THE FEASIBILITY OF IMPLEMENTING CARDIOVASCULAR DISEASE PREVENTION PROGRAMS IN COMMUNITY PHARMACY

Kevin Peter Mc Namara MSc BSc

Submitted to the School of Medicine, Faculty of Health Sciences, at Flinders University in fulfilment of the requirements for the Degree of Doctor of Philosophy

April 2012

Table of Contents

List of Tables

List of Figures

List of Boxes

List of Appendices

Abstract

Cardiovascular disease (CVD) is the greatest contributor to the adult burden of disease in Australia and internationally. Community pharmacists can effectively intervene to reduce CVD risk, but remain underutilised in primary care. The aim of this thesis is to investigate the feasibility of implementing pharmacist-delivered CVD prevention programs into Australian primary care. This thesis presents seven published peer review manuscripts addressing this aim, plus two additional unpublished manuscripts. These identify a rationale for engaging community pharmacists, and provide insights into the feasibility of different intervention models that might reasonably be adopted in practice.

Research for the thesis occurred in three phases. *Phase One* identified rural population needs for additional CVD prevention measures. Randomly selected electoral roll samples (n=3320) from three rural Australian regions were invited to undertake a comprehensive CVD risk assessment and self-report questionnaire. Findings highlighted poor control of key CVD risk factors stemming from widespread failure to diagnose and, if diagnosed, failure to adequately treat. It was also identified that individuals with uncontrolled CVD risk visited community pharmacists regularly, offering opportunities for additional intervention. The second project, examining patients at high risk of diabetes, found that medicines-use guidelines were not appropriately followed if lifestyle intervention could not

achieve CVD risk factor targets. This suggests a need for additional medication management interventions.

Phase Two developed and tested the feasibility of a community pharmacist intervention for the primary prevention of CVD. This intervention adhered to best practice principles for complex intervention development. The intervention systematically identified and addressed multiple cardiovascular health needs, while also integrating patient-centred care and behavioural change strategies. Seventy patients aged 50–74 years and without known CVD or diabetes were recruited from 10 community pharmacies to receive CVD risk assessment and five pharmacist-delivered counselling sessions. The primary outcome was change in mean estimated five-year risk of CVD. Post-intervention, a relative risk reduction of 25% +/- 8% was achieved, along with significant improvements to several individual risk factors. Clinical benefits and stakeholder feedback suggests this is a feasible model to test via randomised controlled trial (RCT).

Phase Three examined the effects of a continuous quality improvement (CQI) program for hypertension management on community pharmacist quality of care. Fifty-five pharmacists from metropolitan and rural Victoria were randomised within strata to one of three groups receiving different levels of CQI support (usual care, guidelines plus written advice, or comprehensive support). Primary outcomes were changes to proportion of treated patients reporting improved blood pressure (BP) management in several areas. Outcomes were inconclusive due to reduced sample at follow up, but suggested no intervention effect. Program adherence by participants was explored as an alternative objective. This identified several features of current practice environments limiting the effectiveness of CQI

initiatives. It suggests that initial efforts to deliver voluntary interventions such as health promotion will wane despite goodwill from pharmacists.

In conclusion, community pharmacists appear competent to deliver much-needed interventions for CVD prevention, but consistent implementation of effective interventions will require improved professional incentives (e.g. remuneration) and supportive systems for preventative care.

Declaration by Candidate

I certify that this thesis does not incorporate without acknowledgment any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

Signature:  Date: 26/9/2012

Kevin Mc Namara

Acknowledgements

I am extremely grateful for the excellent supervision provided to me by Professor James Dunbar, Associate Professor Jennifer Marriott, and Professor Prasuna Reddy during my postgraduate studies. Their support and guidance has extended well beyond their supervisory duties. This has been instrumental not just in shaping my thesis, but also in providing a direction for my future career. In this regard, I am particularly grateful to my primary supervisor, James Dunbar, for taking a gamble when he recruited me to Australia from Ireland in 2003. I hope it has paid off.

The staff and postgraduate students at Greater Green Triangle University Department of Rural Health (Flinders University), and the Faculty of Pharmacy and Pharmaceutical Sciences (Monash University) have been extremely generous in their assistance with research efforts for this thesis. I thank them for their friendship, and for creating a collegial and supportive environment in which to work.

Several of my work colleagues also provided a degree of personal support to my candidature that went beyond what was reasonable for me to expect. Benjamin Philpot has been an invaluable source of statistical and methodological advice, and never failed to help out when needed. Jenny McDowell had the misfortune of sharing an office with me for the entire period of my studies – I thank her for her

good humour, her patience (and chocolate stash) during stressful periods, and for volunteering to edit several lengthy project documents and thesis chapters along the way. Aside from philosophical differences about the use of hyphens, this has been a great experience. I am also grateful for the tireless dedication shown by Peta Trinder and Liz Morabito in supporting the PAART CVD project – it would not have been such a success without them. Edward Janus has provided exceptional insight, commitment and attention to detail in preparing several of the manuscripts included in this thesis. I also wish to state my appreciation for the extensive administrative support and expertise provided by Janet Leeder, Gill Beard and Liz Jackway.

Many additional researchers, health professionals, and patients were involved with the research projects in this thesis. I acknowledge and thank them all for their individual and collective contributions. I would also like to pay special tribute to the National Prescribing Service and the NHMRC National Institute of Clinical Studies for funding my two-year Quality Use of Medicines Fellowship, this was a fantastic opportunity from which I have benefited enormously.

My parents did everything they possibly could to make sure I grew up happy and had a good education. They deserve so much of the credit for getting me to this point. I will always be grateful for the life they have given me. Likewise, my brother, Paul, and two sisters, Julie and Ailís, have always been there to support me –or to take me down a peg or two if I needed that more at the time!

Most of all, my girlfriend Safeera has provided patience, love, comfort and support in abundance during this thesis, as well as many great memories. This has

meant so much to me, especially given that she did all of this while putting up with so many of my terrible jokes. I also thank her parents for their support, and for the many beautiful packed lunches and home-cooked dinners along the way!

Finally, to my reviewers I say thank you so much for taking the time to read my work.

List of Related Publications by the Candidate

All publications listed below emanated partially or entirely from the research described in this thesis.

Peer reviewed publications

Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy* 2012;46(2):183-191.

Mc Namara KP, Dunbar JA, Philpot B, Marriott JL, Reddy P, Janus ED. The potential of pharmacists to help reduce the burden of poorly managed cardiovascular risk. *Australian Journal of Rural Health* 2012;20(2):67-73.

George J, **Mc Namara KP**, Stewart K. The roles of community pharmacists in cardiovascular disease prevention and management. *Australasian Medical Journal* 2011:4(5);266-272. Available from http://www.amj.net.au/.

Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Janus E, Bunker S, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence,

Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010;10:264.

Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R**, Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in rural Australia: prevalence and treatment gaps in evidence based cardiovascular risk management. *Medical Journal of Australia* 2010;192(3):127-132.

Mc Namara K, Philpot B, Janus ED, Dunbar JA. Greater Green Triangle Diabetes Prevention Program: remaining treatment gaps in hypertension and dyslipidaemia. *Australian Journal of Rural Health* 2010;18(1):43-44.

Mc Namara K, Dunbar JA, Reddy P, Philpot B, Vaughan C, Morgan M, Janus E. How population health data can help primary care services to improve population health – a rural case study. *SA Public Health Bulletin* 2009(6);2:21-25.

Chapman A, Bunker S, Dunbar JA, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.

Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. The prevalence, detection and treatment of hypertension in rural Australia: the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medicine Journal* 2008;38(12):879-886.

Letters to the editor

Dunbar JA, Reddy P, **Mc Namara K**, Janus ED. Diabetes research and clinical practice. *Diabetes Research and Clinical Practice* 2010(90):1;e11-e12. doi:10.1016/j.diabres.2010.05.015.

Project Reports

Mc Namara K, Bunker S, Dunbar JA, Duncan G, Emery J, Howarth H, George J, Jackson S, Janus E, O'Reilly S, Peterson G. *Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease*. The Pharmacy Guild of Australia (2009).

Heistaro S, Janus E, Dunbar J, Laatikainen T, Kilkinnen A (editors). *Greater Green Triangle Risk Factor Studies: Limestone Coast and Corangamite Shire Surveys* (2006). Janus E, **Mc Namara K.** Blood pressure. Results section 4.7, p.23-24.

Heistaro S, Janus E, Dunbar J, Laatikainen T, Kilkinnen A (editors). *Greater Green Triangle Risk Factor Studies: Limestone Coast and Corangamite Shire Surveys* (2006). **Mc Namara K**. Medication use. Results section 4.15, p.40-42.

Conference research presentations

Philpot B, Dunbar J, Davis-Lameloise N, **Mc Namara K**, Janus E. *The implications of diabetes risk on cardiovascular disease risk.* Heart Foundation Conference 2011. 17–19 March 2011, Melbourne.

Mc Namara K, Janus E, Philpot B, Dunbar J. *Significant challenges remain to achieve risk reduction targets for cardiovascular secondary prevention and diabetes*. Heart Foundation Conference 2011. 17–19 March 2011, Melbourne.

O'Reilly SL, Dunbar J, Bailey M, George J, **Mc Namara KP**. *A community pharmacist-led primary care intervention can effect change in dietary behaviours*. Nutrition Society of Australia 2010 Annual Scientific Meeting, 29 Nov–3 Dec 2010, Perth.

Mc Namara K. *Characterising community pharmacist interventions to effectively reduce risk of cardiovascular disease onset*. 10th Pharmacy Australia Congress. November 2010, Melbourne.

Mc Namara K, Marriott J, Dunbar JA. *Identifying opportunities for community pharmacy intervention among patients with treated hypertension: patient-reported evidence treatment gaps*. National Medicines Symposium, 26–28 May 2010, Melbourne.

Mc Namara K, George J, Peterson G, Jackson S, Howarth H, O'Reilly S, Dunbar JA, Trinder P, Finch J, Bunker S, Janus E, Morabito L, Emery J, Duncan G, Bailey M. *Community pharmacists preventing primary onset of cardiovascular disease: key clinical outcomes*. Pharmacy Practice Research Summit, 24 March 2010, Canberra.

Mc Namara K, George J, Jackson S, Peterson G, Howarth H, Dunbar JA, Janus E, Finch J, Bunker S, Morabito L, Trinder P, O'Reilly S, Duncan G, Emery J. *Community pharmacists preventing primary onset of cardiovascular disease:*

developing a model of care. Pharmacy Practice Research Summit, 2–4 March 2010, Canberra.

Howarth H, **Mc Namara K**, Peterson G, George J. *The community pharmacy Healthy Heart Intervention Project – Experiences of participant pharmacists*. Australasian Pharmaceutical Science Association Annual Conference. 9–11 December 2009, Hobart.

Mc Namara K, Marriott J, Dunbar JA. *Translating evidence into practice for hypertension management: lessons from a complex primary care intervention*. Health Services Research Conference, 25–27 November 2009, Brisbane.

Mc Namara K, George J, Jackson S, Peterson G, Howarth H, Dunbar JA, Janus E, Finch J, Bunker S, Morabito L, Trinder P, O'Reilly S, Duncan G, Emery J. *Primary prevention of cardiovascular disease in community pharmacy: developing a framework for implementation*. 69th World Congress of Pharmacy and Pharmaceutical Sciences: Responsibility for Patient Outcomes, 3–8 September 2009, Istanbul.

Mc Namara K, Peterson G, George J, Jackson S, Howarth H, O'Reilly S, Dunbar JA, Trinder P, Finch J, Bunker S, Janus E, Morabito L, Emery J, Duncan G, Bailey M. *Clinical outcomes from a community pharmacy feasibility study for the primary prevention of cardiovascular disease.* 69th World Congress of Pharmacy and Pharmaceutical Sciences: Responsibility for Patient Outcomes, 3–8 September 2009, Istanbul.

Mc Namara K, Janus ED, Philpot B, Laatikainen T, Dunbar JA. *Identifying specific cardiovascular health opportunities for community pharmacy: a*

population health approach. 69th World Congress of Pharmacy and Pharmaceutical Sciences: Responsibility for Patient Outcomes, Istanbul, 3–8 September 2009.

Mc Namara K, Dunbar JA, Marriott J. *Integrating professional development into a quality improvement framework in community pharmacy*. 69th World Congress of Pharmacy and Pharmaceutical Sciences: Responsibility for Patient Outcomes, 3–8 September 2009, Istanbul.

Mc Namara K, Janus ED, Philpot B, Laatikainen T, Dunbar JA. *Addressing evidence treatment gaps for cardiovascular disease through primary care collaboration*. General Practice and Primary Health Care Conference: Driving Change. 15–17 July, 2009, Melbourne.

Mc Namara KP, Peterson GM, George J, Duncan GJ, Howarth HD, Dunbar JA, Jackson SL, Janus ED, O'Reilly SL, Oldenburg BF, Bunker SJ, Emery JD. *Healthy Hearts in Pharmacy: developing the framework for a pharmacy-based cardiovascular health program*. 2008 School of Rural Health Research Conference: Chronic Disease Management in Rural Areas, 16 October 2008, Shepparton.

Tideman P, Janus E, Bunker S, Kilkkinen A, **Mc Namara K**, Philpot B, Tirimacco R, Heistaro S, Laatikainen T, Dunbar J. *Detection and treatment of hypertension in rural Australia*. 2nd Annual Australia and New Zealand Endovascular Therapies Meeting, 6–7 August, 2008, Adelaide.

Mc Namara K, Janus ED, Tideman PA, Kilkkinen A, Dunbar JA, Bunker SJ, Philpot B, Tirimacco R, Heistaro S, Laatikainen T. *Dyslipidaemia in rural*

Australia: the evidence treatment gaps. General Practice and Primary Health Care Research Conference: Health for All? 4–6 June, 2008, Hobart.

Mc Namara K, Janus ED, Tideman PA, Kilkkinen A, Dunbar JA, Bunker SJ, Philpot B, Tirimacco R, Heistaro S, Laatikainen T. *Suboptimal use of medicines for dyslipidaemia in rural Australia*. National Medicines Symposium. 14–16 May 2008, Canberra.

Mc Namara K, Dunbar J, Laatikainen T, Philpot B. *Dietary advice to patients receiving pharmacotherapy for cardiovascular disease: is it being delivered?* General Practice and Primary Health Care Research Conference: Optimising Impact, 23–25 May 2007, Sydney.

Glossary

absolute cardiovascular risk	probability of a cardiovascular event occurring in a defined time period
anthropometric	relating to dimensions of the human body, e.g. weight, height, waist
antihypertensive	blood pressure-lowering
antiplatelet	prevent the formation of blood clots
biomedical factors	physiological parameters, e.g. blood pressure, lipid profile
cardiovascular disease	any disorder affecting the ability of the heart or blood vessels to function normally
cardiovascular event	a severe or acute condition relating to the heart or blood vessels, including the following: myocardial infarction, stroke, transient ischaemic attack, peripheral vascular disease, angina and congestive heart failure
co-morbidity	the presence of one or more conditions (or diseases) in addition to a primary disease or disorder
continuous quality improvement	systematic and ongoing evaluation of services as compared to accepted practice standards, and implementation of strategies to address identified deficiencies in the quality of care
coronary heart disease	a condition of the heart caused by narrowing of the blood vessels that supply the heart muscle

diastolic BP	the pressure in the arteries when the heart is at rest
dyslipidaemia/hyperlipidaemia	abnormal blood lipid (fat) levels
familial hypercholesterolaemia	a genetic disorder causing dyslipidaemia
high density lipoprotein (HDL) cholesterol	a type of lipoprotein, commonly referred to as 'good' cholesterol; high blood levels are thought to decrease the risk of heart disease
HAPA model	model for patient behavioural change where health professional support transitions from generating an intention to change, to planning change and supporting maintenance of new behaviours
home medicines review	assessment of patient medication and related issues undertaken by a pharmacist, normally undertaken in the patients home
hypertension	high blood pressure
implementation	efforts designed to get best practice findings and related products into use via effective change/uptake/adoption interventions
low density lipoprotein (LDL) cholesterol	a type of lipoprotein, commonly referred to as 'bad' cholesterol; high blood levels are thought to increase the risk of heart disease
medicines adherence	the extent to which a person takes their medicine in accordance with recommendations from a health professional
monotherapy	a single therapeutic agent
myocardial infarction	commonly known as a 'heart attack'; it is the death or damage of a part of the heart muscle due to insufficient blood supply to the heart muscle

primary care	essential healthcare made available in the community as the first contact in the medical management of a condition
systolic BP	the pressure in the arteries when the heart contracts
therapeutic inertia	health professional's failure to respond with treatment changes to unmet treatment targets
triglycerides	the most common type of fat in the body, it is found in the blood and fat tissue; high levels are linked to heart disease

Acronyms

ACEI	angiotensin converting enzyme inhibitor
ARA	angiotensin II receptor antagonist
ATSI	Aboriginal or Torres Strait Islander
AUDIT	Alcohol Use Disorders Identification Test
BMI	body mass index
BP	blood pressure
CALD	culturally and linguistically diverse
CES-D 10	Center for Epidemiologic Studies Short Depression Scale
CHD	coronary heart disease
CHIP C	Controlling Hypertension through Innovation in Primary Care (study name)
CI	confidence interval
CO	Corangamite Shire
COACH	Coaching patients On Achieving Cardiovascular Health
CP	community pharmacist
CVAR	cardiovascular absolute risk
CVD	cardiovascular disease
DALYs	Disability Adjusted Life Years
DBP	diastolic blood pressure
DPP	Diabetes Prevention Project
DQT	Diet Quality Tool
EHRM	European Health Risk Monitoring
GGT	Greater Green Triangle
GP	general practitioner
HAPA	Health Action Processes Approach
HBPM	home blood pressure monitoring

HIPS	Health Improvement and Prevention Study
HDL	high density lipoprotein
HMR	home medicines review
IQR	interquartile range
KYN	'Know your numbers' blood pressure awareness program
LC	Limestone Coast region
LDL	low density lipoprotein
MMAS	Morisky Medicines Adherence Scale
MONICA	MONItoring of CArdiovascular events
MRFI	multiple risk factor intervention(s)
NHFA	National Heart Foundation of Australia
NHHRC	National Health and Hospital Reform Commission
NHMRC	National Health and Medical Research Council
NSF	National Stroke Foundation
PAART	Pharmacist Assessment of Adherence, Risk and Treatment (study name)
POC	point of care
PRECEDE	Predisposing, Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation
PROCEED	Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development
RA	research assistant
RRMA	Rural, Remote and Metropolitan Area (Classification system)
SBP	systolic blood pressure
SE	standard error
SNAP	Smoking, Nutrition, Alcohol and Physical Activity (Guidelines)
TABS	Tool for Adherence Behaviour Screening
TC	total cholesterol
TG	triglycerides
WHO	World Health Organization
WI	Wimmera region

Chapter 1. Literature Review

The cardiovascular disease burden on society

Global burden of cardiovascular disease

Cardiovascular disease (CVD) is attributed with 31% of total global mortality and 10% of the total global burden of disease.[1] This makes it the leading non-communicable cause of premature death and disability worldwide, equating to roughly double the total burden of cancers.

As a general rule, developed regions such as Australia, Western Europe and North America are considered to be in the fourth (highly advanced) stage of what is known as the 'epidemiological transition' of health burden.[2] From a cardiovascular point of view, this model of health transition suggests that developed societies will experience a reduction in infection-related conditions such as rheumatic heart disease and nutrition deficiency-induced conditions affecting heart muscle. Conversely, there is a pronounced increase in age-adjusted incidence of non-communicable diseases such as CVD induced by changing lifestyles and increasing life expectancies.[1] This process commences when societies progress through the second and third phases of social and economic development.

The fourth phase typically produces a decline in CVD incidence as countries implement systems to better prevent and treat cardiovascular conditions. While age-adjusted mortality rates attributed to CVD have declined consistently over the past three or four decades in these developed countries, the decline in crude mortality rates has stalled in recent years as an ageing society and increased prevalence of obesity and diabetes offset the gains made.[3]

CVD in Australia

CVD remains an enormous health problem in Australia, second only to cancer in terms of its burden on society.[4] According to official statistics, CVD accounts for 18% of the total disease burden in Australia (second to cancer, 19%), and 78% of this burden stems from premature mortality.[4] In 2005, 35% of all Australian deaths and 29% of the fatal burden of disease (years of life lost) could be attributed to CVD and about 6.9% of Australians had a disability directly related to CVD.[4] According to the 2004–2005 National Health Survey, 19% of the population self-reports a current cardiovascular condition. In 2004–2005, CVD had the largest share of health expenditure, with costs estimated at $5.9 billion or 11.2% of all health system expenditure.[5]

Risk factors for cardiovascular disease in Australia

There is a cluster of highly prevalent risk factors and health behaviours that contribute significantly to CVD risk, but which can be controlled or avoided:[2] tobacco smoking, hypertension, overweight and obesity, physical inactivity, dyslipidaemia (high cholesterol), excessive alcohol intake, poor nutrition and diabetes. In fact, the first seven of these eight preventable risk factors were also

estimated to be the seven most important health risks (out of 14 major risks examined) in terms of their contribution to the overall burden of disease among Australians.[4] Diabetes was considered separately in this analysis as a separate 'disease' entity and is attributed as being the fourth largest contributor to the burden of disease after cancer, CVD and mental disorders.[4] Controlling these direct and indirect CVD risk factors is therefore extremely important and comprehensive national guidelines exist to address each risk factor.

Evidence-treatment gaps in the prevention and management of CVD risk factors in Australia

Major evidence–treatment gaps for CVD risk factors remain a significant barrier to optimizing cardiovascular health, and are manifested by the continued enormous contribution of CVD to the national burden of disease, health expenditure and human suffering. For example, around 90% of the risk of myocardial infarction observed worldwide is attributable to the combined effect of dyslipidaemia, smoking, hypertension, diabetes, abdominal obesity, psychosocial factors, physical inactivity and inadequate fruit and vegetable intake. In an Australian context, the significance of these cardiovascular risk factors on a population level is exacerbated by high – and in some cases increasing – prevalences,[6] combined with numerous evidence–treatment gaps in prevention, treatment and management of these conditions:

- **Tobacco use** is the largest single contributor to disease burden in adult Australians. Despite a 30% decline in daily tobacco use between 1991 and 2007, nearly half the population has smoked the equivalent of 100

cigarettes or more over the course their lives, and one in five adults continue to smoke regularly.[7] Although there is a trend towards decreased smoking prevalence with increasing age, one in ten adults aged over 65 years still smokes.[7] From a cardiovascular point of view, tobacco use is quite detrimental to health, increasing both myocardial infarction and stroke risk by a factor of three[8]– the risk increasing with heavier smoking.[9] Overall, one in three smokers will die from a smoking-related illness.[10] Unfortunately, Australian general practitioners (GPs) do not readily deliver smoking cessation advice despite evidence for the effectiveness of this intervention.[11-15]

- **Hypertension** affects about one-third of the adult Australian population.[16] [17] The link is clearly established between blood pressure (BP) control and health outcomes. Meta-analysis of large-scale observational studies demonstrates a progressive positive correlation between increasing BP and death.[18] For every 20 mmHg increase in systolic BP or 10 mmHg increase in diastolic BP above 115/75 mmHg, the risk of vascular death doubles. Cardiovascular mortality benefit associated with achieving BP control through medicines use has also been demonstrated via repeated large-scale clinical trials.[19-21] One-third of people with hypertension are unaware of their elevated BP.[16] The AUSDIAB study suggests that half of all Australians with diagnosed hypertension are not taking medicine, despite it being indicated for about three-quarters.[16] This may stem from a combination of suboptimal patient adherence to therapy and prescribing inertia. Overall, less than half of the patients taking antihypertensive medicines ultimately achieve BP control.[16]

- **Overweight and obesity** affected 60% of adult Australians according to the 1999–2000 AUSDIAB study.[22] More recent rural surveys have found a prevalence of overweight and obesity of 74% in men and 64% women.[23] This high prevalence represents a steady increase since the early 1980s.[23] Obesity is a risk factor for numerous chronic conditions as well as having its own complications.[24] A major US study found that the relative risk of mortality among female adults was 1.25 for weight gain of 5–8 kg, climbing to 2.65 with a weight gain of 20 kg or more.[25] A weight gain of just 10 kg after early adulthood is associated with increased risk of stroke, hypertension, coronary heart disease (CHD) and diabetes.[25 26] Clinicians and other health practitioners can assist by providing basic education and skills training, and raising awareness of important issues including the independent effect that abdominal obesity has in addition to overweight or obesity.
- **Physical inactivity** accounts for 6.6% of the national burden of disease in Australia.[5] Regular physical activity in itself protects against CVD, reduces cardiovascular risk factors such as overweight and high BP, and also increases HDL-cholesterol concentrations ('good' cholesterol). The absence of these benefits invokes a higher risk of multiple chronic conditions including CVD. It also provides moderate relief from several adverse pathophysiological mechanisms affecting cardiovascular function including insulin resistance induced by obesity.[24] In the 2004–2005 Australian National Health Survey,[27] one-third of adults indicated that they had undertaken no leisure-time physical activity in the preceding fortnight, a proportion which has remained relatively constant for the past 20 years.

The National Heart Foundation recommends a minimum 30 minutes moderate or vigorous activity (including walking) on most days of the week. Those who sit for more than 4–5 hours per day may require as much as 60 minutes of daily activity to avoid weight gain and other complications.[28] More recent evidence suggests that spending increasing amounts of time in sedentary activities has a negative effect on metabolic (and therefore cardiovascular) risk that is independent of the amount of physical activity undertaken.[29]

- **Dyslipidaemia** (blood cholesterol disorders) ranks seventh among major risk factors contributing to the overall burden of disease – accounting for 11.6% of total deaths and 6.2% of total DALYs (Disability Adjusted Life Years).[30] The exact relationship between different lipid profiles and constituents with CVD outcomes appears complex and may vary for different population and clinical subgroups, and individual cardiovascular-related outcomes.[31 32] However, after several decades of research, there is little dispute about the significant positive correlation between increasing plasma concentrations of total cholesterol, LDL cholesterol and/or triglycerides, and increasing risk of CVD incidence and mortality; and, a significant positive correlation between decreasing plasma concentrations of HDL cholesterol plasma concentration and increasing risk of CVD incidence and mortality.[31-36]

  About half of the adult population has total cholesterol concentration greater than 5.5 mmol/L,[5] often considered to be the definition of 'high' cholesterol. A balanced diet is essential for control of lipid levels on a population level, and consumption of full-cream dairy products has been

recognised as a reliable indicator of the intake of saturated fats (which increase cholesterol levels) across a population; the National Health Survey suggested that 52% of males and 39% of females still use full-cream dairy products,[37] indicating excess saturated fat intake across much of the population.

- **Poor nutrition** adversely affects a wide range of chronic conditions, including CVD.[38] National Health and Medical Research Council (NHMRC) dietary guidelines recommend sufficient intake of fruits, cereals, vegetables, nuts, fibre and antioxidants, while balancing energy intake and controlling consumption of saturated fat, salt and added sugar.[39] The National Health Survey found that most people (86%) aged 12 years and above consumed less than the NHMRC recommended intake of vegetables (five or more serves per day), and about half (46%) consumed less than the NHMRC recommended intake of fruit (two or more serves per day).[27] Health professional dietary advice to patients has been shown to facilitate increased fruit, vegetable, fibre and antioxidant intake, and reduce saturated fat intake.[40]
- **Diabetes,** an independent risk factor for CVD,[41] is increasing in prevalence as a result of increasingly prevalent CVD risk co-factors such as obesity, physical inactivity and high-fat diets.[42] Type II diabetes affects 7.5% of Australians aged 25 years or older – 50% of whom remain undiagnosed.[43] The greatest cause of mortality for diabetic patients arises from CVD, and even the pre-diabetic state of impaired glucose tolerance can increase CVD risk.[44] Strategies for diabetes risk factor management are very similar to those for other CVD risk factors.[42]

- **Excessive alcohol intake** can have a range of complex effects on the circulatory system, including raised BP, weight gain, increased arrhythmia risk, and some types of cardiac failure. Conversely, there are some cardiovascular benefits from moderate alcohol intake including raised HDL-cholesterol and a mild anticoagulant effect. Benefits of moderate drinking on CVD outcomes are nevertheless currently outweighed in Australia by the negative consequences of drinking to excess.[5] Recent Australian guidelines indicate that these health benefits should be optimised among drinkers of both genders by limiting alcohol intake to no more than two standard drinks on any day.[45] There is a lack of consensus about this limit, with suggestions that it fails to separate the adverse consequences of acute intoxication and long-term consumption. Studies suggests about two in five adult men, and one in five women, consumed alcohol at a level above what is considered healthy, and that increased consumption is associated with a greater likelihood of tobacco use.[46 47]
- **Psychosocial risk factors** are linked with increased CVD risk. A working party for the National Heart Foundation of Australia identified a strong and independent link between depression, social isolation and lack of quality social support, and the causes and prognosis of CHD.[48,49] The evidence was considered less conclusive for issues such as job stress, hostility, or panic and anxiety disorders. Psychiatric disorders affect about 18% of adults each year in Australia.[48] Depression – affecting one in ten adults at any time[50] – accounts for a large proportion of this with about 800,000 patients presenting for medical treatment annually.[51] Only about 40% of these cases present for care and less than one in six receives an

evidence-based treatment.[51] This is particularly an issue for CVD: co-morbid depression is significantly associated with an increased likelihood of recurrent CVD incidence, mortality following CVD onset, and primary CVD onset among those with CVD risk factors;[48,52-54] however, while this prognostic relationship is accepted along with a likely dose–response relationship in terms of depression severity, an *independent* causal relationship between depression and CVD has yet to be conclusively defined.[54,55]

- **Medicines adherence** is a particularly important factor to consider in cardiovascular risk factor management, and several commentators have cited this as an independent behavioural CVD risk factor. The Second Australian National Blood Pressure Study (ANBP-2) of 4,000 older people with hypertension demonstrated that individuals adhering to their antihypertensive medicines regimen were significantly less likely to experience a cardiovascular event.[56] Participants who reported ever forgetting to take their medicine were 28% more likely to experience a first cardiovascular event or death during follow-up. Those who reported sometimes stopping their medicines due to side effects were twice as likely to experience a first onset of heart failure.

