -496.02291

Logit estimates                                   Number of obs   =        802
                                                  LR chi2(10)     =     119.76
                                                  Prob > chi2     =     0.0000
Log likelihood = -496.02291                       Pseudo R2       =     0.1077

------------------------------------------------------------------------------
     smkquit | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |   .6039029   .1422344    -2.14   0.032     .3806164     .958179
     _Isex_2 |   .7167206   .1274418    -1.87   0.061     .5058196    1.015556
  _Iagecat_2 |    .391637   .0750735    -4.89   0.000     .2689772    .5702325
  _Iagecat_3 |    .287496   .0586943    -6.11   0.000     .1926874    .4289537
  _Iagecat_4 |   .1082601   .0394165    -6.11   0.000      .053034    .2209951
 _Ilos3cat_2 |   1.319444   .2823191     1.30   0.195     .8674829    2.006878
 _Ilos3cat_3 |   1.740529   .3084331     3.13   0.002     1.229824    2.463314
 _Imarstat_2 |   2.374851   .8337018     2.46   0.014     1.193489    4.725572
 _Imarstat_3 |   1.052995   .2725302     0.20   0.842     .6340495    1.748757
 _Imarstat_4 |   2.367628   .7624228     2.68   0.007     1.259534    4.450585
------------------------------------------------------------------------------
```

11) Advised to increase physical activity

```
. xi:logit   phys i.diag i.sex i.agecat i.los3cat i.marstat, or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.sex             _Isex_1-2           (naturally coded; _Isex_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)
i.los3cat         _Ilos3cat_1-3       (naturally coded; _Ilos3cat_1 omitted)
i.marstat         _Imarstat_1-4       (naturally coded; _Imarstat_1 omitted)

Iteration 0:   log likelihood = -1197.7337
Iteration 1:   log likelihood = -1099.1552
Iteration 2:   log likelihood = -1098.2398
Iteration 3:   log likelihood = -1098.2389
```

```
Logit estimates                                   Number of obs   =       1800
                                                  LR chi2(10)     =     198.99
                                                  Prob > chi2     =     0.0000
Log likelihood = -1098.2389                       Pseudo R2       =     0.0831

------------------------------------------------------------------------------
        phys | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |    .329455   .0536106    -6.82   0.000     .2394882     .453219
     _Isex_2 |   .8048499   .0905689    -1.93   0.054     .6455504    1.003459
  _Iagecat_2 |   .7513112   .1078369    -1.99   0.046     .5670817     .995392
  _Iagecat_3 |   .4899671   .0685671    -5.10   0.000     .3724327    .6445937
  _Iagecat_4 |   .2558894   .0529657    -6.59   0.000     .1705552    .3839192
 _Ilos3cat_2 |   1.382634   .1921318     2.33   0.020     1.052988    1.815477
 _Ilos3cat_3 |   2.544657   .3131533     7.59   0.000     1.999299    3.238775
 _Imarstat_2 |   .9534833   .2326936    -0.20   0.845     .5909911    1.538315
 _Imarstat_3 |    .628848   .1001152    -2.91   0.004     .4602894    .8591331
 _Imarstat_4 |   .8615406   .1867216    -0.69   0.492     .5633715    1.317518
------------------------------------------------------------------------------
```

12) Advised to follow special diet

```
. xi:logit   specdiet i.diag i.agecat i.los3cat i.emergst,or
i.diag            _Idiag_1-2          (naturally coded; _Idiag_1 omitted)
i.agecat          _Iagecat_1-4        (naturally coded; _Iagecat_1 omitted)
i.los3cat         _Ilos3cat_1-3       (naturally coded; _Ilos3cat_1 omitted)
i.emergst         _Iemergst_1-2       (naturally coded; _Iemergst_1 omitted)

Iteration 0:   log likelihood = -1352.6954
Iteration 1:   log likelihood = -1206.2986
Iteration 2:   log likelihood = -1203.3015
Iteration 3:   log likelihood = -1203.2804
Iteration 4:   log likelihood = -1203.2804

Logit estimates                                   Number of obs   =       1955
                                                  LR chi2(7)      =     298.83
                                                  Prob > chi2     =     0.0000
Log likelihood = -1203.2804                       Pseudo R2       =     0.1105

------------------------------------------------------------------------------
    specdiet | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
-------------+----------------------------------------------------------------
    _Idiag_2 |   .2871926   .0538117    -6.66   0.000     .1989218    .4146333
  _Iagecat_2 |   .6207188   .0782964    -3.78   0.000     .4847589    .7948114
  _Iagecat_3 |   .3166935   .0396421    -9.19   0.000     .2477936    .4047513
  _Iagecat_4 |   .1065147   .0246973    -9.66   0.000     .0676151    .1677936
 _Ilos3cat_2 |   1.457982   .2263996     2.43   0.015     1.075413    1.976648
 _Ilos3cat_3 |   2.397237   .2833393     7.40   0.000     1.901533    3.022163
 _Iemergst_2 |   1.579451   .1836153     3.93   0.000     1.257627     1.98363
------------------------------------------------------------------------------
```

Appendix 3.1

Recruitment materials

Invitation letter for people already on the Heart & Stroke register

The UNIVERSITY of NEWCASTLE
AUSTRALIA

Monday, 5 January 2004

«title» «initial» «surname»
«street»
«suburb» «pc»

Dear «title» «surname»

In «cmonth» «cyear» you kindly agreed to be part of the Hunter Area Health Service Heart and Stroke Register and to receive information on further projects.

One such project is looking at ways to make sure you or your GP receives the most up-to-date information about aspects of your condition The PAVE project is exploring ways to help in the provision of care and prevent further health problems (called secondary prevention).

A cream information sheet is enclosed, explaining what is involved.

If you are willing to take part in the study please fill in the enclosed study consent form and survey. When we previously contacted you, you may then have filled in the survey. However, so that our information is as up-to-date as possible, we would be grateful if you would complete it again.

If you do not wish to participate, please either return the consent form, unanswered, in the prepaid envelope or telephone. That way we know you have received our letter and will not contact you again.

If you have any questions about the Register or filling in the survey or any part of the study, we will be happy to answer these.

Please phone:

49236313	Janet Fisher	Project Manager, Heart and Stroke Register
49236276	Alison Koschel	PhD student

Thank you for helping us improve the health of Hunter residents.

Yours sincerely

Per:Professor Peter Fletcher (Chair Heart and Stroke Health Outcomes Council)

If you have any complaint concerning the manner in which this project is conducted please contact
The Heart and Stroke Register, CCEB, University of Newcastle 2308,
or if an independent person is preferred,
For Hunter Area Health Service Ethics, The Professional Officer, HAREC, C/- HAHS Locked Bag 1, New Lambton 2305, telephone (02) 49214950 or Facsimile (02) 49214818.For University Ethics The Human Research Ethics Officer, Office for Research, The Chancellery The University of Newcastle 2308 telephone (02) 4921633

Invitation letter for people not currently on the Heart & Stroke register

The UNIVERSITY of NEWCASTLE
AUSTRALIA

17 November 2003

«title» «initial» «surname»
«street»
«suburb» «pc»

Dear «title» «surname»

In 1995 the Heart and Stroke Health Outcomes Council of the Hunter Area Health Service set up a Register to monitor heart disease and stroke in the Hunter. This enables us to look at the long term changes in health and quality of life of those people living in the Hunter who have heart disease or a stroke. The Council is particularly interested to identify what needs to be done to improve the health of Hunter residents.

The Register consists of a list of all hospital admissions for heart disease or stroke in the Hunter and notes attendance at outpatient cardiac rehabilitation programmes. Its records hold date of admission, date of discharge, and clinical diagnosis in a coded numerical format. No personal identifying details are held unless you agree.

Register staff, who are members of the Hunter Area Health Service, extract a monthly list consisting of all patients attending public hospitals who were discharged with a diagnosis of heart disease or stroke in the previous month. The records contain name, address, date of birth, gender, date of admission, date of discharge, mode of separation (discharged, transferred, died), the discharge diagnosis in a 5 digit coded format, and any procedures (in an 8 digit code) that may have been performed. The only persons with access to these data are Register staff.

We are writing to you because these hospital records show that you were admitted to «hosp» Hospital in «lmonth» «lyear» and had a heart or stroke problem.

We are asking your permission

- to hold your name and address in our records. This would enable us to link existing hospital admissions to any future admission for heart or stroke related matters at another hospital in the Hunter. We would also link to participation in an outpatient rehabilitation programme, held at one of the Hunter hospitals, if you were to attend. Name and address will be held separately and will be known

to the register staff alone. *This does not involve any further contact by the register staff.*

- to look at your medical records *if the need arises*. We sometimes need to know the severity of a patient's heart condition or stroke and the treatment that was given as this will influence future treatment and outlook. In addition it is important to know if there are any other illnesses or problems that the patient might have that would affect his/her health and the answers he/she might give in our surveys.
- to contact you in the future, either by letter or telephone, to ask about your health, or to invite you to participate in related studies into heart disease or stroke.

Clinical details and information about your health will be strictly confidential and used only for research purposes. Information collected by the Register staff will be used to study patterns of heart disease and stroke and to compare related groups. No identifying details will be given to the researchers and their results will be published as totals only. Participation in the register is *voluntary*. *You may withdraw your consent at any time.* Your continuing medical care will not be affected in any way by your decision. If you should later decide to withdraw please write to or telephone the Heart and Stroke Register at the Royal Newcastle Hospital.

We have enclosed a Register consent form and a short survey on your lifestyle and health habits that we would be grateful if you would fill in. If you do not wish to complete the questionnaire, please either return it unanswered in the prepaid envelope or telephone. That way we know you have received our letter and will not contact you again.

In addition you are invited to participate in the PAVE study (Prevent Another Vascular Event). This study is exploring ways to help in the provision of care and prevent further health problems (called secondary prevention). Details of the study are enclosed, printed on cream paper.

If you have any questions about the Register or filling in the survey or any part of the study, we will be happy to answer these.

Please phone:

- 49236313 Janet Fisher Project Manager
- 49236203 Anne Barr Register Assistant

Thank you for helping us improve the health of Hunter residents.

Yours sincerely
Per:
PROFESSOR PETER FLETCHER (Chair Heart and Stroke Health Outcomes Council)

If you have any complaint concerning the manner in which this project is conducted please contact the Heart and Stroke Register, CCEB, University of Newcastle 2308,
or if an independent person is preferred,
Hunter Area Health Service Ethics, The Professional Officer, HAREC, C/- HAHS Locked Bag 1, New Lambton 2305, telephone (02) 49214950 or Facsimile (02) 49214818.

Reminder letter for PAVE study

Monday, 28 January 2004

«title» «initial» «surname»
«street»
«suburb» «pc»

Dear «title» «surname»,

Recently we sent you a letter inviting you to participate in the PAVE study (Prevent another Vascular Event). This was because our records show that you have recently been in hospital with heart or stroke problems and that you previously agreed that the Heart and Stroke Register could hold your name and invite you to join future studies.

Thank you if you have already filled in the PAVE consent form and returned it to us. Sometimes the letters cross in the post.

If you have not already answered our request we would be grateful if you would take a few minutes to fill in the consent form and return it to us. That way we can tell whether you are interested in this study. If you do not wish to take part, we will then know and not contact you again.

If you need any further information please phone:
49236313 Janet Fisher Project Manager
49236203 Anne Barr Register Assistant

Yours sincerely

Per:
PROFESSOR PETER FLETCHER
(Chair Heart and Stroke Health Outcomes Council)

PAVE study Information sheet

How to Prevent Another Vascular Event (Heart & Stroke)

INFORMATION SHEET

You are invited to participate in a research project being conducted by The University of Newcastle, the Hunter Centre for Health Advancement and the National Heart Foundation, Australia. The aim of this study is to better coordinate your care after hospitalisation and help to prevent further health problems in patients.

Being involved in the study means that the information given to the Heart and Stroke register in the *Register Survey* as well as some additional information on heart disease or stroke, may be mailed to either you or your GP. Participating in this trial involves;

- Receiving information in the mail about my care and that my GP may also receive some information about the care I have reported.

- Access to my hospital medical records to provide the researchers with information regarding my diagnosis and related procedures.

- Access to Health Insurance Commission information on the prescription medications I have used for my condition, enhanced primary care plans and visits to my general practitioner.

- Being contacted by mail or telephone in 6 & 12 months time to complete a questionnaire.

❍ **If you decide that you would like to participate, please complete the coloured consent form and the Register Survey and return these to the study investigators using the self-addressed envelope provided (there is no need for a stamp).**

❍ If you do not wish to take part, but are willing to be part of the register, we ask that you complete the Register Survey and register consent form and return them to the Register. No information about you will be sent to your GP without your permission.

This study is voluntary. You may withdraw from the study at any time. All responses to questionnaires will remain strictly confidential and will be seen only by research staff. Your questionnaire will be assigned a code number and your name will not be used to record or report results.

If you have any questions, please do not hesitate to ring Alison Koschel, Project Manager, on (02) 4923 6276.

Researchers taking part in this study include:
Dr John Wiggers, Director of the Hunter Centre for Health Advancement
Dr Kate D'Este, Associate Professor in Biostatistics with the Centre for Clinical Epidemiology and Biostatistics
Dr Elizabeth Campbell, Projects Manager with the Hunter Centre for Health Advancement
Dr Amanda Nagle, Special Program Manager with the National Heart Foundation
Dr Ben Ewald, Lecturer with the Clinical Centre for Epidemiology and Biostatistics and the Urban Division of General Practice
Mrs Alison Koschel, PhD student with the Centre for Clinical Epidemiology and Biostatistics. This study is part of Mrs Koschel's PhD work and she is being supervised by Dr John Wiggers and Dr Kate D'Este.

You should keep this copy of this Information sheet for your records.

Footnote: The University requires that all subjects are informed that if they have any complaints about the manner in which this research project is conducted, these may be given to the research person listed above or, if an independent person is preferred, to the: University Human Research Ethics Officer, Office for Research, The Chancellery, University of Newcastle, 2308.

If you have any questions or concerns about your rights as a participant in this study or complaints about how the study is being run and you wish to speak to an independent person, please contact Dr Nicole Gerrand Professional Officer Hunter Area Research Ethics Committee Locked Bag No. 1 NEW LAMBTON NSW 2305 Ph: (02) 4921 4950 Fax: (02) 4921 4818

HUNTER HEALTH
Improving Health in the Hunter

The UNIVERSITY of NEWCASTLE
AUSTRALIA

Heart Foundation

How to Prevent Another Vascular Event

CONSENT FORM

I agree to participate in this research trial which is evaluating information feedback systems for patients and their GP's.

I have read the information sheet and I understand that this may involve;

- Receiving information in the mail about my care and that my GP may also receive some information about the care I have reported.

My GP's name _____

GP address _____

GP suburb _____

- Access to my hospital medical records to provide the researchers with information on my diagnosis, and any procedures.

- Access to Health Insurance Commission information on prescription medications, enhanced primary care plans and visits to General Practitioners relevant to my condition. I am providing my Medicare number to enable this information to be collected.

My Medicare Number is

- Being contacted by mail or telephone in 6 and 12 months time to complete a questionnaire.

I understand that participation in the study will be voluntary. All information I give is to be kept strictly confidential. I understand that I am free to withdraw my consent at any time.

Signature _____ Date _____

Phone Number _____

I do not wish to be part of the Prevent Another Vascular Event study ☐
(If you tick this box and return this form to us, we will not contact you further)

6 month follow up survey letter

How to Prevent Another Vascular Event (Heart & Stroke)

Project Manager: Alison Koschel
Level 3, David Maddison Clinical Sciences Building
Royal Newcastle Hospital Newcastle 2300
Ph: (02) 49236276 e-mail
alison.koschel@newcastle.edu.au

HUNTER HEALTH
Improving Health in the Hunter

Wednesday, 19 May 2004

«title» «initial» «surname»
«street»
«suburb» «pc»

The UNIVERSITY of NEWCASTLE AUSTRALIA

Dear «title» «surname»

You may remember agreeing several months ago to be part of the PAVE study. We are interested in your health since your discharge from hospital on «datesep».

Heart Foundation

Please find enclosed a survey asking some questions about your health and the care you have received since your hospital discharge. We would appreciate it if you could complete the survey and return it to us in the reply paid envelope.

Our aim is to provide information to help prevent further Heart Disease and Strokes in the Hunter and your assistance is invaluable.

If you have any questions or require help with the survey, please contact

Alison Koschel or Debbie Quain on phone 4923 6276.

Thank you for your time and participation in this study.

Yours sincerely

Dr John Wiggers (PhD) Director Hunter Centre for Health Advancement	Dr Kate D'Este (PhD) Associate Professor Biostatistics Clinical Centre for Epidemiology Biostatistics	Dr Amanda Nagle (PhD) Special Program Manager National Heart Foundation (Hunter)

Appendix 3.2

Baseline surveys

Baseline Heart survey

HUNTER HEALTH
Improving Health in the Hunter

The UNIVERSITY of NEWCASTLE
AUSTRALIA

Heart and Stroke Register Survey

We are interested in management of heart disease. To help with this we would be grateful if you would answer all of the following questions.

1	Have you **ever** been told by a doctor that you had any of the following conditions?	Yes	No
a)	**High Blood Pressure**?	1	2
b)	**Diabetes**? *(sugar in the blood*)	1	2
c)	**High cholesterol**?	1	2
d)	**Atrial Fibrillation**? *(irregular heartbeat)*	1	2
e)	**Stroke**?	1	2
f)	**Previous heart attack**?	1	2
g)	**Angina**?	1	2
h)	**Heart Failure**? *(often called fluid on the lungs or an enlarged heart or weakness of the heart)*	1	2

Please turn over…

2	Aspirin Use	Yes	No
a)	**Before** your most recent hospital admission were you taking **Aspirin** on a regular basis, that is every day or almost every day? (Some of the more common medications that include; aspirin are: Aspalgin, Aspro, Astrix, Bex, Cardiprin, artia, Decrin, Disprin, Ecotrin, Solprin, Vincents)	1	2
b)	**Since** your most recent hospital admission have you been advised by a medical person (e.g. doctor, nurse, physiotherapist, dietitian) to take **Aspirin** on a regular basis, that is everyday or almost everyday?	1	2
c)	Are you currently taking **Aspirin** on a regular basis, that is every day or almost every day?	1	2
d)	Have you been told by a medical person (eg doctor, nurse) that you should **not** currently be taking **Aspirin**?	1	2

3	Weight and Height		
a)	How tall are you without shoes? *(please write your answer in **either** centimetres or feet & inches)*	cms	Ft/ins
b)	How much do you weigh without clothes/shoes? *(please write your answer in **either** kilograms or stones & pounds)*	kg	St/lb

4	Physical Activity	Yes	No
a)	Since your admission to hospital have you been **advised** by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to do any physical activity?	1	2

Please turn over…

b) Since your hospital admission, in an average week, on <u>how many</u> days of the week would you do at least 30 minutes of physical activity? Physical activity can be walking, swimming, gentle cycling etc. Physical activity can be done in 2 lots of 15 minutes or 3 lots of 10 minutes each day(*please circle the no. of days you have been able to do exercise, i.e. 0 for no days…)*

0 1 2 3 4 5 6 7

	Yes	No
c) Do you have any physical problems (e.g. Arthritis, back problems, hemiparesis) which stop you from doing any physical activity?	1	2

The following statements ask about your intentions to exercise.

(please circle the number that best describes your intention – choose ONE number only)

d) I currently do not exercise and I do not intend to start exercising in the next 6 months 1

e) I currently do not exercise, but I am thinking about starting to exercise in the next 6 months 2

f) I currently exercise, but not regularly 3

g) I currently exercise regularly, but I have only begun to do so within the last 6 months 4

h) I currently exercise regularly, and have done so for longer than 6 months 5

5 Smoking	Yes	No
a) Have you smoked more than 100 cigarettes in your entire life?	1	2
b) Have you smoked any cigarettes in the last 6 months?	1	2
c) Have you smoked any cigarettes in the last week?	1	2

Please turn over…

If you have EVER smoked

(please circle the number that best describes your intention – choose ONE number only)

d) I currently smoke and I do not intend to stop smoking in the next 6 months — 1

e) I currently smoke, but I am thinking about stopping smoking in the next 6 months…… — 2

f) I currently smoke, but not regularly — 3

g) I currently do not smoke, but I have only stopped smoking within the last 6 months… — 4

h) I currently do not smoke, and have not done so for longer than 6 months… — 5

		Yes	No
i)	**If you have smoked in the last 6 months** Since your admission to hospital have you been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to stop smoking?	1	2

		Yes	No
6	**Relatives** Have any of your blood relatives (mother, father, sister, brother) been diagnosed with or died from coronary heart disease before the age of 70? (eg *angina, heart attack, coronary thrombosis, bypass surgery, angioplasty)*	1	2

		Yes	No
7	**Follow up medical care**		
	Since your admission to hospital have you had an appointment with, or seen		
a)	General practitioner	1	2
b)	Specialist	1	2

Please turn over…

8	**Cardiac Rehabilitation**	Yes	No
a)	Since your admission to hospital have you been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to attend an outpatient cardiac rehabilitation programme?	1	2
b)	Have you booked to attend an outpatient cardiac rehabilitation programme?	1	2
c)	Since your hospital admission have you attended any sessions of an outpatient cardiac rehabilitation programme?	1	2

9	**Modified Fat Diet**	Yes	No
a)	Since your admission to hospital have you been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to follow a modified fat diet?…	1	2
b)	Since your hospital admission are you currently following a modified fat diet?……	1	2

The following statements ask about your dietary intentions

(please circle the number that best describes your intention – choose ONE number only)

c)	I currently do not follow a modified fat diet and I do not intend to do so in the next 6 months	1
d)	I currently do not follow a modified fat diet, but I am thinking about doing so in the next 6 months…	2
e)	I currently follow a modified fat diet, but not regularly…	3
f)	I follow a modified fat diet, but I have only started doing so within the last 6 months…	4
g)	I currently follow a modified fat diet, and have done so for longer than 6 months…	5

Please turn over…

10 **Medications**

Please list all the medications that you are currently taking. (Please copy the names as written on the container). Include herbal preparations and vitamins.

I do not take any medications (tick box if applicable)

Date of completing questionnaire ...../...../.....

We appreciate your assistance with this questionnaire.

Heart and Stroke Health Outcomes Council
Mrs Janet Fisher
Project Manger (02) 4923 6313

HUNTER HEALTH
Improving Health in the Hunter

The UNIVERSITY of NEWCASTLE
AUSTRALIA

Heart and Stroke Register Survey

We are interested in management of stroke. To help with this we would be grateful if you would answer all of the following questions.

1	Have you **ever** been told by a doctor that you had any of the following conditions?	Yes	No
a)	**High Blood Pressure**?	1	2
b)	**Diabetes**? *(sugar in the blood*)	1	2
c)	**High cholesterol**?	1	2
d)	**Atrial Fibrillation**? *(irregular heartbeat)*	1	2
e)	**Heart attack**?	1	2
f)	**Previous stroke**?	1	2
g)	**Angina**?	1	2
h)	**Heart Failure**? *(often called fluid on the lungs or an enlarged heart or weakness of the heart)*	1	2

Please turn over…

2	Aspirin Use	Yes	No
a)	**Before** your most recent hospital admission were you taking **Aspirin** on a regular basis, that is every day or almost every day? (Some of the more common medications that include; aspirin are: Aspalgin, Aspro, Astrix, Bex, Cardiprin, artia, Decrin, Disprin, Ecotrin, Solprin, Vincents)	1	2
b)	**Since** your most recent hospital admission have you been advised by a medical person (e.g. doctor, nurse, physiotherapist, dietitian) to take **Aspirin** on a regular basis, that is everyday or almost everyday?	1	2
c)	Are you currently taking **Aspirin** on a regular basis, that is every day or almost every day?	1	2
d)	Have you been told by a medical person (eg doctor, nurse) that you should **not** currently be taking **Aspirin**?	1	2

3	Weight and Height		
a)	How tall are you without shoes? *(please write your answer in **either** centimetres or feet & inches)*	cms	Ft/ins
b)	How much do you weigh without clothes/shoes? *(please write your answer in **either** kilograms or stones & pounds)*	kg	St/lb

4	Physical Activity	Yes	No
a)	Since your admission to hospital have you been **advised** by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to do any physical activity?	1	2

Please turn over…

b) Since your hospital admission, in an average week, on <u>how many</u> days of the week would you do at least 30 minutes of physical activity? Physical activity can be walking, swimming, gentle cycling etc. Physical activity can be done in 2 lots of 15 minutes or 3 lots of 10 minutes each day

(*please circle the no. of days you have been able to do exercise, i.e. 0 for no days…)*

0 1 2 3 4 5 6 7

	Yes	No
c) Do you have any physical problems (e.g. Arthritis, back problems, hemiparesis) which stop you from doing any physical activity?	1	2

The following statements ask about your intentions to exercise.

(please circle the number that best describes your intention – choose ONE number only)

d)	I currently do not exercise and I do not intend to start exercising in the next 6 months	1
e)	I currently do not exercise, but I am thinking about starting to exercise in the next 6 months	2
f)	I currently exercise, but not regularly	3
g)	I currently exercise regularly, but I have only begun to do so within the last 6 months	4
h)	I currently exercise regularly, and have done so for longer than 6 months	5

5	Smoking	Yes	No
a)	Have you smoked more than 100 cigarettes in your entire life?	1	2
b)	Have you smoked any cigarettes in the last 6 months?	1	2
c)	Have you smoked any cigarettes in the last week?	1	2

Please turn over…

If you have EVER smoked

(please circle the number that best describes your intention – choose ONE number only)

d)	I currently smoke and I do not intend to stop smoking in the next 6 months	1
e)	I currently smoke, but I am thinking about stopping smoking in the next 6 months……	2
f)	I currently smoke, but not regularly	3
g)	I currently do not smoke, but I have only stopped smoking within the last 6 months…	4
h)	I currently do not smoke, and have not done so for longer than 6 months…	5

		Yes	No
i)	**If you have smoked in the last 6 months** Since your admission to hospital have you been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to stop smoking?	1	2

		Yes	No
6	**Relatives**		
	Have any of your blood relatives (mother, father, sister, brother) been diagnosed with or died from coronary heart disease before the age of 70? (eg *angina, heart attack, coronary thrombosis, bypass surgery, angioplasty)*	1	2

		Yes	No
7	**Follow up medical care**		
	Since your admission to hospital have you had an appointment with, or seen		
a)	General practitioner	1	2
b)	Specialist	1	2

Please turn over…

8	**Stroke Rehabilitation**	Yes	No
a)	Since your hospital admission have you attended an inpatient rehabilitation programme?	1	2
b)	Since your hospital admission have you attended any sessions of an outpatient rehabilitation programme?	1	2

9	**Community Services** Please indicate if you have attended or been visited in your home by staff from any of the following	Yes	No
a)	Community stroke service	1	2
b)	Stroke recovery group…	1	2
c)	Stroke and disability information service	1	2

10 **Medications**

Please list all the medications that you are currently taking. (Please copy the names as written on the container). Include herbal preparations and vitamins.

I do not take any medications (tick box if applicable)

Date of completing questionnaire ...../...../.....

We appreciate your assistance with this questionnaire.

Heart and Stroke Health Outcomes Council
Mrs Janet Fisher
Project Manger (02) 4923 6313

Appendix 3.3

GP randomisation protocol

- GP's should be grouped in a practice address and given an individual practice number (i.e. each address will have an individual practice number). If a link exists between multiple practices, i.e. there is a GP who is linked with more than one surgery, they should be grouped together as one surgery and coded with a practice code number to reflect this and to minimize risk of contamination between GP's.

- Where possible an estimate of the number of study subjects likely to be seen by any GP of the practice should be made based on information supplied by the Register.

- Stratification into sub groups should be made based on GP practice estimates. Each of the Divisions should be stratified separately.

- Once each Division is stratified correctly a random process should be applied to each strata in both Divisions separately (using the randomisation process of Stata).

- The randomisation process should have four groups, Intervention with GP only, No Intervention at all, Intervention with patient only, Intervention with patient and GP.

- All Doctors should be pre randomised. When the study subject consents to be part of PAVE, the Intervention should be applied according to the code of GP randomisation.

- The randomisation process is final no changes of stratification nor group can occur post randomisation.

Problems with NO nominated GP

- If no GP is nominated and the study subject is in a nursing home then they become exclusion after consent.

- If no GP is nominated the RA calls the study subject and confirms the name of the GP, if the person refuses to name the GP then they become exclusion after consent.

These study subjects need to be deleted from the pave agreed table and they need to have details changed in the “preply” column in pavesent (New preply code is 333).

Movement of GP’s throughout study period

- Throughout the study GP’s may move into new lone practices or join other practice groups, each case will be dealt with on an individual basis to determine what changes need to occur to keep randomisation true.

Process for GP who is in database but not at stated suburb location

- GP is nominated on the consent form but not at the suburb in the database. The yellow pages should be consulted on line and through a service operator if required to obtain the address of the practice in the nominated suburb. If this process is not successful then the original practice is contacted for updated details of new practice.

- If the GP is found at a new suburb then the RA checks the practice list for new address, if it is found as an existing address then the GP is added and keeps the same individual practice number and the group practice number and the same random number. If it is not found as an existing address but a new address, the GP is added as a new practice to the address practice list and assigned a new practice number but added to the group practice number originally assigned to the GP (also retains the same random number).

- If the GP is not found at the new suburb, then the RA checks the address practice list for same suburbs and phones all practices until one has

the GP in question, if found the GP is added and keeps the same individual practice number and the group practice number and the same random number, If it is not found then the RA phones the study subject for more details about the GP address.

Process for GP who is not in the database (for example a new GP to the area)

- The RA should first check the GP's address against our practice addresses to see if they have joined an existing practice.

- The RA checks the yellow pages for the GP at the new suburb. If the new GP is found at an already recorded suburb then the GP is added and keeps the same individual practice number and the group practice number and the same random number, if it is not found then the GP is added and assigned a new individual practice number and group practice number and random number.

- If the GP is not found then the RA checks the address practice list for the same suburbs and phone all practices until one has GP in question, if found the GP is added and keeps the same individual practice number and the group practice number and the same random number, if not found then the RA phones the study subject for more details about the GP address.

Appendix 3.4

Intervention materials – report card and letters

Heart - Patient Letter

How to Prevent Another Vascular Event (Heart & Stroke)

HUNTER HEALTH
Improving Health in the Hunter

The UNIVERSITY of NEWCASTLE AUSTRALIA

Heart Foundation

Project Manager: Alison Koschel
Level 3, David Maddison Clinical Sciences Building
Ph: (02) 49236276
e-mail akoschel@mail.newcastle.edu.au

22nd August 2002

Mrs ……
Address
Suburb

Dear Mrs …..

Recently you completed a Questionnaire from the Heart and Stroke Register, from your answers we have put together a summary which highlights the health advice and care you reported in that survey. This summary also suggests areas which current research shows are likely to help you avoid further heart problems.

From your report, the areas of **your** health which may need to be addressed in a care plan include :

- Blood Pressure control
- Cholesterol control
- Physical Activity increase
- Diet changes

A new health program in the Hunter is helping patients and General Practitioners work as a team to improve the health of people with heart problems. This may result in your GP developing a care plan for you which includes appropriate specialist services such as physiotherapists, dietitians, occupational therapists, rehabilitation etc. Dr Simpson has also received a report detailing your risk factors.

A package attached to this letter contains

1) a map which lists locations and phone numbers of local services

2) a report which lists your heart disease risk factors as well as National Health Recommendations to help you reduce the risk of further heart problems.
We hope you will find this package useful.

When you next visit your doctor please take your summary sheet to help plan your care. You may need to ask for a longer consultation, which you can still claim from medicare.