  Unfortunately, therapy discontinuation is common for conditions such as hypertension and dyslipidaemia. Patients rarely experience symptoms from these conditions, but perceive many associated costs with therapy (e.g. attending appointments, side effects, paying for medicines).[57] In fact about half of patients will discontinue antihypertensive medicines within

one year of commencement – one in five will not even collect a second month's supply or a repeat prescription.[58,59] About 60% of Australian patients will have discontinued lipid-lowering therapy within one year,[59] and a substantial proportion of discontinuation is without medical consultation.[60] A US study indicated that just 35% of patients taking medicines for both lipid disorders and hypertension will remain adherent to treatment for both conditions at 12 months.[61]

These risk factors frequently have overlapping and cumulative influence on a range of chronic disease outcomes. Smoking, raised lipids and raised BP act multiplicatively to increase the risk of CVD events. The importance of addressing such cardiovascular risk factors extends beyond CVD; the risk of co-morbid conditions stemming from the same risk factors suggests the benefit of a more holistic patient needs assessment. With old age being a key non-modifiable risk factor for CVD and most other chronic diseases, ageing populations in developed countries such as Australia will increasingly compound the public health burden induced by the above factors.[3]

Measuring population risk of CVD

The scale of CVD health and economic burden makes it important to ensure a comprehensive understanding of (1) contemporary trends in cardiovascular health status, (2) the complex interactions of environmental, healthcare and individual-level influences on risk status and health outcomes, and (3) the effects of policies and interventions on cardiovascular health outcomes. This understanding requires regular monitoring of cardiovascular health using validated survey instruments

and reliable measurement techniques that can be repeated accurately. The Seven Countries Study in the 1960s used standardised techniques to compare lifestyles and biomedical measurements with cardiovascular outcomes across seven countries.[62] It provided some of the first pieces of epidemiological evidence linking lifestyle and a traditional Mediterranean diet with cardiovascular outcomes.

Despite these findings stemming back almost half a century, few programs currently exist that collect such data on a regular basis. The Framingham Study (United States) and Finnish longitudinal population health surveys are prominent examples.[63,64] Such unique studies have provided invaluable epidemiological information as well as validated clinical tools such as cardiovascular risk score algorithms and diabetes risk scores.[63,64] Epidemiological data has also been invaluable in guiding health services adaptation. For example, Finnish researchers have tracked declining lipid levels across the population since the Seven Countries Study;[62] consequently, they were able to detect unexpected increases to triglyceride concentrations and decreased HDL-cholesterol concentrations among children and young adults in the late 1980s.[65 66] The availability of trends in dietary information and anthropometric data allowed them to link this issue to increasing obesity and changing lifestyle at those ages, and to guide health promotion and policy to address it.

There are limitations to population health data available from Australian settings. The only regular monitoring occurs via Computer-Assisted Telephone Interviews (CATI) undertaken by organisations such as the Australian Institute of Health and Welfare and Department of Human Services in Victoria.[67,68] This process relies on

self-reports of risk status and various health behaviours, an approach acknowledged as acceptable but potentially inaccurate (e.g. people overestimating their physical activity and underestimating body weight).[69] There have been several other adult chronic disease population studies undertaken in Australia which collected clinical measurements, and self-reported demographic and health behavior data using different protocols. Notable local studies have been undertaken in Fremantle (among individuals with diabetes),[70] Busselton,[71] North-West Adelaide and Dubbo (60 years and over).[72,73] A small number of national studies have also been undertaken. Most surveys are now somewhat dated, and the only major population surveys occurring in the past decade have focussed on an elderly rural population (Dubbo)[73] or have significantly under-sampled from rural areas.[74] Given the excess coronary mortality in rural and remote areas,[75] the lack of current Australian data and an ageing population, there are clear benefits to be gained from an accurate understanding of CVD risk in rural areas, and in the population above the historical 'standard' upper age limit for participants of 75 years.

Primary healthcare responses to cardiovascular healthcare needs

Best practice for CVD prevention

Evidence-based Australian guidelines acknowledge significant evidence–treatment gaps and the need to work towards best-practice clinical management for all of the major individual risk factors described above.[26,28,30,39,49,76-78] These documents all have condition-specific assessment and management

recommendations, but share several general themes regarding treatment recommendations:

- Treatment decisions should be taken with regard to a patient's overall cardiovascular risk, not just the individual risk factor. Systematic review suggests the process of formal cardiovascular absolute risk (CVAR) assessment may also facilitate modest clinical effects due to its effects on subsequent practice.[79] CVAR is an estimate of the overall likelihood of experiencing a cardiovascular event over a given time period, taking into account the combined effect of key risk factors. Limited research suggests that Australian GPs largely do not undertake CVAR assessments using recognised algorithms or otherwise.[80] Ideally, patients' CVAR should be established and proper management requires all suboptimal risk factors to be addressed.
- Lifestyle modification is recommended where possible for all patients at high risk.[81] Tobacco use, diet, obesity, excess alcohol intake, and physical activity are major modifiable risk factors with independent effects on both CVD development and prognosis,[82,83] and the onset and prognosis of the major anthropometric and biomedical CVD risk factors including BP, lipid profile, obesity, diabetes, and psychosocial health.[84-89] All lifestyle factors should be assessed, and related behavioural change should be facilitated when appropriate for any biomedical CVD risk factor, regardless of the decision to treat with medicines.[90,91]
- Net benefits of using medicines to treat risk factors are relative, increasing as CVD risk levels rise. In Australia, treatment at baseline should only be

considered for patients at high CVD risk (if the likelihood of developing CVD or having a cardiovascular event over the next five years is 15% or greater). For patients with lesser risk, lifestyle modification should be attempted first, with longer periods of trialling lifestyle modification as the risk decreases. The exception is smoking cessation, where pharmacotherapy can be initiated immediately to overcome psychological and physiological nicotine dependence.

- At the time of undertaking this thesis, use of antiplatelet therapy such as aspirin was considered to have a net beneficial effect in appropriate patients where the risk of heart disease is greater than 1% per annum.[92] Subsequent studies have led to great uncertainty regarding use for primary prevention of heart disease and primary prevention, particularly for people with diabetes.[93,94]
- Adherence to medicines and healthy behaviours is suboptimal and should be directly addressed with patients. Adherence to prescribed medicines and lifestyle recommendations is considered to be a great challenge in all CVD prevention areas, especially for conditions such as hypertension and lipid disorders where often no obvious symptoms of the condition exist. Adherence to lipid lowering and antihypertensive medicines 12 months after initiation of therapy is only about 50%, consistent with international evidence.[58,59] Nonadherence to antihypertensive and lipid-lowering therapy substantially increases the risk of fatal or nonfatal CVD, although the exact risk is dependent on baseline CVD risk and the extent of nonadherence.[56,95]

- The psychosocial wellbeing of patients should be considered in assessing an individual's CVAR. In particular, co-morbid depression has been identified as a CVD risk factor to be screened for and treated.[48] A recent meta-analysis (albeit with methodological heterogeneity) identified a clear link between depression and myocardial infarction onset (pooled odds ratio of 1.60, 95% CI 1.34 – 1.92) and a risk of CVD onset from clinically-diagnosed depression on a par with diabetes and tobacco use.[54] Mental stress is also increasingly linked with CVD and hypertension.[96]

Current management of CVD risk factors

The evidence-based Australian guidelines cited in the previous section identify widespread failure to achieve guideline targets on a population basis for the management of all the major CVD risk factors.[26,28,30,45,49,76-78] Repeated audits of patient care in general practice and other medical settings confirm that suboptimal management in primary care contributes heavily to this problem.[97,98]

Unfortunately, responsibility in primary care for ensuring achievement of patient therapeutic targets rests almost entirely with general practice, a setting with clear shortcomings in terms of facilitating achievement of therapeutic targets. Data from 2618 consecutive patients attending 99 GPs participating with the BEACH (Bettering the Evaluation and Care of Health) registry identified a 'management gap' (failure to screen, treat with medication, or treat to target) relating to hypertension detection and management for 30% of patients, and relating to lipid disorder detection management for 71% of patients.[98] Separate studies of patients with diabetes in Australian general practice reveal similar issues.[99,100] Australian literature suggests that similar substantial management gaps for cardiovascular

care are also present in specialist outpatient settings,[101] acute care settings,[102] and Indigenous healthcare settings.[103] Management gaps may be even greater for rural and Indigenous patients.[104 105] Gaps in medical risk factor management, defined by failure to follow appropriate guidelines, appear common for high-risk patients and the general population across the developed world in primary care settings.[106-110]

Several factors explaining deviations from ideal care described above in this setting have been identified. As mentioned previously, GPs appear to frequently underestimate, or fail to estimate, the CVAR for patients with CVD risk factors, and infrequently use validated tools for risk estimation. The AusHEART study examined perceptions of 322 Australian GPs about CVD risk for a combined 5293 patients from their practices aged 50 years or over. GPs estimated that just 40% of 1345 patients with established CVD were at high risk of a cardiovascular event (≥ 15% risk over 5 years), whereas guidelines indicate that anybody with established CVD is at high risk.[105] Depending on the method of risk assessment, GPs were thought to have estimated the correct risk category for 47% to 60% of patients without CVD, with underestimation of risk much more common among those incorrectly estimated. Smaller studies confirm that Australian GPs infrequently undertake risk factor assessments of appropriate patients, or carry out CVAR assessments using recommended risk algorithms.[80,111,112]

Underestimation of risk is a serious issue because GP perception of overall cardiovascular risk is a key driver of the decision to initiate preventive health interventions for uncontrolled risk factors.[107] A qualitative study of 36 Sydney-based GPs examining why doctors did not engage with risk assessment tools

suggested they may see this more as an aid to patient education.[80] They preferred to rely on 'clinical gut feeling' for risk assessment. Concerns that patients would not understand concepts of overall risk were prominent – indeed most doctors interviewed could not differentiate between absolute risk and relative risk. They felt that the lack of lifestyle factors such as diet or exercise in these tools was a disadvantage because one could not demonstrate to patients the benefit of good behaviours. Indeed, many were uncomfortable with inclusion of age as a risk factor in equations because to do so was perceived as encouraging more intensive treatment for older rather than younger patients; they intuitively felt younger patients should be treated more intensively. This is despite increasing evidence increasingly suggesting benefits of intensive hypertension treatment for elderly patients.[113,114]

Treatment inertia (failure to treat with sufficient intensity) is also evident. GPs do not regularly refer high-risk patients to lifestyle programs,[115] and vary on the extent to which they personally deliver lifestyle interventions to those at risk.[111] This is perhaps unsurprising given the range of Australian and international studies demonstrating a failure among GPs to embrace health promotion behavioural modification interventions.[116-118] A number of barriers have been identified, including a lack of time, lack of confidence in delivering interventions and a failure to acknowledge health promotion as a core role of GPs.[116-118]

There is also a failure to initiate antihypertensive and lipid-lowering medication use for appropriate patients, combined with a failure to intensify treatment when needed for those using pharmacological therapy.[98] Webster et al. found that 8% of all general practice patients not receiving antihypertensive therapy (AHT) and

41% not currently receiving lipid-lowering therapy (LLT) should in fact be treated.[98] Moreover, 41% prescribed AHT and 38% prescribed LLT in that study had not achieved their clinical targets and required more intensive treatment. These findings are reinforced by those showing therapeutic inertia in general practice high-risk patients with diabetes.[99] Results reflect population-based studies on this topic in Australia;[16] overall gaps in care for hypertension and lipid disorders still follow the 'rule of halves' principle coined two decades ago – only half those with suboptimal risk status are screened, only half those screened are initiated on treatment, and only half those initiated on treatment are treated to target.[119]

Addressing shortcomings in the primary care response

As mentioned above, the current consensus for preventing CVD is to assess and to treat individuals in the context of their overall CVD risk. Optimal management involves addressing multiple risk factors and engaging multiple clinical interventions to optimise the potential reduction in CVD risk for an individual patient. It is outside the scope of this literature review to describe the large number of primary care-based randomised controlled trial (RCT) studies conducted internationally to test interventions aimed at improving health service activities for the prevention of CVD via multiple risk factor management. In Australia, many 'healthy heart' and CVD prevention programs exist, but a recent review of current preventive services in rural Australia identified very few comprehensive programs that target multiple risk factors and multiple patient behaviours.[120]

A search of Australian literature on this topic does however reveal several clinical trials over the past decade or so examining the efficacy of new models of primary care delivery on multiple (more than one) CVD risk factors. Methods used to identify literature included: searching the Medline database using appropriate search terms to identify relevant Australian clinical trials over the past fifteen years; repeating the search in Embase and Google Scholar using a streamlined range of search terms; hand-searching of references used by key studies identified, and scanning the titles of papers citing key references; searching the Roadmap Of Australian primary health care Research (ROAR) database, an extensive database of Australian primary care research activities operating since 2003; scanning titles of the relevant topic archives of the Medical Journal of Australia; hand-searching reports for projects funded by Community Pharmacy Agreements (the main source of Australian pharmacy research funding for the past 10-12 years); and, examining the university websites of key Australian authors identified. Results are summarised in Table 1.1, and indicate the need for comprehensive primary prevention strategies:

The Coaching patients On Achieving Cardiovascular Health (COACH) program targets patients discharged from hospital following diagnosis of coronary heart disease (CHD).[121] Although not strictly a 'primary healthcare' model, it is worth mentioning as an effective model aimed at ambulatory patients and as a framework for a subsequent (ongoing) Australian clinical trial involving primary healthcare professionals.[15] The program is delivered via telephone by trained allied health practitioners (dietitians and nurses) who do not have prescribing rights. While there is no stated theoretical framework for achieving improved

patient self-management, the emphasis is placed on motivating the patient to achieve the following important clinical targets:

- total cholesterol <4.0 mmol/L
- complete smoking cessation
- BP < 140/90 mmHg
- fasting glucose levels < 6.1 mmol/L
- body mass index <25
- saturated fat intake less than 10% of total energy intake
- 30 minutes or more of moderate-vigorous intensity exercise on most or all days of the week.

The RCT evaluation of this program (n=679) documented significant improvements at six months to most coronary risk factors and also to quality of life. The primary outcome was total cholesterol, and a reduction of 0.54 mmol/L was observed in the intervention group compared with 0.18 mmol/L for the usual care group ($p<0.0001$). Several other secondary endpoints including systolic BP, diastolic BP, bodyweight, BMI, nutrient intake, self-perceptions of mood and health, and symptoms of chest pain had significantly improved outcomes in the intervention group.

The Women's Wellness Program was a 12-week lifestyle modification program conducted among a subset of the Queensland Midlife Women's Health Study (n=244).[122] Participants were menopausal or postmenopausal women aged 45–60 years. Intervention group participants were provided with a 40-minute nurse consultation along with a 12-week lifestyle modification program; control group

participants received usual care. The primary outcomes for this study are not clearly defined in the published outcomes paper, but outcomes examined included exercise and physical activity, tobacco use, and biophysical CVD risk factors (BP, bodyweight, BMI, waist–hip ratio and resting heart rate). The intervention group significantly improved across all risk factors except heart rate, but only behavioural information was collected for control group participants so the efficacy of the intervention cannot be assumed.

The effect of nurse-led lifestyle intervention was again tested by Woollard et al., (2008),[123] using nurse-counsellors to apply a cognitive-behavioural approach in general practice and comparing results with usual GP care. The target group was existing patients on practice registers with hypertension, type II diabetes or CHD. Participants were randomised to either a general practice control group, a low intensity nurse-intervention group (monthly contact by telephone for 1 year plus one face-to-face counselling session), or a high-intensity nurse-intervention group (one hour of face-to-face counselling at monthly intervals for one year). Both intervention groups were also provided with a training manual. Significant positive changes were observed within all groups for several important outcomes (including energy intake, saturated fat intake, LDL-cholesterol and triglycerides), but not for BMI which slightly increased. Some of the benefits were sustained at 18 months.

Importantly, no significant between-group variation was observed in this study for any clinical changes at either 12 months or 18 months, suggesting little effect of intervention.[123] Interpretations of lipid profile changes are difficult due to a substantial difference between groups in terms of prevalence of use of lipid-

lowering medication at baseline, and substantial variation between groups in initiation of such agents during the study. This study adds to heterogeneous findings internationally in terms of effectiveness of general practice nurse interventions for reducing CVD risk when compared with a control group.[124]

Diabetes prevention issues to be addressed are very similar to those for general CVD prevention owing to the common risk factors, hence certain complex interventions studies in diabetes prevention are worth mentioning. The Greater Green Triangle Diabetes Prevention Project (GGT DPP) was a national demonstrator implementation trial and forerunner for the 'Life' program being rolled out statewide throughout Victoria.[125] The intervention consisted of a structured group program delivered by trained nurses in rural primary healthcare settings. Six 90-minute sessions were delivered over an 8-month period in 2004–2006, facilitated by specially trained nurses with input from physiotherapists and dietitians.

The GGT DPP focussed on lifestyle modification issues only and engaged the Health Action Process Approach (HAPA) to behavioural change.[126] One year after commencement with the GGT DPP, significant improvements were seen in participants' mean weight (-2.52 kg), mean fasting glucose (-0.14 mmol/L), plasma glucose two hours after oral glucose challenge (-0.58 mmol/L), total cholesterol (-0.29 mmol/L), LDL-cholesterol (-0.25 mmol/L), triglycerides (-0.15 mmol/L), systolic BP (-1.01 mmHg) and diastolic BP (-2.14 mmHg). Significant improvements were also found for most psychological measures, a facet of diabetes prevention interventions not previously demonstrated. Clinical outcomes were comparable with the benchmark Finnish Diabetes Prevention Study on

which it was based.[89] The GGT DPP was cost-effective and achieved an estimated 40% reduction in the relative risk of progression to type II diabetes. The intervention is now being trialled as an RCT in metropolitan areas to test if this intervention should be translated to a broader Australian population. Pharmacological interventions for CVD risk factors were not considered as part of the intervention for this study.

The Ballarat Diabetes Prevention Pilot Initiative (BDPPI) developed a 12-month intervention also investigating feasibility of implementing a diabetes prevention project in a low-resource setting.[127] This was again a lifestyle-focussed intervention modelled on successful previous trials. Individual goals were set for participants: to lose of a minimum 5% of body weight, to undertake 150 minutes moderate-intense physical activity each week plus resistance training, and to have diets with less than 30% of energy from total fat intake and less than 10% from saturated fat.

The BDPPI intervention consisted of goal setting, a self-management education program (6 sessions at weekly intervals, 1.5 hours per session), a resistance-training program, and a maintenance program including three 2-hour group reinforcement sessions.[127] Whilst a single-cohort study, participants were randomly allocated to one of two resistance training regimens within the intervention. Changes to cardiovascular risk factors (with the exception of diabetes status) were not primary outcomes for the study but were measured. Most key parameters demonstrated significant improvements, but it is important to note that mean measurements for key risk factors remained close to or above guideline recommendations. This indicates that a significant proportion of patients remained

above target for key parameters. The intervention was designed for implementation in 'low resource settings', but yet required the involvement of dietitians, psychologists, exercise therapists, and the availability of a gymnasium. Although this may be feasible in urban and larger rural centres, the availability of these resources in many socially disadvantaged or geographically isolated localities is questionable. As with the GGT DPP, the intervention did not consider recourse to pharmacological therapies for patients with persistent uncontrolled CVD risk factors.

The Healthy Lifestyle Program (HELP) is one of the few studies examining the effects of lifestyle interventions with Indigenous populations in Australia.[128] This was again a single cohort study with a majority of the 101 participants either diabetic or with impaired fasting glucose (all patients were required to be either diabetic or overweight). The results of this study appear inconclusive despite claims by the authors of a trend towards improving cardiovascular risk profile. Overall significant improvements were found to have occurred with waist circumference, diastolic BP, and total cholesterol and triglyceride concentrations. However, HbA1c values among diabetics and overall HDL-cholesterol values became significantly worse after six months. Systolic BP failed to improve to a statistically significant extent (Table 1.1). Hence, none of the primary outcomes (BP, LDL-cholesterol and HbA1c) had improvements with the exception of diastolic BP. It is important to note that the total:HDL cholesterol ratio, not the total cholesterol concentration on its own, better predicts CVD risk. Judging from the parameters as presented, this ratio also appears to have worsened during the trial (although perhaps not significantly), raising the question of whether

participants were able to differentiate between sources of good and bad cholesterol when making dietary changes. Establishing a genuine marginal improvement in CVD risk profile was difficult because the local Indigenous population declined participation in a control group.

Baker et al. examined the potential of a cardiovascular risk reduction program among another marginalised group – community-dwelling patients with diagnosed psychiatric disorders.[129] This single-cohort pilot study comprised an intensive lifestyle modification program delivered by a trained therapist, with regular supervision by a psychologist. Appropriate patients were also provided with nicotine replacement therapy according to a protocol. The relatively high retention rate within the program is notable given the high prevalence of documented psychological and social disadvantage. Just five out of 48 recruited participants did not attend post-intervention assessment at 20 weeks, and 36 completed all nine sessions.

Various measures in the Baker et al. study suggest a decline in smoking prevalence and nicotine dose received from tobacco products – investigators based this finding on both self-reports by participants and measurements of expired carbon monoxide.[129] Significant reductions were also observed in weight, waist circumference and overall CHD risk percentiles. Self-reported physical activity also appeared to have improved. It is noticeable that key biological CVD risk markers – blood sugar levels and lipid profile – did not improve, and neither did diet quality. It is of concern that changes to BP were not reported despite it being one of three key biological risk factors examined and the other two having had no significant changes. Measures of alcohol use, substance use (cannabis,

caffeinated beverages), quality of life and psychological symptoms remained unchanged; addressing these 'upstream' determinants of cardiovascular health may be essential for sustained effects with this population.

RCTs examining the effect of integrated care on CVD outcomes and risk factors have also been undertaken in Australian settings. In the Integrated Care for the Reduction of Secondary Stroke (ICARUSS) study,[130] the intervention group had care from their specialist stroke unit and GP coordinated by a hospital coordinator, as well as receiving ongoing contact and education. Significant improvements were observed in the treatment group for systolic BP, BMI and number of walks taken when compared with controls. This finding is supported by a significant group difference in amount of counselling received. These clear benefits to the intervention group are evidence of the benefits that external 'assistance' to facilitate evidence-based care can influence GP activity. The intervention group for this study was significantly younger than the usual care group; while it may have influenced changes to physical activity and use of anticoagulation, it is unlikely to account for all of the benefits observed.

Halbert et al. examined the effect on cardiovascular risk factors of introducing an exercise specialist into general practice.[131] In this study, the intervention was limited to exercise advice and an individualised exercise plan. Its effect on a range of cardiovascular risk factors (BP, lipid profile, bodyweight) was examined. This study found no significant improvements to cardiovascular risk, and in fact inferior changes to bodyweight and quality of life among intervention group women. The only significant improvements observed among intervention group participants were in the domain of physical activity. The fact that the intervention

was relatively weak compared with the other trials (20 minutes on a single occasion vs. several hours over multiple sessions) may have been a deciding factor. International evidence suggests that the early stages of a lifestyle intervention should be frequent and intensive.[132] The authors themselves note that physical fitness rather than physical activity confers cardiovascular benefits; given the low baseline fitness of the intervention group, a more intensive approach may have delivered more promising results. Additionally, the 'control' group appears to have had a diet-focussed intervention comparable in scale to the intervention group, which may have delivered confounding effects on therapy; moreover, changes to management by GPs in terms of prescribing were not monitored.

Hourihan et al. engaged community pharmacists to undertake a comprehensive health promotion and screening program for CVD risk in rural New South Wales.[133,134] This included point of care testing for BP, total cholesterol and BMI. Among those 389 adults screened, a majority at baseline had a BMI greater than 25 kg/m^2, had total cholesterol concentrations greater than 5.0 mmol/L, and undertook suboptimal physical activity.[134] Twenty-eight percent had hypertension, defined as BP greater than or equal to 140/90 mmHg. Most received lifestyle advice, one-third required a GP referral and one-quarter had never previously had their cholesterol tested, suggesting that community pharmacists are well-placed to identify individuals requiring interventions to improve CVD risk factors.[134] A majority was recommended referral or follow up, and this group was followed up at three months to assess the effects of this screening. Findings suggested significant potential benefits to BP, total cholesterol and physical activity, with a majority (62%) reporting acting upon pharmacist referrals to GPs.[134]

Emerson et al. directly demonstrated the clinical effectiveness of a GP–pharmacist collaboration on CHD risk in rural New South Wales communities.[135] Using continuous quality improvement methods, they compared usual care (6 sites/68 patients) with a low-intensity professional intervention where collaboration was encouraged but not actively facilitated (one site/60 patients) and a high-intensity intervention where regular small group meetings between professions were organised. Patients in the high intervention group achieved a 13% relative risk reduction in CHD likelihood, with a significant difference in effect size between groups. This was achieved through minor gains across a range of medicines management and lifestyle issues. Several indicators also suggested more intensive management of those patients attending intervention group pharmacies. It is unclear how well the proposed interdisciplinary collaboration model would work in urban or metropolitan areas where clinical (and personal) links between professionals may be less strong. It is important to note that the Framingham CVAR risk equation was applied to all patients including those with existing CVD, a group for which this algorithm is not validated. In addition, many patients recruited at baseline failed to present at 12-months for follow-up, possibly affecting results. Non-completers were younger than completers and more likely to be male.

Clifford et al. conducted an RCT in Australia among patients taking part in the Fremantle Diabetes Study cohort.[136] The study was one of the first adequately powered trials internationally examining the independent effects of a pharmaceutical care program on vascular risk factors in diabetic patients. The 12-month trial recruited 198 community-based patients in Western Australia of

southern European and Anglo-Celtic origin; 180 completed the study. The intervention group received face-to-face goal-directed lifestyle and medicine advice (including medicines adherence) from an experienced clinical pharmacist on three occasions (0, 6 and 12 months) plus 6-weekly telephone follow ups. Compared with control group participants, this intervention achieved clinical and statistically significant improvements in HbA1c, fasting blood glucose, BMI, systolic BP and diastolic BP. There was also a greater likelihood of commencing beneficial angiotensin converting enzyme inhibitor (ACEI) or angiotensin II receptor antagonist (ARA) therapy for intervention group patients. A significant independent effect from pharmaceutical care was observed even after accounting in analysis for the impact of changes to pharmacotherapy. This suggests a potential effect on lifestyle modification and/or medicines adherence resulting from pharmacist interventions.

Krass et al. strengthened the case for claiming that local community pharmacists without significant clinical specialisation training could also deliver interventions for diabetic patients that would bring clinical improvements to vascular risk.[137] This study had a larger sample size (n=335), and was undertaken in 56 pharmacies across four states. Intervention group pharmacists received only two days training plus a project manual prior to undertaking the intervention. The primary outcome, change to mean HbA1c concentration, showed a statistically significant moderate improvement in the intervention group compared with controls, accompanied by a significantly increased use of glucose-lowering medications.

However, researchers in this study relied on GPs for clinical information and it was not always forthcoming: in addition to those who withdrew, this meant final

data was missing for one in every four patients (n=72). Systolic and diastolic BP, total cholesterol and triglycerides all improved significantly within the intervention group, but not when compared with the control group, in which improved risk was also observed. In terms of vascular risk management, it is therefore difficult to draw conclusions about the intervention. On one hand, it may be that simply recruiting control group participants and asking questions may have in itself acted as an 'intervention' and improved control patient awareness and health behaviour. On the other hand, improvements to both groups may reflect wider improvements to quality of care provided at that time. Equally, intervention group pharmacists may have focussed more on glycaemic control than cardiovascular risk.

Several additional CVD prevention studies in Australian general practice are currently underway or awaiting publication of results. The large Health Improvement and Prevention Study (HIPS, n=5000) is welcome as an intervention that embraces risk screening, lifestyle and medication use; however, an emphasis on medicines adherence, psychosocial wellbeing and processes for patient-centred care remain absent from the protocol.[138] The 'Logan Healthy Lifestyle Study' also sought to demonstrate improved lifestyle modification among general practice patients with type 2 diabetes and hypertension provided with telephone counselling, when compared with usual care.[139] This study, now complete, is claimed to have produced significant within-group diet and physical activity improvements in both groups, but not between-group differences.[140] Detailed outcomes are yet to be published.