Yours sincerely

Heart – Patient Report Card

Patient Summary of Prevention Care
Name: Mrs …… DOB: ……..
(as reported on your Heart and Stroke Survey 20/1/2002)

	You reported that you:	Discuss with your GP *
Cardiac Rehabilitation	• *have booked to attend cardiac rehabilitation*	
Blood Pressure	• have a history of high blood pressure • have been advised to increase physical activity • have not been advised to follow a modified fat diet • **are currently taking:** **Amlodipine, Captopril, Renitec, Atenolol**	*
Physical Activity	• are exercising for 30 mins on 3 days/week • have been advised to increase physical activity. • have been exercising more than 6 months	*
Smoking	• have never smoked	
Cholesterol	• have a history of high cholesterol • do not follow a modified fat diet • have not been advised to follow a modified fat diet • are thinking about following a modified fat diet • **are currently taking:** **Pravastatin**	*
Weight	• weigh 65kg and your height is 154cm • within the healthy weight range	
Diabetes	• do not have a history of diabetes	
Aspirin / Antiplatelet	• have been advised to take aspirin • **are currently taking:** ***Cartia, Clopidogrel***	

*** = You and your GP can make a difference - discuss a plan for your ongoing Heart care with your GP**

Help Prevent Another Vascular Event (Heart and Stroke)

Separated into two documents for this appendix

Patient Summary of Prevention Care

Name: Mrs …… DOB: ……..

Diagnosis: **Myocardial Infarction** Discharge Date: **22 Jan 2002**

Summary of Heart Foundation Recommendations for Care

- Attending cardiac rehabilitation can reduce your risk of further heart problems, discuss with your GP
- Contact your local cardiac rehabilitation coordinator (see resource map)
- Have BP and medication checked regularly by your GP
- Reduce salt and modify/lower fat in your food
- Consult a dietitian (Resource Map) or contact Heartline **1300362787**
- Reduce alcohol intake to two standard drinks per day
- Manage physical activity (**Heart**moves /Resource map)
- Manage weight
- At least 30 minutes or more of moderate physical activity on **5** or more days of the week (3 lots of 10 minutes is ok)
- Discuss and get clearance from GP before starting exercise
- Consider referral to **Heart**moves
- Avoid smoke filled rooms and cars as passive smoke increases your risk of further heart problems
- Have cholesterol levels and medication checked regularly by your GP
- Modify / lower amount of fat in your diet
- Consult dietitian or ring Heartline on **1300362787**
- Limit alcohol intake
- Increase physical activity (**Heart**moves /resource map)
- Manage / reduce weight
- Maintaining healthy weight by regular physical activity and healthy eating reduces the risk of more heart problems
- Diabetes can increase your risk of heart disease
- Please see your GP for routine annual screening.
- Small doses of Aspirin are usually prescribed for people with heart disease (prevents clots from forming)

Heart - GP Letter

How to Prevent Another Vascular Event (Heart & Stroke)

Project Manager: Alison Koschel
Level 3, David Maddison Clinical Sciences Building
Ph: (02) 49236276 e-mail akoschel@mail.newcastle.edu.au

22nd August 2002

<GP Name>
<Address>
<Suburb Postcode>

Dear <GP>

Re: <Patient Name>
<Address>
<Hospital> <Discharge Date> <Diagnosis>

Results of a self-reported survey of patients discharged in the Hunter Region with heart disease or stroke showed that

- *72% of all patients were taking aspirin,*
- *81% of patients with high cholesterol were on cholesterol lowering medication,*
- *50% reported receiving advice to increase physical activity.*
- *42% reported receiving advice to follow a modified fat diet*
- *and about half the smokers reported receiving advice to stop smoking.*

These results are good, but by improving on these figures we hope to Prevent Another Vascular Event in a larger proportion of patients.

The Hunter Heart and Stroke Health Outcomes Council routinely collects information from patients on the Hunter Register 3-4 months post hospital discharge by means of a self report survey where patients identify their own risk factors, treatment and current medications. <Patient Name> has consented to providing this information for you to facilitate the secondary prevention of cardiovascular disease.

Attached to this letter is a report detailing <patient name>'s self reported responses to the Heart and Stroke Register Survey. This report, complete with contact details for relevant health services, may be useful if you are intending to develop an Enhanced Primary Care plan. You are probably aware that a Health Assessment can attract a medicare rebate of up to $172.25, a Multidisciplinary Care Plan can attract a medicare rebate of up to $156.60. Advice for assistance with completing a care plan can be obtained by contacting your local division of general practice or accessing the web.

We have also included a current copy of secondary prevention heart guidelines as a support tool for you.

<patient name> has also received a summary of this information and how <gender> can reduce further risk of cardiovascular disease. <patient name> may come to see you to discuss these issues.

If you have any questions, please do not hesitate to ring Alison Koschel on 49 236 276.

Yours sincerely

Heart - GP Report Card

Summary of patient reported Secondary Prevention Care (Heart & Stroke)

Name: **Mrs ……**

DOB: **……..**

Diagnosis: **Myocardial Infarction**

Admit Date: **22Jan 2002**

(This report based on Heart and Stroke Register Survey 31/1/2001)

	Patient reported:	***Potential area development**
Cardiac Rehabilitation	• attending cardiac rehabilitation	
Blood Pressure	• a history of high blood pressure • having been advised to increase physical activity • not having been advised to follow a modified fat diet • **currently taking:** **Amlodipine, Captopril, Renitec, Atenolol**	*
Physical Activity	• exercising for 30 mins on 3 days/week • they have been exercising more than 6 months • being advised to increase physical activity	*
Smoking	• never smoking	
Cholesterol	• a history of high cholesterol • not following a modified fat diet ▪ not being advised to follow a modified fat diet ▪ thinking about following a modified fat diet	*
Weight	• weighing 65kg and height of 154 cm • being within the healthy weight range	
Diabetes	• not having a history of diabetes	
Aspirin / Antiplatelet	• being advised to take aspirin • **currently taking:** **Cartia, Clopidogrel**	

ACTION FOR GENERAL PRACTITIONER

* Areas identified by patient report for further management and as a potential focus for EPC planning

Step 1 Guidelines
For details of recommended best practice, refer to National Heart Foundation Guide to Risk Reduction for patients with CVD (see attached)

Step 2 Local Resources
For details of other potential local care providers for referrals and support with EPC planning see attached location map

Stroke - Patient Letter

How to Prevent Another Vascular Event (Heart & Stroke)

Project Manager: Alison Koschel
Level 3, David Maddison Clinical Sciences Building
Ph: (02) 49236276
e-mail akoschel@mail.newcastle.edu.au

22nd August 2002

Mrs ……
Address
Suburb

Dear Mrs …..

A new health program in the Hunter is helping patients and General Practitioners work as a team to improve the health of people with stroke problems. This may result in your GP developing a care plan for you which includes appropriate specialist services such as physiotherapists, dietitians, occupational therapists, rehabilitation etc.

From your answers to the Heart and Stroke Register Survey which you mailed back recently we put together a summary which highlights the health advice and care you reported in that survey. This summary also suggests areas which current research shows are likely to help you avoid further stroke problems.

From your report, the areas of **your** health which may need to be addressed in a care plan include :

- Blood Pressure control
- Physical Activity increase
- Control of Atrial Fibrillation

Dr ……. has also received a report detailing your risk factors.

This package also contains a map of some relevant health services within the Hunter Region. We hope you will find this package useful.

When you next visit your doctor please take your summary sheet to help plan your care. You may need to ask for a longer consultation, which you can still claim from medicare, to discuss this with your GP.

Yours sincerely

Stroke – Patient Report Card

Patient Summary of Prevention Care
Name: Mrs …… DOB: ……
(as reported on your Heart and Stroke Survey 20/1/2002)

	You reported that you:	Discuss with your GP *
Blood Pressure	• have a history of high blood pressure • have been advised to increase physical activity • **Currently taking:** **Amlodipine, Captopril, Renitec, Atenolol**	*
Atrial Fibrillation	• a history of atrial fibrillation	*
Physical Activity	• exercise for 30 mins x **3** days per week • are thinking about exercising more regularly • have been advised to increase physical activity	*
Smoking	• have never smoked	
Cholesterol	• do not have a history of high cholesterol	
Weight	• Height 154cm Weight 65kg • are within the healthy weight range	
Diabetes	• do not have a history of diabetes	
Aspirin / Antiplatelet	• being advised to take Aspirin • **Currently taking:** **Cartia, Clopidogrel**	

*** = You and your GP can make a difference - discuss a plan for your ongoing Stroke care with your GP**

Help Prevent Another Vascular Event (Heart

Separated into two documents for this appendix

Stroke – Patient Report Card

Patient Summary of Prevention Care

Diagnosis: **Ischaemic Stroke** Admit Date: **22 Jan 2002**

Summary of Heart Foundation Recommendations for Care

- Have BP and medication checked regularly by your GP
- Reduce salt and modify/lower fat in your food
- Consult a dietitian (Resource Map) or contact Heartline **1300362787**
- Reduce alcohol intake to two standard drinks per day
- Manage physical activity (**Heart**moves /Resource map)
- Manage weight

- Atrial fibrillation is an irregular pulse and increases the risk of stroke. Warfarin

(medication) reduces this risk. Have your pulse and medication checked regularly

by your GP

- At least 30 minutes or more of moderate physical activity on **5** or more days of the week (3 lots of 10 minutes is ok)
- Discuss and get clearance from GP before starting exercise
- Consider referral to **Heart**moves

- Avoid smoke filled rooms and cars as passive smoke increases your risk of further heart problems

- Have cholesterol levels and medication checked regularly by your GP
- Modify / lower amount of fat in your diet
- Consult dietitian or ring Heartline on **1300362787**
- Limit alcohol intake
- Increase physical activity (**Heart**moves /resource map)
- Manage / reduce weight .

- Maintaining healthy weight by regular physical activity and healthy eating reduces the risk of more heart problems.

- Diabetes can increase your risk of heart disease. Please see your GP for routine

- Small doses of Aspirin are usually prescribed for people with heart disease (prevents clots from forming).

Help Prevent Another Vascular Event (Heart

How to Prevent Another Vascular Event (Heart & Stroke)

Project Manager: Alison Koschel
Level 3, David Maddison Clinical Sciences Building
Ph: (02) 49236276 e-mail akoschel@mail.newcastle.edu.au

22nd August 2002

<GP Name>
<Address>
<Suburb Postcode>

Dear <GP>

Re: <Patient Name>
<Address>
<Hospital> <Discharge Date> <Diagnosis>

Results of a self-reported survey of patients discharged in the Hunter Region with heart disease or stroke showed that

- *72% of all patients were taking aspirin,*
- *81% of patients with high cholesterol were on cholesterol lowering medication,*
- *50% reported receiving advice to increase physical activity.*
- *42% reported receiving advice to follow a modified fat diet*
- *and about half the smokers reported receiving advice to stop smoking.*

These results are good, but by improving on these figures we hope to Prevent Another Vascular Event in a larger proportion of patients.

The Hunter Heart and Stroke Health Outcomes Council routinely collects information from patients on the Hunter Register 3-4 months post hospital discharge by means of a self report survey where patients identify their own risk factors, treatment and current medications. «title» «surname» has consented to providing this information for you to facilitate the secondary prevention of cardiovascular disease.

Attached to this letter is a report detailing «title» «surname»'s self reported responses to the Heart and Stroke Register Survey. This report, complete with contact details for relevant health services, may be useful if you are intending to develop an Enhanced Primary Care plan. You are probably aware that a Health Assessment can attract a medicare rebate of up to $172.25, a Multidisciplinary Care Plan can attract a medicare rebate of up to $156.60. Advice for assistance with completing a care plan can be obtained by contacting your local division of general practice or accessing the web.

We have also included a current copy of secondary prevention guidelines as a support tool for you.

If you have any questions, please do not hesitate to ring the PAVE Project Manager, Alison Koschel on 49 236 276.

Yours sincerely

Stroke - GP Report Card

Summary of patient reported Secondary Prevention Care (Heart & Stroke)
Name: Mrs ……..
DOB: ……
Diagnosis: **Ischaemic Stroke**
Admit Date: **22Jan 2002**
(This report based on Heart and Stroke Register Survey 31/1/2001)

	Patient reported:	***Potential areas for care plan development**
Blood Pressure	• a history of high blood pressure • having been advised to increase physical activi • **Currently taking:** **Amlodipine, Captopril, Renitec Atenolol**	
Atrial Fibrillation	• a history of atrial fibrillation	
Physical Activity	• exercising for 30 mins on **3** days per week • they are thinking about exercising more regular • being advised to increase physical activity	
Smoking	• reports NEVER smoking	
Cholesterol	• not having a history of high cholesterol	
Weight	• Height 154cm Weight 65kg • being within the healthy weight range	
Diabetes	• not having a history of diabetes	
Aspirin /Antiplatelet	• being advised to take Aspirin • Currently taking: **Cartia, Clopidogrel**	

ACTION FOR GENERAL PRACTITIONER

* Areas identified by patient report for further management and as a potential focus for EPC planning

Step 1 Guidelines
For details of recommended best practice, refer to National Heart Foundation Guide to Risk Reduction for patients with CVD (see attached)

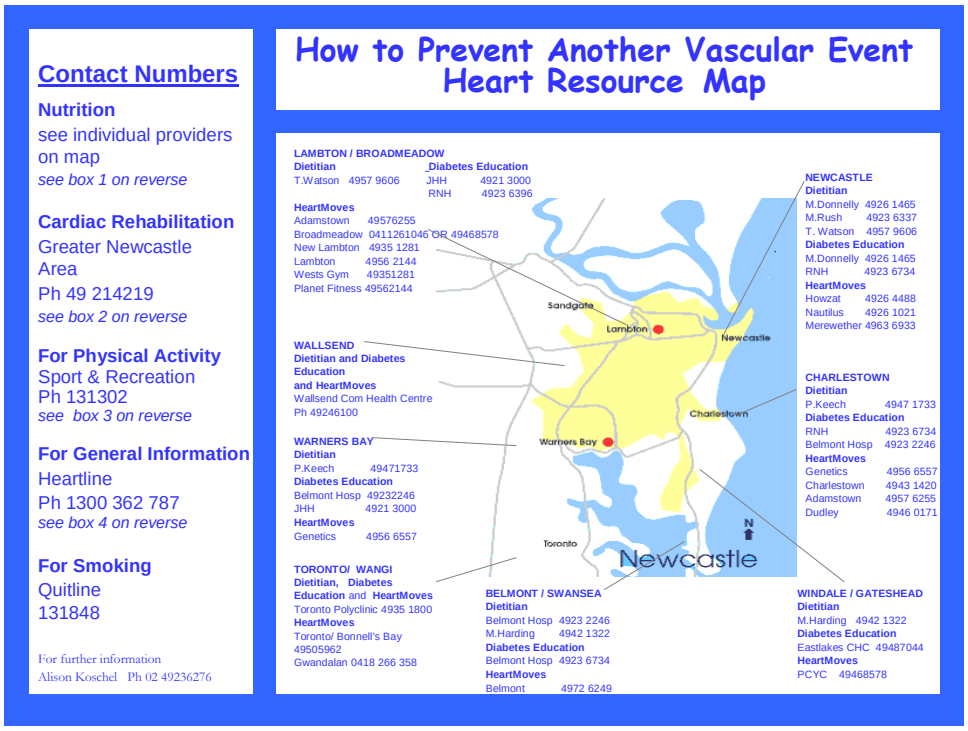
Step 2 Local Resources
For details of other potential local care providers for referrals and support with EPC planning see attached location map

Appendix 3.5

Intervention materials – resource maps

Resource map – Heart diagnosis

Heart – Newcastle Urban Map



1. Nutrition Intervention
Encourage patients to base their eating patterns on the following guidelines:

- Use margarine spreads instead of butter or dairy blends.
- Use a variety of oils for cooking - some suitable choices include canola, sunflower, soybean, olive and peanut oils.
- Use salad dressings and mayonnaise made from oils such as canola, sunflower, soybean and olive oils.