Another general practice study identified as underway, 'Absolute risk assessment in general practice – a pilot study to measure impact on prescribing and adherence to guidelines', appears designed mainly to examine the impact of using overall CVD risk assessment tools on GP CVD risk factor management, rather than clinical outcomes. The PEACH study, a cluster RCT currently underway in general practice, will additionally help to define the benefits to cardiovascular outcomes of patient self-management support from practice nurses for diabetic patients with poorly controlled HbA1c.[15]

The Fremantle Primary Prevention Study, published since completion of research for this thesis, did demonstrate a modest, but significant, absolute risk improvement within the intervention group but not between groups.[141] Only 'classic' risk factors appear to have been addressed. In addition, this study appears to have only tested the effect of visit frequency on CVD risk, with little apparent emphasis on how the intervention should be delivered. A counselling role by practice nurses as part of the intervention is hinted at in the discussion, but not described. Studies assessing the effectiveness of truly comprehensive models of primary healthcare for prevention of CVD onset are rare in Australia and internationally, and are warranted.

In summary, many options to improve primary prevention of CVD in Australian primary care remain unexplored. This review of Australian primary care programs reveals studies of varying quality. It could be argued that the scope of interventions is relatively narrow, encompasses a relative abundance of lifestyle-only programs and tends to use more comprehensive interventions in patients with established CVD and diabetes. A small number of studies focus on treatment

pathways for co-morbid depression. In terms of primary prevention, all identified multiple risk factor interventions were concerned only with lifestyle interventions and few examined the potential roles of primary care practitioners other than GPs and practice nurses. This appears also to reflect current services offered to Australian communities. Jones et al. identified 52 such health promotion programs available to rural Australian communities.[120] Many involve GP-delivered interventions which seek to improve behavioural and cardiovascular outcomes using various techniques such as telephone or internet-based support, or nursing support for lifestyle modification.[123]

Despite many RCTs in Australia and internationally exploring the efficacy of interventions for primary CVD prevention, it is difficult to identify existing models of primary CVD prevention from the literature that embody all of the evidence-based strategies and principles outlined previously and embraced by most relevant Australian and international guidelines. Examination of trials included in a Cochrane systematic review and meta-analysis (updated 2011) of multiple risk factor interventions for primary prevention underscores this concern,[142] with authors expressing uncertainty about the overall effectiveness of previously examined interventions. Of 55 included trials, just thirteen appeared to explicitly deal with medication management. Within these thirteen trials:

- Seven medicines interventions were restricted to hypertension for six trials (includes a propranolol RCT) and did not consider lipid-modifying therapy;
- Two were restricted to medicines management for lipid disorders (includes a pravastatin RCT) without considering hypertension; and

- Just four actively managed both lipid-lowering and antihypertensive medicines use (just one post-1995, none in Australia)

In addition, only three of 55 interventions (including two from the 13 trials with medication interventions) appear to consider medicines adherence as an intervention or outcome, despite strong associations between nonadherence and increased risk of fatal and nonfatal CVD;[56] overall, primary prevention trials seldom specified behavioural change strategies, or considered quality of life or cost-effectiveness as outcomes.[142]

Lifestyle-only interventions included in this meta-analysis – the bulk of interventions – appear to 'assume' appropriate prescribing of medicines concurrently in usual care, but evidence is lacking to support that this happens. A comprehensive approach to primary prevention should include:

- systematic CVAR assessment using validated algorithms; and
- screening for and appropriately addressing all negative influences on CVD outcomes, including: (1) major biomedical and behavioural risk factors, (2) medicines nonadherence or non-persistence, and (3) psychosocial wellbeing of patients.[48,78,91]

Improved outcomes are also delivered through:

- protocols that mandate using evidence-based guidelines;[143]
- employing multiple evidence-based cognitive-behavioural and structural behavioural change strategies;[132] and

- engaging in patient-centred care and ensuring appropriate referrals to other health professionals.[144]

No primary prevention study identified explicitly incorporates all of these principles into the intervention process, and it can be argued that more ambitious interventions should be tested. Optimising use of lipid-lowering and antihypertensive therapies in particular has been identified in a recent groundbreaking study as one of the few cost-effective preventative measures capable of delivering a large impact on Australia's population health (>100,000 DALYs per year).[145] Equally, meta-analysis suggests they are a key component of effective primary prevention interventions.[142]

It is logical that these therapies should be a component of any comprehensive prevention program, yet their consideration is routinely, and noticeably, absent from most programs. The nature of interventions for primary prevention examined suggests that reservations about the effectiveness of primary prevention programs may reflect interventions that have not integrated 'ideal' models of care, rather than an intrinsically ineffective intervention.

The importance of incorporating a theoretical model to underpin the intervention process should also be noted. Supporting patients to improve self-management of their health is at the core of chronic disease management – important lifestyle choices in areas such as diet, physical activity, smoking cessation and medicines adherence must be made many times each day and ultimately these choices are made by the individual patient. Over the past several decades we have

significantly advanced our understanding of how to promote healthier patient behaviours.

Early attempts at ensuring healthy behaviours consisted of didactic education and instructional counselling, sometimes with coercion. In the 1980s and 1990s, health promotion researchers described how generating an internal patient motivation to change may be more effective than imposing ideas through didactic instruction.[146] This could be achieved by exploring the behaviour in question and resolving patient ambivalence about change through a process known as motivational interviewing.[146] Around the same period, several individual psychosocial determinants of intention to change were confirmed – the patient's perceived self-efficacy, understanding of risks and benefits associated with current behaviour, and belief that changes to behaviours will generate a benefit (outcomes expectancy).[147,148] Addressing these psychosocial determinants has become a core component of most intervention models, along with development of therapeutic goals and addressing wider ecological barriers to behavioural change.[147,149]

However, intention to change and its psychosocial determinants, which are the focus of cognitive-behavioural models, predict only about one-third of variance in behavioural change.[148] Self-regulation theories have further added to our understanding of the change process by examining what happens after the intention to change is generated, and identify the specific importance of planning for change initiation and maintenance of change. In practical terms, these manifest as activities such as formulating action plans ('behaviour activation'), developing problem-solving skills and setting personal goals.[150-152] More sophisticated

models in practice today will incorporate all of these aspects of change facilitation.[151,153] Structural equation modelling can now demonstrate how each of these strategies contributes to overall behavioural change and subsequently improved health status.[153]

The transtheoretical model of behaviour change has been very popular in primary care – perhaps for the simplicity of its concept as much as the evidence underpinning its effectiveness.[154] Health professionals must classify a patient's temporal 'readiness to change' into one of five phases and act accordingly, recognising that patients will progress and regress through these phases in a cyclical manner.[154] However, it has been criticised in recent years for several shortcomings.[155] For example, when trying to classify readiness to change for a behaviour such as diet, a patient might have already attempted to change one aspect of diet (e.g. use low-fat dairy products), but be unwilling to contemplate reducing red meat consumption. Hence the patient does not fit into a neat category of readiness. Categorisation is also difficult because patient readiness to change can alter quickly.[155,156] For example, a patient may exhibit little motivation to exercise if they are tired or stressed when they visit a health professional, but later that day might feel much better and keen to undertake physical activity.

The model places less of a focus on active intervention for patients not contemplating or engaged in improving the health behaviour of interest, which can be problematic for such patients categorised as pre-contemplative.[154] It also assumes that patients consciously plan to change behaviours, when in fact there is evidence that most smokers' attempts to quit are the result of a sudden decision – they may not even finish their packet of cigarettes.[157] Related models such as

HAPA, which attempt to motivate towards, and subsequently maintain healthy behaviours, are increasingly being explored as alternatives to address these identified shortcomings.[154] It is important to clarify the behavioural change approaches used in clinical trials so that the true nature of the intervention is understood. If successful, it can then be replicated by others with greater fidelity, and add to our understanding of what strategies work (or not) for specific contexts. Coming from a tradition where interventions are highly standardised by nature (e.g. a specific drug with a defined molecular structure and given at a stated dose), behaviour-focussed interventions in the medical and pharmacy literature are often missing this information.

Engaging pharmacists in primary prevention

In light of the previously mentioned Australian community pharmacy studies, it is reasonable to argue that community pharmacists might contribute effectively to CVD prevention. Those studies provide Australian primary care evidence that trained community pharmacists can competently screen for multiple risk factors,[133] provide brief interventions leading to improved cardiovascular health outcomes,[134] and also provide effective long-term disease state management in diabetes that leads to improved cardiovascular outcomes.[137 136]

There are several additional compelling reasons for examining the potential role of community pharmacists in primary prevention. These include:

1. **Ability to collaborate with general practice**. Pharmacists share apothecary roots with their general practice counterparts, which has led to similar ethical viewpoints and generalist competencies being espoused

across medicines use and health promotion.[158] Repeated studies in Australia and elsewhere have demonstrated effective pharmacist–GP collaborations for the management of cardiovascular-related conditions such as heart failure,[159] smoking cessation,[160] hypertension,[161] and prevention of coronary heart disease.[135]

2. **Accessibility.** It is reasonable to argue that no other generalist medicines expert is available to most communities in Australia, especially rural and remote communities. Given that CVD mortality and morbidity is worse for non-metropolitan residents compared with metropolitan counterparts,[75] reform of rural primary healthcare delivery is essential and must involve models of care feasible in these low-access settings.[162] Canadian research suggests that patients with diabetes, one of the key groups at high risk of CVD, interact with their community pharmacist almost twice as often as with their GP.[163] Given the similarities between populations and health systems, this trend might be similar in Australia. A high prevalence of regular medication use suggests that other target groups, such as individuals with established CVD or who have one or more treatable CVD risk factors, are also likely to use pharmacy services reasonably frequently. There is no Australian evidence around use of community pharmacy by these high-risk groups, but an investigation might help to better understand patient use of healthcare and how pharmacists might best work with other health professionals to prevent CVD and its complications.
3. **Enhanced workforce flexibility.** Most research exploring team-based primary care in Australia has looked within the general practice setting to GPs working with practice nurses as a means of improving care. Relying

on this single combination can be limiting for implementation purposes; recent evidence that just 4% of GP encounters involved a general practice nurse and just 3% of Medicare claims were made by practice nurses suggests a small workforce capacity at present.[164] In addition, chronic shortages exist in rural and remote areas for several key health professionals including GPs, nurses, dentists and key allied health professionals.[165] According to Health Workforce Australia, this situation represents 'a chronic problem that cannot be absolutely 'fixed'', and requires innovative and flexible models of care to manage future demands on the health system.[162]

Modelling for the Australian medical workforce suggests 'an entrenched, long-term shortage in this [GP] workforce'.[166] It suggests that a 60% increase in supply of medical graduates between 2005 and 2010 failed to stem declining per capita GP supply; most graduates instead opt for specialist and non-specialist hospital positions.[166] The inverse care law, that 'availability of good medical care tends to vary inversely with the need for it in the population served',[167] compounds this problem – despite increasing graduate numbers, per capita overall medical workforce in regional Australia is half that in metropolitan areas.[168] A flexible approach to service delivery may well act to improve equity of access in geographically and socially disadvantaged areas.

4. **Clinically effective interventions.** International RCT evidence supports findings from the above Australian trials suggesting that pharmacists can deliver clinically and statistically significant improvements to the management of individual CVD risk factors, and complex disease states

such as diabetes and heart failure. Systematic reviews and meta-analyses confirm the clinical effectiveness of pharmacist interventions (mainly involving community pharmacists) to improve patient outcomes for a range of major disease states and preventive health activities relating to CVD: heart failure (reduced all-cause and heart failure admissions),[159] diabetes (HbA1c reduction of 0.62% compared with control, p=0.03),[169] smoking cessation (improved cessation rates),[170] hyperlipidaemia (total cholesterol reduction of 0.57 mmol/L over control, p=0.034; LDL cholesterol reduction of 0.84 mmol/L, p=0.004),[171] and hypertension (reduction in systolic BP of 6.9 +/- 12.1 mmHg over control, p=0.05).[172]

5. **Capacity to implement.** In recent years, evidence from chronic disease management programs relating to diabetes, asthma and BP and operating interstate has demonstrated that effective, widescale implementation of such initiatives into community pharmacies across Australia is quite feasible.[173]

The justification for further investigation of pharmacist interventions in key areas of CVD prevention and management is supported by ambitious trials undertaken internationally, with adequate power and multifaceted intervention demonstrating meaningful patient benefits. For example, in the United States, Lee et al. demonstrated substantial clinical benefits from a single-centre RCT involving 200 community-dwelling individuals.[174] Following a comprehensive pharmaceutical care intervention, the intervention group had clinically and statistically significant improvements to systolic BP, medicine adherence and medicine persistence. Generalisabilty of these findings needs to be considered as the patients were

mostly community-dwelling elderly males attending an army medical centre. The Canadian SCRIP trial was an RCT of community pharmacist lipid management involving 1,000 patients at high risk of vascular events. It demonstrated a 13.4% relative reduction in LDL-cholesterol among high-risk patients with uncontrolled LDL-cholesterol, equivalent to an average reduction of 0.5 mmol/L.[175 176] In the SCRIP-HTN trial (n=227) involving many of the same investigators,[177] a community pharmacist –primary care nurse collaboration produced systolic BP reductions 5.6 mmHg greater in the intervention group compared with controls (p=0.008). For patients whose baseline systolic BP exceeded 160 mmHg, that benefit was extended to an average 24.1 mmHg (p<0.001).

Pharmacists have increasingly been examined as part of more complex interventions and have been found to be important aspects of care. Koshman et al. concluded from their meta-analysis of heart failure trials involving pharmacists that the profession's involvement significantly enhances the effectiveness of team-based care.[159] Similarly, meta-analysis by Carter et al. has investigated pharmacist involvement with hypertension management, and also identified that pharmacist management (especially in collaboration with physicians) provides a significant benefit to BP when compared with patients receiving 'usual care'.[161]

In summary, substantial evidence exists to support the idea that Australian community pharmacists can deliver a disease state management program for primary CVD prevention. Currently no other widely available programs in primary care comprehensively and equally address:

- medicines use

- medicines adherence
- lifestyle modification
- adherence to relevant national guidelines.

Given the need for an increase in the capacity of Australian primary care for CVD prevention and management, it is timely to investigate the feasibility of engaging the pharmacy profession, a nationwide network of underutilised health professionals, for the task.

Table 1.1. Summary of key Australian studies examining the efficacy of health professional models of care with multiple risk factor interventions for the prevention of cardiovascular disease

Title	Subjects	Key health professionals identified in intervention	Intervention setting	Primary outcome (s)	Secondary outcomes	Intervention	Key results
Health promotion and screening for cardiovascular risk factors in NSW: a community pharmacy model[134]	282 adult patients screened for CVD and diabetes in community pharmacies and requiring referral/follow up (mean age 44 years, 70% female)	Community pharmacists	Rural community pharmacies	Changes to CVD risk factors	Uptake of pharmacist advice and referrals	Prospective cohort intervention; community pharmacist screening and targeted intervention for elevated CVD risk factors	Significant within-group improvements to self-reported physical activity, and systolic and diastolic BP. Significant reduction in proportion with elevated total cholesterol. 62% acted on a pharmacist referral to their GP
A collaborative, interdisciplinary evidence based approach to reducing coronary heart disease in rural areas[135]	Adults 40–65 years attending community pharmacies and using CVD medicines (mean age 58 years, 61% male)	Community pharmacists, GPs	Rural community pharmacies	Change to overall CVD risk of recruited patients	Changes to individual risk factors, health behaviours and care-process KPIs	Pseudo-RCT of usual care vs. Low intensity QI intervention vs. high intensity CQI intervention	The high intensity intervention produced significant improvements to overall CVD risk status, BP and lipid profiles compared with other groups
The Pharmacy Diabetes Care Program: assessment of a community	289 adults with type 2 diabetes, elevated HbA1c and medicated for glycaemic	Community pharmacist	Five meetings with a community pharmacist over 6 months	Changes to HbA1c	BP, lipid profile, quality of life, changes to prescribing of glucose-	RCT in 56 pharmacies (28 intervention, 28 control)	Intervention associated with a significant moderate improvement to HbA1c over controls (-0.7%). There were significant within-group improvements to other vascular risk

Title	Subjects	Key health professionals identified in intervention	Intervention setting	Primary outcome (s)	Secondary outcomes	Intervention	Key results
pharmacy diabetes service model in Australia[137]	control, hypertension, elevated lipids or angina (mean age 62 years, 51% male).				lowering medication		factors in the intervention group but not significant between-group differences
Clifford et al.[136]	198 community based adults with type 2 diabetes, self-identifying as southern European or Anglo-Celtic and taking at least one medicine (mean age 70 years, 48% of intervention group and 57% of control group were male)	Clinical pharmacist	Unspecified face to face plus telephone interviews	Change to HbA1c at 12 months.	Changes to serum lipids, BP, fasting plasma glucose, albumin to creatinine ratio; and, 10-year absolute CVD risk using UKPDS risk engine (in subgroup without established CVD)	RCT of comprehensive baseline assessment, structured face to face pharmaceutical care at 0,6,12 months , plus telephone counselling at 6 months. Lifestyle and medicines management with goal-setting and referral	Statistically significant improvements to HbA1c, fasting plasma glucose, systolic and diastolic BP, and BMI in IV group compared with control group. Commencement of key pharmacological therapies was also more common. Pharmacist care was seen to have an independent beneficial effect above that of changes to therapy
Physical activity and cardiovascular risk factors: effect of advice	299 sedentary adults aged 60 years or over (mean age 68 years, 46%	Exercise specialist	Metropolitan general practice	Changes to physical activity (self-reports), cardiovascular risk factors (BP,	Not specified	RCT of physical activity advice intervention versus usual care. IV group: 20-	At 12 months, there were no significant between-group differences for CVD risk factors or energy expenditure. There were significant LDL cholesterol and TG

Title	Subjects	Key health professionals identified in intervention	Intervention setting	Primary outcome (s)	Secondary outcomes	Intervention	Key results
from an exercise specialist in Australian general practice[131]	male)			body weight, serum lipid levels) and quality of life		minute physical activity advice plus written exercise plan encouraging routinisation. Control group: 20 minute session and pamphlet on nutrition	reduction within both groups. Changes to bodyweight and quality of life were significantly better for control group women compared with IV group. Physical activity improved significantly compared with the control group, except for time spent walking
Coronary heart disease risk reduction intervention among overweight smokers with a psychotic disorder: pilot trial[129]	43 adult, community-dwelling patients with psychosis who smoked and were overweight (mean age 36 years, 58% male)	Psychologists and therapist	Community clinics or research centre in metropolitan centres	Changes to overall Framingham CHD risk percentiles, smoking prevalence, and mean bodyweight	Changes to physical activity, diet, BP, lipid profile, BSL, alcohol and illicit consumption use, psychiatric symptoms and quality of life	Single cohort pilot study. All patients received a pre-treatment assessment followed by nine 1-hour individual sessions of motivational interviewing and cognitive-behavioural therapy	Significant improvements to CVD risk percentiles, tobacco use, mean waist circumference and mean bodyweight. Lipids and blood sugar levels did not improve, and BP results are not presented. Diet did not improve but there were self-reported increased in moderate physical activity
Greater Green Triangle Diabetes Prevention Project (GGT DPP) [125]	Adults aged 40 years or over, at high risk of diabetes (mean age 57 years, 27% male)	Practice nurses (within general practice), physiotherap-ists, dietitians	Rural primary healthcare	Changes to mean impaired fasting glucose concentrations at 12 months	Vascular risk factors	Single cohort implementation study. Intensive group-based self-management sessions	Significant improvements to mean fasting and 2-hr plasma glucose; BMI, weight, waist circumference, all key lipid elements and BP. Also demonstrated improved psychosocial status

Title	Subjects	Key health professionals identified in intervention	Intervention setting	Primary outcome (s)	Secondary outcomes	Intervention	Key results
						facilitated by trained nurses	
Integrated Care for the Reduction of Secondary Stroke (ICARUSS) study[130]	186 patients with stroke aged 20 years or older admitted to metropolitan referral centres (mean age 63 years[intervention group] and 68 years [control group], 55% male)	Specialist stroke services, hospital coordinators, GPs	Primary care and secondary care	Change to BP at 12 months	Change to management of other vascular risk factors at 12 months: cholesterol levels, atrial fibrillation, smoking, alcohol intake, weight and physical activity (deliberate exercise walks)	Integrate care coordination between specialist stroke service, hospital coordinator and GP, with ongoing patient contact and education	Significant improvements were seen in the intervention group compared with controls for mean systolic BP, BMI and amount of walking undertaken. No significant differences to prevalence of AF, smoking or alcohol use. Significantly more IV group patients were taking warfarin at 12 months. IV group participants received significantly more advice about risk factor and lifestyle modification
Healthy Lifestyle Program (HELP)[128]	101 Indigenous adults aged 20 years or over, and either diabetic or overweight (mean age 57 years [if diabetic], 43 years [no diabetes], 24% male)	Not specified	Community-based program in urban Queensland	All participants: BP, fasting LDL-cholesterol Diabetic patients: HbA1c. Changes at 6 months	Microalbuminuria, insulin resistance, triglyceride and homocysteine levels	Community based and culturally appropriate education program including self-monitoring of FPG (diabetics) and physical activity (all)	Significant improvements ($P<0.05$, two-tailed) for the following CVD-relevant endpoints: waist circumference (-3.1cm), diastolic BP (-4.6 mmHg), total cholesterol (-0.26 mmol/L), TG (-0.18 mmol/L). Small but statistically significant disimprovements were observed in HbA1c (diabetics, +0.31%), HDL cholesterol (-0.09 mmol/L)

Title	Subjects	Key health professionals identified in intervention	Intervention setting	Primary outcome (s)	Secondary outcomes	Intervention	Key results
Ballarat Diabetes Prevention Pilot Initiative (BDPPI)[127]	122 adults (78% women) at elevated risk of diabetes, mean age 53 years recruited from community	Dietitian, psychologist, exercise therapists	Regional clinical outpatient facility	Plasma glucose	Changes to BP, blood lipid profile, body composition and lifestyle	All patients engaged in a standardised lifestyle self-management program and maintenance program; participants were randomised to gym- or home-based resistance training program	Significant improvements in most key parameters: mean fasting- and 2h- plasma glucose (-0.15 mmol/l, -0.34 mmol/L); significant reductions in systolic BP (-10.5 mmHg) diastolic BP (-4 mmHg), LDL cholesterol (-0.21 mmol/L), TG (-0.17 mmol/L), TC:HDL cholesterol ratio (-0.21), BMI (-1.46), weight (-4.07kg) and waist circumference (-4.7 cm). These were accompanied by significant improvements to physical activity and dietary fat/energy intake
Effects of a general practice-based intervention on diet, body mass index and blood lipids in patients at cardiovascular risk[123]	211 males and females aged 20-75 years with hypertension, type 2 diabetes or CHD (mean age 60 years, 49% male)	Practice nurses	Metropolitan general practice (RCT)	Changes to dietary intake, BMI and blood lipids at 12 and 18 months	Changes to weight, physical activity, alcohol intake, sodium intake, saturated fat and omega-3 consumption	RCT. Group 1: usual care Group 2: additional monthly (10-15 minutes) telephone-based cognitive-behavioural therapy (CBT) counselling from nurse for one year, one face-to-face session.	Significant within-group improvements for energy intake at 12 months (all groups), only significant at 18 months by group 3.No between group differences in response. Significant within-group improvements for saturated fat intake at 12 months (all groups) were maintained at 18 months. No between group differences in response. Significant within-group

Title	Subjects	Key health professionals identified in intervention	Intervention setting	Primary outcome (s)	Secondary outcomes	Intervention	Key results
						Group 3: additional monthly (up to one hour) face-to-face CBT for 12 months	improvements for total cholesterol, LDL cholesterol and triglycerides intake at 12 months (all groups) were maintained at 18 months. No between group differences in response BMI increased in all groups, with no significant differences between groups Results suggest no significant benefit observed from nurse counselling compared with usual care
Coaching patients On Achieving Cardiovascular Health (COACH)[178]	792 males and females post-discharge from teaching hospital following a coronary event or surgery (mean age 58 years, 77% male)	Dietitian or nurse	Community post-discharge	Changes to total cholesterol at 6 months	Other CVD risk factors (BP, weight, BMI, fasting blood glucose), dietary fat and saturated fat intake, fibre intake, walking for exercise, depression, anxiety, self-reported general health and cardiac symptoms	Group 1: Telephone-based personal coaching and mail-outs to achieve clinical goals; delivered by dietitians and nurses Group 2: Usual care	TC, several other risk factors and health behaviours improved significantly

Title	Subjects	Key health professionals identified in intervention	Intervention setting	Primary outcome (s)	Secondary outcomes	Intervention	Key results
The effects of a multimodal intervention trial to promote lifestyle factors associated with the prevention of cardiovascular disease in menopausal and postmenopausal Australian women[179]	90 Menopausal and postmenopausal women aged between 50 and 65 years of age (61% aged 55-60 years)	Registered nurse	Subset of Queensland Midlife Women's Health Study (QMWHS)	Changes to exercise/activity, smoking, and biophysical CVD risk factors		Single cohort: 40 minute nurse consultation followed by 12 week lifestyle change program and written educational materials	The intervention modestly but significantly improved aerobic activity, use of tobacco, BMI, waist to hip ratio, diastolic BP and weight
The Fremantle Primary Prevention Study: a multicentre randomised trial of absolute cardiovascular risk reduction[141]	1200 patients aged 40-80 years (mean age 62 years, 65% female)	GPs	Three general practices in Western Australia	Changes to absolute CVD risk score	Changes to biophysical CVD risk factors, physical activity, and general self-rated health	Opportunistic (two visits) versus intensive treatment (five visits) over twelve months. Principles of treatment between groups did not differ	There was a significant but very modest within-group improvement to overall risk only in the intensive treatment group. There was no difference between groups. Total cholesterol, LDL-cholesterol, total:HDL cholesterol ratio and waist circumference were all significantly improved in the intensive group compared to the opportunistic visit group

Thesis Aim and Objectives

The aim of this thesis is to examine the feasibility of implementing CVD prevention strategies in community pharmacies in Australia.

In addressing this aim, the thesis will have the following supporting objectives:

- To establish how evidence–treatment gaps for CVD prevention in rural areas compares with those for metropolitan areas
- To measure the potential reach of community pharmacists to target those with elevated risk of cardiovascular disease on a population level
- To determine the potential effect on cardiovascular risk of community pharmacist interventions
- To examine how an effective community pharmacist intervention might best be delivered

Chapter 2. Overview of Thesis Structure

About this Thesis

Thesis structure

Research findings for this thesis will be structured around a series of chapters focusing on aspects of the overall aim and objectives. Each chapter describing research undertaken uses the text from a manuscript that has been published, accepted for publication, or prepared for review by a peer-review research journal. Minor modifications to published chapters (e.g. number of tables etc) have been made where necessary to allow a cohesive thesis format. Declarations by co-authors for all papers are provided in Appendix 1, in alphabetical order according to co-author surname. These signed declarations summarise my role in the preparation of each manuscript.

Brief segue sections will be inserted between chapters to provide any necessary additional information about the chapter (e.g. methodological details, expansion of background information), and to provide justification for inclusion of that research as part of a cohesive overall body of work. These segues will also describe the extent of my involvement in the relevant research project, and where applicable will describe additional components and findings from these research projects which complement the narrative presented.

A cohesive body of research

Chapters have been collated in the chronological order in which the research was undertaken to reflect an evolving program of work that continually builds on new insights gained into practice and research methodology (Table 2.1). There are three major phases to this work. Phase One examined the current state of cardiovascular heath in rural areas and primary care management of cardiovascular risk. To describe this phase, I have included three papers (chapters 3–5) in my thesis for which I was not primary author, but was part of the study team and a co-author. These studies were a key driver for subsequent work in this thesis, and have been included to enhance the context and logical narrative.

Having identified significant areas of unmet public health need, I then examined the theoretical logic of using community pharmacists as catalysts for better primary care management of cardiovascular risk. Phase Two investigated the feasibility and potential benefits to patients of a community pharmacy-based model of care to prevent CVD onset. This adopts what could be considered an 'ideal' intervention framework for community pharmacists requiring significant additional practitioner support. In contrast, Phase Three considers whether or not similar improvements to the nature and extent of pharmacists' preventative health interventions are feasible within the constraints of current pharmacy practice.

A summary of how these phases of research relate to thesis chapters and prepared manuscripts are provided in Table 2.1.

Table 2.1. A framework describing the relationship between projects undertaken and research output produced for this thesis

Project title	Chapter	Brief description	Manuscript details
Phase One examined whether there is a population need in rural areas for additional CVD prevention strategies, and a rationale for community pharmacist involvement in such strategies			
Greater Green Triangle Risk Factor Surveys (GGT RFS)	3,4,5	These population health surveys were used to identify how key evidence–treatment gaps for management of CVD risk in rural southeast Australia compared with previous surveys focussed on metropolitan populations	Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. The prevalence, detection and treatment of hypertension in rural Australia: the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medicine Journal* 2008;38(12):879-886. Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in rural Australia: prevalence and treatment gaps in evidence based cardiovascular risk management. *Medical Journal of Australia* 2010; 192(3):127-132.