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- Make vegetables, and grain based foods such as bread, pasta, noodles and rice the major part of each meal.
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3. Heartline
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Heart- Newcastle Regional map

Contact Numbers

For Physical Activity
Sport & Recreation
Ph 131302

For Smoking
Quitline
131848

For General Information
Heartline
Ph 1300 362 787

Cardiac Rehabilitation
Upper & Lower Hunter Area Ph 49 214219

Community Stroke Service
Ph 49257803

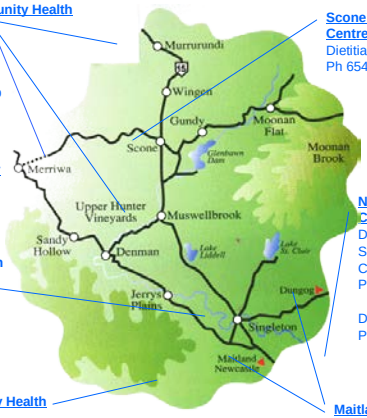
For further information
Alison Koschel Ph 02 49236276

How to Prevent Another Vascular Event Heart Resource Map

Muswellbrook Community Health Centre
Dietitian
Diabetes Education
Cardiac Rehabilitation
Stroke Recovery Group
Ph 6571 9248

Singleton Community Health Centre
Dietitian
Diabetes Education
Ph 6571 9248
Cardiac Rehabilitation
Ph 6571 9244

Cessnock Community Health Centre
Diabetes Education Ph 4991 0438
Dietitian Ph 4991 0425
Heart Moves Ph 4991 1304



Scone Community Health Centre
Dietitian
Ph 6540 2136

Nelson Bay Com. Health Centre
Dietitian
Stroke Recovery Group
Cardiac Rehabilitation
Ph 4984 0730

Diabetes Education
Ph 4982 0020

Maitland and Dungog
Diabetes Education
Ph 4923 6734

Hunter Rural Resources

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Resource map – Stroke diagnosis

Stroke – Newcastle Urban Map

Contact Numbers

Community Stroke Team
Ph 4925 7800

National Stroke Foundation
Ph 1800 787 653

For Physical Activity Sport & Recreation
Ph 131302

Hydrotherapy Pools Hunter Rehabilitation Servic Ph 4921 4110

Stroke Clubs
Ph 4943 9786

For Smoking Quitline
131848

For further information
Alison Koschel Ph 02 49236276

How to Prevent Another Vascular Event Stroke Resource Map

NEWCASTLE
Community Health Centre
4925 7800
The team is part of the Hunter Stroke Service with Hunter Area Health. There is an Occupational Therapist, Physiotherapist and Speech Pathologist.

The service offers education regarding stroke, its causes, effects and prevention; education on how to manage after stroke; retraining in mobility, communication, swallowing, leisure.

There is NO charge for this service

NEWCASTLE WEST
Community Nutrition Unit
4924 6100
For dietary and nutrition advice

Diabetes Education
RNH 4923 6734

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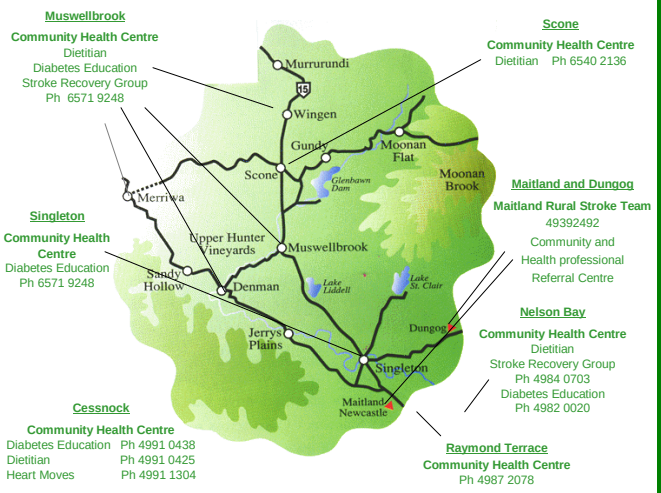
How to Prevent Another Vascular Event
Stroke Resource Map



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Dietitian Ph 6540 2136

Singleton
Community Health Centre
Diabetes Education
Ph 6571 9248

Maitland and Dungog
Maitland Rural Stroke Team
49392492
Community and Health professional Referral Centre

Nelson Bay
Community Health Centre
Dietitian
Stroke Recovery Group
Ph 4984 0703
Diabetes Education
Ph 4982 0020

Cessnock
Community Health Centre
Diabetes Education Ph 4991 0438
Dietitian Ph 4991 0425
Heart Moves Ph 4991 1304

Raymond Terrace
Community Health Centre
Ph 4987 2078

Hunter Rural Resources

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Name: «title» «christn» «surname»
Address: «street» «suburb» «pc»
DOB: «datebrth»
Diagnosis: «clindText»

Appendix 3.6

Intervention materials – GP guidelines

Stroke Guidelines

Guidelines for Secondary Prevention of Stroke

Pathology of stroke (diagnosed by: CT brain scan within 3 weeks of stroke onset, reported by: Specialist referral l, CT scan report, Hospital discharge diagnosis):

Aetiology of ischaemic stroke: atherothromboembolic, cardioembolic, small artery microatheroma, dissection, other (specify)

Aetiology of haemorrhagic stroke: hypertension, arteriovenous malformation, aneurysm, bleeding diathesis, other (specify)

Tailor stroke intervention to the aetiology (cause) of the stroke

ISCHAEMIC STROKE/TIA's WITHOUT ATRIAL FIBRILLATION **(Only indicated when intra-cerebral haemorrhage has been excluded except with haemorrhagic transformation)**		
Stroke Source/ Mechanism	**Assessment**	**Goal**
Large artery atherothromboembolism **Small artery disease** **Valvular heart disease** **Cardioembolic** **Infective endocarditis**	When intracerebral haemorrhage has been excluded antiplatelet therapy should be considered for patients diagnosed as having ischaemic stroke or TIA. Determine evidence of prior surgery such as carotid endarterectomy or stent to correct stenosis (Neurologist referral if not performed)	Risk Factor Control eg Statins Antihypertensives Smoking cessation. (see Risk Factor details below).

ISCHAEMIC STROKE/TIA's WITH ATRIAL FIBRILLATION **(Only indicated when intra-cerebral haemorrhage has been excluded except with haemorrhagic transformation)**		
Ischaemic Stroke with Atrial Fibrillation	**Initial Investigations:** Check pulse rhythm routinely while measuring BP and check for history of palpitations. **Further investigations:** On basis of clinical suspicion of resting ECG and or holter monitoring. Risk Stratification: High Risk of stroke (>6% per year): Any of following: over 75 years, history of hypertension, diabetes and previous stroke/TIA Intermediate risk of stroke (2-5% per year): Over 65 years no other risk factors Low risk (<2% per year): age < 65 years and no risk factors Risk factors for haemorrhage: increasing age, high INR, leukoaraiosis on CT brain scan NOTE: Atrial Fibrillation without prior Stroke or TIA – see guideline for primary stroke prevention	Diagnosis and management Patients taking Warfarin: Maintain therapeutic levels. Target INR 2.5 range: 2.0-3.0

HAEMORRHAGIC STROKE		
Intracerebral Haemorrhage	Determine evidence of prior surgery to correct AVM or aneurysm (referral to Neurosurgeon if not performed)	Reduce further complications of bleeding Control Blood Pressure (see risk factor details below)
Subarachnoid Haemorrhage including Arteriovenous Malformation/ Aneurysm		

RISK FACTOR	ASSESSMENT (in addition to obtaining history and physical examination)	GOAL
Hypertension	Baseline BP for all adults ≥ 18 yrs Base diagnosis of hypertension (SBP ≥ 140 mm Hg and/or DBP ≥ 90 mm Hg) on multiple BP measurements on several separate occasions. Initial investigations: Urine dipstick testing for blood + protein (if abnormal – urine microscopy); Blood analysis for Na, K, urea, creat., uric acid, glucose, lipids; ECG (Note: Echocardiogram is more sensitive than ECG for detection of left ventricular hypertrophy, but interpretation can be variable.) Further investigations: On basis of clinical suspicion of secondary hypertension (note: primary aldosteronism is not excluded by normokalaemia).	< 130/85 –adults less than 65 yrs; –adults with renal insufficiency; or –diabetes. < 140/90 –65 yrs or older (unless diabetes and/or renal insufficiency – see above).
Smoking	Interview: As part of routine evaluation, record status: current former never passive Note quit date if ex-smoker. If smoker, then record: age when started; number per day; after waking, how long before first cigarette.	Complete cessation.
Diabetes	Interview re diabetes management + review all CVD risk factors.	Maintain optimal BSL (HbA1c ≤ 7%). Manage other CVD risk factors.
Overweight: [BMI: 25–30] Obese: [BMI: > 30]	As part of routine evaluation record: Ht and Wt for BMI [BMI = Wt (kgs)/Ht (m)²] Waist circumference	BMI < 25 [set intermediate achievable goals] Waist circumference Male: ≤ 90 cm; Female ≤ 80 cm

RISK FACTOR	ASSESSMENT (in addition to obtaining history and physical examination)	GOAL
Hyper-lipidaemia[i]	Interview: To assess risk [Box 3] Baseline fasting lipid profile for: All adults ≥ 45 yrs Adults <45 years if at least one of: - known CHD* -known ischaemic cerebrovascular disease -known peripheral arterial disease, AAA -chronic renal failure or renal transplantation -Aboriginal peoples and Torres Strait Islanders -History of familial hypercholesterolaemia -History of familial combined hyperlipidaemia -smoker -significant family history of CHD (first degree relative < 60 years) -overweight /obesity -hypertension -impaired fasting glucose or impaired glucose tolerance -microalbuminuria and/or renal impairment (serum creatinine > 130 μmol/l) *CHD patients - either within 24 hours of the onset of Acute Coronary Syndromes or 6/52 post this	Lipid goals for higher risk patients [see Box 3] LDL-C → < 2.5 mmol/l TC → < 4.0 mmol/l HDL-C → > 1.0 mmol/l Triglyc. (TG) → < 2.0 mmol/l Note: Any lowering of plasma LDL-C or TC and any rise in HDL-C levels are beneficial even if target levels are not achieved.
Physical Inactivity	Interview: Routinely ask about: physical activity habits. Advise if no significant neurological impairment.	30 minutes or more of moderate physical activity on 5 or more days/week (ie 150 mins/week minimum), or 30 minutes or more of vigorous activity on 3 or more days/week (ie 90 mins/week minimum) [see Box 1]

ISCHAEMIC STROKE/TIA's WITHOUT ATRIAL FIBRILLATION

(Only indicated when intra-cerebral haemorrhage has been excluded except with haemorrhagic transformation)

Intervention	Review
Aspirin Naive (not previously on Aspirin therapy) • **Recommend** Aspirin Aspirin Failure • **Recommen**d Aspirin and Dipyridamole or Clopidogrel Aspirin Intolerance • **Recommend** Clopidogrel Taking enhanced Aspirin therapy prior to event • **Referral** to Neurologist	Aspirin compliance BP, serum lipids, smoking cessation
As above plus Long term antibiotics in consultation with Neurologist	Review all of above plus antibiotic therapy if indicated

ISCHAEMIC STROKE/TIA's WITH ATRIAL FIBRILLATION

(Only indicated when intra-cerebral haemorrhage has been excluded except with haemorrhagic transformation)

Immediately post-stroke Aspirin therapy (300mg daily) for 2 weeks **>2 weeks post-stroke** Anti-coagulation therapy should be considered for those in atrial fibrillation (AF) who are at high risk (>6% per year), and intermediate risk (depending on risk of haemorrhage).**Referral:** Specialist referral for assessment should be considered to a cardiologist to confirm the diagnosis of AF, establish the cause of the AF, and risk of systemic embolism. If warfarin contraindicated then consider antiplatelet substitute.	Patients being commenced on warfarin: INR daily until therapeutic levels reached on two consecutive days, then 2 – 3 times per week for 1 – 2 weeks, when stable INR checks 4 – 6 weeks.

HAEMORRHAGIC STROKE	
Cease all anti-coagulation or Antiplatelet therapy immediately. **Referral:** Specialist referral for assessment and management of conditions requiring blood thinning agents should be considered.	At each visit.

INTERVENTION	REVIEW
All hypertensive patients – Lifestyle: [limit alcohol intake to ≤ 20g/day ± manage weight ± ↑ physical activity.] Nutrition intervention: [See Box 2 + ↓ salt] ± referral to dietitian ± referral to Heartline teleinfo service [1300 36 27 87]. For SBP 140-180 or DBP 90-110 on several occasions intervene according to absolute cardiovascular risk status, ie: a) Commence medication without delay in those with: • any of the following conditions: diabetes, cerebrovascular disease, heart disease, renal disease (renal failure: plasma creat. > 177 μmol/l; diabetic nephropathy), vascular disease (symptomatic arterial disease; dissecting aneurysm), advanced hypertensive retinopathy; or • any of the following (target organ damage): LVH, proteinuria or slight elevation plasma creat. (106–177 μmol/l), ultrasound or radiological evidence of atherosclerotic plaque (coronary, carotid, iliac, femoral arteries, aorta), narrowing of retinal arteries; or • 3 or more of following risk factors: age (men > 55 yrs, women > 65 yrs), smoking, total cholesterol (TC) > 6.5 mmol/l, family history premature CVD (ie onset < 60 yrs). b) Commence medication after 3–6/12 lifestyle mod. if SBP remains ≥ 140 or DBP ≥ 90 in those with 1–2 of following risk factors: age (men > 55 yrs, women > 65 yrs), smoking, TC > 6.5 mmol/l, family history premature CVD. c) Commence medication in others after 6–12/12 lifestyle mod. if SBP remains ≥ 150 or DBP ≥ 95. ± Referral – SBP ≥ 180; DBP ≥ 110; secondary hypertension suspected; difficult to manage hypertension. Choice of antihypertensive drug: For details, see NHFA 1999 Guide to Management of Hypertension for Doctors.	All patients should be given appropriate lifestyle advice on a continuing basis. a) Patients not taking antihypertensive medication – at each visit or: SBP DBP Recheck < 130 < 85 2 yr 130–139 85–89 1 yr 140–159 90–99 < 2/12 160–179 100–109 < 1/12 ≥ 180 ≥ 110 < 1/52 evaluate and refer (or immediately, depending on clinical situation). Note: If systolic and diastolic categories are different, use the recommendation which allows for shorter follow-up. b) After initiation of antihypertensive medication Initially see patients at intervals ranging from a few days or up to 1–2/12, as needed. Stabilise treatment, then adjust review periods as appropriate (e.g. every 3/12 for the next 6/12 and every 6/12 thereafter).
Counselling: Appropriate for stage in behaviour change model. Strongly encourage patient and family to stop smoking. Provide passive smokers with appropriate facts on smoking. ± Referral to smoking cessation program ± referral to Quitline: Ph 131 848; ± Nicotine replacement therapy if smoking > 20/day and first cigarette within 30 minutes of waking. ± Other pharmacotherapy (Bupropion)	At each visit.
As per risk factor profile.	As suggested for risk factors present or minimum 3/12 interval.
Counselling: Re regular moderate physical activity and nutrition ± referral to Heartline teleinfo service [1300 36 27 87- see below]. Dietitian referral.	For high risk → highest risk patients 2/52 for 6/52 and at each subsequent visit. For lower risk patients with BMI ≥ 25 At each visit.