Project title	Chapter	Brief description	Manuscript details
			Chapman A, Bunker S, Dunbar JA, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009(30);5:352-356.
Wimmera Risk Factor Surveys (WRFS)	6	WRFS was the third and final component of GGT RFS. We adapted the patient questionnaire to allow examination of how a rural population interacts with community pharmacists. This chapter focuses on the extent of interaction with pharmacists and GPs by individuals with uncontrolled CVD risk factors	**Mc Namara K,** Philpot B, Dunbar JA, Marriott JM, Reddy P, Janus ED. The potential of pharmacists to help reduce the burden of poorly managed cardiovascular risk. *Australian Journal of Rural Health* 2012;20(2):67-73.
Greater Green Triangle Diabetes Prevention Project (GGT DPP)	7	GGT DPP tested how well the international gold-standard lifestyle intervention model for diabetes prevention could be implemented in rural	**Mc Namara K**, Philpot B, Janus ED, Dunbar JA. Greater Green Triangle Diabetes Prevention Program: remaining treatment gaps in hypertension and dyslipidaemia. *Australian Journal of Rural Health* 2010;18(1):43-44.

Project title	Chapter	Brief description	Manuscript details
		general practice. This secondary analysis of results examined whether necessary medicines-related interventions occurred as a matter of course for these patients, or whether additional strategies – potentially involving pharmacists – are appropriate	
Phase Two developed and tested the feasibility and potential health benefits of a model for pharmacist-delivered interventions for multiple CVD risk factors			
Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD)	8,9	Literature reveals that models of care for primary prevention of CVD are limited in scope. PAART CVD involves the development and evaluation of a comprehensive intervention delivered by pharmacists for the primary prevention of CVD	**Mc Namara KP**, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010;10:264.

Project title	Chapter	Brief description	Manuscript details
			Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *Annals of Pharmacotherapy* 2012;46(2):183-191.
Phase Three explored the potential for quality improvement processes to improve management of hypertension in everyday pharmacy practice			
Controlling Hypertension through Innovations in Primary Care (CHIP C)	10,11	The benefits of pharmacist intervention are well-established for hypertension management, yet such interventions do not occur regularly in practice. CHIP C evaluates the feasibility of applying commonly used quality improvement methods to improve quality of hypertension management by community pharmacists	**Mc Namara KP**, Dunbar JA, Marriott JL. Management of hypertension in primary care will benefit from basic health professional interventions [unpublished]. **Mc Namara KP**, Marriott JL, Dunbar JA. The feasibility of practice audit as part of a sustained quality improvement program in community pharmacy: lessons from a hypertension control program [unpublished].

PHASE ONE. THE POPULATION HEALTH NEED FOR IMPROVED PREVENTION OF CARDIOVASCULAR DISEASE IN RURAL AUSTRALIA

Background to the research

The Greater Green Triangle Risk Factor Surveys (GGT RFS) were undertaken in 2004-2006 in the Limestone Coast (LC, South Australia), Corangamite Shire (CO, Victoria) and Wimmera (WI, Victoria) rural regions. These surveys were designed to address shortcomings of previous population health surveys in determining evidence–treatment gaps for rural areas of Australia.

The papers described in this thesis outline evidence–treatment gaps related to the management of lipid disorders, hypertension and smoking cessation. Additional studies were undertaken by the research team to describe prevalence, awareness and treatment of metabolic syndrome and obesity, inadequate physical activity, poor dietary habits and related health behaviours.[6,23,180] Findings have also been compared with a metropolitan population and suggest similar prevalence and treatment gaps for CVD risk factors.[181] Additional analysis of GGT data has modelled the potential health benefits of interventions geared towards the general population and high-risk patients if they could fully achieve targets for BP, cholesterol, and smoking cessation.[182]

Additional information about Phase One

We undertook population-level chronic disease risk factor surveys in three rural areas of southwest Victoria and southeast South Australia during 2004–2006. This involved approaching age-sex stratified random electoral roll samples of the adult population to undertake a comprehensive chronic disease risk assessment. For the Limestone Coast and Corangamite Shire, individuals aged 25-74 years were approached. For the Wimmera Survey, individuals aged 25-84 years were approached. Of the 3320 approached, a total of 1609 participants were recruited (49%). The same protocol (excepting minor amendments) was used to complete all three surveys, and these provide the data for Chapters 3–5, and Chapter 7. Data collection was consistent with the internationally validated WHO MONICA and EHRM protocols.[183,184] This process comprised physical and biomedical measurement of key risk factors, along with an extensive self-completed questionnaire examining self-reported risk factors, health behaviours and use of health services. The methods used to collect biomedical and anthropometric data are described in Appendix 2.

My role in this research

As part of a large research team, I was engaged to undertake specific roles relating to quality of data pertaining to medicines use. This included the direction of coding and categorisation of medicines for databases. I was also involved in a review of data collection processes prior to the third survey. I was not involved with this research group at the point when the overall concepts for this study were being developed, when the overall methods were established, or for the initial

population survey in the Limestone Coast area of South Australia. Likewise, I had no role in overseeing the data collection or ensuring its quality.

For the three manuscripts presented in Chapters 3-5, I was part of the core writing team of about five people (varied) that met at regular intervals over two years for drafting and revision. I was involved in all aspects of the writing and analysis of data for these papers as part of that core group, but had particular responsibilities in relation to interpreting data around medicines use. Statements to this effect are provided by co-authors in Appendix 1.

Chapter 3. Prevalence, Detection and Treatment of Hypertension in Rural Australia: the Greater Green Triangle Risk Factor Study 2004-2006

Citation details:

Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, detection and treatment of hypertension in rural Australia: the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medicine Journal* 2008;38(12):879-886

Co-author declarations confirming the nature of my involvement are detailed in Appendix 1.

Introduction

Hypertension is a major risk factor for heart disease, stroke, peripheral vascular disease and renal failure, accounting for 7.3% of the total disease burden in Australia.[185] Control of blood pressure (BP) is crucial in preventing these adverse outcomes. As hypertension is often asymptomatic, many people with hypertension are unaware of their condition. Detection and control of blood pressure is therefore a major public health challenge.

During the last 20 years, treatment of hypertension has improved as new antihypertensive drugs have been introduced and national and international evidence based guidelines for detection and management of hypertension have been published.[84,186,187] Limited findings available from Australia indicate that the prevalence of hypertension has decreased during the last decades.[16,188] In the most recent population surveys, AusDiab in 1999-2000, 28.6% of population had high BP;[16] however, only half the participants with hypertension were treated and 40% of these controlled.[16] Although mortality from cardiovascular disease (CVD) is higher in rural regions, there is no published findings specifically including BP in rural regions.[185]

This is the first report on the prevalence, detection and treatment of hypertension in rural Australia.

Methods

Three cross-sectional population surveys of chronic disease risk factors and related health behaviour were carried out in the Greater Green Triangle (GGT)

region.[189] The first survey was conducted in August 2004 to October 2004 in Limestone Coast (LC), in the south east of South Australia, the second in February 2005 to March 2005 in Corangamite Shire (CO), south-west Victoria and the third in May 2006 to October 2006 in the Wimmera region (WI) in western Victoria. These regions are predominantly rural farming areas.

Each survey utilised a stratified random sample of the population aged 25 to 74 years drawn from the electoral roll. Stratification was by sex and ten-year age groups with the exception of the combined 25 to 44-year age-group considered as one stratum. The original samples were 1,120 persons in LC, 1,000 persons in CO and 1500 in WI. After excluding participants who were deceased or had left the region, a total of 552 persons in LC (participation rate 51%), 415 persons in CO (42%) and 596 persons in WI (53%) participated in the study. The WI sample included an additional 127 subjects (participation rate 44%) from the age-group 75-84 years.

The survey methodology closely followed the WHO MONICA protocol[183] and recommendations from the more recent European Health Risk Monitoring project.[184] Surveys comprised a self-administered questionnaire, physical measurements and laboratory tests.

The questionnaire, which included questions on health behaviour, symptoms and diseases, medical history, socioeconomic background, and psychosocial factors, together with the invitation to attend the health check, was sent by mail to all selected participants. Health checks, including anthropometric measurements and

venous blood sampling, were carried out in local health centres or other survey sites by specially trained nurses.

BP was measured in a sitting position using a mercury sphygmomanometer. Blood pressure measurements were taken from the right arm of the subject after 5 min of rest. First phase Korotkoff sounds were recorded as the systolic blood pressure and fifth phase as diastolic blood pressure. Two measurements were taken one minute apart. If they differed by more than 10 mmHg systolic or 6 mmHg diastolic, a third measurement was made. The mean value of the two closest measurements was used in the analysis. Those having systolic blood pressure (SBP) 140 mmHg or more and/or diastolic blood pressure (DBP) 90 mmHg or more and/or reporting use of antihypertensive treatment were regarded as having hypertension.[187] Participants who had been diagnosed with hypertension were considered to be aware of their hypertension.

Hypertension was considered controlled in those on drug treatment if their measurements were SBP ≤140 mmHg and DBP ≤90 mmHg. Participants were asked to provide names of antihypertensive medications they were taking. For analysis, these were classified according to pharmacological class (angiotensin converting enzyme inhibitors (ACEI), angiotensin II receptor antagonists (ARA), beta-blockers, diuretics, calcium channel blockers and others). Thirty-four participants who reported taking medication for hypertension did not provide details. Participants were asked when they last had their BP measured. Response categories (during the last 6 months, between 6 months and 1 year, between 1 and 5 years, more than 5 years ago, never, I do not know) were combined in the analyses as ‘within 12 months’, ‘1 to 5 years ago’, and ‘other’.

Ethics approval was received from Flinders University Clinical Research Ethics Committee (research application number 207/034). Informed consent was received from participants.

Statistical analyses

Statistical analyses were undertaken using SPSS version 14.0. In addition to age- and sex-specific prevalence figures, overall prevalence figures are presented. Overall prevalence rates were age-standardised according to local populations and the 2001 Australian population aged 25-74 years as appropriate. Each prevalence is accompanied by a 95% confidence interval (CI).[190]

Results

Of the total 1690 participants, information on BP measurement, medication and awareness was available for 1506 participants.

The overall mean SBP and DBP levels were 127 mmHg (95% CI 126-128) and 76 mmHg (95% CI 76-77), respectively (Tables 3.1 and 3.2). Compared with men, women, especially in the youngest age-group (25-44 years), had lower BP levels. BP levels, especially SBP, increased with age and were higher in LC compared with the other two regions.

Overall, one-third of participants had hypertension (Table 3.3). The prevalence was slightly higher in men than in women with no differences between regions. The prevalence of hypertension was 20% (95% CI 13-27) and 8% (95% CI 4-13) in 25-44 years old men and women respectively, and increased to 72% (95% CI 66-78) in men and 74% (95% CI 68-80) in women in the 65- to 74-year age-

Table 3.1. Mean diastolic blood pressure (mmHg) with 95% CI by gender, age and surveys region; the Greater Green Triangle Risk Factor Study, 2004-2006

		Limestone Coast (n=472)			**Corangamite Shire (n=404)**			**Wimmera Region (n=630)**			**All (n=1506)**		
		mean	lower CI	upper CI	mean	lower CI	upper CI	mean	lower CI	upper CI	mean	lower CI	upper CI
men	*all 25-74 (n=667)*	*81.80*	*80.39*	*83.21*	*75.92*	*74.27*	*77.57*	*79.25*	*78.09*	*80.41*	*79.28*	*78.47*	*80.08*
	25-44 (n=116)	78.72	75.74	81.69	74.50	70.82	78.18	79.76	76.37	83.15	77.82	75.92	79.72
	45-54 (n=174)	85.48	82.74	88.23	76.80	72.28	81.33	81.56	79.51	83.61	81.70	80.01	83.39
	55-64 (n=182)	83.94	80.71	87.18	76.77	74.02	79.52	79.76	78.09	81.44	80.40	78.89	81.90
	65-74 (n=195)	80.27	78.11	82.43	77.04	74.07	80.02	76.53	74.19	78.87	77.99	76.57	79.42
	75-84 (n=57)	n/a	n/a	n/a	n/a	n/a	n/a	74.58	72.44	76.72	74.58	72.44	76.72
women	*all 25-74 (n=736)*	*75.25*	*73.87*	*76.63*	*72.44*	*70.95*	*73.92*	*72.26*	*71.09*	*73.42*	*73.28*	*72.51*	*74.06*
	25-44 (n=131)	71.81	68.69	74.93	69.34	66.88	71.80	70.84	67.86	73.82	70.65	69.03	72.27
	45-54 (n=209)	76.38	74.09	78.67	74.68	71.61	77.74	73.58	71.40	75.76	74.84	73.43	76.26
	55-64 (n=211)	79.83	77.41	82.25	74.10	71.12	77.07	74.11	71.75	76.46	76.08	74.58	77.58
	65-74 (n=185)	77.05	74.61	79.49	73.58	69.28	77.88	74.25	72.15	76.36	74.91	73.24	76.57
	75-84 (n=46)	n/a	n/a	n/a	n/a	n/a	n/a	73.57	69.82	77.31	73.57	69.82	77.31
all	*all 25-74 (n=1403)*	*78.48*	*77.45*	*79.51*	*74.03*	*72.92*	*75.14*	*75.62*	*74.75*	*76.49*	*76.16*	*75.58*	*76.74*
	25-44 (n=247)	75.34	73.11	77.58	71.59	69.44	73.74	74.93	72.53	77.33	74.02	72.71	75.33
	45-54 (n=383)	80.39	78.48	82.31	75.54	72.99	78.08	77.54	75.93	79.15	77.96	76.82	79.10
	55-64 (n=393)	81.72	79.73	83.70	75.26	73.22	77.31	76.86	75.34	78.37	78.08	77.00	79.16
	65-74 (n=380)	78.82	77.20	80.44	75.42	72.87	77.96	75.32	73.76	76.88	76.49	75.39	77.59
	75-84 (n=103)	n/a	n/a	n/a	n/a	n/a	n/a	74.13	72.11	76.14	74.13	72.11	76.14

Table 3.2. Mean systolic blood pressure (mmHg) with 95% CI by gender, age and surveys region; the Greater Green Triangle Risk Factor Study, 2004-2006

		Limestone Coast (n=472)			**Corangamite Shire (n=404)**			**Wimmera Region (n=630)**			**All (n=1506)**		
		mean	lower CI	upper CI	mean	lower CI	upper CI	mean	lower CI	upper CI	mean	lower CI	upper CI
men	*all 25-74 (n=667)*	*131.74*	*129.26*	*134.22*	*126.94*	*124.57*	*129.30*	*129.77*	*127.74*	*131.80*	*129.40*	*128.09*	*130.72*
	25-44 (n=116)	122.69	118.73	126.66	122.13	117.53	126.73	123.84	119.26	128.43	122.91	120.46	125.35
	45-54 (n=174)	133.45	129.35	137.55	122.66	118.23	127.09	128.46	125.30	131.62	128.70	126.47	130.92
	55-64 (n=182)	137.15	131.68	142.62	131.73	126.60	136.86	133.43	129.54	137.32	134.25	131.51	136.99
	65-74 (n=195)	151.32	146.65	155.98	139.95	135.39	144.51	142.16	137.78	146.54	144.66	141.99	147.33
	75-84 (n=57)	n/a	n/a	n/a	n/a	n/a	n/a	149.09	143.56	154.62	149.09	143.56	154.62
women	*all 25-74 (n=736)*	*127.52*	*125.08*	*129.95*	*125.15*	*122.76*	*127.53*	*122.57*	*120.21*	*124.94*	*124.87*	*123.48*	*126.25*
	25-44 (n=131)	117.75	113.93	121.57	114.76	111.20	118.32	116.04	110.94	121.15	116.16	113.76	118.56
	45-54 (n=209)	125.46	121.19	129.74	126.94	122.41	131.47	119.50	115.60	123.40	123.66	121.23	126.10
	55-64 (n=211)	136.53	132.76	140.29	130.68	126.39	134.96	129.16	124.94	133.39	132.16	129.79	134.52
	65-74 (n=185)	148.88	144.28	153.47	140.08	134.99	145.18	141.70	137.24	146.16	143.40	140.67	146.13
	75-84 (n=46)	n/a	n/a	n/a	n/a	n/a	n/a	147.91	139.09	156.74	147.91	139.09	156.74
all	*all 25-74 (n=1403)*	*129.60*	*127.86*	*131.34*	*125.96*	*124.28*	*127.65*	*126.03*	*124.44*	*127.62*	*127.05*	*126.08*	*128.01*
	25-44 (n=247)	120.28	117.53	123.03	117.97	115.08	120.87	119.61	116.11	123.12	119.33	117.58	121.08
	45-54 (n=383)	128.98	125.95	132.02	125.20	121.99	128.42	123.95	121.37	126.54	125.95	124.27	127.63
	55-64 (n=393)	136.81	133.62	140.01	131.14	127.89	134.38	131.24	128.37	134.11	133.13	131.34	134.92
	65-74 (n=380)	150.21	146.96	153.47	140.01	136.66	143.36	141.91	138.82	145.01	144.05	142.15	145.95
	75-84 (n=103)	n/a	n/a	n/a	n/a	n/a	n/a	148.56	143.66	153.46	148.56	143.66	153.46

Table 3.3. Prevalence, awareness, treatment and control of hypertension for those aged 25-74 years by sex and survey region; the Greater Green Triangle Risk Factor Study, 2004-2006

	Prevalence of hypertension (%)			**Percentage of those with hypertension who are aware of their condition**			**Percentage of those with hypertension on drug treatment**			**Percentage of those with hypertension who are controlled**			**Percentage of those on drug treatment who are controlled**		
	Men (n=230)	Women (n=242)	All (n=472)	Men (n=321)	Women (n=324)	All (n=645)	Men (n=321)	Women (n=324)	All (n=645)	Men (n=321)	Women (n=324)	All (n=645)	Men (n=165)	Women (n=207)	All (n=372)
LC	38.0 (31.7, 44.4)	33.6 (27.5, 39.7)	35.8 (31.4, 40.2)	55.6 (45.1, 66.2)	67.3 (56.9, 77.7)	61.2 (53.7, 68.7)	47.6 (37.0, 58.2)	54.4 (43.4, 65.5)	50.9 (43.2, 58.5)	8.2 (2.4, 13.9)	24.1 (14.6, 33.6)	15.8 (10.2, 21.4)	17.1 (5.5, 28.7)	44.3 (29.4, 59.3)	31.0 (21.0, 40.9)
CO	34.0 (27.2, 40.8)	34.0 (27.7, 40.2)	34.0 (29.4, 38.6)	49.6 (37.3, 61.9)	76.1 (66.5, 85.8)	64.0 (56.0, 72.0)	40.4 (28.3, 52.5)	61.2 (50.1, 72.2)	51.7 (43.3, 60.0)	20.9 (10.9, 30.9)	39.4 (28.4, 50.5)	31.0 (23.2, 38.7)	51.7 (32.3, 71.7)	64.5 (50.6, 78.3)	59.9 (48.5, 71.3)
WI	41.8 (35.7, 47.9)	29.7 (24.3, 35.2)	35.5 (31.4, 39.6)	55.5 (46.0, 65.1)	72.5 (62.8, 82.3)	62.9 (56.0, 69.9)	41.2 (31.8, 50.6)	67.4 (57.1, 77.6)	52.6 (45.4, 59.8)	17.7 (10.4, 25.0)	38.7 (28.0, 49.3)	26.8 (20.4, 33.2)	42.9 (28.1, 57.7)	57.4 (44.2, 70.5)	51.0 (41.0, 60.9)
All	36.9 (33.2, 40.6)	31.8 (28.4, 35.2)	34.3 (31.8, 36.8)	53.6 (47.4, 59.9)	71.1 (65.3, 77.0)	62.1 (57.7, 66.4)	42.4 (36.3, 48.6)	60.4 (54.1, 66.7)	51.1 (46.6, 55.6)	14.9 (10.4, 19.3)	33.4 (27.3, 39.5)	23.8 (20.0, 27.7)	35.1 (25.9, 44.2)	55.4 (47.1, 63.6)	46.6 (40.4, 52.9)

group. In WI in the 75-to 84-year age group, 79% (95% CI 68-90) of men and 78 % (95% CI 66-90) of women had predominantly systolic hypertension.

Overall, two-thirds of participants with hypertension were aware of their condition (Table 3.3). Over two-thirds of women but only half of men were aware of their hypertension. No differences were found between regions. The awareness increased with age from 12% (95% CI 1-23) in the youngest age-group (25-44 years) to 64% (95% CI 56-73) in the 45- to 54-year age group and reached 78% (69-87) in the oldest age group (75-84 years) in WI.

Half of the participants with hypertension were treated (Table 3.3). Treatment was more common in women than men and there were no regional differences. Only 9% (95% CI 0-18) of the youngest participants (25-44 years) were treated compared with 49% (95% CI 40-58) of the 45- to 54-year age-group. In the age-group 75-84 years in WI 69% (95% CI 55-82) of men and 81% (95% CI 68-94) of women were treated.

One-quarter of participants with hypertension were controlled, fewer men than women (Table 3.3). Fewer younger (25-44 years) participants were controlled (6%, 95% CI 0-14). Blood pressure control was worse in LC compared with CO and WI.

Among hypertensives who were treated, nearly half were controlled, including a considerably higher proportion of women than men (Table 3.3). In LC less than one-third were controlled compared with more than half in CO and WI.

Overall, 77% (95% CI 74-80) of women had a measurement within the last 12 months compared with 70% (95% CI 66-73) of men. The proportion of

participants who had had blood pressure measured within the last 12 months increased with age (Table 3.4). In LC measurement within last 12 months was less frequent 68% (95% CI 64-72) than in CO 77% (95% CI 73-81) and WI 76% (95% CI 72-80).

Among hypertensive subjects on treatment 99% had a BP measurement within the last 12 months with no variation between age-groups, sex or region (Table 3.4). Among hypertensives not on medication only 69% had a BP measurement within the last 12 months, the likelihood increasing with age. Slightly more women (77%, 95% CI 69-86) than men (64%, 95% CI 56-72) had a measurement within the last 12 months.

Overall, monotherapy was used by 55% (95% CI 48-61) of treated hypertensives. The prevalence of use of monotherapy was similar in men and women and also in the three regions. The proportion of treated participants who were on monotherapy reduced from 62% (95% CI 49-74) at 45-54 years down to 43% (95% CI 36-51) at 65-74 years. Control of BP was poor for those taking drug monotherapy, with 49% (95% CI 41–58) controlled, and also for those on more than one drug therapy, with 42% (95% CI 32–52) controlled.

ACEI's were the most frequently used antihypertensive class in men, whereas in women ACEI, ARA, and diuretics were widely used (Table 3.5). Fewer LC men were taking beta-blockers than in CO or WI. Only 22% of LC women were taking ARA compared with approximately half in CO and WI.

Table 3.4. Time from the last measurement of blood pressure; The Greater Green Triangle Risk Factor Study, 2004-2006

Age-group	Time from the last measurement	Hypertensive, medicated (n=294)	Hypertensive, not medicated (n=432)	Normotensive (n=780)	All (n=1506)
All 25-74	*<12 month*	98.7 (97.2, 100.0)	69.3 (63.3, 75.2)	68.1 (65.1, 71.2)	73.7 (71.4, 76.0)
	1-5 yr	1.3 (0.0, 2.8)	25.9 (20.2, 31.5)	24.4 (21.6, 27.2)	20.6 (18.5, 22.7)
	other	0.0 (0.0, 0.0)	4.9 (2.1, 7.6)	7.5 (5.8, 9.2)	5.7 (4.5, 6.9)
25-44	*<12 month*	100.0 (100.0, 100.0)	58.1 (40.7, 75.4)	61.0 (54.5, 67.6)	61.1 (55.1, 67.2)
	1-5 yr	0.0 (0.0, 0.0)	35.5 (18.6, 52.3)	29.1 (23.0, 35.2)	29.6 (23.9, 35.2)
	other	0.0 (0.0, 0.0)	6.5 (0.0, 15.1)	9.9 (5.9, 13.9)	9.3 (5.7, 12.9)
45-54	*<12 month*	98.3 (95.1, 100.0)	65.1 (53.3, 76.9)	71.9 (66.5, 77.4)	74.9 (70.6, 79.3)
	1-5 yr	1.7 (0.0, 4.9)	27.0 (16.0, 37.9)	25.4 (20.1, 30.7)	21.9 (17.8, 26.1)
	other	0.0 (0.0, 0.0)	7.9 (1.3, 14.6)	2.7 (0.7, 4.7)	3.1 (1.4, 4.9)
55-64	*<12 month*	99.2 (97.7, 100.0)	73.8 (64.1, 83.4)	81.3 (75.7, 87.0)	85.8 (82.3, 89.2)
	1-5 yr	0.8 (0.0, 2.3)	22.5 (13.3, 31.7)	13.7 (8.7, 18.7)	11.2 (8.1, 14.3)
	other	0.0 (0.0, 0.0)	3.8 (0.0, 7.9)	4.9 (1.8, 8.1)	3.1 (1.4, 4.8)
65-74	*<12 month*	98.3 (96.4, 100.0)	84.8 (77.8, 91.9)	89.3 (83.4, 95.3)	92.4 (89.7, 95.0)
	1-5 yr	1.7 (0.0, 3.6)	14.1 (7.3, 21.0)	8.7 (3.3, 14.2)	6.8 (4.3, 9.4)
	other	0.0 (0.0, 0.0)	1.0 (0.0, 3.0)	1.9 (0.0, 4.6)	0.8 (0.0, 1.7)
75-84	*<12 month*	100.0 (100.0, 100.0)	90.5 (77.9, 100.0)	100.0 (100.0, 100.0)	98.1 (95.4, 100.0)
	1-5 yr	0.0 (0.0, 0.0)	9.5 (0.0, 22.1)	0.0 (0.0, 0.0)	1.9 (0.0, 4.6)
	other	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)

Table 3.5. Use of antihypertensive medication for those aged 25-74 years by gender and region; The Greater Green Triangle Risk Factor Study, 2004-2006

	Limestone Coast	**Corangamite Shire**	**Wimmera Region**	**All**
Diuretics	*(n=38)**	*(n=28)*	*(n=47)*	*(n=113)*
men	19.6 (6.7, 32.5)	16.5 (1.3, 31.7)	26.3 (13.2, 39.5)	22.2 (13.9, 30.4)
women	42.2 (26.7, 57.6)	34.5 (20.4, 48.5)	39.3 (25.8, 52.7)	38.9 (30.6, 47.3)
all	31.3 (20.9, 41.7)	28.3 (17.5, 39.1)	33.3 (23.8, 42.9)	31.8 (25.7, 37.8)
Beta-blockers	*(n=26)*	*(n=21)*	*(n=28)*	*(n=75)*
men	12.2 (1.5, 22.8)	35.2 (15.6, 54.8)	22.0 (9.7, 34.4)	21.1 (13.0, 29.2)
women	29.6 (15.4, 43.9)	14.4 (4.0, 24.7)	16.1 (5.9, 26.2)	20.1 (13.2, 27.0)
all	21.2 (12.0, 30.5)	21.5 (11.6, 31.4)	18.8 (10.9, 26.7)	20.5 (15.3, 25.8)
ACE Inhibitors	*(n=55)*	*(n=36)*	*(n=66)*	*(n=157)*
men	54.9 (38.8, 71.1)	40.8 (20.6, 61.0)	61.4 (46.9, 75.9)	54.6 (44.8, 64.5)
women	41.3 (25.9, 56.7)	36.4 (22.2, 50.7)	38.1 (24.7, 51.5)	38.5 (30.2, 46.9)
all	47.9 (36.6, 59.1)	37.9 (26.3, 49.6)	48.9 (38.7, 59.0)	45.4 (39.0, 51.9)
ANG II Receptor Antagonists	*(n=26)*	*(n=43)*	*(n=46)*	*(n=115)*
men	28.6 (13.9, 43.3)	33.1 (13.8, 52.5)	18.2 (6.7, 29.7)	25.9 (17.2, 34.6)
women	21.7 (8.8, 34.6)	50.3 (35.5, 65.1)	44.0 (30.3, 57.7)	38.5 (30.2, 46.9)
all	25.0 (15.3, 34.8)	44.4 (32.5, 56.4)	32.1 (22.6, 41.6)	33.1 (27.0, 39.2)
Calcium Channel Blockers	*(n=30)*	*(n=23)*	*(n=33)*	*(n=86)*
men	24.0 (10.1, 37.8)	15.1 (0.4, 29.8)	30.9 (17.1, 44.7)	23.6 (15.1, 32.0)
women	22.1 (9.1, 35.0)	28.1 (14.8, 41.4)	13.9 (4.3, 23.4)	21.4 (14.3, 28.4)
all	23.0 (13.5, 32.4)	23.6 (13.4, 33.9)	21.7 (13.4, 30.1)	22.3 (16.9, 27.7)
Other	*(n=3)*	*(n=0)*	*(n=1)*	*(n=4)*
men	0.9 (0.0, 4.1)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	0.5 (0.0, 1.9)
women	2.7 (0.0, 7.9)	0.0 (0.0, 0.0)	1.0 (0.0, 3.7)	1.3 (0.0, 3.3)
all	1.9 (0.0, 4.9)	0.0 (0.0, 0.0)	0.5 (0.0, 2.0)	1.0 (0.0, 2.2)

* Number of participants using selected medication

Discussion

The findings of this study indicate that one-third of rural population has hypertension. Only half of the participants with hypertension were treated and less

than half of these were controlled indicating suboptimal detection and treatment of hypertension, especially in men and younger participants. Limited findings available, mainly from urban populations, on prevalence of hypertension in Australia indicate that the prevalence of hypertension among men decreased from 47% to 31% between 1980 and 1995.[191] Among women, the prevalence decreased from 32% to 23% between 1980 and 1989 and was 25% in 1995. In the latest population survey, AusDiab 1999-2000,[16] the prevalence of hypertension was 32% in men and 27% in women which is slightly lower than in the present study. These results suggest that either there is no further improvement or the situation is poorer in rural areas compared with urban and metropolitan centres. These Australian trend findings have to be interpreted with caution as there are differences between studies in BP measurement protocols and survey samples, for example, only the more recent studies have included subjects aged 65 years and over, the age-group in which hypertension is more common.