INTERVENTION	REVIEW
Nutrition intervention: Give general healthy eating advice [Box 2] ± referral to dietitian ± referral to Heartline teleinfo service [1300 36 27 87]. Other lifestyle advice: ± ↑ physical activity ± weight management, limit alcohol in those with raised TG. Treatment. For those considered to be at higher absolute risk [Box 3] and above target levels. Monitor diet fortnightly for 6 weeks, then retest lipid levels. If still above target(s), consider commencing lipid-modifying therapy taking into account PBS initiation criteria and guidelines. With known CHD (eg. hospitalised with CHD events) and TC > 4.0mmol/l, consider commencement of drug treatment without awaiting assessment of the effects of dietary intervention. Notes: Use clinical judgement in those inappropriately classified by this definition of risk. A high cholesterol level alone may not warrant aggressive drug treatment. However, apparently healthy subjects with an LDL-C > 6.0 mmol/L as the only known coronary risk factor should be considered for more active intervention because of the possibility of underlying familial hypercholesterolaemia. PBS criteria allow eligibility for subsidy for Rx in men aged 35-75 yrs and postmenopausal women up to 75 yrs with TC>7.5 mmol/l or TG >4 mmol/l and in other age groups with TC>9.0 mmol/l or TG>8.0 mmol/l, regardless of other risk factors. For further details including choice of lipid lowering drug and monitoring recommendations see NHFA/CSANZ Lipid Management Guidelines-2001	If lipid modifying therapy commenced, retest fasting lipids every 2 months until a satisfactory and stable response has been achieved. All patients at high risk should have lipid levels measured at least annually as part of ongoing assessment and management of overall CVD risk. Other individuals assessed initially as being at lower risk, for example those with an isolated abnormality in single risk factors should also receive ongoing preventive and lifestyle advice and be reassessed within 5 years to determine whether they satisfy criteria for lipid testing and lipid modifying intervention. Individuals identified as being at low absolute risk should commence regular, at least 5 yearly, lipid testing from the age of 45 years onwards.
Counselling: Appropriate for stage in behaviour change model and for patient profile, especially regarding weight ± referral to Heartline teleinfo service [1300 36 27 87]. You may suggest that patients accumulate their physical activity in shorter bouts of 10 minutes duration. You may also choose to provide a guide for monitoring symptoms and intensity level of the activity for individual patients [e.g. heart rate, whistle/talk test, Angina, Dyspnoea, Claudication Scales or Borg Scale]. For all patients: Negotiate appropriate physical activity goal.	At each visit.

Heartline (1300 36 27 87) is the Heart Foundation's national telephone information service, providing information on nutrition and physical activity and other CVD risk factors for professionals and patients for the cost of a local call.

Drug Therapy

Antiplatelet Agents Aspirin Naive (not previously on Aspirin therapy)

Start aspirin 100–300 mg/day, if not contraindicated, in those with existing coronary heart disease, or history of TIA/stroke.

Aspirin Failure

Use combination therapy. Start Aspirin 100–300 mg/day and Dipyridamole 225mg/day or Clopidogrel 75mg/day

Aspirin Intolerance

Start Clopidogrel 75mg/day

Anticoagulants Warfarin may be indicated in some patients (e.g. atrial fibrillation, previous thrombo-embolism, mural thrombus).

(Refer to NHFA professional paper Non-valvular atrial fibrillation and stroke prevention for target INR.)

ACE Inhibitors post stroke Start Ramipril (2.5mg – 10mg) or Perindopril 4mg/day (HOPE and PROGRESS trials)

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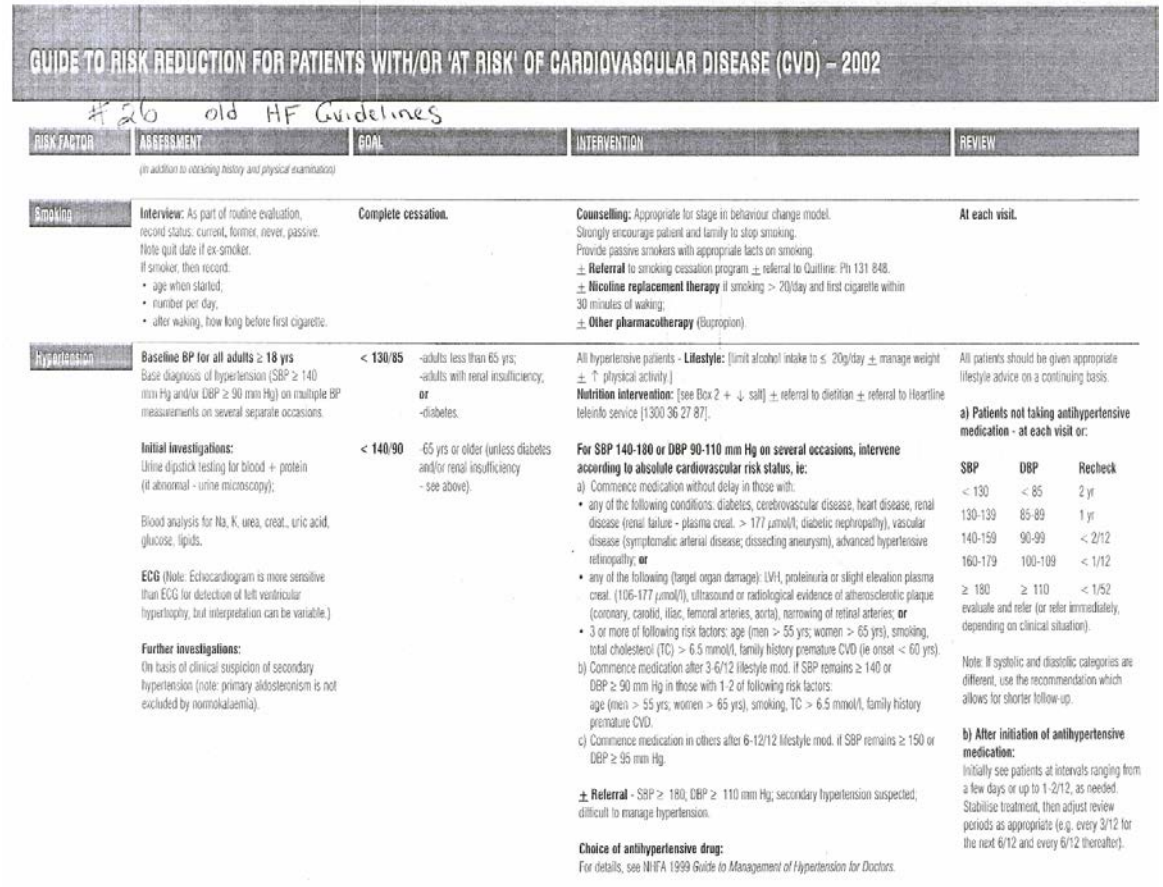
The Medical Journal of Australia.

Heart Guidelines



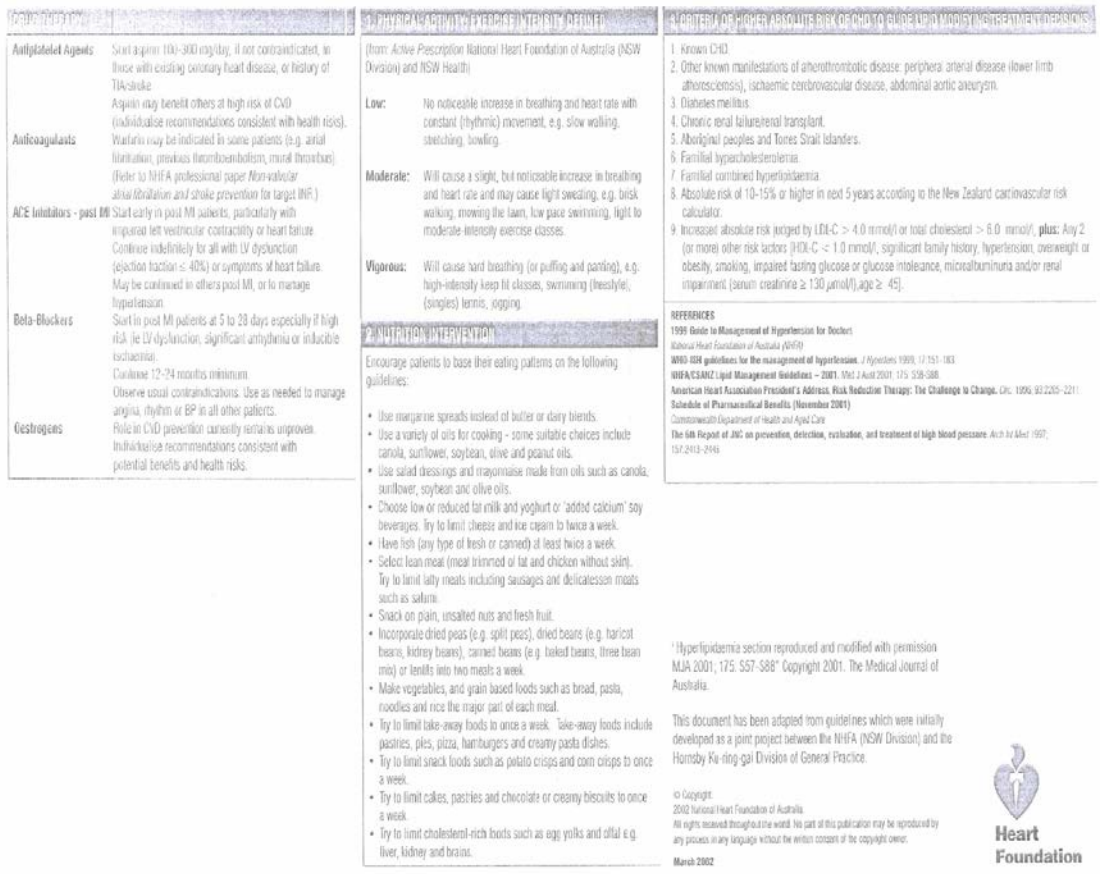
GUIDE TO RISK REDUCTION FOR PATIENTS WITH/OR 'AT RISK' OF CARDIOVASCULAR DISEASE (CVD) – 2002

#26 old HF Guidelines

RISK FACTOR	ASSESSMENT (in addition to obtaining history and physical examination)	GOAL	INTERVENTION	REVIEW
Smoking	**Interview:** As part of routine evaluation, record status: current, former, never, passive. Note quit date if ex-smoker. If smoker, then record: • age when started; • number per day; • after waking, how long before first cigarette.	**Complete cessation.**	**Counselling:** Appropriate for stage in behaviour change model. Strongly encourage patient and family to stop smoking. Provide passive smokers with appropriate facts on smoking. ± **Referral** to smoking cessation program ± referral to Quitline: Ph 131 848. ± **Nicoline replacement therapy** if smoking > 20/day and first cigarette within 30 minutes of waking; ± **Other pharmacotherapy** (Bupropion).	**At each visit.**
Hypertension	**Baseline BP for all adults ≥ 18 yrs** Base diagnosis of hypertension (SBP ≥ 140 mm Hg and/or DBP ≥ 90 mm Hg) on multiple BP measurements on several separate occasions. **Initial investigations:** Urine dipstick testing for blood + protein (if abnormal - urine microscopy); Blood analysis for Na, K, urea, creat., uric acid, glucose, lipids. **ECG** (Note: Echocardiogram is more sensitive than ECG for detection of left ventricular hypertrophy, but interpretation can be variable.) **Further investigations:** On basis of clinical suspicion of secondary hypertension (note: primary aldosteronism is not excluded by normokalaemia).	**< 130/85** -adults less than 65 yrs; -adults with renal insufficiency; **or** -diabetes. **< 140/90** -65 yrs or older (unless diabetes and/or renal insufficiency - see above).	All hypertensive patients - **Lifestyle:** [limit alcohol intake to ≤ 20g/day ± manage weight ± ↑ physical activity.] **Nutrition intervention:** [see Box 2 + ↓ salt] ± referral to dietitian ± referral to Heartline teleinfo service [1300 36 27 87]. **For SBP 140-180 or DBP 90-110 mm Hg on several occasions, intervene according to absolute cardiovascular risk status, ie:** a) Commence medication without delay in those with: • any of the following conditions: diabetes, cerebrovascular disease, heart disease, renal disease (renal failure - plasma creat. > 177 µmol/l, diabetic nephropathy), vascular disease (symptomatic arterial disease; dissecting aneurysm), advanced hypertensive retinopathy; **or** • any of the following (target organ damage): LVH, proteinuria or slight elevation plasma creat. (106-177 µmol/l), ultrasound or radiological evidence of atherosclerotic plaque (coronary, carotid, iliac, femoral arteries, aorta), narrowing of retinal arteries; **or** • 3 or more of following risk factors: age (men > 55 yrs; women > 65 yrs), smoking, total cholesterol (TC) > 6.5 mmol/l, family history premature CVD (ie onset < 60 yrs). b) Commence medication after 3-6/12 lifestyle mod. if SBP remains ≥ 140 or DBP ≥ 90 mm Hg in those with 1-2 of following risk factors: age (men > 55 yrs; women > 65 yrs), smoking, TC > 6.5 mmol/l, family history premature CVD. c) Commence medication in others after 6-12/12 lifestyle mod. if SBP remains ≥ 150 or DBP ≥ 95 mm Hg. ± **Referral** - SBP ≥ 180, DBP ≥ 110 mm Hg; secondary hypertension suspected; difficult to manage hypertension. **Choice of antihypertensive drug:** For details, see NHFA 1999 *Guide to Management of Hypertension for Doctors.*	All patients should be given appropriate lifestyle advice on a continuing basis. **a) Patients not taking antihypertensive medication - at each visit or:** **SBP / DBP / Recheck** < 130 / < 85 / 2 yr 130-139 / 85-89 / 1 yr 140-159 / 90-99 / < 2/12 160-179 / 100-109 / < 1/12 ≥ 180 / ≥ 110 / < 1/52 evaluate and refer (or refer immediately, depending on clinical situation). Note: If systolic and diastolic categories are different, use the recommendation which allows for shorter follow-up. **b) After initiation of antihypertensive medication:** Initially see patients at intervals ranging from a few days or up to 1-2/12, as needed. Stabilise treatment, then adjust review periods as appropriate (e.g. every 3/12 for the next 6/12 and every 6/12 thereafter).

Hyperlipidaemia	**Interview:** To assess risk [Box 3] **Baseline fasting lipid profile for:** • All adults ≥ 45 yrs • Adults < 45 years if at least one of: - known CHD* - known ischaemic cerebrovascular disease - known peripheral arterial disease, AAA - chronic renal failure or renal transplantation - Aboriginal peoples and Torres Strait Islanders - history familial hypercholesterolaemia - history of familial combined hyperlipidaemia - smoker - significant family history of CHD (first degree relative < 60 years) - overweight /obesity - hypertension - impaired fasting glucose or impaired glucose tolerance - microalbuminuria and/or renal impairment (serum creatinine ≥ 130 μmol/l) *CHD patients - **either** within 24 hours of the onset of Acute Coronary Syndromes **or** 6/52 post this	**Lipid goals for high risk patients [see Box 3]** LDL-C → < 2.5 mmol/l TC → < 4.0 mmol/l HDL-C → > 1.0 mmol/l Triglyc. (TG) → < 2.0 mmol/l **Note:** Any lowering of plasma LDL-C or TC and any rise in HDL-C levels are beneficial even if target levels are not achieved.	**Nutrition intervention:** Give general healthy eating advice [Box 2] ± referral to dietitian ± referral to Heartline teleinfo service [1300 36 27 87]. **Other lifestyle advice:** ± ↑ physical activity ± weight management, limit alcohol in those with raised TG. **Treatment** For those considered to be at higher absolute risk [Box 3] and above target levels: Monitor diet fortnightly for 6 weeks, then retest lipid levels. If still above target(s), consider commencing lipid-modifying therapy taking into account PBS initiation criteria and guidelines. With known CHD (e.g. hospitalised with CHD events) and TC ≥ 4.0mmol/l, consider commencement of drug treatment without awaiting assessment of the effects of dietary intervention. **Notes:** • Use clinical judgement in those inappropriately classified by this definition of risk. • A high cholesterol level alone may not warrant aggressive drug treatment. However, apparently healthy subjects with an LDL-C > 6.0 mmol/l as the only known coronary risk factor should be considered for more active intervention because of the possibility of underlying familial hypercholesterolaemia. • PBS criteria allow eligibility for subsidy for Rx in men aged 35-75 yrs and post-menopausal women up to 75 yrs with TC > 7.5 mmol/l or TG > 4 mmol/l and in other age groups with TC > 9.0 mmol/l or TG > 8.0 mmol/l, regardless of other risk factors. For further details including **choice of lipid lowering drug** and monitoring recommendations see NHFA/CSANZ Lipid Management Guidelines 2001.	• If lipid modifying therapy commenced, retest fasting lipids every 2 months until a satisfactory and stable response has been achieved. • All patients at high risk should have lipid levels measured at least annually as part of ongoing assessment and management of overall CVD risk. • Other individuals assessed initially as being at lower risk, for example those with an isolated abnormality in single risk factors should also receive ongoing preventive and lifestyle advice and be reassessed within 5 years to determine whether they satisfy criteria for lipid testing and lipid modifying intervention. • Individuals identified as being at low absolute risk should commence regular, at least 5 yearly, lipid testing from the age of 45 years onwards.