There is evidence of higher rates of CVD mortality in rural compared with urban areas.[75] Comparisons between rural and metropolitan risk factor data are necessary to see whether these differences may be contributing to the mortality differences.

Important determinants of blood pressure include overweight and obesity, physical inactivity, high sodium intake, increased alcohol intake and increasing age.[84,192] There are limited Australian findings available to allow us to analyse whether the level of these risk factors may have changed over time. However, in our rural survey population,[23] the prevalence of overweight and obesity was even higher than in previous Australian surveys.[191] It is therefore likely that increasing

overweight and obesity over time is an important contributor to the failure to observe a sustained reduction in the prevalence of hypertension.[193]

A substantial problem of under detection and under treatment of hypertension has always been identified. In Australia, in 1999-2000, just under half of those with hypertension were taking hypertensives. Of those who were not taking antihypertensive drugs, 54% had a high absolute risk of CVD and based on current guidelines this group would benefit from antihypertensive medication.[16] In our study, we did not estimate absolute CVD risk in those with hypertension who were not on treatment. For those already on treatment, we were unable to calculate a pretreatment risk. Although this paper focuses on hypertension as a single risk factor, clearly there needs to be greater emphasis on the assessment of absolute cardiovascular risk when making the decision to initiate antihypertensive drug treatment.[187] Younger men make up a particularly challenging group. Because age is an important determinant of risk, many will have lower absolute CVD risk levels and might not need antihypertensive drug treatment. Many of those who do need treatment are not being detected because they do not access healthcare.

The 'rule of halves' for hypertension states that: 'half the people with high blood pressure are not known ('rule 1'), half of those known are not treated ('rule 2') and half of those treated are not controlled ('rule 3').[194] In this study, 'rule 1' remained true only for men with half aware of their hypertension compared with two-thirds of women. Our result that awareness is greater in women than in men is in line with observations from several other countries.[195-197] Reviewing data

from Finland,[195] US,[198] and UK,[197] also indicates that a higher proportion of women have been treated and controlled over time.

Although the prevalence of hypertension, awareness and treatment was similar across three survey regions, the control of hypertension, especially for men, was less in LC which translates to higher mean blood pressures. The variability in medication usage between regions may reflect lack of systematic application of guidelines and clinical evidence in the treatment of hypertension. Further, blood pressure measurement within the last 12 months was less frequent in LC indicating differences in monitoring.

National Heart Foundation of Australia (2004) Guidelines state that combination therapy is often necessary as less than 50% of patients will achieve optimal blood pressure response with monotherapy.[187] In our study combination therapy was used in just under half the subjects suggesting that there is still room for improvement. Even with multidrug therapy, many were still not controlled. We do not know what their pretreatment BP was or whether they were particularly resistant to treatment.

This makes it difficult to compare the two groups reliably. The most striking observation was the extent to which the newer classes of drugs (ARA and ACEI) appear to have become the most commonly used therapy, either as single-agent products or as fixed-combination products with diuretics. This may be the result of not only the co-morbidities such as diabetes and CVD but also pharmaceutical company marketing strategies.

Although there are comprehensive Australian guidelines there is still a substantial gap between evidence and practice.[187,199] Much work still needs to be done to overcome barriers for implementation at patient, professional, organizational, social, economic and political levels.[200] To improve the detection and management of hypertension in the community, there is a specific need for system improvements within general practice to manage hypertension and other CVD risk factors better. These systems are sometimes called chronic disease management programs, the elements of which include a database of all patients with hypertension, a periodic recall system to check risk factors against the guidelines, and commencement of appropriate treatment including lifestyle changes.[201,202] These systems can incorporate the broader contributions of other health professionals including practice nurses and pharmacists. Improvements have already occurred in the management of cardiovascular risk factors through the Australian National Primary Care Collaboratives.[203] In parallel with these systems, there is a need for population-based approaches to encourage people to have their BP measured and to reduce their sodium intake.

Study limitations and strengths

As the overall participation rate in the surveys was (49%) and the number of participants is some sub-group analyses were small, some caution is needed when interpreting the results. A comparison of the socioeconomic background – including primary occupation, rate of unemployment and total gross income of the survey participants – with population statistics available[190] did conclude that the participants reflected the true populations of the regions surveyed. The strengths of the study are the provision of findings on rural areas and elderly Australians.

Conclusions

Overall, one-third of participants had hypertension; of these, two-thirds, 54% (95% CI 47-60) of men and 71% (95% CI 65-77) of women, were aware of their condition. Half of the participants with hypertension were treated and nearly half of these were controlled. Both treatment and control was more common in women (60%, 95% CI 54-67 and 55%, 95% CI 47-64) compared with men (42%, 95% CI 36-49 and 35%, 95% CI 26-44). Monotherapy was used by 55% (95% CI 48-61) of treated hypertensives. ACEI were the most frequently used class of antihypertensive in men, whereas ACEI, angiotensin receptor antagonists and diuretics were all widely used among women.

This study emphasises issues of suboptimal detection and treatment of hypertension in rural Australia, which will have serious future consequences in terms of cardiovascular outcomes if left unaddressed. There is a need for robust comparable results from regular risk factor prevalence surveys of the population in the future to measure the effects of our prevention and treatment strategies and to achieve ongoing success as seen in the reduction in cigarette smoking.

Acknowledgements:

Ms Anna Chapman, Dr Andrew Baird, the nurses carrying out the survey and regional hospitals providing facilities for the study.

This study was supported by the Australian Government Department of Health and Ageing, Royal Australian College of General Practitioners, Sanofi-Aventis PL, Pfizer Inc, Roche Diagnostics and Servier Laboratories Australia PL.

Précis

In a rural Australian population (n=3320) one-third had hypertension. Of these two-thirds were aware, half were treated and nearly half of those controlled, highlighting suboptimal detection and treatment of hypertension.

Chapter 4. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management

Citation details:

Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in rural Australia: prevalence and treatment gaps in evidence based cardiovascular risk management. *Medical Journal of Australia* 2010; 192(3): 127-132

Co-author declarations confirming the nature of my involvement are detailed in Appendix 1.

Introduction

Cardiovascular disease (CVD) accounts for 18% of the total Australian burden of disease,[4] and the burden of CVD is higher in rural areas.[75] Large clinical trials have demonstrated that treatment of hypercholesterolaemia is effective in both primary and secondary prevention of CVD,[204] and target lipid goals have been progressively lowered reflecting recent trial evidence. Treatment of hyperlipidaemia should be based on assessment of global CVD risk rather than plasma cholesterol alone since high risk groups benefit most.[205]

Little is known about the prevalence of risk factors or treatment patterns for CVD in rural areas even though CVD is more prevalent.[75] This is the first report of rural Australian population lipid levels, hyperlipidaemia awareness and assessment of adherence to more recent 2001[205]and 2005[30] Australian guidelines.

Methods

Three cross-sectional population surveys of chronic disease risk factors and related health behaviour were undertaken in the Greater Green Triangle region in South Australia and Victoria, in 2004–2006; these have been described previously.[17,23] Each survey took a random sample from the electoral roll of people aged 25 to 74 years, stratified by 10-year age and sex, with the exception of those aged 25–44 years, who were considered as one stratum. Strata sample sizes were 140 from the Limestone Coast (2004), 125 from Corangamite (2005) and 150 in Wimmera (2006). Analysis for this article was performed on data from participants who had all information required for 5-year CVD risk calculation.

Aboriginal and Torres Strait Islander participants (n = 11) were not included in this analysis due to under-representation in the surveys and as the available risk calculators, based on Framingham data, have not been validated for use in this population.[30]

The survey methodology closely followed the World Health Organization MONICA (multinational MONItoring of trends and determinants in CArdiovascular disease) Project protocol and European Health Risk Monitoring recommendations.[183,184] A postal questionnaire examined history of chronic disease, medication use, and lifestyle habits. Health checks, including anthropometric measurements and venous blood sampling (after fasting for 10 hours), were carried out at survey sites by specially trained nurses. Blood samples were analysed at Flinders Medical Centre Clinical Trials Laboratory.[23]

Participants were divided into five mutually exclusive groups based on presence of established CVD or diabetes, lipid-lowering treatment, and CVD risk (Box 4.1). The 2001 guideline therapeutic target levels used were < 4 mmol/L for total cholesterol (TC), < 2.5 mmol/L for low-density lipoprotein cholesterol (LDL-C), > 1.0 mmol/L for high-density lipoprotein cholesterol (HDL-C) and < 2.0 mmol/L for triglycerides (TG) updated to < 1.5 mmol/L for TG in the 2005 guidelines.[30,205] The extent to which a lower 2007 guideline LDL-C target (< 2.0 mmol/L) was achieved among patients with established CVD or diabetes, was also examined.[90] These cut off levels differ from those used in defining metabolic syndrome.[23]

Ethics approvals were received from the Flinders University Clinical Research Ethics Committee.

Box 4.1. Definitions used to categorise risk groups

Group I: established CVD/diabetes (treated). Individuals with any vascular disease and/or diabetes already on lipid-lowering drug treatment.

Group II: established CVD/diabetes (untreated). Individuals with any vascular disease and/or diabetes not on lipid-lowering drug treatment.

Group III: other high CVD risk (treated). Individuals on drug treatment but without known vascular disease or diabetes (baseline pre-treatment characteristics not available).

Group IV: other high CVD risk (untreated). Untreated individuals without established known vascular disease or diabetes but with 10%–15% or greater risk of a cardiovascular event in the next 5 years, according to any of the following three criteria:

- the New Zealand cardiovascular risk calculator, which takes into account a participant's sex, age, blood pressure, smoking habits, TC:HDL-C ratio, and history of diabetes.
- judged by LDL-C > 4.0 mmol/L or TC > 6.0 mmol/L plus any two (or more) other risk factors (HDL-C < 1.0 mmol/L, significant family history, hypertension, overweight or obesity, smoking, impaired fasting glucose, age ≥45 years. Data for glucose intolerance, microalbuminuria and/or renal impairment not available).
- chronic renal failure, familial hypercholesterolaemia or familial combined hyperlipidaemia (data not available).

Group V: low CVD risk. Low absolute risk of CVD (< 10% over 5 years).

CVD= cardiovascular disease. TC =total cholesterol. LDL-C =low-density lipoprotein cholesterol.

HDL-C= high-density lipoprotein cholesterol

Statistical analyses were undertaken using Stata, version 10.1 (StataCorp, College Station, Tex, USA). Age-specific means and prevalence data were calculated using the commands mean and CI, with 95% confidence intervals for prevalence data based on the Agresti–Coull interval. Analyses involving combined age groups were weighted to the local population and utilised survey-specific modules. Overall means and prevalence data were calculated using the commands mean and tabulate. P values for the differences between groups I–V and I–IV were calculated with the test command, following linear regression (continuous outcomes) or logistic regression (dichotomous outcomes) including age and sex in the models as covariates.

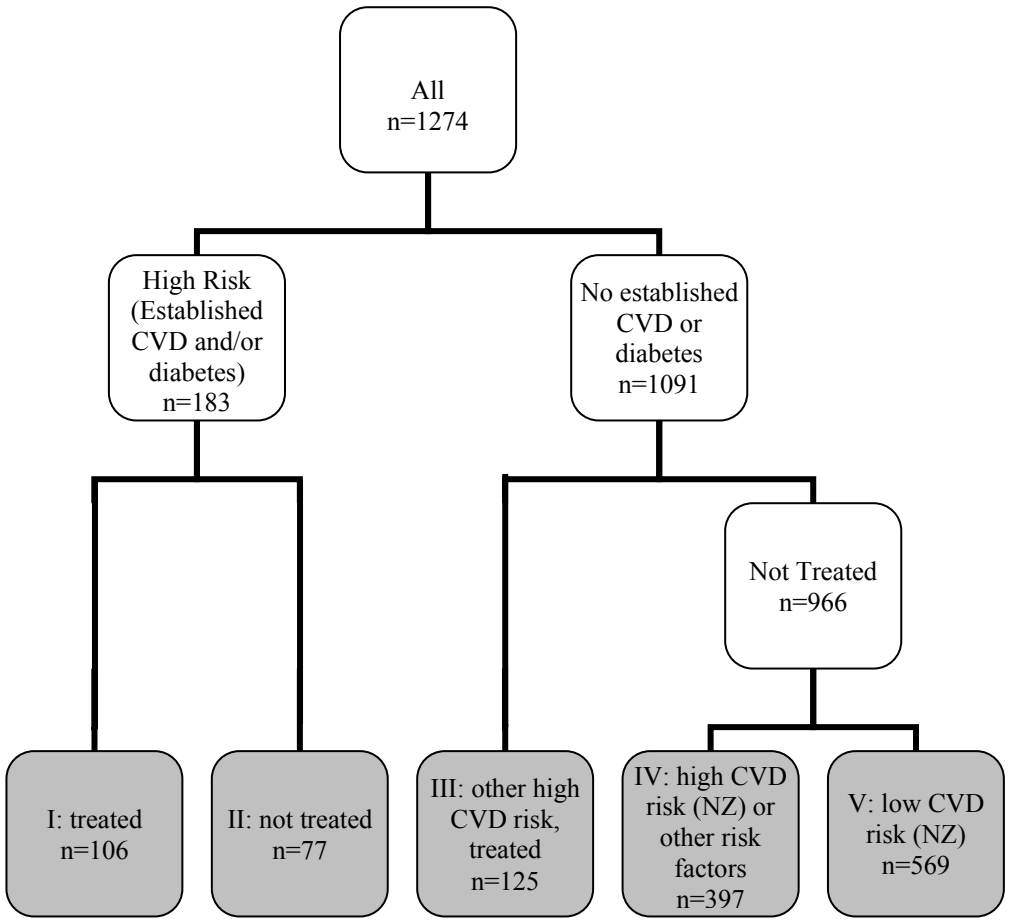
Results

Overall, 3320 individuals were selected. After excluding 108 who had died or had left the area, there were 1563 participants (48.7%). Information on blood lipids, lipid-lowering medication, CVD risk, and history of CVD and diabetes was available for 1274 participants (40% of sample). Categorisation of participants is shown in Box 4.2. Overall population-weighted mean TC concentration was 5.38 mmol/L (95% CI, 5.30–5.45). Table 4.1 shows detailed results by age and sex. TC concentration exceeded 5.5 mmol/L for 39% of participants and 6.5 mmol/L for 13%. A wider definition of hypercholesterolaemia, constituting those with a TC concentration > 5.5 mmol/L or on cholesterol-lowering medication, gave a prevalence of 48%.

Overall population-weighted mean TG, LDL-C and HDL-C concentrations were 1.50 mmol/L (95% CI, 1.43–1.56), 3.23 mmol/L (95% CI, 3.16–3.30) and 1.46

mmol/L (95% CI, 1.44–1.49), respectively. Almost a third of the population had LDL-C concentration > 3.5 mmol/L, and prevalence of high TG and low HDL-C concentrations were 17% and 7%, respectively. In the population not on treatment, overall mean concentration of TC was 5.43 mmol/L (95% CI, 5.35–5.52), LDL-C was 3.30 mmol/L (95% CI, 3.22–3.38), HDL-C was 1.47 mmol/L (95% CI, 1.44–1.49), and TG was 1.45 mmol/L (95% CI,1.38–1.52).

Box 4.2. Categorisation of participants by CVD risk status and lipid lowering medication use



CVD = cardiovascular disease. NZ =New Zealand.

Table 4.1. Mean blood lipids (95% CI) and prevalence (95% CI) of abnormal concentrations by gender and age group

	Age group (years)	**n**	**Total Cholesterol**			**LDL Cholesterol**			**HDL Cholesterol**			**Triglycerides**		
			Mean	**95% CI**	**>5.5 mmol/l**	**Mean**	**95% CI**	**>3.5 mmol/l**	**Mean**	**95% CI**	**<1.0 mmol/l**	**Mean**	**95% CI**	**>2.0 mmol/l**
Men	All	607	5.40	5.28-5.52	39.2 (34.7-43.9)	3.31	3.20-3.42	35.9 (31.5-40.5)	1.33	1.30-1.36	11.3 (8.6-14.8)	1.64	1.53-1.76	19.3 (15.9-23.2)
	25-44	100	5.37	5.15-5.58	34.0 (25.4-43.7)	3.30	3.09-3.51	32.3 (23.8-42.2)	1.34	1.28-1.40	11.0 (6.1-18.8)	1.59	1.35-1.83	15.0 (9.2-23.4)
	45-54	162	5.66	5.51-5.81	51.2 (43.6-58.8)	3.54	3.40-3.69	50.0 (42.3-57.7)	1.32	1.26-1.38	12.3 (8.1-18.4)	1.75	1.57-1.94	27.8 (21.4-35.1)
	55-64	169	5.36	5.21-5.51	44.4 (37.1-51.9)	3.27	3.14-3.40	34.9 (28.1-42.5)	1.36	1.31-1.42	8.9 (5.4-14.2)	1.58	1.44-1.72	15.4 (10.7-21.6)
	65-74	176	5.08	4.93-5.23	31.3 (24.9-38.4)	2.99	2.85-3.13	28.2 (22.0-35.3)	1.32	1.27-1.37	13.6 (9.3-19.5)	1.68	1.55-1.81	23.9 (18.1-30.7)
Women	All	667	5.36	5.26-5.45	39.4 (35.4-43.7)	3.15	3.06-3.24	28.6 (24.9-32.6)	1.59	1.56-1.63	2.8 (1.6-4.8)	1.35	1.30-1.41	14.4 (11.7-17.6)
	25-44	124	5.05	4.89-5.21	29.0 (21.7-37.6)	2.98	2.83-3.12	21.0 (14.7-29.0)	1.56	1.50-1.63	1.6 (0.1-6.1)	1.12	1.03-1.21	6.5 (3.1-12.4)
	45-54	187	5.46	5.31-5.61	42.8 (35.9-49.9)	3.19	3.05-3.34	30.5 (24.3-37.4)	1.62	1.56-1.68	3.7 (1.7-7.7)	1.43	1.33-1.54	18.2 (13.3-24.4)
	55-64	191	5.81	5.65-5.96	53.9 (46.8-60.8)	3.45	3.30-3.60	41.3 (34.5-48.4)	1.64	1.58-1.70	3.1 (1.3-6.8)	1.55	1.44-1.66	19.4 (14.4-25.6)
	65-74	165	5.62	5.45-5.79	50.9 (43.3-58.4)	3.24	3.08-3.40	34.4 (27.5-41.9)	1.65	1.59-1.71	2.4 (0.7-6.3)	1.60	1.49-1.71	22.4 (16.7-29.4)

In total, 231 participants (12% population weighted) reported using lipid lowering medication (Box 4.2). Of the 208 for whom lipid-lowering medication details were known, 199 (96%) were using statin monotherapy. Of the 1043 participants who were not treated, 77 (7%) had established vascular disease or diabetes, 397 (38%) had high 5-year risk of CVD and 569 (55%) had low 5-year risk.

Untreated high-risk participants without CVD or diabetes (Group IV) had a mean TC level of 6.37 mmol/L and a mean LDL-C level of 4.14 mmol/L (Table 4.2). Between 19% and 30% of untreated high-risk individuals (groups II and IV, respectively) reported doctor-diagnosed high cholesterol. Almost all individuals being treated had their cholesterol measured in the previous year, compared with about half for untreated high-risk participants. Overall, three-quarters of participants aged 45 years or older had their cholesterol measured in the previous 5 years.

Three per cent of the high-risk study population had all lipids at target (Table 4.3). HDL-C and 2001 TG target levels were reached by most high-risk participants. TC and LDL-C levels were largely inadequate; treated patients with established CVD or diabetes (Group I) were most likely to be controlled.

Table 4.4 compares lipid levels from our study with those found in previous Australian studies.

Table 4.2. Population Characteristics by lipid lowering medication usage and CVD risk status

	Established CVD/Diabetes (treated)*	Established CVD/Diabetes (untreated)*	Other High CVD Risk (Treated)*	Other High CVD Risk (Untreated)*	Low CVD Risk*	Whole study population*	P value
	I	II	III	IV	V		
n	106	77	125	397	569	1274	
Men	57.6%	56.3%	44.2%	61.1%	45.2%	50.1%	<0.001
Age (years)	64.1 (1.0)	54.3 (2.5)	60.4 (0.9)	55.8 (0.7)	42.2 (0.2)	48.4 (0.1)	<0.001
< 55 years	16.5%	49.7%	30.8%	43.0%	85.9%	66.6%	<0.001
TC (mmol/l)	4.67 (0.11)	5.38 (0.13)	5.18 (0.10)	6.37 (0.08)	5.06 (0.04)	5.38 (0.04)	<0.001
LDL-C (mmol/l)	2.46 (0.10)	3.30 (0.13)	2.84 (0.09)	4.14 (0.09)	2.99 (0.04)	3.23 (0.04)	<0.001
HDL-C (mmol/l)	1.38 (0.04)	1.27 (0.04)	1.49 (0.04)	1.38 (0.02)	1.52 (0.02)	1.46 (0.01)	<0.001
TC/HDL-C ratio	3.63 (0.11)	4.51 (0.18)	3.72 (0.12)	4.97 (0.11)	3.53 (0.05)	3.94 (0.05)	<0.001
TG (mmol/l)	1.82 (0.09)	1.77 (0.09)	1.86 (0.09)	1.95 (0.10)	1.23 (0.03)	1.50 (0.03)	<0.001
LDL-C/HDL-C ratio	1.91 (0.09)	2.81 (0.16)	2.05 (0.09)	3.17 (0.08)	2.11 (0.04)	2.38 (0.04)	<0.001
SBP (mmHg)	136.0 (2.0)	134.2 (2.9)	136.9 (1.6)	137.2 (1.1)	120.3 (0.6)	126.9 (0.5)	<0.001
DBP (mmHg)	72.7 (1.0)	78.5 (1.8)	78.6 (1.2)	81.5 (0.6)	74.5 (0.5)	76.6 (0.4)	<0.001
BP medication	66.3%	30.3%	50.3%	20.1%	5.8%	16.6%	<0.001
BMI (kg/m^2)	29.3 (0.5)	30.9 (1.0)	30.3 (0.6)	29.4 (0.3)	26.8 (0.2)	28.0 (0.2)	<0.001
Current smoker†	8.7%	17.1%	7.7%	22.6%	13.8%	15.4%	<0.001
Self reported high TC	na	19.1%	na	29.9%	8.1%	24.2%	<0.001
TC measured in:							
Previous year	94.7%	58.4%	86.1%	40.6%	23.8%	37.4%	<0.001
Previous 5 years‡	98.3%	69.3%	100%	68.7%	48.2%	60.2%	0.004
Previous 5 years (age 45 + years)‡	98.2%	92.4%	100%	72.1%	69.1%	77.5%	<0.001

CVD= cardiovascular disease. TC =total cholesterol. LDL-C=low-density lipoprotein cholesterol. HDL-C=high-density lipoprotein cholesterol. SBP, systolic blood pressure. DBP, diastolic blood pressure. BP, blood pressure; BMI, body mass index. na =not applicable.

*Data are mean (SE) unless otherwise specified. †Current smoker includes those who smoke daily or had quit during preceding year. ‡Group III is excluded from analysis as 100% have been measured within 5 years.

Table 4.3. Control of blood lipids by lipid lowering medication usage and CVD risk status

	Established CVD/Diabetes (treated) I	Established CVD/Diabetes (untreated) II	Other High CVD Risk (Treated) III	Other High CVD Risk (Untreated) IV	High Risk Study Population	P value
n	106	77	125	397	705	
At target TC	23.7%	6.1%	8.3%	1.7%	6.1%	<0.001
At target LDL-C						
2001 & 2005	58.7%	17.1%	38.3%	3.3%	18.0%	<0.001
2007	25.3%	3.9%	14.7%	1.5%	7.0%	<0.001
At target HDL-C	78.1%	72.9%	86.1%	78.5%	79.0%	0.488
At target TG						
2001	63.1%	73.6%	63.2%	67.8%	67.2%	0.190
2005 & 2007	40.9%	43.6%	39.2%	39.4%	40.1%	0.649
All lipids at target						
2001[1]	11.8%	3.6%	3.8%	0.8%	3.1%	0.001
2005[2]	11.8%	3.6%	3.8%	0.8%	3.1%	0.001
2007[3]	8.5%	1.8%	2.3%	0.8%	2.2%	0.005

[1] Target levels: TC <4.0 mmol/l, LDL-C <2.5 mmol/l, HDL-C >1.0 mmol/l, and TG <2.0 mmol/l (Lipid Management Guidelines – 2001)

[2] Target levels: TC <4.0 mmol/l, LDL-C <2.5 mmol/l, HDL-C >1.0 mmol/l, and TG <1.5 mmol/l (Position Statement on Lipid Management–2005)

[3] Target levels: TC <4.0 mmol/l, LDL-C <2.0 mmol/l, HDL-C >1.0 mmol/l, and TG <1.5 mmol/l (Position Statement on Lipid Management 2007)

Table 4.4. Mean Lipid results from serial Australian population studies

	1980 NHF [206]	1983 NHF [207]	1989 NHF [208]	1999 AusDiab[209]	2005 GGT
Chol M	5.60	5.61	5.42	5.6	5.40
Chol F	5.55	5.65	5.30	5.6	5.36
Trig M	1.43	1.27	1.41	-	1.64
Trig F	0.99	0.96	1.02	-	1.35
HDL M	1.21	1.26	1.18	1.3	1.33
HDL F	1.46	1.56	1.50	1.5	1.59
LDL M	-	-	-	-	3.31
LDL F	-	-	-	-	3.15

[1] Analysis of lipid profiles for NHF studies were performed by CDC certified laboratories.
[2] Lipid lowering medication taken by 8.2% of men and 7.1% of women. Study population aged 30-74, with results weighted to the 1998 estimated Australian population.
[3] Lipid lowering medication taken by 11.2%. Study population aged 25-74, with results weighted to the local population. Although GGT study used a direct HDL method while previous studies used precipitation methods, results are comparable.

Discussion

In this rural population, a comprehensive examination of lipid levels, prevalence and assessment of adherence to guidelines for dyslipidaemia was completed, examining both the 2001 Australian guidelines and the 2005 guidelines, which became available shortly before the end of the study.

The National Health and Hospitals Reform Commission (NHHRC) has proposed tracking national progress towards tackling health inequities.[210] Ample evidence exists to show that access to services is poorer in rural and remote areas than in

metropolitan areas. Differences exist in statin prescribing in Australia after adjusting for age, sex and socioeconomic circumstance, with the highest prescribing rates seen in metropolitan areas.[211] The NHHRC has proposed the establishment of a National Prevention Agency to build an evidence base, with the capacity and infrastructure to report on progress towards achieving better health outcomes.

This article represents an example of the baseline data a National Prevention Agency would require. Periodic follow-up to track progress would also be needed — without it, health inequality due to rurality will persist. The participation rate in our study was low, so some caution is needed when interpreting the results. A comparison of the socioeconomic background — including primary occupation, rate of unemployment and total gross income of the survey participants — with population statistics available indicated that the participants closely represented the true populations of the areas surveyed.[23] The participation rate was also comparable to those of other studies of this type.[209,212,213] We cannot be sure of the effect that non-respondents would have on the results of this study. We suggest that as non-respondents typically have higher morbidity and mortality rates than respondents,[214] their absence from our study would, if anything, result in a more conservative conclusion.

Analysing trends in blood lipid concentrations and prevalence of hyperlipidaemia in Australia over the past three decades is complex because of opposing changes in factors influencing blood lipid levels and methodological issues between the studies. The prevalence of overweight and obesity, dietary factors, exercise patterns, alcohol consumption and use of lipid-lowering medication all influence

plasma lipid concentrations. Of particular note is the dramatic increase in prevalence of overweight and obesity, especially central obesity, over the past two decades.[23] Increased body mass index is a causative factor of higher TG and lower HDL-C levels. The predominant non-genetic determinants of increased TC and LDL-C levels are dietary saturated fats, whereas TC and LDL-C levels are reduced by increasing dietary polyunsaturated fat and water-soluble fibre content.[215]

It is currently unknown whether there are differences in risk factor prevalence between metropolitan and rural populations. Although differences in HDL-C analysis methods exist between studies, results are still comparable. Similar methods were used for all studies for TC and TG analyses. Early studies by the National Heart Foundation of Australia (NHFA) did not estimate LDL-C (now the key target for modification), and were confined to metropolitan populations.[206-208] AusDiab (the Australian Diabetes, Obesity and Lifestyle Study) did not report rural prevalence.[209]

A major concern is that in four large, primarily urban population studies there have been no improvements in mean TC levels since the early 1980s, and our study showed only a 0.2 mmol/L decline (Table 4.5). Although even a small improvement in the population mean favourably affects overall population CVD risk, the decline in the mean TC levels achieved is disappointing compared with what can be achieved.[216] Mean HDL-C levels have shown minimal change (about 0.1 mmol/L). Mean TG levels appear to have deteriorated, especially among women (about 0.35 mmol/L), among whom increasing overweight and obesity is a major issue.[23]

The prevalence of hypercholesterolaemia (TC > 5.5 mmol/L) that we observed (39%) is lower than in previous studies (range, 47% to 51%),[206-209] but the wider definition that includes both those with TC > 5.5 mmol/L or on cholesterol lowering medication reveals a prevalence of 48% in our study, unchanged from the 1980s.

Our study, completed just after the release of the 2005 Australian lipid guidelines in November 2005, provides unique opportunities to quantify adherence to guidelines in Australia. Previous Australian NHFA/CSANZ (Cardiac Society of Australia and New Zealand) lipid management guidelines (2001),[205] which focus on absolute risk rather than lipid cut-offs, along with those from New Zealand, are considered among the most potentially effective in the world in reducing CVD-related deaths.[217] This emphasis on absolute risk further enhances the effectiveness of treatment.[30,90] A recent study of the AusDiab 1999–2000 population, primarily focusing on primary prevention, strongly argued this point and noted limitations in the corresponding Pharmaceutical Benefits Scheme criteria for treatment.[218] Optimal implementation of current NHFA/CSANZ guidelines would further enhance the cost-effectiveness of lipid-lowering medication in Australia.

There has been a dramatic increase in lipid-lowering medication use, from minimal in the 1980s, to 7.1% (women) and 8.2% (men) in 1999–2000,[218] and 12% in our study. Lipid-lowering medication is almost solely comprised of statins, which have potent effects on TC and LDL-C levels, but little effect on HDL-C or TG levels. Dispensed prescriptions for lipid-lowering medications have trebled, from 6.1 to 18.0 million between 1997 and 2005 (Ms Debra Rowett,

Director, Drug and Therapeutics Information Service, Repatriation General Hospital, Adelaide, personal communication, 2008). The total cost of lipid-lowering medications (including patient co-payments) in 2005 in Australia was $1.16 billion.

Results from our study using absolute risk show that current rates of detection and treatment are suboptimal. Many individuals requiring secondary or primary prevention were untreated. Even among those at high risk who were treated, a high proportion was not treated to targets. Elevated TG levels, especially according to the 2005 guidelines, were a major issue in all groups, and there was little use of fibrates, which is the most effective medication class for high TG levels.

Our results demonstrate the need for a national lipid guideline implementation program focussed on primary care coupled with universal adoption of primary care chronic disease management systems such as the Australian National Primary Care Collaboratives.[219] Strategies aimed at reducing mean TC levels in the whole population have a greater impact on overall burden of CVD than targeted treatment of high-risk individuals alone.[205,220] The findings that mean Australian population TC has improved only a little over the past two decades reflect a lack of effective health promotion strategies, and an absence of population health monitoring and surveillance as recommended by the NHHRC. If better information becomes available about the impact of the strategies implemented, these initiatives can be modified or new ones implemented and the impact can be measured. It may be that some specific strategies will be required in rural areas and that not all rural areas will prove to be the same.

The balanced application of both targeted high-risk and population strategies is essential for the effective prevention of CVD. The proposed National Prevention Agency could undertake population-based strategies and also promote the implementation of evidence so that a high proportion of the population at risk of CVD is treated to the targets set out in national guidelines.

We hope that the National Prevention Agency will work to reduce the health inequality of high rates of CVD in rural and remote Australia.

Acknowledgements

We thank Ms Anna Chapman, Dr Andrew Baird, the nurses who carried out the survey and the regional hospitals that provided facilities for the study. This study was supported by the Australian Government Department of Health and Ageing, the Australian Health Ministers' Advisory Council (Priority Driven Research in Population Health grant no. 01/14), the Royal Australian College of General Practitioners, Sanofi-Aventis, Pfizer, Roche Diagnostics and Servier Laboratories Australia.

Competing interests

None identified.

Chapter 5. Rural Smokers: a Prevention Opportunity for GPs

Citation details:

Chapman A, Bunker S, Dunbar JA, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.

Co-author declarations confirming the nature of my involvement are detailed in Appendix 1.

Introduction

Tobacco smoking, a major risk factor for coronary heart disease, stroke, peripheral vascular disease, cancer and other diseases,[7] is estimated to cost the Australian community $(AUD) 31.5 billion per annum,[221] and responsible for more than 15,500 Australian deaths in 2003.[4]

Overall Australian smoking rates have declined since the 1950s, with daily smoking among patients aged 18 years and over declining from 19.2% in 1998–99 to 16.1% in 2006–07.[222] Recently, an estimated one in six Australians aged 14 years and over smoked daily (around 2.9 million) and altogether 19.4% currently smoked.[7] More men (18.0%) than women (15.2%) smoked daily. Former smokers, 25.1% of the population (men 27.9%, women 22.4%), outnumbered smokers; 55.4% had never smoked (men 50.9%, women 59.8%).

Previous Australian population studies assessing smoking status were primarily urban with little comparable rural data.[7,27,223] This study describes smoking prevalence and characteristics of rural smokers to guide GPs in targeting particular groups.

Methods

Participants

Three cross-sectional population surveys of chronic disease risk factors and related health behaviour were conducted in the Greater Green Triangle (GGT) region of south east Australia[189] between October 2004 and October 2006 in Limestone Coast (LC), Corangamite Shire (CO), and Wimmera (WI). These

regions are predominantly classified as 'other rural areas' by the Rural, Remote and Metropolitan Areas (RRMA) classification.[224] The populations were predominately Anglo-Celtic with very few of Aboriginal or Torres Strait Islander (ATSI), or other ethnic origin.

A random sample, stratified by gender and age, was selected from the electoral role of the three survey regions. Individuals who died or had left the region were excluded. The number of individuals in this final sample was 1563; 552 in LC, 415 in CO and 596 in WI. An invitation to participate was sent by mail to each individual. If they agreed they were asked to complete a written consent form and were sent a self administered questionnaire and invitation to present for a health check.

Participants gave written consent to participate. The study was approved by the Flinders University Clinical Research Ethics Committee.

Measures

The survey methodology comprised self-administered questionnaires, physical measurements and venous blood sampling.[23] The questionnaire and health check invitations were mailed to selected participants. Based on structured questions assessing smoking history, participants were classified into the following categories:

- Daily smoker: Smoked regularly (daily or almost daily) for at least one year and smoked yesterday or today
- Occasional smoker: Smoked on at least 100 occasions in their lifetime and smoked during the previous month

- Ex-smoker: Smoked daily or occasionally but not during the previous month
- Never smoker: Smoked on less than 100 occasions in their lifetime.

Furthermore, daily and occasional smokers were grouped as current smokers, and questioned on concern about smoking, willingness to quit, previous quitting attempts and quitting advice received.[189]

Education tertiles were defined according to years of full time education, and separately classified as low, medium, or high, for each age stratum. This allowed comparison between smoking and level of education without biasing by obvious age/education correlation.

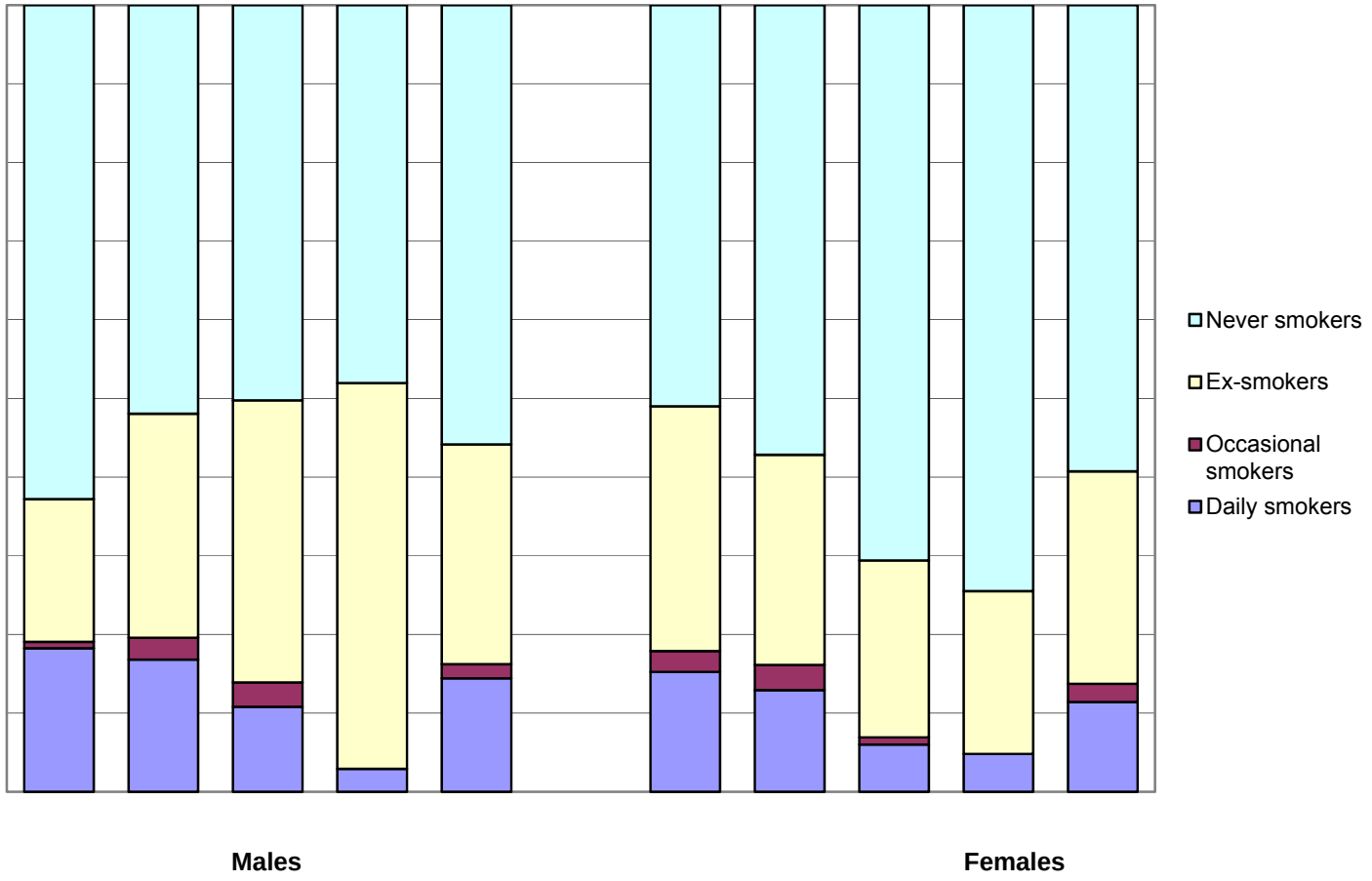
Statistical analyses

Statistical analyses were undertaken using SPSS version 14.0. Age-specific and overall prevalence figures are presented. Overall prevalence was adjusted for age using population weights derived from the regions' populations according to the electoral roll.

Results

The participation rate was 48.7%. Complete smoking data were available for 1494 participants. Overall current smoking prevalence was 14.9% (95% CI 13.1-16.7), slightly higher in men (16.2%, 13.5-19.0) than women (13.8%, 11.4-16.2) (Figure 5.1). In both genders, current smoking prevalence decreased with age. More than half of participants were never smokers and almost one-third ex-smokers. Smoking habits were similar across the three areas.

Figure 5.1. Prevalence of smoking in the GGT region by age and gender



Approximately 90% of current smokers were somewhat or very concerned about smoking (Table 5.1), consistent across areas and genders. Over 60% indicated a desire to stop, particularly younger participants. In the older age groups, most of those who had ever smoked were already ex-smokers (Figure 5.1). Almost half of current smokers had attempted cessation in the previous year (Table 5.1). Only 4% in the 25-44 years age group had never tried to stop compared with one-quarter in older age groups.

In the previous year, three-quarters of current smokers were advised to stop (Table 5.2). Although 87% of current smokers reported visiting a GP in the previous year, only one-third reported advice from a doctor, increasing from 30% of youngest to 60% of oldest smokers. One-fifth was advised to stop by another health professional and two-thirds by a family member, ranging from half of the oldest to three-quarters of the youngest.

Compared with the highest tertile, persons with low education were three times more likely to smoke (Figure 5.2). The association between smoking and education weakened with increasing age, with no differences found in the oldest age group.

Discussion

We believe this is the first study presenting smoking data exclusively for rural Australian adults. Although participation rate was modest (48.7%), a comparison of socioeconomic characteristics of survey participants with population statistics

Table 5.1. Concerns and attitudes to smoking cessation in daily and occasional smokers in the GGT region by age, as % (95% CI)

	Age group (yrs)				
	25 - 44	**45 - 54**	**55 - 64**	**65 - 74**	**All**
	n=51	n=70	n=42	n=16	n=179
Concern					
Very concerned	45.1 (31.4, 58.8)	42.9 (31.3, 54.5)	38.1 (23.4, 52.8)	31.2 (8.5, 54.0)	42.1 (35.6, 48.5)
Somewhat concerned	47.1 (33.4, 60.8)	42.9 (31.3, 54.5)	52.4 (37.3, 67.5)	37.5 (13.8, 61.2)	47.4 (40.8, 53.9)
Not much concerned	7.8 (0.5, 15.2)	14.3 (6.1, 22.5)	7.1 (0.0, 14.9)	25.0 (3.8, 46.2)	10.0 (6.1, 13.9)
Not at all concerned	0.0 (n/a)	0.0 (n/a)	2.4 (0.0, 7.0)	6.2 (0.0, 18.1)	0.6 (0.0, 1.6)
Total	100%	100%	100%	100%	100%
Like to stop					
No	5.9 (0.0, 12.3)	10.0 (3.0, 17.0)	9.5 (0.6, 18.4)	31.2 (8.5, 54.0)	9.2 (5.4, 13.0)
Yes	72.5 (60.3, 84.8)	64.3 (53.1, 75.5)	64.3 (49.8, 78.8)	43.8 (19.4, 68.1)	64.9 (58.6, 71.1)
I am not sure	17.6 (7.2, 28.1)	20.0 (10.6, 29.4)	21.4 (9.0, 33.8)	25.0 (3.8, 46.2)	21.1 (15.7, 26.4)
I do not smoke at present	3.9 (0.0, 9.2)	5.7 (0.3, 11.2)	4.8 (0.0, 11.2)	0.0 (n/a)	4.9 (2.0, 7.7)
Total	100%	100%	100%	100%	100%
Attempted to stop					
Up to one year ago	47.1 (33.4, 60.8)	38.6 (27.2, 50.0)	52.4 (37.3, 67.5)	43.8 (19.4, 68.1)	45.1 (38.5, 51.6)
More than one year ago	49.0 (35.3, 62.7)	44.3 (32.6, 55.9)	31.0 (17.0, 44.9)	31.2 (8.5, 54.0)	45.1 (38.6, 51.6)
Never tried to stop smoking	3.9 (0.0, 9.2)	17.1 (8.3, 26.0)	16.7 (5.4, 27.9)	25.0 (3.8, 46.2)	9.8 (5.9, 13.7)
Total	100%	100%	100%	100%	100%

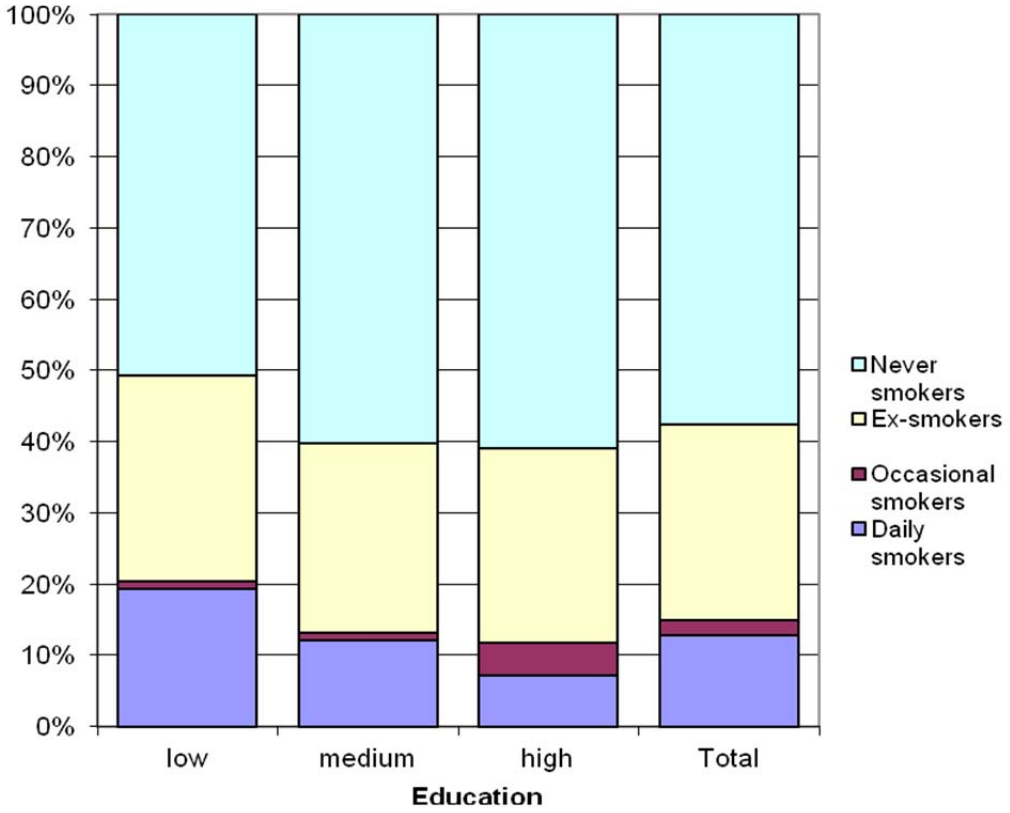
Table 5.2. Sources of smoking cessation advice in the GGT region by age group (years), as % (95% CI)

	25 - 44 n=51	**45 - 54 n=70**	**55 - 64 n=42**	**65 - 74 n=16**	**All n=179**
Doctor	27.5 (15.2, 39.7)	42.9 (31.3, 54.5)	45.2 (30.2, 60.3)	62.5 (38.8, 86.2)	34.3 (28.1, 40.5)
Other health professional	11.8 (2.9, 20.6)	27.1 (16.7, 37.6)	16.7 (5.4, 27.9)	12.5 (0.0, 28.7)	15.6 (10.9, 20.4)
Doctor*	31.1 (17.6, 44.6)	50.9 (37.9, 63.9)	47.4 (31.5, 63.2)	62.5 (38.8, 86.2)	38.6 (31.8, 45.5)
Other health professional**	14.3 (1.3, 27.2)	35.4 (21.9, 48.9)	22.2 (6.5, 37.9)	25.0 (0.0, 55.0)	21.4 (14.4, 28.3)
Family member or other	78.4 (67.1, 89.7)	55.7 (44.1, 67.4)	71.4 (57.8, 85.1)	50.0 (25.5, 74.5)	69.8 (63.8, 75.8)
Any of the above	80.4 (69.5, 91.3)	74.3 (64.0, 84.5)	81.0 (69.1, 92.8)	81.2 (62.1, 100.0)	78.4 (73.0, 83.8)

* excludes n=23 participants who did not visit a doctor in the previous 12 months
** excludes n=68 participants who did not visit any other health professionals in the previous 12 months

available indicated that participants closely represented the true populations of the areas.[190]

Figure 5.2. Prevalence of smoking in the GGT region by education tertile



Our study differs from other Australian surveys not only by the population sampled but also by the different definitions and age-groups for smoking status, and different methodologies. In particular, other population surveys sampled individuals under 25, in whom smoking rates were high. Omitting individuals aged 18 to 24 from our study may contribute to a lower estimate of overall smoking prevalence. This difference needs to be recognised when comparing studies. Studies for comparison include the 2004-5 National Health Survey (NHS),[27] the 2006 Victorian Population Health Survey (VPHS),[223] and the 2007 National Drug Strategy Household Survey (NDSHS).[7] Overall smoking rates in

these studies were 23.0%, 20.5%, and 19.4% respectively. Smoking rates for men ranged from 26.2% (NHS) to 21.1% (NDSHS) and women from 20.4% (NHS and NWAHS) to17.7% (NDSHS). Prevalence of current smoking in the GGT region for participants aged 25-74 appears lower overall (14.9%), and in both genders (men 16.2%, women 13.8%). In all studies, smoking decreased with age.[7,27,223]

This study also highlights concerns and attitudes of current smokers, previous attempts to stop, and cessation advice received. The finding that most smokers including younger ones would like, and do, attempt to stop is consistent with earlier studies from other countries. [225,226] Therefore, it is likely applicable to other rural and also urban areas in Australia.

Strategies for smoking prevention and cessation should be targeted at all people. Specific issues for culturally and linguistically diverse (CALD) and indigenous groups may need consideration.

Our findings suggest younger individuals should be targeted more aggressively. As very few individuals first start smoking after 21 years of age, focussing on deterring smoking initiation in young people is the best strategy. [227,228] At every opportunity GPs should attempt this. Older groups, particularly those aged over 65, already seem to have a large number of ex-smokers.

Most participants were concerned about harmful consequences of smoking but for one-third of current smokers this did not translate into a desire to stop. Only 30% of current smokers in the youngest age group who saw a GP in the previous 12 months reported cessation advice. Similarly, only 14% of this age group who saw another health professional reported cessation advice. This youngest group was

most likely to want to stop or attempt cessation, but least likely to receive cessation advice from a GP or other health professional. This highlights an important opportunity for GPs and other health professionals to assist a motivated group to stop smoking.

Although the study considers the 25-44 year age group as one stratum, post hoc analyses comparing 25-34 with 35-44 year old participants were conducted. Although small sample size limits comparisons, the only difference was desire to stop which was significantly higher in the 35-44 age group (81.8% vs. 50.7%).

Advice, even brief, from GPs has significant positive effects on smoking cessation rates.[229] An increasing proportion of GP encounters are with older patients, including 'baby boomers' currently aged 45-64 years.[222] Whilst this may contribute to increased delivery of smoking advice in these age groups, GPs may be missing opportunities to address smoking with younger people.

Despite declining smoking rates, smoking remains the largest cause of preventable disease in Australia and is particularly problematic in younger age groups.[230] This study provides baseline smoking data for rural areas and identifies intervention opportunities. General practice is well placed to implement validated tools and interventions for smoking prevention and cessation, including setting up systems and procedures.[231,232] GPs, Practice Nurses and other health professionals should aim to address smoking at every patient encounter.

Implications for general practice

Current smoking is most prevalent in young adults (25-44 years) when compared with older age groups, and declines markedly after age 55 years.

Compared with older smokers, those in the 25-44 years age group are:

- more likely to want to stop smoking
- more likely to have attempted to stop smoking
- less likely to have received GP advice to stop smoking

GPs should take every opportunity to address both smoking prevention and cessation in younger people (e.g. using the '5As' model)

Acknowledgements

Dr Philip Tideman and Ms Rosy Tirimacco from Cardiovascular Medicine, Flinders Medical Centre and Integrated Cardiovascular Clinical Network Adelaide, SA: major investigators in the Limestone Coast Risk Factor Study. Dr Nathalie Davis-Lameloise for assistance in producing the manuscript. Ms. Anna Kao-Philpot, the nurses carrying out the survey, and the regional hospitals providing facilities for the study. This study was supported by the Australian Government Department of Health and Aging, Royal Australian College of General Practitioners, Sanofi-Aventis Pty Ltd, Pfizer Inc, Roche Diagnostics Australia and Servier Laboratories Pty Ltd.

Competing Interests

None declared

Chapter 6. The Potential of Pharmacists to Help Reduce the Burden of Poorly Managed Cardiovascular Risk

Citation details:

Mc Namara KP, Dunbar JA, Philpot B, Marriott JL, Reddy P, Janus ED. The potential of pharmacists to help reduce the burden of poorly managed cardiovascular risk. *Australian Journal of Rural Health* 2012;20(2):67-73.

Co-author declarations confirming the nature of my involvement are detailed in Appendix 1.

Background to the research

The third of the three surveys comprising the GGT RFS was undertaken in the Wimmera region of Victoria. The survey forms were amended to collect information about use of community pharmacists for health purposes so that that the current use of this profession by patients with chronic disease risk could be estimated. From a health services research perspective, this survey allowed us to gain a relatively unique perspective of potential roles for pharmacists. The WHO MONICA protocol and EHRM guidelines upon which the survey form is based[183,184] enquired about participants about their use of doctors, nurses, dietitians and other health professionals for health service planning purposes;

however, use of community pharmacists have not been examined as part of these internationally used population surveys.

Absence of pharmacist-related data from population health surveys leaves two major gaps in the literature:

1. We do not know how often patients at risk of CVD (and other chronic diseases) use community pharmacy services relative to other services. This makes it difficult to develop interdisciplinary strategies to maximise use of opportunistic interventions for key patient target groups.
2. Other studies examining CVD risk among community pharmacy patients tend to recruit patients who self-nominate for risk screening progammes.[133,173,233] These samples are not necessarily representative of the pharmacy population.

It should be noted that the question added to the survey regarding the community pharmacist (as opposed to pharmacy) specifically asks about frequency of use *for health purposes*. This is somewhat different to previous surveys which have asked about frequency of visit to community pharmacies in general. This clarification was added to our survey to avoid inclusion of general retail services offered by many pharmacies, where opportunities for intervention by pharmacists are somewhat limited.

To my knowledge, this is the first paper seeking to address this issue. We specifically restricted analysis to compare use of pharmacists only with use of GPs because other health professionals (dietitians, nurses, dentists, specialists etc) were not commonly used by patient groups of interest.

My role in this research

I was part of the group that revised the survey form in advance of the Wimmera survey. In particular, I suggested the need for examination of use of community pharmacist services, and provided appropriate wording to the research group.

I formulated the initial concept and design of the manuscript, led the writing and analysis of the manuscript that constituted this chapter of results and undertook the majority of the work involved. As lead author I prepared several drafts for comment from co-authors; statistical analysis was completed with significant assistance from co-author Benjamin Philpot.

Declarations from co-authors are available in Appendix 1.

Introduction

Substantial evidence–treatment gaps for cardiovascular disease (CVD) risk factors persist in rural Australia, resulting in an enormous health burden.[17,98,234] The current primary healthcare system does not adequately facilitate detection or management of CVD risk factors or established CVD by health professionals. Given that CVD mortality and morbidity is worse for non-metropolitan residents compared with their metropolitan counterparts,[75] reform of rural primary healthcare delivery is essential.[162]

Quality of primary care has a strong positive association with population health.[235] Consequently, shortages of several key health professionals in rural and remote areas – including General Practitioners (GPs) – represent a key challenge to improving primary healthcare.[165] This situation represents 'a chronic problem that cannot be absolutely "fixed" ', and requires innovative models of care to manage future health system demands.[162] A 60% increase in medical graduate numbers between 2005 and 2010 failed to stem declining per capita GP supply; most graduates instead chose specialist and non-specialist hospital positions. An 'entrenched, long-term shortage' of GPs is predicted.[166,168] The inverse care law, that 'availability of good medical care tends to vary inversely with the need for it in the population served',[167] compounds this problem – per capita overall medical workforce in regional Australia is half that in metropolitan areas.[168]

Engaging Community Pharmacists (CPs) to collaborate more extensively with GPs and other health professionals is one means by which more comprehensive primary care might be achieved. Despite RCT evidence supporting the

effectiveness of CP interventions for major CVD risk factors,[137,171,172,236] they remain largely underutilised in terms of potential contributions to multidisciplinary primary care.

The aim of this study is to establish the frequency of contact with GPs and CPs by individuals at high risk of CVD or with inadequately controlled CVD risk factors. Understanding patterns of health professional use by these individuals will provide insights into opportunities for enhanced CP involvement in cardiovascular healthcare.

Methods

Methods have been described previously.[17,234] A cross sectional population survey of chronic disease risk factors and related health behaviour was conducted in 2006 in the predominately Anglo-Celtic Wimmera region of Victoria. The Rural, Remote and Metropolitan Areas classification system categorises most of the region as 'other rural areas' apart from the small rural centre of Horsham. The main population centres in this region all had at least one general practice and community pharmacy. However, some smaller localities with general practices did not have a local community pharmacy.

A stratified random sample of 1500 adults aged 25-84 years, was selected from the electoral roll of this region. Stratification was made by gender and 10-year age group, with the exception of the 25-44 age group, which was considered as one stratum. In total, 150 people from each gender were sampled within each age stratum. Mailed invitations to participate in this health check were sent to each

individual. Deceased individuals and those no longer living within the region were excluded.

Participants completing a written consent form were sent a self-administered questionnaire and invitation to present for a health check. All processes were in accordance with the WHO MONICA protocol.[183] Health checks consisted of physical measurements and venous blood sampling. Physical measures included weight, waist and hip circumferences, body mass index (BMI), and blood pressure. Venous blood samples were used to determine 12-hour fasting plasma glucose concentrations and lipid profiles at an internationally accredited laboratory. The self-administered questionnaire sought demographic, social and health service utilisation information, including self-reported previous medical diagnosis of diabetes, established CVD and CVD risk factors. It also investigated key health behaviours including diet, alcohol intake, physical activity, smoking status and weight management.