Physical Inactivity	**Interview:** Routinely ask about physical activity habits.	30 minutes or more of moderate physical activity on 5 or more days/week (ie 150 mins/week minimum), **or** 30 minutes or more of vigorous activity on 3 or more days/week (ie 90 mins/week minimum) [see Box 1]	**Counselling:** Appropriate for stage in behaviour change model and for patient profile, especially regarding weight ± referral to Heartline teleinfo service [1300 36 27 87]. You may suggest that patients accumulate their physical activity in shorter bouts of 10 minutes duration. You may also choose to provide a guide for monitoring symptoms and intensity level of the activity for individual patients [e.g. heart rate, whistle/talk test, Angina, Dyspnoea, Claudication Scales or Borg Scale]. **For all patients:** Negotiate appropriate physical activity goal.	**At each visit.**
Overweight: [BMI: 25-30] Obese: [BMI: > 30]	**As part of routine evaluation record:** Ht and Wt for BMI [BMI = Wt (kgs)/Ht (m)^2] Waist circumference	**BMI < 25** [set intermediate achievable goals] **Waist circumference** Male: ≤ 90 cm; Female ≤ 80 cm	**Counselling:** Re regular moderate physical activity and nutrition ± **referral** to Heartline teleinfo service [1300 36 27 87 – see below]. **Dietitian referral.**	**For high risk → highest risk patients:** 2/52 for 6/52 and at each subsequent visit. **For lower risk patients with BMI** ≥ 25: At each visit.
Diabetes	**Interview re diabetes management + review all CVD risk factors.**	**Maintain optimal BSL (HbA_{1c} ≤ 7%). Manage other CVD risk factors.**	**As per risk factor profile.**	**As suggested for risk factors present or minimum 3/12 interval.**

Heartline (1300 36 27 87) is the Heart Foundation's national telephone information service, providing information on nutrition and physical activity and other CVD risk factors for professionals and patients for the cost of a local call.



Antiplatelet Agents Start aspirin 100–300 mg/day, if not contraindicated, in those with existing coronary heart disease, or history of TIA/stroke.
Aspirin may benefit others at high risk of CVD (individualise recommendations consistent with health risks).

Anticoagulants Warfarin may be indicated in some patients (e.g. atrial fibrillation, previous thromboembolism, mural thrombus) (Refer to NHFA professional paper *Non-valvular atrial fibrillation and stroke prevention* for target INR.)

ACE Inhibitors - post MI Start early in post MI patients, particularly with impaired left ventricular contractility or heart failure.
Continue indefinitely for all with LV dysfunction (ejection fraction ≤ 40%) or symptoms of heart failure.
May be continued in others post MI, or to manage hypertension.

Beta-Blockers Start in post MI patients at 5 to 28 days especially if high risk (ie LV dysfunction, significant arrhythmia or inducible ischaemia).
Continue 12–24 months minimum.
Observe usual contraindications. Use as needed to manage angina, rhythm or BP in all other patients.

Oestrogens Role in CVD prevention currently remains unproven.
Individualise recommendations consistent with potential benefits and health risks.

3. PHYSICAL ACTIVITY: EXERCISE INTENSITY DEFINED

(from *Active Prescription* National Heart Foundation of Australia (NSW Division) and NSW Health)

Low: No noticeable increase in breathing and heart rate with constant (rhythmic) movement, e.g. slow walking, stretching, bowling.

Moderate: Will cause a slight, but noticeable increase in breathing and heart rate and may cause light sweating, e.g. brisk walking, mowing the lawn, low pace swimming, light to moderate-intensity exercise classes.

Vigorous: Will cause hard breathing (or puffing and panting), e.g. high-intensity keep fit classes, swimming (freestyle), (singles) tennis, jogging.

2. NUTRITION INTERVENTION

Encourage patients to base their eating patterns on the following guidelines:

- Use margarine spreads instead of butter or dairy blends.
- Use a variety of oils for cooking - some suitable choices include canola, sunflower, soybean, olive and peanut oils.
- Use salad dressings and mayonnaise made from oils such as canola, sunflower, soybean and olive oils.
- Choose low or reduced fat milk and yoghurt or 'added calcium' soy beverages. Try to limit cheese and ice cream to twice a week.
- Have fish (any type of fresh or canned) at least twice a week.
- Select lean meat (meat trimmed of fat and chicken without skin). Try to limit fatty meats including sausages and delicatessen meats such as salami.
- Snack on plain, unsalted nuts and fresh fruit.
- Incorporate dried peas (e.g. split peas), dried beans (e.g. haricot beans, kidney beans), canned beans (e.g. baked beans, three bean mix) or lentils into two meals a week.
- Make vegetables, and grain based foods such as bread, pasta, noodles and rice the major part of each meal.
- Try to limit take-away foods to once a week. Take-away foods include pastries, pies, pizza, hamburgers and creamy pasta dishes.
- Try to limit snack foods such as potato crisps and corn crisps to once a week.
- Try to limit cakes, pastries and chocolate or creamy biscuits to once a week.
- Try to limit cholesterol-rich foods such as egg yolks and offal e.g. liver, kidney and brains.

1. IDENTIFY HIGH ABSOLUTE RISK OF CHD TO GUIDE LIPID MODIFYING TREATMENT DECISIONS

1. Known CHD.
2. Other known manifestations of atherothrombotic disease: peripheral arterial disease (lower limb atherosclerosis), ischaemic cerebrovascular disease, abdominal aortic aneurysm.
3. Diabetes mellitus.
4. Chronic renal failure/renal transplant.
5. Aboriginal peoples and Torres Strait Islanders.
6. Familial hypercholesterolemia.
7. Familial combined hyperlipidaemia.
8. Absolute risk of 10–15% or higher in next 5 years according to the New Zealand cardiovascular risk calculator.
9. Increased absolute risk judged by LDL-C > 4.0 mmol/l or total cholesterol > 6.0 mmol/l, **plus:** Any 2 (or more) other risk factors [HDL-C < 1.0 mmol/l, significant family history, hypertension, overweight or obesity, smoking, impaired fasting glucose or glucose intolerance, microalbuminuria and/or renal impairment (serum creatinine ≥ 130 μmol/l),age ≥ 45].

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The 6th Report of JNC on prevention, detection, evaluation, and treatment of high blood pressure. *Arch Int Med* 1997; 157:2413-2446.

[1] Hyperlipidaemia section reproduced and modified with permission MJA 2001; 175: S57-S88" Copyright 2001. The Medical Journal of Australia.

This document has been adapted from guidelines which were initially developed as a joint project between the NHFA (NSW Division) and the Hornsby Ku-ring-gai Division of General Practice.

March 2002

Heart Foundation

Appendix 3.7

Tailored recommendations

Report Card response options and relevant recommendations

Blood Pressure Response options and relevant recommendations

Response	Recommendation
a history of high blood pressure OR a history of high blood pressure and reported taking …… OR no history of high blood pressure but reported taking …… OR * no report of history of high blood pressure but reported taking OR * no report of history of high blood pressure	Have BP and medication checked regularly by your GP Reduce salt and modify/lower fat in your food Consult a dietitian (see resource map) or contact Heartline 1300362787 Reduce alcohol intake to two standard drinks per day Manage physical activity (see Physical Activity below) Manage weight (see Weight below)
no history of high blood pressure	Have blood pressure checked regularly by your GP

Cholesterol Response options and relevant recommendations

Response	**Recommendation**
a history of high cholesterol OR a history of high cholesterol and reported taking ….. OR no history of high cholesterol OR no history of high cholesterol but reported taking …… OR no report of history of high cholesterol but reports taking ……. OR * no report of history of high cholesterol	Have cholesterol levels and medication checked regularly by your GP Modify/lower amount of fat in your diet Consult dietitian or ring Heartline on 1300362787 Limit alcohol intake Increase physical activity (see physical activity over page) Manage/reduce weight (see weight below)

Aspirin Response options and relevant recommendations

Response	**Recommendation**
currently taking Aspirin and list these medications …. OR not currently taking Aspirin but report taking ……. OR currently taking Aspirin but no medication listed	Small doses of Aspirin are usually prescribed for people with heart disease (prevents clots from forming)
not currently taking Aspirin OR no report of currently taking	Small doses of Aspirin are usually prescribed for people with heart disease (prevents clots from forming). Discuss

Aspirin but report taking …… OR * no report of currently taking Aspirin	with your GP There are alternatives to Aspirin that can thin your blood , discuss treatment with your GP
having been advised NOT to take Aspirin OR having been advised NOT to take Aspirin but report taking ……	There are alternatives to Aspirin that can thin your blood, discuss treatment with your GP

Atrial Fibrillation response options and relevant recommendations

Response	**Recommendation**
a history of atrial fibrillation OR no history of atrial fibrillation OR a history of atrial fibrillation and are taking …… OR no history of atrial fibrillation but are taking …… OR no report of atrial fibrillation but are taking ……. OR * no report of atrial fibrillation	Atrial Fibrillation is an irregular pulse and increases the risk of stroke Warfarin (medication) reduces this risk Have your pulse checked regularly by your GP

Physical Activity Response options and relevant recommendations

Response	**Recommendation**
exercising for 30 minutes on 0 - 4 days of the week OR * no report of exercising for 30 minutes on ANY day	At least 30 minutes or more of moderate physical activity (like walking) on 5 or more days of the week is advised (3 lots of 10 minutes each day is OK) Discuss and get clearance from GP before exercising Consider Heartmoves (see resource map)
exercising for 30 minutes on 5 - 7days of the week	Keeping up at least 30 minutes each day of moderate exercise (like walking) on most days of the week will help maintain your heart health Consider Heartmoves (see resource map)

Smoking Response options and relevant recommendations

Response	**Recommendation**
never smoking	Avoid smoke filled rooms and cars as passive smoke increases your risk of further heart problems
not smoking in the last 6 months	Congratulations. You have done much of the hard work already. The next 6-12 months are still considered a risky time for taking up smoking again. Talk to your local pharmacist or Quitline if cravings recur
not smoking in the last week, but having smoked in the last 6 months	Congratulations, quitting is an excellent choice Giving up smoking is the most important thing you could do to help prevent further heart and stroke problems There is a risk of you taking up smoking again in the next 6 months Use of nicotine replacement therapy will reduce the cravings and withdrawal and will double

	your chances of successfully quitting see your GP or pharmacist During cravings ring the Quitline 1341848
having smoked in the last week OR * no report of smoking	Complete smoking cessation is strongly recommended as smoking reduces oxygen and damages artery walls Use of Nicotine Replacement Therapy doubles the chances of quitting successfully. Discuss medications with your GP Contact Quitline for support, or your local pharmacist

Cardiac Rehabilitation Response options and relevant recommendations

Response	**Recommendation**
attending Cardiac Rehabilitation OR booking to attend Cardiac Rehabilitation OR not attending but having booked Cardiac Rehabilitation	Attending Cardiac Rehabilitation helps most heart patients reduce their risk of further problems
not attending Cardiac Rehabilitation OR not booking to attend Cardiac Rehabilitation OR * no report of booking/attending Cardiac Rehabilitation	Attending Cardiac Rehabilitation can reduce your risks of further heart problems, discuss with your GP Contact your local Cardiac Rehabilitation Co-ordinator (see resource map)

BMI Response options and relevant recommendations

Response	**Recommendation**
are within healthy weight range	Maintaining healthy weight by regular physical activity and healthy eating reduces the risk of more heart problems
are not within healthy weight range OR * no report of height or weight	Congratulations if you are already moving toward a healthier weight Modify/lower amount of fat in your diet Consult dietitian or ring Heartline on 1300362787 Limit alcohol intake Increase physical activity (see physical activity above)
are not within the healthy weight range	Consult GP, dietitian or ring Heartline on 1300362787

Diabetes Response options and relevant recommendations

Response	**Recommendation**
a history of diabetes	Having diabetes can increase your risk of heart disease. Please discuss these risks and treatment with your GP
no history of diabetes OR * no report of history of diabetes	Diabetes can increase your risk of heart disease. Please see your GP for routine annual screening

Report Card Key to Asterisk insertion

Patient Summary of Prevention Care *Name:* *DOB:*
(as reported on your Heart and Stroke Survey) **Diagnosis**: **Discharge Date**:

	You reported that you:	**Discuss with your GP** *	**Summary of Heart Foundation Recommendations for Care**
Cardiac Rehabilitation	• no report of cardiac rehabilitation • not having attended & not having booked cardiac rehabilitation	*	•
• Blood Pressure	• having a history of high blood pressure & no report of medication & no exercise & not following diet (any negative response) • no report of history of high blood pressure • not having a history of high blood pressure & list medication	• • *	•
• Physical Activity	• no report of exercise • Heart – doing less than 5 days per week • Stroke – doing less than 3 days per week	• *	•
• Smoking	• no report of smoking • having smoked in last 6 months	• *	•
• Cholesterol	• no report of high cholesterol • having a history of high cholesterol & no medication • not having a history of high cholesterol & list medications	• *	•
• Weight •	• not being within the weight range • no report of weight or height	• *	•
• Diabetes	• no report of diabetes • history of diabetes	• *	•
• Aspirin /Antiplatelet	• no report of aspirin • are not currently taking aspirin • report being told NOT to take aspirin but list medication (except Ticlodipine & Clopidogrel)	• *	•
• Atrial Fibrillation	• having a history of AF and no report of medications • no report of AF	• **	•

*** = You and your GP can make a difference - discuss a plan for your ongoing Heart care with your GP**

Help Prevent Another Vascular Event (Heart and Stroke)

Appendix 3.8

Pre-testing of Intervention Materials

PAVE Pre test protocol for patient intervention material

Aim of Pre testing

Purpose of PAVE :

To help patients who have had a stroke or heart attack prevent a further stroke or heart attack.

Purpose of the group

To get some feedback on the acceptability, readability, clarity and comprehensibility of PAVE intervention material.

Group Composition/ Representativeness

We are interested in a range of opinion therefore the greater the mix of people, the better. Groups will include people who have heart problems, or stroke and where possible, their carers. Factors to be considered include age, sex, ethnic background, education, employment status, area of residence, and current health status.

Recruitment

How to recruit groups

An informal network of colleagues including dietitians, diabetic educators, physiotherapists, cardiac rehabilitation nurses, leaders of community stroke groups will be approached to obtain access to representative groups of people who have suffered Stroke or Heart problems.

A discussion with individual group leaders will be necessary to determine the suitability of the group members for pre-testing, for example, whether or not group members speak and read English; how acute is the condition of the majority of the group. Once the group's suitability is determined, a list of participants including name, address age and sex should be completed. (Age and sex will be used for the purpose of data analysis) A date for pre-testing is set with the group leader.

Pre-test information letter and consent form will be given to the group leader to distribute to each member of the group prior to the planned visit. This letter will include the date and time of the Pre-testing session. The group leader will be contacted during the week prior to the session and asked to remind the group of the impending visit, reiterating that members are under no obligation to attend the session or be part of the pre testing. Patients should also be reassured that the decision to refuse to participate in the pre-testing session will not influence in any way their current or future treatment.

Carers will be asked, where possible, if they would like to participate. Carers are to be given a copy of the intervention materials. If the carer is helping a participant

complete the pre-test, the carer may not wish to complete a separate pre-test. It should be noted that the carers' response to the intervention material is just as valuable as that of the participant, as in many cases it is the carer who attends to household correspondence.

Participant Information
The 'How to Prevent another vascular Event (Heart and Stroke) pre-test invitation letter includes a relatively comprehensive outline of the PAVE project and the aims and objectives of pre-testing the patient intervention material. Patients who do participate in pre-testing will be given a further oral explanation of the PAVE project and aims and objectives of Pre-testing the patient intervention material at the beginning of the pre-test session.