The following questions were included in the survey to assess the number of times participants had visited either a GP or CP for health purposes:

'How many times have you visited a general practitioner (GP) in the last 12 months?'

and

'How many times have you visited a community pharmacist for health reasons in the past 12 months?'

We used the following criteria as indicators of inadequately controlled risk factors or suboptimal health behaviours for the general population:

CVD risk factors

- BMI ≥30 kg/m^2
- waist circumference ≥ 94 cm (men) or 80 cm (women)
- blood pressure ≥ 140 mmHg systolic and/or 90 mmH diastolic
- total cholesterol ≥ 5.0 mmol/L
- LDL cholesterol ≥ 3.0 mmol/L
- total:HDL cholesterol ratio ≥ 5.0
- Fasting Plasma Glucose (FPG) ≥ 5.6 mmol/L.

Health behaviours

- history of smoking in the past 12 months
- consumes 14 or more units of alcohol each week
- reports most leisure activity not involving physical activity
- undertakes less than 30 minutes physical activity every day (work or leisure time)
- eats less than 4 serves of vegetables per day
- eats less than 2 serves of fruit per day.

All participants responding to questions about use of GP and CP services were included in analysis.

The study was approved by the Flinders University Clinical Research Ethics Committee.

Statistical analyses

Statistical analyses were undertaken using Stata 11.2 (StataCorp, USA). Age-specific and overall results are presented. Median numbers of GP and/or CP visits (with lower and upper quartiles) are presented because of the highly skewed distributions. Proportion visiting GP and/or CP and prevalence figures for uncontrolled risk factors are presented with 95% confidence intervals. Pearson's chi-square statistic was used to make comparisons between genders. P-values of 0.05 or less were deemed to be statistically significant. All age-combined analyses were adjusted for age using population weights derived from the region's population according to the electoral roll.

Results

Seventy five patients were excluded because they had died or moved from the area. From the remaining 1425 invited to take part, 723 (51%) participated in the study and a final sample of 694 had essential information relating to use of GPs and CPs (Table 6.1). Previous studies have shown the socioeconomic background of participants in Greater Green Triangle Risk Factor Studies to be representative of the local population.[23]

Half the respondents (51%) were women and 40% were aged 65 years or over. Nine out of ten participants (92%) visited their GP or CP (or both) at least once during the previous 12 months. More individuals visited GPs at least once in the previous 12 months compared with CPs (89% vs. 67%, $p<0.001$), and there was also a greater median number of reported visits to GPs (Table 6.2). Participants visited these practitioners a median combined total of 6 times per annum; this

increased from a median (IQR) of 4 (2-8) visits at 25-44 years, to 6 (2-14) visits at 45-64 years, and 13 (6-18) visits at 65-84 years (Table 6.1).

Table 6.1. Number of visits to General Practitioners and Community Pharmacists made in the previous 12 months by the Wimmera population

		Women		**Men**		**Overall**	
	Age (yrs)	N	Median (Q1-Q3)	N	Median (Q1-Q3)	N	Median (Q1-Q3)
General Practitioner	25 - 44	51	3 (2-6)	43	1 (1-3)	94	2 (1-4)
	45 - 54	82	3 (2-6)	79	2 (1-4)	161	2 (1-5)
	55 - 64	82	3 (2-5)	80	3 (1-4.5)	162	3 (1-5)
	65 - 74	86	5 (2-7)	75	4 (2-6)	161	4 (2-6)
	75 - 84	54	5 (3-10)	62	5.5 (4-8)	116	5 (3-8)
	Total	**355**	**4 (2-6)**	**339**	**2 (1-4)**	**694**	**3 (1-6)**
Community Pharmacist	25 - 44	51	2 (1-8)	43	1 (0-3)	94	2 (0-4)
	45 - 54	82	4 (0-12)	79	2 (0-5)	161	2 (0-6)
	55 - 64	82	2 (0-12)	80	2 (0-6.5)	162	2 (0-10)
	65 - 74	86	8 (1-12)	75	6 (0-12)	161	6 (0-12)
	75 - 84	54	5 (0-12)	62	12 (4-12)	116	10 (1-12)
	Total	**355**	**3 (0-12)**	**339**	**2 (0-6)**	**694**	**2 (0-10)**
Combined number of visits	25 - 44	51	7 (4-13)	43	3 (1-6)	94	4 (2-8)
	45 - 54	82	8 (3-15)	79	4 (1-8)	161	5 (2-12)
	55 - 64	82	7 (3-15)	80	5.5 (1.5-13)	162	6 (2-14)
	65 - 74	86	11.5 (6-18)	75	10 (3-16)	161	11 (4-18)
	75 - 84	54	12 (6-20)	62	16 (8-19)	116	15 (8-20)
	Total	**355**	**8 (4-16)**	**339**	**4 (2-10)**	**694**	**6 (2-14)**

Women were more likely than men to have made any visits to a GP (91% vs. 86%, p=0.06), a CP (72% vs. 62%; p=0.02), or either GP or CP (95% vs. 88%, p=0.01). Compared with men, women also made a significantly higher number of visits in the previous 12 months to GPs (p=0.003) or CPs (p<0.001) and a significantly greater average combined number of visits (p<0.001). Both women (p=0.01) and men (p<0.001) visited their CP with increasing frequency as age

increased (Table 6.1); men, unlike women, reported significantly greater visit frequency to GPs with increasing age ($p<0.001$).

In keeping with the overall population, those at high risk of primary CVD onset or undiagnosed diabetes, and those with established CVD or diabetes, were more likely than low-risk individuals to have visited a GP at least once during the previous year; however, median visit frequency for these groups was greater for CPs than for GPs. Those with individual uncontrolled risk factors visited GPs and CPs with similar frequencies (Table 6.2). Although the proportion attending a practitioner did not substantially increase if the combined visits were compared with visits to GPs alone, the median number of visits did substantially increase – more than doubling in several instances – for any uncontrolled CVD risk factor or for those at high overall CVD risk.

One in five participants with excessive alcohol intake did not visit a GP or CP. This is partly explained by the fact that, of participants who drank excessively, 85% were men and thus inherently less likely to visit GPs or CPs. Participants with other poorly controlled health behaviours (diet, physical activity, smoking) were very likely to visit one or both type of professionals regularly (Table 6.2).

Table 6.2. Average number of visits per annum to General Practitioners and Community Pharmacists for participants with uncontrolled risk factors

	Overall prevalence of risk factor							
			GP visits		CP visits		GP plus CP visits	
	n	% (95% CI)	Proportion who visits	Number of visits	Proportion who visits	Number of visits	Proportion who visits	Number of visits
Overall	**694**	-	88.5 (85.2-91.1)	3 (1-6)	66.8 (62.3-70.9)	2 (0-10)	91.6 (88.5-93.9)	6 (2-14)
Obesity								
BMI >= 30 kg/m2	192	29.6 (25.7-33.8)	89.9 (83.5-94.0)	3 (1-6)	66.9 (58.8-74.0)	2 (0-12)	94.8 (89.5-97.5)	7 (2-16)
Waist ≥ 94.0cm (M)/80.0cm (F)	399	58.6 (53.8-63.3)	84.4 (78.7-88.9)	2 (1-4)	70.7 (65.2-75.7)	4 (0-12)	94.6 (80.2-91.6)	8 (3-16)
Blood pressure								
BP ≥ 140/90 mmHg	235	31.0 (27.4-34.8)	89.8 (82.5-94.3)	4 (1-6)	70.7 (63.8-76.7)	4 (0-12)	94.6 (90.8-96.9)	8 (3-16)
Lipids								
Total cholesterol ≥ 5.0 mmol/L	390	62.7 (57.8-67.3)	85.8 (80.9-89.6)	2 (1-5)	65.9 (60.3-71.0)	2 (0-6)	89.8 (85.2-93.1)	5 (2-13)
LDL cholesterol ≥ 3.0 mmol/L	329	54.2 (49.3-59.0)	86.7 (81.3-90.7)	2 (1-5)	67.0 (61.0-72.6)	2 (0-6)	90.4 (85.4-93.8)	5 (2-13)
Total:HDL cholesterol ratio ≥ 5.0	92	16.4 (13.3-20.1)	87.7 (77.4-93.7)	2 (1-5)	68.4 (56.9-78.0)	2 (0-8)	93.8 (85.8-97.5)	4 (2-12)
Fasting plasma glucose (FPG) concentration								
5.6 - 6.9 mmol/l	114	16.8 (13.6-20.5)	86.4 (73.4-93.6)	3 (2-6)	69.9 (58.6-79.2)	4 (0-12)	94.2 (88.6-97.2)	8 (3-18)
7.0 mmol/l or over	24	3.3 (2.2-5.0)	92.0 (73.0-98.0)	6 (4-8)	87.2 (69.7-95.3)	12 (4-20)	96.3 (78.0-99.5)	14 (6-31)
Diet								
< 2 servings of fruit per day	363	58.1 (53.7-62.3)	89.2 (84.2-92.7)	3 (1-5)	65.7 (59.3-71.5)	2 (0-6)	91.5 (86.8-94.7)	6 (2-14)
< 4 servings of vegetables per day	469	70.8 (66.4-74.9)	89.3 (85.1-92.5)	3 (1-5)	66.1 (60.7-71.1)	2 (0-8)	93.0 (89.3-95.5)	6 (2-14)
Physical activity								
Most leisure activities do not involve physical activity	106	15.6 (12.4-19.4)	89.2 (78.7-94.9)	4 (2-6)	66.3 (54.9-76.1)	4 (0-10)	93.6 (84.6-97.5)	8 (3-15)
Does not achieve minimum 30 minutes physical activity every day (during work or leisure time)	181	30.3 (26.2-34.7)	89.9 (85.8-97.5)	3 (2-5)	68.0 (57.9-76.6)	2 (0-8)	91.9 (86.2-95.4)	6 (2-13)

Continued. next page…

Table 6.2. Average number of visits per annum to General Practitioners and Community Pharmacists for participants with uncontrolled risk factors

		Overall prevalence of risk factor						
			GP visits		CP visits		GP plus CP visits	
	n	% (95% CI)	Proportion who visits	Number of visits	Proportion who visits	Number of visits	Proportion who visits	Number of visits
Smoking status								
Current smoker	75	13.8 (10.6-17.8)	93.9 (85.8-97.5)	3 (2-5)	71.7 (55.2-83.9)	3 (0-12)	96.2 (89.0-98.8)	8 (3-16)
Alcohol intake								
More than 14 standard drinks per week	114	17.5 (14.5-20.9)	75.2 (63.1-84.3)	2 (1-4)	54.3 (43.3-64.9)	1 (0-4)	80.5 (68.2-88.9)	3 (1-8)
Overall CVD risk								
>15% CVD risk, primary prevention, or undiagnosed diabetes (Australian risk charts)	128	14.9 (13.4-16.6)	94.8 (88.4-97.8)	4 (2-6)	70.4 (61.1-78.3)	6 (0-12)	97.8 (93.3-99.3)	12 (5-18)
History CVD or T2DM	115	14.1 (11.9-16.7)	99.3 (95.6-100.0)	6 (0 -12)	81.3 (72.6-87.6)	10 (4-14)	99.3 (95.6-99.9)	16 (8-24)

Discussion

This may be the first Australian population survey comparing use of CPs and GPs by individuals with inadequately controlled CVD risk. Findings demonstrate extensive population reach by both CPs and GPs in terms of opportunities to identify and intervene with uncontrolled CVD risk factors and elevated overall risk. Different patterns of use existed for the two types of health professionals. There was a greater likelihood of accessing GPs across the overall population; conversely older patients and those at higher risk of CVD visited CPs more frequently, perhaps related to more regular medicines use by these groups. Regular health professional feedback plays an important role in maintaining health improvements.[132] Pharmacists are already embedded within the usual care pathway for key target groups and could potentially double the number of opportunities to deliver targeted interventions compared with relying solely on general practitioners.

Recent evidence suggests great scope to improve quality of primary care for CVD risk factors.[98,182] The potential for CPs to effectively contribute to CVD risk reduction via screening, monitoring and optimising medicines use is well established.[137,171,172,236] In saying this, the population reach of CPs in our study was less than for GPs, and visit frequency by key groups to CPs was more variable; hence it might be wise to generally view community pharmacy as a useful addition to existing screening services and general practice coordination of care for cardiovascular risk, rather than an alternative.

Establishing collaborative models of care for communities and individuals that address significant professional cultural barriers should be a focus of future health reform. The pharmacy profession will need to embrace new roles and adopt a more proactive approach to counselling and intervention.[237,238] Effective collaboration at a local level would ultimately require GP endorsement of significantly expanded pharmacist roles. This will be highly dependent on their satisfaction that pharmacists are competent and acting within their scope of professional practice. Hence training and accreditation requirements for expanded roles should not be ignored if relevant.

Societal expectations of pharmacy need to be addressed in order to drive demand for enhanced pharmacy services. There is reasonable public endorsement of CPs delivering many cardiovascular health services, but this attitude is not universal.[239] Half of Australian adults reportedly never actively seek health advice from CPs.[240] A 2002 study from rural New South Wales suggests that GPs remain the preferred healthcare provider and are considered most important by their communities.[241] Interestingly, CPs consistently rated as the second-preferred healthcare provider.[241]

Fears of turf encroachment by both professions need to be overcome to enable widespread formal collaboration. Tensions surrounding a number of issues (e.g., pharmacist prescribing, dispensing doctors) often hamper interprofessional dialogue at a national level; similarly, there are no widely used multidisciplinary models in practice to encourage a coordinated focus on population health. New 'Medicare Local' agencies may provide an effective vehicle for brokering local interprofessional collaborations if national-level dialogue progresses too slowly.

University Departments of Rural Health are ideally placed to develop and evaluate new models for collaboration in rural and remote areas.

Limitations of the data have been previously discussed.[6] The authors are unaware of similar Australian studies comparing patient use of GPs and CPs, hence the representativeness of findings for other populations remains unknown. However, Canadian data examining pharmacy use by patients with diabetes reported similar visit frequency to our study and no difference between rural and urban areas.[163] Importantly, measurement of the frequency of use of each type of health professional does not indicate the quality or nature of advice provided.

Conclusions

General practice and community pharmacy are ideally placed to collaborate for better prevention and management of CVD; however, there remain many challenges to effectively implementing programs. Such an initiative would require changes to the culture of primary healthcare, and expectations from the general public.

Acknowledgments

KM is a pharmacist-academic at Greater Green Triangle UDRH, a position funded by the Department of Health and Ageing through the Rural and Remote Pharmacy Workforce Development Program. We thank Ms Anna Chapman and the nurses who carried out the survey and the regional hospitals that provided facilities for the study. This study was supported by the Australian Government Department of Health and Ageing and Servier Laboratories Australia.

Chapter 7. Greater Green Triangle Diabetes Prevention Program: Remaining Treatment Gaps in Hypertension and Dyslipidaemia

Citation details:

Mc Namara K, Philpot B, Janus ED, Dunbar JA. Greater Green Triangle Diabetes Prevention Program: remaining treatment gaps in hypertension and dyslipidaemia (short report). Australian Journal of Rural Health 2010; 18(1): 43-44.

Co-author declarations confirming the nature of my involvement are detailed in Appendix 1.

Background to the research

The Greater Green Triangle Diabetes Prevention Program (GGT DPP) was adapted from a global benchmark model for diabetes prevention with proven effectiveness already developed in Finland.[242] The GGT DPP model was developed for use in low-resource settings (general practice). Its relevance to this

thesis lies in the fact that the patient group involved are also at elevated risk of CVD, and the goals and principles of therapy overlap to a substantial degree with those that are desirable for CVD prevention.[125]

Like most CVD prevention programs, [142] I noticed there was often an exclusive focus in GGT DPP on intensive support for lifestyle modification but no systematic approach to medicines use. While the GGT DPP was highly successful in reducing diabetes and CVD risk, there still remained a high proportion of individuals who have not reached their clinical targets.[125,242] When extensive lifestyle modification has not worked, guidelines generally recommend use of drug therapy for lipids and hypertension if cardiovascular is sufficiently elevated.[30,78]

I was interested to see whether or not GGT DPP participants, through increased emphasis on CVD risk factors and GP/patient awareness, automatically received drug therapy. If not, it would suggest some justification for additional intervention focussed on optimising medicines use. While the data is somewhat limited in quality (based on patient self-report, and no dosage information), this issue has not previously been investigated and I felt a brief exploration might be beneficial.

My role in the research

I did not play any direct role in this research project, although I did engage with the research team to discuss the merits of collecting medicines use data. After GGT DPP was completed, I suggested running analyses on these data and coordinated a short report with the limited data available.

Introduction

Within 20 years diabetes will become the leading contributor to overall burden of disease in Australia and worldwide, particularly as the population ages and becomes more obese.[243]

Several RCTs have demonstrated that lifestyle modification reduces risk of progression to diabetes.[89] The 2004–2006 Greater Green Triangle Diabetes Prevention Program (GGT DPP) demonstrated that lifestyle modification was feasible and effective in Australian primary care.[125] Cardiovascular risk dramatically increases in patients at risk of diabetes, and cost-effective diabetes prevention programs should aim to address not just diabetes risk, but also cardiovascular disease (CVD) risk factor management. At 12 months, GGT DPP reduced the estimated risk of progression to diabetes by 40% and the estimated risk of CVD by 16%.

National Heart Foundation guidelines[187 205] for the management of lipid disorders and hypertension recommend consideration of pharmacological management where lifestyle management has not been sufficiently effective and CVD risk remains moderate to high. This study examines the extent to which untreated high-risk patients commence pharmacological treatment for blood pressure (BP) or lipid disorders during or after a diabetes prevention lifestyle intervention.

Participants, methods and results

Methods for this longitudinal pretest and post-test study have been previously described.[125] Overall, 311 individuals aged 40–75 years at moderate to high risk of developing type 2 diabetes were recruited through general practices. Participants received six 90-min lifestyle modification counselling sessions facilitated by specially trained nurses over eight months.

Outcome measures at baseline, three and 12 months included body mass index, waist circumference, fasting and two-hour oral glucose tolerance test plasma glucose, lipids and BP. After the study, participants were asked to recall whether they were taking lipid lowering or antihypertensive medication at baseline and 12 months.

Of 237 participants who attended baseline and 12 months clinical testing and at least one session, 220 had sufficient information on BP, CVD risk (according to 2004 BP guidelines[187]) and BP medication. At baseline, 71 individuals were already on antihypertensives, with 47 (66%) of these inadequately controlled at 12 months. Of 17 at high CVD risk who were not treated at baseline, 15 did not achieve BP targets at 12 months, with only one of these commencing drug treatment.

A total of 217 participants had sufficient information on CVD risk (according to 2001 lipid guidelines[205]), lipid-lowering medication status and lipid control. In total, 76 participants had at least 10% CVD risk at baseline and were not receiving lipid lowering medication. Only four commenced lipid lowering treatment during

the 12-month intervention. All 76 participants still had lipids above target levels at 12 months. However, only 54 still had greater than 10% CVD risk.

Comment

Despite significant improvements in diastolic BP and lipids, our results suggest that evidence–treatment gaps exist for the pharmacological management of hypertension and dyslipidaemia for patients who have completed a 12-month diabetes prevention program. GPs were informed of oral glucose tolerance test, BP and lipid levels. Given the lack of treatment initiation by 12 months among patients with sustained elevated CVD risk, we could conclude that separate initiatives might be required to ensure optimal pharmacological management.

Pharmacists are one of the few non-medical health professionals regularly accessed in most rural communities. They are perhaps the only non-medical professional in many communities with medicines use and health promotion expertise. There is overwhelming evidence for an effective role by community pharmacists in reducing BP and increasing evidence for roles in lipid management and management of multiple CVD risk factors through lifestyle modification and pharmacological management.[135,244] We recommend further research into the role pharmacists might play as part of a primary care team in the management of CVD risk.

Acknowledgements

The general practices: Hamilton Medical Group, Hawkins Clinic, Mount Gambier and Horsham general practitioners. Funding from Australian Government Department of Health and Ageing.

PHASE TWO. DEVELOPMENT AND FEASIBILITY TESTING OF A MODEL FOR PHARMACIST-DELIVERED INTERVENTIONS FOR MULTIPLE CVD RISK FACTORS

Background to the research

Findings from previous chapters suggested the need for better management of cardiovascular risk at both individual and population levels. Community pharmacists were identified as well-placed to provide interventions for individuals with uncontrolled CVD risk factors, or with high overall CVD risk. I wanted to investigate whether community pharmacists could play a meaningful role in CVD risk reduction for patients with multiple CVD risk factors. Consequently, I developed and pilot-tested (along with several co-investigators) a model of care for the primary prevention of CVD to be delivered by community pharmacists.

Primary prevention was chosen because my literature review identified the absence of comprehensive models of care in Australia or internationally. The first half of this phase describes the development of a detailed intervention study protocol, and is followed by a description of clinical outcomes from the intervention. These components constitute the first two of four steps required for rigorous development of a complex primary care intervention – establishing the

theoretical basis for an intervention and testing the intervention for feasibility. Complex interventions are simply defined as interventions with several interacting components.[245] For this intervention, some of the dimensions which add complexity include:

- multiple, interrelated behavioural and clinical outcomes
- interacting clinical and behavioural intervention components (e.g. recommendation to initiate therapy vs. support for diet change),
- different groups targeted by the intervention (e.g. patients, pharmacists, GPs),
- the variation in setting (e.g. urban vs. rural, solo pharmacy vs. multiple pharmacists, Victoria vs. Tasmania), and
- variation in patients receiving the intervention (e.g. high vs. low risk of CVD, male vs. female).

In undertaking a feasibility study, we can assess whether the protocol should be varied for different settings or patient groups, and whether or not an intervention appears possible in everyday practice.[245] If positive results are established, it would provide justification for future phase three and phase four intervention trials (RCT and implementation trial), and informs adaption to make the intervention in practice more efficient and effective in the later, more resource-intensive phases.[246,247] In this phase, we present a detailed analysis of the patient-level outcomes. However, a full accompanying process evaluation has been undertaken to inform future development of this intervention.

Theoretical framework for this intervention

In Phase II, the principles of the Health Action Process Approach (HAPA) and motivational interviewing strongly influenced the intervention framework. Community pharmacists were trained in motivational interviewing, with an emphasis on small achievable goals and simple health messages for behaviour change. This was reinforced via the baseline report, where a small number of defined targets were proposed to the patient, and the potential reduction in CVD risk arising was estimated if targets were met. Written frameworks for counselling were provided for each session, with checklists to ensure adherence. This framework mandated a transition in the focus of care in keeping with HAPA principles. During initial sessions, pharmacists focused on risk communication, basic education around treatment benefits, patient attitudes to health behaviours, and barriers to change. This supports development of an intention to change behaviour. The emphasis then evolved more to action planning, reflection on progress, and subsequent revision of strategies, or adoption of additional strategies where necessary to bolster maintenance and relapse prevention. This was accompanied by feedback on progress towards behavioural goals at each session as a means of continued motivation.

My role in this research

I was principal investigator for this research project, which involved leading all aspects of the project, including:

- Developing the concept and research design, and putting together a research team
- Drafting a successful grant application, with input from co-investigators

- Specifying the study protocol and project plan, and managing project personnel
- Analysis of data and writing of the interim and final reports to the funding body, and manuscripts for peer review included in this thesis.

Declarations from co-authors for this paper are available in Appendix 1. Chapter eight has been written in the future tense because it was a published trial trial protocol, written prior to completion of the project.

The final report, with additional process evaluation not reported in this thesis, is attached as Appendix 3.

Chapter 8. Engaging Community Pharmacists in the Primary Prevention of Cardiovascular Disease: Protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) Pilot Study

Citation details:

Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. BMC Health Services Research 2010, 10:264. DOI:10.1186/1472-6963-10-264.

Co-author declarations confirming the nature of my involvement are detailed in Appendix 1.No communication was received from Prof Jon Emery about this request.

Background

Cardiovascular disease (CVD) is the leading cause of death globally, accounting for an estimated 17.1 million deaths per annum – 29% of all deaths.[248] The relative contribution of CVD to the burden of disease remains high in countries with low-, middle-, and high incomes.[248] Despite significant gaps in research, there is sufficient evidence (particularly from developed nations such as the United States and United Kingdom) to suggest that the primary prevention of CVD represents a cost effective approach to reducing this burden.[249]

There is a cluster of highly prevalent CVD risk factors in many developing and most developed countries including Australia which can be controlled or avoided: tobacco smoking, hypertension, overweight and obesity, physical inactivity, dyslipidaemia (high cholesterol), poor nutrition and diabetes.[5,248] Significant evidence–treatment gaps remain in the management of each of these, culminating in substantially elevated incidences of CVD in most countries. Community pharmacists are highly accessible health professionals in most communities and have demonstrated an effective role in the management of several of these risk factors.[170,172,176,250] Guidelines on primary CVD prevention now highlight the importance of overall CVD risk assessment rather than traditional individual risk factor assessment, resulting in a much greater emphasis on multiple risk factor management.[30,78,91,251-253]

The expertise of community pharmacists in medicines management including adherence screening and management, and a growing role in health promotion has resulted in several studies demonstrating effective pharmacist involvement with

multiple CVD risk factor management.[135-137] However, we are not aware of any multiple risk factor study specifically examining structured, pharmacist-led disease state management programs for primary CVD prevention in a non-diabetic population. The *Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD)* was developed as a pilot project to address this evidence gap.

This paper describes the research protocol developed for the PAART CVD project, a community pharmacy-based CVD primary prevention pilot project in a non-diabetic, adult population. We also identify the theoretical framework, local issues affecting implementation decisions, and gaps in current knowledge experienced to facilitate future adaptation.

Goals of research

1. To assess the feasibility of implementing a primary CVD prevention program in a community pharmacy setting
2. To measure changes to cardiovascular health for patients receiving the PAART CVD intervention.

Methods and Design

Study design and setting

This is a longitudinal pre- and post-test study to be undertaken with a single cohort of patients. Ten pharmacies from two States (Victoria and Tasmania) will be recruited – five each from rural and metropolitan locations. Each pharmacy will be asked to approach a convenience sample of patients meeting the inclusion

criteria, with a goal of recruiting 10 participants per pharmacy. Local general practices and general practice organisations will be informed about the project.

Outcomes examined

The primary outcome for the intervention will be the average change to estimated 5-year risk of primary onset of CVD between baseline and six months calculated using the New Zealand CVD risk scores,[251] a modified version of the Framingham-based risk equation.[63] Secondary health outcomes include change to blood pressure, lipid profile, random blood glucose, waist, body mass index (BMI), and depression score.

Pharmacist training

Over two consecutive days, pharmacists from recruited pharmacies will attend training focussed on the following key topics:

- health promotion and behavioural change
- overall CVD risk and CVD risk assessment
- medicines adherence
- medicines management for cardiovascular risk factors
- lifestyle modification (diet, physical activity, weight management, alcohol consumption)
- antiplatelet use for primary CVD prevention
- smoking cessation
- managing patients who screen positively for diabetes, alcohol abuse or depression; and
- General Practitioner (GP) and other health professional engagement.

All training, including training materials, will be consistent with relevant national guidelines and will be tailored to suit a generalist community pharmacist audience. Emphasis will be placed on the need for pharmacists to act within their professional competencies and take appropriate action if situations arise outside their competencies (e.g. patient screens positive for depression). Written guidelines will be provided to identify patients with complex or urgent clinical needs that warrant referral to a GP or another health professional (e.g. dietitian). Pharmacists will also be advised on options for referral (e.g. how to access specialist dietary or smoking cessation advice) when they might deem it appropriate.

Subject eligibility criteria

Inclusion criteria

To be eligible for participation in the study, patients need to be

- aged 50-74 years
- currently taking one or more medicines for cholesterol and/or hypertension, and
- free from established cardiovascular disease, diabetes or a cardiovascular event.

Individuals will be excluded from the study in the following instances:

- patients with a complex debilitating coexisting medical condition
- target organ damage
- any cognitive impairment
- reliance on a carer or living in a residential aged care facility

- recent hospital inpatients who were medical admissions and discharged less than four weeks prior to recruitment
- non-English speaking
- living more than 40 km from a participating pharmacy
- patients who have received a Home Medicines Review (HMR) in the past 12 months
- deemed inappropriate for the intervention by the patient's GP; or
- patients of GPs who express a desire not to have any involvement with this project.

Patient recruitment

Pharmacists will initially be asked to conduct a simple pre-screening of potential participants based on the inclusion criteria outlined above. The information required (CVD history, use of CVD medicines, and age) is quick and easy to obtain from dispensing records and patient interview. Potential participants expressing interest will be provided with written patient information and an Expression Of Interest (EOI) form to be completed and returned to researchers.

Upon receipt of EOIs or direct patient-initiated contact via a free telephone number, a formal assessment of all eligibility requirements will be undertaken by researchers and a provisional baseline assessment date agreed. If eligible, consent must be obtained to contact their GP in writing and to provide the GP with an opportunity to comment on the appropriateness of participation. Written consent for participation and sharing of health information with relevant health professionals is to be provided by patients prior to baseline assessment.