Participants will be reminded that

- Participation in pre-testing is strictly voluntary
- All information discussed during the session is confidential
- Participant response is anonymous
- An information sheet will be given to participants at the beginning of the session explaining the scenario.
- Participants will also be given enough time to decide if they still wish to take part.
- Participants will need to complete the participation form giving consent.

How many groups
Three separate groups have been suggested

- Diabetic nutrition group (Catherine Roe)
- Newways Stroke Club
- Cardiac Rehabilitation group

How many people to a group
Invite 10 people, and ideally six or seven should turn up. This allows for refusal and non-attendance.

Location
Group leaders will be consulted on the location of groups, whether they are at the end of a planned session or whether a new time is agreed upon by the group leader. The group leader will be consulted about the provision of afternoon or morning tea.

Groups to be held at the respective meeting places of the patients – for convenience of participants

PAVE will provide all staff and equipment required for the pre-test process (i.e. pens, paper etc). PAVE will provide afternoon tea to make the pre-testing more informal, social and conducive to discussion.

Appreciation
Appreciation will be shown by providing at the completion of the pre testing a National Heart Foundation Cookbook.

Session Procedure

- Group facilitator to run All the groups (for consistency)
- Second person to scribe comments and important information relevant to the session
- Data to be collated within 24 hours of group session – so that impressions, feelings, memories are still fresh
- Refreshments are made available at the beginning of the session to allow time for late comers and to give participants time to begin to feel comfortable
- Seating: circular arrangement of seats

Rules for the session

- It should be noted that all attempts will be made to minimise any disruption to the group's normal activities, such as scheduling at the completion of a normal group session.
- Pre-testers will respect the needs and requests of participants and respond appropriately.
- If at any time one or more of the participants or leaders requests termination of the session (for ANY reason), the session will be terminated for that person.
- Participants should be made feel comfortable, and open, informal discussion encouraged.
- It is the responsibility of the PAVE group facilitator to keep the discussion 'on track' and to encourage fair participation across the group. The monopolisation of discussion by one or two members should be discouraged to allow all willing participants an opportunity to voice their opinion.
- There is an expectation that all members of the group will have a say.
- People should say what they think and not what they think someone else wants to hear.
- There are no right or wrong answers.
- The group facilitator will reinforce that we are interested in many different opinions and points of view.
- Special Consideration should be given to participants experiencing difficulty with communication. Some possible reasons for this include a non- English speaking background, dysphasia or aphasia as a result of stroke, dementia, depression, confusion, short or long term memory loss, brain cell degeneration.
- All participants will be treated with respect, and the facilitator will be sensitive to the needs of all members of the group. There will be no discrimination of participants.

Agenda for the session:

- Introduction
- Group leader introduces Project Manager
- Welcome and thankyou for your time and interest in the PAVE project
- Project Manager briefly and informally introduces herself
- Brief overview of the PAVE project

- Aim of PAVE (secondary prevention of CVD)
- How are we going to bring about change through PAVE (Intervention Materials)
- Brief discussion of the Hunter Heart and Stroke Register
- Brief discussion of Register patient questionnaire
- Tying the results of Register questionnaire with current national guidelines for CVD to produce the Intervention material
- The need for Pre-testing Intervention Materials
- Any questions so far? (ask of participants and carers)
- The rules for the session (see attached).
- Outline of the session
- read material (15 minutes allowed for reading the material)
- pen and paper survey etc
- oral questions
- To help participants understand the material, provide the following scenario.
- When the group is ready, distribute the questionnaire sheet with the structured questions and allow each participant enough time to complete each question. Be prepared to clarify information as required.
- Commence the group discussion based on key questions.
- The scribe should be taking notes on what the group is saying.
- Remind the group that they will not be required to complete any further surveys or interviews regarding the information.
- Session wind-up and Thankyou

Data Analysis

- Group characteristics noted by scribe i.e.
- Group name and type eg Cardiac Rehabilitation group
- Number of participants
- Sex
- Age range
- Ethnic mix
- Chief diagnostic characteristic of group
- Number and characteristics of carers
- Results of pen and paper survey (quantitative)
- Results of oral questions (qualitative)
- Scribe to take additional notes throughout the session (qualitative)

Reference:
Hawe.P., Degeling.D., Hall.J. 1995 Evaluating Health Promotion: A health workers guide, Maclennan + Petty, Sydney.

PAVE pre test protocol – patient information sheet

Patient Information Pre-test Instructions

Setting the scene
"Imagine you are a patient who has just been discharged from hospital after having a heart problem. Several weeks after discharge you receive a letter in the mail from the Hunter Heart and Stroke Register. The Hunter Heart and Stroke Register keeps a record of all patients in the Hunter who have been discharged from hospital after having had a stroke or a heart problem. You are also asked to fill out the Hunter Heart and Stroke Register questionnaire. This questionnaire asks about your history for example have you ever been told by a medical person that you have high blood pressure or diabetes. The questionnaire also asks about diet, exercise, smoking, and medications.

You agree to have your details kept on the Hunter Heart and Stroke Register, and you fill out the questionnaire. Two weeks later you receive a letter in the mail. The information in the letter has been put together according to the diagnosis you were given upon discharge from hospital, for example acute myocardial infarction (heart attack). The report also incorporates the answers YOU gave in the Hunter Heart and Stroke Register questionnaire."

Patient Material 'Pre-Test' Information

A group of researchers in the Hunter are doing a study which involves sending people who have been discharged from hospital with either a heart or stroke problem some written material in the mail. We would like to see if the material we are planning to send is appropriate and acceptable.

How can you help
By reading the material that we have designed for the 'How to Prevent Another Vascular Event (Heart and Stroke)' project, and telling us what you think about it.

Testing the material
The process should take approximately 45 minutes and will be informal. It will involve reading the provided documents as if they had just arrived in the mail, and answering some written questions as well as a brief discussion about the material.

The documents will include
1. Patient Letter
2. A Summary Stroke or Heart Report (created for a particular patient)
3. A Resource Map

Information is anonymous
Participation is voluntary. You may withdraw from the study at any time. All responses to questionnaires will remain strictly confidential and will be seen only by research staff. Your questionnaire will be assigned a code number and your name will not be used to record or report results. Any comments you make regarding the material (or any other matter) will remain anonymous and confidential.

If you have any questions, please do not hesitate to ring Alison Koschel, Project Manager, on (02) 4923 6276.

You should keep this copy of this Information sheet for your records.

Alison Koschel
Project Manager
Prevent Another Vascular Event
Level 3 David Maddison Clinical Sciences Building
Royal Newcastle Hospital
Newcastle NSW 2300
Ph: (02) 49 236276
e-mail: akoschel@mail.newcastle.edu.au

Footnote: The University requires that all subjects are informed that if they have any complaints about the manner in which this research project is conducted, these may be given to the research person listed above or, if an independent person is preferred, to the: University Human Research Ethics Officer, Office for Research, The Chancellery, University of Newcastle, 2308.

If you have any questions or concerns about your rights as a participant in this study or complaints about how the study is being run and you wish to speak to an independent person, please contact Dr Nicole Gerrand Professional Officer Hunter Area Research Ethics Committee Locked Bag No. 1 NEW LAMBTON NSW 2305 Ph: (02) 4921 4950 Fax: (02) 4921 4818

Patient Material 'Pre-Test'

Consent Form

I have read and understood the information letter about the *How to Prevent Another Vascular Event (Heart and Stroke)* patient material pre-test. I understand that participation in the testing will be voluntary. All information I give is to be kept strictly confidential. I know I can withdraw at any time.

Signature	Date

I do not wish to participate in the Prevent Another Vascular Event (Heart and Stroke) patient material pre-test. ☐

(If you tick this box and return this form to us, we will not contact you further)

How to Prevent Another Vascular Event
(Heart and Stroke)

Question 1 Would you have read this material if it was sent to you in the mail?

Patient Letter	Summary Report	Resource Map
A) Yes	A) Yes	A) Yes
B) No	B) No	B) No
C) Unsure	C) Unsure	C) Unsure

Question 2 How much information is on each page?

Patient Letter	Summary Report	Resource Map
A) Too much	A) Too much	A) Too much
B) Too little	B) Too little	B) Too little
C) Just enough	C) Just enough	C) Just enough

Question 3 The material is

Patient Letter	Summary Report	Resource Map
A) Easy to understand	A) Easy to understand	A) Easy to understand
B) Difficult to understand	B) Difficult to understand	B) Difficult to understand
C) Unsure	C) Unsure	C) Unsure

Question 4. Is the print size

Patient Letter	Summary Report	Resource Map
A) Too small	A) Too small	A) Too small
B) Too big	B) Too big	B) Too big
C) Suitable	C) Suitable	C) Suitable

Question 5 *Is the colour scheme*

Patient Letter	Summary Report	Resource Map
A) Suitable	A) Suitable	A) Suitable
B) Unsuitable	B) Unsuitable	B) Unsuitable

Question 6 Could you please circle any words on any of the forms that you think might be difficult for some people to understand.

Oral Questions

1) What is the main point of the patient letter?

……
……

2) What does this letter ask you to do?

……
……

3) If you are unsure as to what to do

How can we state our message more clearly?

……
……

4) Would you take the report to your GP?
And *If not, Why not*?

……
……

5) *If you won't take this report to your GP,*
Would you act independently and contact resources on the resource map to try and reduce your risk of a further heart or stroke event?

……
……

Appendix 3.9

Six month follow up survey

PAVE 6 month Survey

We are interested in your health since you filled in the last health questionnaire for the **Heart** and Stroke Register and Pave study. We would be grateful if you would answer all of the following questions.

1	Have you **ever** been told by a doctor that you had any of the following conditions?	Yes	No
a)	**High Blood Pressure**?	1	2
b)	**Diabetes**? *(sugar in the blood*)	1	2
c)	**High cholesterol**?	1	2
d)	**Atrial Fibrillation**? *(irregular heartbeat)*	1	2
e)	**Stroke**? / Heart?	1	2
f)	**Previous heart attack**? / Previous stroke?	1	2
g)	**Angina**?	1	2
h)	**Heart Failure**? *(often called fluid on the lungs or an enlarged heart or weakness of the heart)*	1	2

2	Aspirin Use	Yes	No
a)	Have you ever been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to take Aspirin on a regular basis, that is everyday or almost everyday?	1	2
b)	Are you currently taking **Aspirin** on a regular basis, that is every day or almost every day?	1	2
c)	Have you been told by a medical person (eg doctor, nurse) that you should **not** currently be taking **Aspirin**?	1	2

Please turn over…

3 Weight and Height

a) How tall are you without shoes? *(please write your answer in **either** centimetres or feet & inches)* cms Ft/ins

b) How much do you weigh without clothes/shoes? *(please write your answer in **either** kilograms or stones & pounds)* kg St/lb

4	Physical Activity	Yes	No
a)	Since your admission to hospital have you been **advised** by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to do any physical activity?	1	2

b) Since your hospital admission, in an average week, on <u>how many</u> days of the week would you do at least 30 minutes of physical activity? Physical activity can be walking, swimming, gentle cycling etc. Physical activity can be done in 2 lots of 15 minutes or 3 lots of 10 minutes each day

(*please circle the no. of days you have been able to do exercise, i.e. 0 for no days…)*

0 1 2 3 4 5 6 7

		Yes	No
c)	Do you have any physical problems (e.g. Arthritis, back problems, hemiparesis) which stop you from doing any physical activity?	1	2

The following statements ask about your intentions to exercise.

(please circle the number that best describes your intention – choose ONE number only)

d) I currently do not exercise and I do not intend to start exercising in the next 6 months 1

e) I currently do not exercise, but I am thinking about starting to exercise in the next 6 months 2

f) I currently exercise, but not regularly 3

Please turn over…

g) **I currently exercise regularly, but I have only begun to do so within the last 6 months** 4

h) **I currently exercise regularly, and have done so for longer than 6 months** 5

	What types of the following activities do you do to get your physical activity? (***please circle either 1 for yes or 2 for no for each item)***	Yes	No
i)	**Sports activities (such as golf, bowls etc)?....**	1	2
j)	**Supervised groups (such as tai chi, heartmoves, pilates, aqua aerobics, gentle exercise classes etc)?...**	1	2
k)	**Individual activities (such as walking, running, yoga, swimming, cycling, walking machine etc)?...**	1	2
l)	**Incidental activity (such as housework, gardening, lawn mowing etc)?**	1	2

5	Smoking	Yes	No
a)	**Have you smoked more than 100 cigarettes in your entire life?**	1	2
b)	**Have you smoked any cigarettes in the last 6 months?**	1	2
c)	**Have you smoked any cigarettes in the last week?**	1	2

If you have EVER smoked

(please circle the number that best describes your intention – choose ONE number only)

d) I currently smoke and I do not intend to stop smoking in the next 6 months 1

e) I currently smoke, but I am thinking about stopping smoking in the next 6 months…… 2

Please turn over…

f) I currently smoke, but not regularly 3

g) **I currently do not smoke, but I have only stopped smoking within the last 6 months…** 4

h) **I currently do not smoke, and have not done so for longer than 6 months…** 5

		Yes	No
i)	**ıave smoked in the last 6 months**	1	2
	Since your admission to hospital have you been advised by a medical person (eg. doctor, nurse, physiotherapist, dietitian) to stop smoking?		
j)	**ou made any attempts to quit smoking?**	1	2

k) **If you have tried to quit smoking**, how many times have you been able to stop for more than 24 hours?

(please write the number of times in the box)….

If you have tried to quit smoking, what ways have you tried to stop smoking?

(*please circle **all** the ways you have tried to stop smoking)*

		Yes	No
l)	**Cut down on strength of cigarette**	1	2
m)	**Cut down on number of cigarettes smoked**	1	2
n)	**Cold turkey (stopped abruptly)**	1	2
o)	**Using Nicotine Replacement Therapy (patches, inhalers, gum)**	1	2
p)	**Using Zyban (Buproprion)**	1	2
q)	**Called the Quitline for assistance**	1	2
r)	**Used written material such as a Quit Kit**	1	2
s)	**Hypnotism**	1	2

Please turn over…

t)	**Acupuncture**	1	2
u)	**Discussed options and had assistance from Pharmacist**	1	2
v)	**Discussed options and had assistance from your doctor**	1	2
w)	**Other *(Please write here)*.**	1	2

6	Cardiac Rehabilitation	Yes	No
a)	**Have you been advised by a medical person (e.g. doctor, nurse, physiotherapist, dietitian) to attend an outpatient cardiac rehabilitation programme?**	1	2
b)	**Have you booked to attend an outpatient cardiac rehabilitation programme?**	1	2
c)	**Have you attended any sessions of an outpatient cardiac rehabilitation programme?**	1	2
d)	**Have you completed all but one session of an outpatient cardiac rehabilitation programme?**	1	2
7	Modified Fat Diet	Yes	No
a)	**Have you been advised by a medical person (e.g. doctor, nurse, physiotherapist, dietitian) to follow a modified fat diet?**	1	2
b)	**Are you currently following a modified fat diet?.**	1	2

The following statements ask about your dietary intentions

(please circle the number that best describes your intention – choose ONE number only)

c)	I currently do not follow a modified fat diet and I do not intend to do so in the next 6 months	1
d)	I currently do not follow a modified fat diet, but I am thinking about doing so in the next 6 months	2

Please turn over…

e)	I currently follow a modified fat diet, but not regularly	3
f)	**I follow a modified fat diet, but I have only started doing so within the last 6 months**	4
g)	**I currently follow a modified fat diet, and have done so for longer than 6 months**	5

8	**Health Care Services**	Yes	No
a)	**Since you last completed a questionnaire have you visited your General Practitioner?**	1	2

b) **<u>If you have visited your General Practitioner</u>, how many times have you been?**

(please write the number of times in the box).

c)	Have you visited, or been visited by any other health care professional?	Yes	No

(*please circle either 1 for yes or 2 for no for each item)*

Specialist	1	2
Physiotherapist	1	2
Dietitian	1	2
Acupuncturist	1	2
Occupational therapist	1	2
Massage therapist	1	2
Pharmacist	1	2
Other (please write here)	1	2

Please turn over…

9 **Medications**

Please list all the medications that you are currently taking. (Please copy the names as written on the container). Include herbal preparations and vitamins.

I do not take any medications (tick box if applicable)

THIS SECTION WAS ONLY SENT TO THOSE WHO WERE IN A PATIENT INTERVENTION GROUP

Several months ago we sent you a letter and some other information in the mail. This package contained a letter about our study, a report card highlighting some areas of your care that could be improved, a resource map for your area, and a cookbook.

	Information package	Yes	No
10	**Do you remember receiving the letter and information in the mail?.**	1	2

Please turn over…

11	Report Card	Yes	No
a)	**Do you remember receiving the report card mailed in your package?**	1	2
b)	**Do you remember reading the information in the report card?**	1	2
c)	**Do you remember if you found the information in the report card useful?**	1	2
d)	**Do you remember if you found the information in the report card easy to understand?**	1	2
e)	**Do you remember if you kept the report card to use again?**	1	2
f)	**Do you remember if you took the report card to your doctor?**	1	2
g)	**Do you remembmer if you either left your report card with your doctor or left a copy of your report card with your doctor?**	1	2

12	Resource Map	Yes	No
a)	**Do you remember receiving the resource map mailed in your package?**	1	2
b)	**Do you remember reading the information in the resource map?**	1	2
c)	**Do you remember if you found it useful to have information on services near your area?**	1	2
d)	**Do you remember if you found the information in the resource map easy to understand?**	1	2
e)	**Do you remember if you kept the resource map to use again?**	1	2
f)	**Do you remember if you made contact with any of the services on your resource map?**	1	2

Please turn over…

13	Cookbook	Yes	No
a)	**Do you remember receiving the cookbook mailed in your package?**	1	2
b)	**Do you remember reading the information in the cookbook?**	1	2
c)	**Do you remember if you found the information in the cookbook useful?**	1	2
d)	**Do you remember if you kept the cookbook to use again?**	1	2

14 Are there any other comments you would like to make about the information mailed to you?
(please write on the lines below)

What treatment or event do you think has helped the most?.
(please write on the lines below)

Did you complete all the pages of this questionnaire? *(the tick boxes may help you)*

Page 1 ☐ Page 2 ☐ Page 3 ☐ Page 4 ☐ Page 5 ☐ Page 6 ☐

Page 7 ☐

Date of completing questionnaire ...../...../.....

We appreciate your assistance with this questionnaire

Appendix 3.10

Database process instructions for assistants

SELECTION CRITERIA FOR APPROACH

Study subject is discharged from hospital and the new admissions patient data is received in a batch from the HAH, based on hospital discharge data in an Access file. Data is imported from access into SAS program for manipulation as a new patient or readmission by Register staff. Each batch is given source code i.e. December 2002 is 1202, January 2003 is 0103. Data only for those to be contacted is then imported into Access database "AINDEX, table abase".

(i) Age limit - The Register currently uses over 20 with no upper limit at the current age of this admission

Register – Table abase is cleared (those who are resolved i.e. never need to be contacted again get macro to backup)

Check status of admissions (if admitted & discharged in 6 months prior - ineligible as per Register rule (see 6 month rule)

6 month rule A person is admitted some time in Dec 02 but has also been admitted some time in 6 months previous and has been sent before from the Register for that prior admission. If they have said yes to that invite they become a PH or PS and are okay for PAVE. Those that have not responded should not be sent again unless they are readmitted more than 6 months after the initial admission. Rationale: Protects the study subject who has not yet responded to invite because they may be too ill or may be back in hospital.

Dependant on inclusion criteria (see separate appendix) and register status (i.e. already on register) everyone is categorised as follows.

RH	Register heart	ineligible for study, PAVE contact ceases here, numbers only required for upfront
RS	Register stroke	ineligible for study, PAVE contact ceases here, numbers only required for upfront
AH	Alison heart	New admissions, mailed out by register
AS	Alison stroke	New admissions, mailed out by register
PH	PAVE heart	Already on register, PAVE sends out consent
PS	PAVE stroke	Already on register, PAVE sends out consent

MAIL OUT PROCEDURE

The register assistant mails out information letters and consent forms for both register and PAVE for the following;

Register mail-out packs for RH, RS, AH & AS

The Pave study assistant mails out information letters and consent forms for Pave only for the following;

PAVE mail-out packs for PH & PS

Each mail-out a log is kept for the source code and a hard copy of the send out is also filed in a study subject envelope in a locked draw in the study filing cabinet.

MAILOUT CHECK PROCEDURE WITH PAVEMASTER

The register assistant exports study subjects with AH/AS/PH/PS codes into the PAVEMASTER/Pavesent table. AINDEX source and PAVEMASTER source based on source code should be equal. All discrepancies should be listed and discussed with the Heart & Stroke Manager for amendment through SAS into the appropriate database and table.

MAILOUT FOLLOW UP – NON RESPONDERS

Those who have not responded in two weeks get a reminder letter

PH resend in Aindex sort source code and then ask Pave reply for -1 (not responded)

Those who have not responded in six weeks get a reminder pack (consent forms)

Those who have not responded a week after the six week reminder get a last reminder letter

PH and PS SEND OUT PROTOCOL (Readmission Send- outs for PAVE)

Readmissions are in Aindex./ABASE

All readmissions have a source starting with “p” and then either “h” for a heart questionnaire or “s” for a stroke questionnaire. This month they also have a nsource number such as 1202, so the whole thing is either “ph1202” or “ps1202”

- Print a query selecting all the readmissions make 2 copies
- Find the consent form in the cabinets and check there is nothing to say don’t send on it
- If ok then write on the back “PAVE and the date”
- Change the criteria by putting for example “ph1202” as the criteria for the source field
- Print labels and check to ensure quality.
- Print letters on Heart and Stroke letterhead & have H & S Register Manager sign
- Write Id number on consent form and questionnaire
- Package includes letter, cream information sheet, cream consent form, appropriate Heart or Stroke questionnaire, reply paid envelope
- Ensure both envelopes are stamped with Heart and Stroke Register Private and Confidential
- Enter details of sendout on whiteboard
- Record dates and future dates in log file, ask register assistant to record in documentation file
- File one copy of sendout in filing cabinet (PAVE SENDOUTS) other to Register assistant

- This same protocol can be used for the 2 week reminder letter, the 6 week reminder letter and the final reminder letter

RESPONDERS - DATA ENTRY ABASE

Replies to Register and PAVE study will be entered in Register database

- Patient returns consent form and baseline survey for both Register and PAVE study
- Patient returns consent form and baseline survey for Register and PAVE study consent form is missing or ticked NO. Reply = 1 and date entered & Pave = 5 (PAVE contact ceases here)
- Patient returns baseline survey & neither Register nor PAVE study consent form & source code is AH or AS. Register assistant sends letter & both consent forms and baseline survey put in pending file until consent form comes back. Reply = 6 & Pave = 6
- Patient returns baseline survey & no PAVE study consent form & source code is PH or PS. Pave assistant sends letter on Register letterhead & consent forms and baseline survey put in pending file until consent form comes back. Pave = 6 (Reply will already be 1)
- Register assistant notified by post RTS = 2 or by phone not heart = 4 or notified of death = 3 for both reply and pave

RESPONDERS - UPDATE DATA ENTRY ABASE

After Register assistant updates codes, they run macro to move patients into Gen2002 for general entry of baseline survey data & run macro to update patients reply codes in pavemaster/pavesent (PAVE Code is -1 until reply then changes after macro runs to 11 in abase)

RESPONDERS - PAVEMASTER DATABASE

- Updated records for consented in Pavemaster/pavesent should match those in Pavemaster/pave agreed
- Pave consent forms entered into Pavemaster/pave agreed form

- Once GP name has been selected a random group will be generated (see separate protocol)

MONITORING

Progress rates

Regular reporting monthly to investigators group of progress rates Run query **preply rates progress,** update numbers in log sheets

For consented group - complete Send out for different points, i.e. send out one, after two weeks, after 6 weeks and after another week

Denominators

Denominators required for progress rates. Run query **source group rate**

update numbers in log sheets

Target response rate

Denominators required for progress rates. Run query **pave group count**

update numbers in log sheets

Intervention processed status

Required for progress rates. Run query **how many processed**

update numbers in log sheets

DATA ENTRY - BASELINE SURVEY

- Baseline surveys coded by RA prior to entry, check for logic
- Coding manuals to be followed
- Enter data in “gen 2002” for general entry
- Enter medications on back page in “medicines form”

Duplicate surveys

- This gets rid of duplicates in the Gen2002 database
- To clean the gen 2002 database you need to first run the query “find duplicates”.
- Table “general” retains the newest (most current date) version
- Table “general duplicates” gets the oldest version of the questionnaire
- To move the old version to duplicates, open the append query – “move duplicates” (in design view). Enter fstno, fmonth, fyear (this was found in previous

find duplicates query) and then run, then change query from append to delete query and run, do not save query as delete query though leave as append query

- To move old version medications to “medsdup”
- Open append query – “move duplicate medications” (in design view) enter fstno, fmonth, fyear (this was found in previous query) and then run, then change query from append to delete query and run, do not save query as delete query though leave as append query

INTERVENTION – compilation stage

GP only group (group 1)

Heart

GP letter

GP report

GP guidelines (heart guidelines in bottom of filing cabinet)

Resource map (urban or rural dependant on patient address)

GP only group (group 1)

Stroke

GP letter

GP report

GP guidelines (stroke guidelines created as box above)

Resource map (urban or rural dependant on patient address)

Stroke GP referral

GP & Patient group (group 2)

Heart

GP letter

GP report

GP guidelines (heart guidelines in bottom of filing cabinet)

Resource map (urban or rural dependant on patient address)

Patient letter

Patient Report

Resource map (urban or rural dependant on patient address)

Cook book

GP & Patient group (group 2)

Stroke

GP letter

GP report

GP guidelines (stroke guidelines created as box above)

Resource map (urban or rural dependant on patient address)

Stroke GP referral

Patient letter

Patient Report

Resource map (urban or rural dependant on patient address)

Cook book

Stroke Patient referral

Patient group (group 3)

Heart

Patient letter

Patient Report

Resource map (urban or rural dependant on patient address)

Cook book

Patient group (group 3)

Stroke

Patient letter

Patient Report

Resource map (urban or rural dependant on patient address)

Cook book

Stroke patient referral

Control group (group 4)

Heart & Stroke

No Intervention materials

INTERVENTION – Process

Each Monday Pave assistant will check paveagreed (not processed), patient datesent and gp datesent = blank then reports and letters will be generated dependant on group assignment. Control group should be default date

Merge Questionnaire and Register data using two separate Merge Databases

- PAVEGPMerge mdb
- PAVEPatientMerge mdb

Open PAVEpatient merge (opens to switchboard)

NOTE: F11 allows you to see directly tables and queries and forms

Using Mail Merge templates, merge demographic and questionnaire data into patient and GP report cards

Using Mail Merge templates, merge data into accompanying letters for Patients and GP's, as well as Stroke Guidelines

Creation intervention list

1) Ensure all Pave Consents and Questionnaires have been entered
2) Go to PAVE Patient Data Merge mdb
3) In PAVEPatientMerge mdb select CREATE FINAL MERGE TABLE
4) Clear all previous data in medmerge table by pressing CLEAR button
5) Clear all previous data in Final Merge Table by pressing CLEAR button
6) Update Medmerge Table (Press UPDATE button)
7) Update Final Merge Table (Press UPDATE button),ALL DONE Message comes up when process complete.
8) Open Final Merge Table
9) Examine data – looking for any missing data
10) Delete the following records from the final merge table

11) Any Record without a PAVEGROUP Number

12) Any Record without questionnaire data

13) Check for missing dates, Titles etc

14) SAVE Final Merge Table

NOTE: at this stage the total number of patients in Patient and GP Merge Final Merge Tables should be equal

15) Select Queries in PAVEPATIENTMerge mdb

16) Run Intervention List Query

17) PRINT LIST

18) Exit data base

Merging data

1) When merging documents always check merge options – choose the PAVEGROUP number that you need for this particular document then merge

2) Check through the merged documents to ensure that you have the correct group of patients. If you don't, you must go back and select the appropriate database and query for your document

3) Print reports and letters

Completion of process

1) Collate intervention materials for Patients and GP's for mail out

2) De-identify Patient and GP Reports

3) Copy GP and Patient Reports for storage

4) File Questionnaires, Consent forms, Reports etc.

5) Update mail list log

INTERVENTION - Patient

To generate Patient Report cards

- Print number of maps required
- Select Patient Heart Report Card, document opens in format mode
- Press merge Icon on toolbar
- Select query options
- Choose Pavegroup number for Group 2 & 3, select OK
- Select Merge

- Check that the names on Reports correspond to names on Intervention checklist
- Format report, check that data is correct, check Aspirin /Warfarin
- Save document
- Print one copy in colour
- Print one copy in Greyscale (filing)
- Close document
- Repeat Process for Strokes using Stroke Templates

To generate Patient Letter

- Letter is attached to query in PAVEpatient merge/final merge table
- Select the appropriate template for each group of patients eg
- Patient Heart Letter Group 2
- Patient Heart Letter Group 3
- Change date to today's date and save document
- Press merge Icon on toolbar
- Select query options
- Ensure Pavegroup number has been selected, select OK
- Select Merge
- Check that the names on Letters correspond to names on Intervention checklist
- Format letters
- Check that data is correct
- Print letters
- DO NOT SAVE; DO NOT PRINT A COPY
- Repeat Process for Strokes using Stroke Templates

INTERVENTION – GP

- In PAVEGPMerge mdb, opens on Switchboard Page
- Select CREATE FINAL MERGE TABLE
- Clear all previous data in medmerge table by pressing CLEAR button
- Clear all previous data in Final Merge Table by pressing CLEAR button
- Update Medmerge Table (Press UPDATE button)
- Press OK to continue
- Update Final Merge Table (Press UPDATE button)

- ALL DONE Message comes up when process complete
- Open Final Merge Table
- Examine data – looking for any missing data
- Delete the following records from the final merge table
- - Any Record without a PAVEGROUP Number
- - Any Record without questionnaire data
- Check for missing dates, Titles etc
- SAVE Final Merge Table
- Exit Database

To generate GP Report cards

- Select GP Heart Report Card, document opens in format mode
- Press merge Icon on toolbar
- Select query options
- Choose Pavegroup number 1 for Group 1 & 2, select OK
- Select Merge
- Check that the names on Reports correspond to names on Intervention checklist
- Format report
- Check that data is correct, check Aspirin /Warfarin
- Save document
- Print one copy in colour (for GP)
- Print one copy in Greyscale (filing)
- Close document

Repeat process for Stroke template

To generate GP Letter

- Select the appropriate template for each group of patients eg
  - GP Stroke Letter Group1
  - GP Stroke Letter Group 2
- Change date to today's date and save document
- Press merge Icon on toolbar
- Select query options
- Ensure Pavegroup number has been selected, select OK

- Select Merge
- Check that the names on Letters correspond to names on Intervention checklist
- Format letters
- Check that data is correct
- Print letters
- DO NOT SAVE; DO NOT PRINT A COPY
- Repeat process for Heart template

INTERVENTION – Stroke Guidelines

- Select Copy of Stroke Guideline Merge
- Document opens in format mode
- Press merge Icon on toolbar
- Select query options
- Ensure Pavegroup numbers 1 and 2 have been selected
- Select OK
- Select Merge
- Check that the names on Guidelines correspond to names on Intervention checklist
- Format Demographic details on Guidelines if necessary
- Check that data is correct
- Delete any blank pages between documents
- Print Guidelines as double sided documents
- DO NOT SAVE; DO NOT PRINT A COPY