Patient data collection

Baseline and final (6 month) patient information will be collected by trained research assistants (RAs). This process will take 60-90 minutes on both occasions and can take place in the patient's home (preferred), or in a private area at the pharmacy or their workplace. Assessment involves anthropometric and Point of Care (POC) biomedical testing, and an administered questionnaire using validated scales where possible. Lipid profiles and fasting blood glucose levels will be obtained using Cholestech LDX® Analyzers,[254,255] in accordance with instructions provided by the manufacturer. This device uses finger-prick testing and provides results within 10 minutes. Quality control samples will be used to validate the machine prior to measurements. Patients will be advised that the most accurate results for cholesterol and blood glucose levels would be obtained by fasting 12–16 hours prior to the initial assessment interview and testing, and to take their medications as normal on the day of clinical assessment. Fasting time will be recorded to aid clinical interpretation.

When the patient is rested, blood pressure (BP) will be measured using an Omron 1A1B® automated BP monitor in accordance with WHO MONICA Monitoring of Trends and Determinants of Cardiovascular Diseases and the European Health Risk Monitoring protocols amended for use with an automated monitor.[183,184] The average of two measurements taken 2-3 minutes apart will be used, but if systolic BP measurements differ by 10 mmHg or greater, or diastolic BP differ by 6 mmHg or greater, a third reading will be taken. In this instance the average of the two closest systolic and two closest diastolic BP measurements will be used to

define the BP. The RA will advise patients to seek immediate medical attention if systolic BP is 180 mmHg or greater, or if diastolic BP is 110 mmHg or greater. Weight, height, and waist and hip circumferences will be measured in accordance with the EHRM protocol.[184]

The remainder of the assessment will consist of a researcher-administered questionnaire (all interviewing researchers have pharmacy qualifications). This questionnaire, which includes several validated survey instruments, covers a range of health indicators:

- demographic and social information, including some questions based on the WHO MONICA (MONItoring of CArdiovascular events) protocol,[183] as adapted for the Greater Green Triangle Chronic Disease Risk Factor Studies[6]
- brief patient medical history and family history of CVD events
- details of current medicines
- details of recent testing for CVD risk factors prior to baseline
- adherence to current medications advice using the Tool for Adherence Behaviour Screening (TABS)[256] and the Morisky scale[257]
- smoking, physical activity and weight management status – including some screening questions from the 'Lifescripts' program[258] and questions from surveys used by the Greater Green Triangle Chronic Disease Risk Factor Studies[6]
- nutrition and adherence to national dietary guidelines, based on Dietary Guidelines for Australian Adults (2003)[39] and using a number of questions

from the National Nutrition Survey 1995,[259] and the Cancer Council of Victoria Food Frequency Questionnaire[260]

- screening for excess alcohol consumption using the AUDIT C tool[261]
- screening for depression using the Center for Epidemiological Study of Depression Scale (CES-D)[262]
- quality of life measure using the SF-12v2 Health Survey™ [263].

Pharmacists will be asked to supply medicines dispensing data for the six months' period prior to baseline data collection and the six months prior to follow up data collection. To account for medicines collected elsewhere, patients will be asked during their interviews to recall any quantities of medicines obtained elsewhere for the specified period.

Intervention part one: accredited pharmacist review

Using relevant national clinical guidelines as the benchmark for management, pharmacists accredited to undertake collaborative, structured medicines management reviews in community settings (known as 'Home Medicines Reviews') will produce a written report for each patient highlighting the estimated 5-year CVD risk, suboptimal CVD risk factors, and medication adherence and other medicines use issues (see Appendix 3 – sample report is in Appendix 3 of final project report). The report will also suggest patient treatment goals and opportunities for beneficial lifestyle changes and improved medicines management to achieve goals. This report will be provided to the patient's community pharmacist with summaries for the patient and their general practitioner.

Intervention part two: community pharmacist facilitating patient change

Community pharmacists will be trained to deliver their interventions in accordance with the Health Action Process Approach (HAPA)[126] to behaviour change over five counselling sessions conducted at monthly intervals. The emphasis in counselling progresses from change motivation initially (via improved self-efficacy, belief in the need for change and belief that change will generate positive outcomes), through to change maintenance and relapse prevention strategies. Written, achievable goals will be encouraged.

The first session with the patient will prioritise basic health education regarding individual CVD risk and the benefits of potential treatments. It also establishes acceptable goals for the treatment process through patient consultation, and how these might be achieved. Finally, the pharmacist will discuss with the patient any specific medication changes identified in the baseline report that are recommended to improve adherence to CVD guidelines. Community pharmacists will not be trained or asked to make interventions related specifically to diabetes or mental health issues, but will be alerted to any suboptimal assessment results in these areas and asked to discuss with the patient the potential need for GP input. Such issues will also be identified in the baseline assessment summary provided to the GP.

If a patient's overall 5-year CVD risk score is 5% or less (considered very low risk) they will be advised to discuss with their pharmacist whether they are likely to benefit from continuing with the intervention. The decision to continue will be left to the pharmacist and the patient. Pharmacists will be expected to assess and document patient motivation to undertake various medication and lifestyle

changes. Following discussion with each patient, the pharmacist will then forward the clinical summary to the patient's GP with any additional comments considered relevant.

Subsequent sessions will involve: ensuring necessary changes to medicines have been made; monitoring of medicines adherence especially for new medicines; linking patients with local health and other services that provide relevant patient support; initiating lifestyle change and supporting maintenance and relapse prevention. Throughout these sessions, patient progress towards goals will be continually reassessed, as will be the goals themselves. GP input to patient treatment plans will also be invited.

Primary outcomes

The primary outcome for the PAART CVD intervention is the average change to overall estimated 5-year risk of CVD onset, calculated using the New Zealand adaptation of the Framingham-based CVD risk score.[63,251]

Secondary outcomes

Other outcomes examined include:

- changes to individual modifiable CVD risk factors (blood pressure, lipid profile, body mass index, waist circumference, smoking status, depression)
- changes in medicines adherence assessed using Morisky[257] and TABS scales;[256] and
- changes in key health behaviours (physical activity, diet, alcohol intake, weight management).

Additional outcomes to be assessed include stakeholder satisfaction (GP, pharmacist, patient) and process audit based on community pharmacist documentation of counselling sessions.

Sample size

With 80 subjects this study would have a 90% power to show an absolute reduction in risk of 1% based on a standard deviation in the change of risk of 2.7% with a two sided p-value of 0.05. To account for potential subject drop out and loss to follow-up of 20% we will aim to recruit 100 subjects.

Statistical analysis

Univariate comparisons between groups will be conducted using chi-square test for equal proportion (or Fisher's exact tests where numbers are small) and reported as numbers and percentages. Continuous normally distributed variables will be compared using Student's t-tests and reported as means (standard error) whilst non-parametric data will be compared using Wilcoxon rank-sum tests and reported as medians (interquartile range). Pairwise differences between pre and post values will be calculated using paired t-tests for normally distributed data and Wilcoxon sign rank tests for non-normally distributed data. To account for the large number of comparisons being made, we will employ a reduced 2-sided p-value of 0.01 to indicate clear statistical significance.

If any parameter from POC finger prick testing is found to be outside the measurable range for the machine, the value of the closest measurable limit will be given to that patient.

Health behaviours will largely be measured using existing scales associated with the survey instruments incorporated into baseline and follow-up assessment. For the dietary assessment, no validated tools are available for use in an Australian population so a study-specific tool has been devised. This tool is a 13-item questionnaire addressing dietary quality in this study population and using previously validated questions from the National Nutrition Survey and Cancer Council of Victoria Food Frequency Questionnaire relating to the nutrients of concern for primary prevention of CVD.[259,260] Responses for each item will be scored between zero (least healthy response option) and 10 (healthiest option) – consistent with the developing literature in this area of nutrition research.[264] This scoring allows for an overall diet score to be generated ranging from 0 to 130.

The general quality of dietary intake will be interpreted using the guidance provided in table 8.1.

Table 8.1. Scoring mechanism used to assess overall quality of dietary intake

Diet score using nutrition tool	**Interpretation**
104–130	High level of compliance with CVD dietary guidelines (80% or more)
78–103	Medium level of compliance with CVD dietary guidelines (60–79%)
77 or less	Low level of compliance with CVD dietary guidelines (59% or less)

This score allows a good estimate of the level of adherence to key diet-related behaviours. Constituent elements of the 13-item questionnaire also allowed

development of sub-scales for these areas of significant influence on cardiovascular health:

- fruit and vegetable intake (soluble fibre and antioxidants)
- saturated fat and total fat intake
- omega-3 fatty acid intake
- fibre intake (insoluble fibre); and
- salt intake.

The sub-scales enable community pharmacists to deliver more tailored dietary advice to participants.

The study protocol was approved by Monash University Human Research Ethics Committee (HREC), University of Tasmania HREC, Flinders University Social and Behavioural Research Ethics Committee and the Australia and New Zealand Clinical Trials Registry (Trial Number ACTRN12609000677202).

Discussion

The protocol and methods outlined above provide an intervention framework for managing multiple CVD risk factors in community pharmacy or other primary care settings. There is considerable incentive to demonstrate feasibility and effectiveness of such a service in community pharmacy, given the caution with which expanded roles for pharmacists in vascular care have been greeted by some.[265] While there is evidence of pharmacists' ability to conduct cardiovascular risk assessments and deliver basic post-screening counselling with some clinical benefits,[133,134,266] evidence is lacking to demonstrate the full potential of their comprehensive, ongoing management of multiple CVD risk factors. This has led to concerns about fragmentation of care and lack of communication of results with doctors.[265]

The HAPA model underpinning the approach to behavioural change was chosen because of its success in lifestyle-oriented diabetes prevention programs addressing similar risk factors for non-diabetic populations, including an implementation study based in Australian primary care.[125,242] Collection of process audit data is important to see how well this approach is adhered to by pharmacists. The emphasis on use of assessment scales for medicines adherence and various health behaviours is designed to promote ease of interpretation of clinical assessments by community pharmacists who are generalists in terms of their practice.

Several aspects of the protocol are context-specific and their adoption by other researchers or health service program managers may require consideration. Key issues include:

- The restriction of eligibility to patients aged 50-74 years is in keeping with national guidelines advocating that screening of overall risk outside the 45-74 years age bracket is not economically viable[91]
- The use of accredited pharmacists has been adopted to integrate with existing pharmacy skills networks and remuneration systems, and to alleviate time pressure for participating community pharmacists; there may be alternative workforce options to produce clinical reports in different settings.
- Patients with established diabetes and CVD will be excluded because there are existing evidence-based models of care already in practice or at implementation stage; and
- Community pharmacy represents a key setting and pharmacists are one of the most accessible healthcare providers in Australia, with expected competencies in both medicines use and health promotion.

Limitations of study protocol

If the pilot testing indicates the feasibility of effective community pharmacy interventions, it will be important to validate this study with larger numbers and a control group to comprehensively determine effectiveness, cost-effectiveness and generalisability. Similarly, the six month timeframe limits a full understanding of outcomes from two perspectives. First, it does not allow testing of the sustainability of patient behaviour changes for any meaningful period following

the intervention, and second, it may not be a sufficient period of time to for the full effect of the intervention to occur. Also, self-report of some health behaviours – while often the only option –may be unreliable.

Validated dietary quality tools for cardiovascular health are not available for the Australian population, so we rely on a pilot with only face and content validity developed by one of the authors (SOR). Current Australian guidelines for lipid disorders claim a lack of evidence regarding appropriate cholesterol targets for primary CVD prevention, thus restricting guidance for practitioners. We relied on expert consensus developed from examination of eligibility criteria for subsidised lipid lowering medicines in Australia, previous guidelines, and values used for pathology lab reporting.

Conclusions

The proposed intervention integrates guideline evidence and validated assessment tools where possible, but several key knowledge gaps remain to preventing an entirely evidence-informed approach. Protocols adopted for other primary CVD prevention studies have not been widely disseminated; hence this paper provides a starting point for future research and implementation programs in a primary care setting.

Acknowledgments

The authors thank Professor Graham Giles of the Cancer Epidemiology Centre of The Cancer Council Victoria, for permission to use the Dietary Questionnaire for Epidemiological Studies (Version 2), Melbourne: The Cancer Council Victoria, 1996. This project, and KM's position at institution (2) is funded by the

Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia. We would also like to acknowledge the contributions of the community and accredited consultant pharmacists in this study.

Competing interests

None declared.

Authors' contributions

KM is lead investigator and wrote the first draft with input from SOR, JD and JG. All authors provided input with subsequent drafts and read and approved the final manuscript.

Chapter 9. A Pilot Study Evaluating Multiple Risk Factor Interventions by Community Pharmacists to Prevent Cardiovascular Disease

Citation details:

Mc Namara K, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy* 2012;46(2):183-191.

Co-author declarations confirming the nature of my involvement are detailed in Appendix 1.

Background

Cardiovascular Disease (CVD) is the leading cause of death worldwide.[248] Effective preventive cardiovascular health interventions in primary care for susceptible individuals are recognised as a key activity to reduce incidence rates of CVD.[182,267] Clinical trials and systematic reviews examining the effects of pharmacist interventions for improved CVD prevention and management suggest positive health outcomes.[136,137,159,169] The clinical focus of such studies are varied and typically involve a mix of medication use (including medication adherence) and lifestyle interventions to treat major individual CVD risk factors, and cardiovascular outcomes in patients with diabetes and heart failure.[136,137,159,169,171,172] The competence of pharmacists in screening and monitoring for poorly controlled CVD risk factors, and in the assessment of overall CVD risk for individuals has also been established.[133,266] This suggests pharmacists are capable of contributing substantially to efforts to reduce the burden of CVD.

Recent guidelines for CVD risk management have emphasised a holistic approach for primary CVD prevention.[91,252,253,268] This requires concurrent assessment and management of multiple risk factors for individual patients. CVD prevention necessitates interventions relating to medication use and adherence, and lifestyle modification. Community pharmacists in developed countries are unique among non-physician healthcare providers in being highly accessible in most communities and proficient with the management of medicine, medication adherence, and lifestyle modification. In addition, the profession already engages extensively in individual CVD prevention and management activities. However, the absence of studies designed to demonstrate a professional capacity to support overall CVD risk management

runs the risk of marginalising pharmacist involvement in preventive care and sidelining a significant community health resource.

The *Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease* (PAART CVD) pilot project was a single-cohort intervention study that examined the feasibility of engaging community pharmacists to run disease state management programs for reducing risk of CVD. The aim of this study was to measure the effect of the PAART CVD intervention on the risk of primary onset of CVD for participants.

Methods

Pharmacist training

Methods for the PAART CVD trial have previously been described in detail.[269] In addition, a brief description of certain technical terms and instruments used to assess health behaviours are provided in Appendix 4. Briefly, twelve pharmacists from ten community pharmacies (5 rural, 5 metropolitan) were recruited and provided intensive training on assessment, prevention and management of CVD risk factors. Equal focus was placed on optimisation of medicine prescribed, medication adherence, and lifestyle modification. Pharmacists were instructed according to the Health Action Process Approach (HAPA).[126] This has been already implemented in lifestyle interventions for similar populations as a means of facilitating patient behavioural change.[125,242]

Patient recruitment

Each pharmacy was asked to recruit up to 10 patients aged 50-74 years who took medicine for cholesterol, high blood pressure (BP) or both, and who did not have a self-reported history of CVD or diabetes. Researchers later screened these patients further and, based on patient self-report, excluded the following patients: those who did not speak English, were

reliant on a carer or living in a residential aged care facility, had a hospital inpatient stay in the previous four weeks, had target organ damage, had cognitive impairment or any complex debilitating medical condition, or who lived more than 40km from the community pharmacy. Treating General Practitioners (GPs, equivalent to Family Physicians) were informed of patients' desire to participate and asked to inform researchers if patients did not meet criteria.

Health outcomes data collection

At baseline and 6 months, research assistants collected the following information:

- BP (via Omron 1A1B automated BP monitor), weight, height, waist and hip circumference measurements, in accordance with established protocols.[183,184,270]
- Point of care lipid profile and blood glucose via finger-prick testing using Cholestech LDX® Analyzers (Cholestech Corporation, Hayward CA, USA) in accordance with manufacturer protocols.
- Patient medical history, medication use, medication adherence, health behaviours (smoking, diet, weight management, alcohol intake, physical activity) and psychosocial health via an administered questionnaire, using several validated scales.[269 256-258,261-263] Further information on these scales is available in Appendix 4. The Diet Quality Tool (DQT), subsequently validated in an Australian secondary prevention cohort, was used to assess overall diet quality.[271] DQT allows calculation of a score in relation to cardiovascular disease risk – range 0 (no adherence) to 130 (maximum dietary guideline adherence)– and DQT subscales assessed fibre, added salt, total and saturated fat, and omega-3 intake.

The intervention

Two pharmacists with accreditation to undertake home medicine reviews (one in each State) used baseline data to write a report using a standardised template. This report was then provided to the patient's local community pharmacist and GP, and a summary given to the patient. This report highlighted the patient's overall CVD risk based on the Framingham risk score; for individual reports, risk scores for certain participants were adjusted upwards (+5%) in accordance with guidelines if the Framingham equation was thought to underestimate individual risk (if obese, family history of CVD or particular ethnicity).[91,63] Reports also suggested specific, evidence-based targets for treatment and strategies for improving CVD risk through medication use, lifestyle modification and medication adherence.

Community pharmacists offered five sessions to each patient at monthly intervals in a private counselling area. Pharmacists were advised that the initial visit should take about 30 minutes, and that subsequent visits should take 15-20 minutes. In keeping with HAPA, lifestyle goals and achievable treatment targets were established collaboratively with patients. The emphasis on patient behavioural counselling was initially focussed around establishing motivation to change, and progressed to maintenance of behaviour change and relapse prevention. GP and patient involvement in decision-making was encouraged and incorporated into clinical protocols. This included provision to GPs of written information about the process and recommendations for care on at least three occasions. Patients at low risk of CVD onset (less than 5% over five years) were given the option of withdrawing or reducing the intervention intensity. All patients, including these low-risk patients, were invited to receive follow-up assessment regardless of extent of participation in the intervention.

Primary Outcome

The primary outcome examined was the mean change to five-year risk of CVD onset between baseline and six month follow up. This was assessed using the Framingham-based risk equation.[63]

Secondary outcomes

Change to mean 'individualised' five-year risk score (individual Framingham scores adjusted upwards) was a secondary clinical outcome.[91] Changes to mean systolic and diastolic BP, lipid profile, body mass index (BMI), weight, waist circumference and smoking status were assessed as were changes to diet, alcohol intake, tobacco use, and physical activity.

As discussed in chapter eight, the study was approved by relevant university ethics committees and is registered on the Australia and New Zealand Clinical Trials Registry (Trial Number ACTRN12609000677202).

Statistical analysis

Analysis was performed using SPSS version 19.0 (SPSS Inc., Chicago Ill., USA) and SAS version 9.2 (SAS Institute Inc., Cary, NC, USA). Univariate comparisons between groups were conducted using chi-square test for equal proportion (or Fishers exact tests where numbers were small) and reported as percentages (n) or as percentages (95% CI). Continuous normally-distributed variables were compared using student t-tests and reported as means (95% confidence interval). Non-parametric data were compared using Wilcoxon rank-sum tests, and reported as medians (interquartile range). Pair-wise differences between pre- and post-values were calculated using paired t-tests for normally distributed data, Hodges Lehman Median Difference Estimate for non-normally distributed continuous variables and related samples Mc Nemar's test for changes to proportions. To account for the large number

of comparisons made, a reduced 2-sided p-value of 0.01 was chosen to indicate clear statistical significance. All patients attending follow-up assessment were included in analysis. Where data for one or more cases was missing when calculating a statistic, a new denominator was specified.

Results

Participation in the intervention

Seventy eligible patients from the ten pharmacies were recruited and received baseline assessment. Three patients withdrew prior to completion of the final assessment. Another three patients opted not to proceed beyond the initial session following advice that they had low CVD risk and may not benefit from intervention. All three patients consented to follow-up assessment. Most patients (54/67, 81%) attended all five counselling sessions, including 54 of the 64 patients (84%) advised to complete the full intervention.

Patient characteristics

Demographic characteristics are summarised in Table 9.1. The majority of participants were female (73%) and the overall mean age was 60 years. Almost half had a concession card allowing access to government-subsidised prescription medicine with a small co-payment, and 90% were Australian-born. They had a median of 4 (3 – 5) self-reported chronic conditions and used a median of 6 (4 – 7) regular medicines (including non-prescription). At baseline, most (88.1%) used antihypertensive medicine and a majority (56.7%) used lipid-lowering medicine.

Baseline cardiovascular health

Mean estimated cardiovascular absolute risk (CVAR) score was 6.8% over five years at baseline (Table 9.2); males had significantly higher baseline CVAR compared with females

(11.2% [8.7 – 13.7%] vs. 5% [4.3 – 6.0%]; p<0.001].[63] The mean 'individualised' CVAR was 9.6% (8.3 – 10.9%), with increases due to obesity, ethnicity and family history of CVD applicable to 38 participants. Half had uncontrolled BP (≥ 140/90 mmHg), one third had a BMI of 30 or greater and five out of every six had excess waist circumferences (Table 9.2). One in eight tested participants (8/66) screened positively for depressive symptoms.

Table 9.1. Baseline demographic characteristics of participants (n = 67)

Baseline characteristic	**Overall (N=67)**
Number (%) women	49 (73)
Number (%) male	18 (27%)
Average age (years)	60.4 +/- 1.42
Number (%) aged 60 years plus	38 (57)
Ethnic background	
Number (%) of Aboriginal or Torres Strait Islander (ATSI) ethnic background	2 (3)
Number (%) born in Australia	60 (90)
Overall number (%) with high CVD risk ethnic background (ATSI, Maori, Polynesian, Indian)	4 (6)
Mean number of years full-time education (± SD)	11.3 +/- 0.62
Number (%) recruited from Victorian pharmacies	28 (42)
Number (%) recruited from Tasmanian pharmacies	39 (58)
Number (%) recruited from rural pharmacies	45 (67)
Number (%) recruited from metropolitan pharmacies	22 (33)
Number (%) with concession card	30 (45)
Number (%) reporting family history of premature coronary heart disease before age 60 years	28 (42)

Baseline health behaviours

Two in every five patients indicated a degree of nonadherence to cardiovascular medicine (Table 9.3). Forgetfulness was the most commonly cited cause of nonadherence. Average DQT scores were as follows: overall diet (84/130); total and saturated fat (34/50), fibre intake (20/30), added salt (10/20) and omega-3 intake (7.5/10). The median Lifescripts physical

activity score was 6/21, with 42 (63%) reporting physical activity scores considered 'adequate' (5 or greater).[258] Twenty–two of the 65 (33%) responding reported increased bodyweight in the previous year, compared with 9 (13%) reporting decreased weight (the remainder were unchanged). Forty–one out of 67 (61%) patients consumed alcohol at low levels of risk (AUDIT C score less than 4)[258,261]

Clinical outcomes

Changes to clinical characteristics at six months are presented in Table 9.2. Mean CVAR score significantly reduced to 5.1% at 6 months (absolute risk reduction 1.7%, 95% CI -2.3 – -1.0%), equivalent to 25% (+/- 8%) proportional risk reduction. Mean individualised CVAR scores also reduced significantly, as did the proportion of participants at high risk. Among the 29 participants with moderate-high individualised risk (>10% over five years), a mean absolute reduction of 2.6% (1.3 – 3.8%) was achieved; a reduction of 1.0% (0.5 – 1.5%) occurred among those 38 at low risk of CVD.

Significant reductions were also observed in mean systolic BP (-11.0 mmHg; $p<0.001$), mean diastolic BP (-5.0 mmHg; $p<0.001$) and mean waist circumference (–1.3cm; $p=0.01$). Improvements were also observed in most other risk factors, but were not statistically significant. These included declines in average total cholesterol, LDL cholesterol, triglycerides, total:HDL cholesterol ratio, BMI and the proportion with waist circumference at target. A modest increase in HDL cholesterol was also observed.

No significant changes were observed to average quality of life or depression scores.

Table 9.2. CVD risk parameters at baseline and 6 months follow-up assessment

	N	Overall at baseline	Overall at 6 months	Change since baseline	P-value (change)
Cardiovascular risk					
Mean (95% CI) 'calculated' five-year CVD risk (%)	67	6.8 (5.7 – 7.9)	5.1 (4.2 – 6.0)	-1.7 (-2.3 – -1.0)	<0.001
Mean (95% CI) individualised 'total' five-year CVD risk (%)	67	9.6 (8.3 – 10.9)	8.0 (7.0 – 9.1)	-1.6 (-0.9 – -2.3)	<0.001
Number (%) with total risk ≥ 15% over five years	67	7 (10)	3 (5)	–4 (-6)	
Number (%) with 10–15% total risk over five years		22 (33)	15 (22)	-7 (-10)	
Number (%) with <10% total risk over five years		38 (57)	49 (73)	+11 (+16)	0.01
Lipid profile					
Median (IQR) total cholesterol (mmol/L) †[a]	67	4.83 (4.32 – 5.47)	4.66 (4.32 – 5.16)	-0.12 (-0.29 – 0.05)*	0.16
Median (IQR) LDL cholesterol (mmol/L)[b]	59‡	2.60 (2.31 – 3.30)	2.60 (2.04 – 3.06)	-0.14 (-0.32 – 0.03)	0.08
Median (IQR) HDL cholesterol (mmol/L)[c]	67	1.25 (0.98 – 1.47)	1.27 (1.00 – 1.53)	+0.02 (-0.04 – 0.09)	0.43
Median (IQR) triglycerides (mmol/L)[d]	67	1.38 (1.01 – 2.13)	1.57 (1.04 – 2.03)	-0. 01 (-0.17 – 0.18)	0.99
Median (IQR) total:HDL cholesterol ratio	67	3.89 (3.35 – 4.65)	3.58 (3.17 – 4.72)	-0.17 (-0.40 – 0.04)*	0.13
Blood pressure					
Mean (95% CI) systolic BP (mmHg)	67	137.5 (133.2 – 141.7)	126.4 (122.6 – 130.3)	-11.0 (-14.9 – -7.2)	<0.001
Mean (95% CI) diastolic BP (mmHg)	67	85.7 (83.6 – 87.9)	80.8 (78.4 – 83.1)	-5.0 (-7.1 – -2.8)	<0.001
Number (%) with uncontrolled BP (≥ 140/90 mmHg)	67	34 (50.7)	20 (29.9)	-14 (–21)	0.003
Random blood glucose					
Mean (95% CI) concentration (mmol/L)	67	5.3 (5.1 – 5.6)	5.4 (5.2 – 5.6)	0.1 (-0.1 – 0.3)	0.38
Anthropometric measures					
Mean (95% CI) weight (kg)	67	81.29 (76.69 – 85.90)	80.54 (76.1 – 84.94)	-0.75 (-1.44 – -0.07)	0.03
Mean (95% CI) BMI (kg/m^2)	67	29.7 (28.1 – 31.3)	29.5(27.9 – 31.0)	-0.3 (0.02 – 0.5)	0.04
Number (%) with BMI ≥ 30 (obese)	67	23 (34)	24 (36)	1 (1)	1.00
Mean (95% CI) waist circumference (overall)		96.0 (92.55 – 99.45)	94.7 (91.4 – 97.9)	-1.3(-2.4 – -0.3)	0.01
Median (IQR) waist circumference (men, cm)	18	97.6 (93.8 – 111.6)	97.6 (92.4 – 107.4)	–2.2 (-4.4 – -0.2)	0.04
Median (IQR) waist circumference (women, cm)	49	92.2 (83.7 – 99.5)	90.2 (82.1 – 101.4)	–0.97 (-2.1 – 0.2)	0.10
Number (%) meeting recommended waist circumference (women <80 cm, men <94 cm)	67	11 (16)	16 (24)	+7 (+10)	0.125

† IQR = interquartile range * 95% CI has been presented instead of the IQR because data is normally distributed ‡ LDL cholesterol values were unable to be detected for eight patients when tested [a] Corresponding median total cholesterol levels (mg/dL) at baseline, at six months and change since baseline are 186.44 (166.75 – 211.14), 179.88 (166.75 – 199.18), and -4.63 (-11.19 – 1.93) respectively. [b] Corresponding median LDL cholesterol levels (mg/dL) at baseline, at six months and change since baseline are 100.36 (89.17 – 127.38), 100.36 (78.74 – 118.12), and -5.40 (-12.35 – 1.16) respectively. [c] Corresponding median HDL cholesterol levels (mg/dL) at baseline, at six months and change since baseline are 48.25 (37.83 – 56.74), 49.02 (38.6 – 59.06), and 0.77 (-1,54 – 3.47) respectively. [d] Corresponding median TG levels (mg/dL) at baseline, at six months and change since baseline are 122.13 (89.39 – 188.51), 138.95 (92.04 – 179.66), and -0.89 (-15.05 – 15.93) respectively.

Changes to health behaviours

Several self-reported health behaviours also improved (Table 9.3). The proportion of respondents reporting medication nonadherence reduced by 16% (p=0.001), largely attributed to a significantly decreased proportion forgetting to take medicine (13%; p=0.004). Mean overall diet score significantly increased by 9.6 points (p<0.001). In the dietary subscales, significant improvements were observed in the median total and saturated fat score (+4.5/50) and added salt score (+2.5/20). The proportion reporting specific dietary habits for weight reduction increased from 9.0% (6/67) to 22.4% (15/67; p=0.04). The increase in proportion reporting a weight loss diet was 5 times higher for those with higher CVD risk (≥10% risk; +7/29, +24%) than for lower risk individuals (+2/38, +5%). A significant increase of 0.5 (IQR 0.0 –1.5) was reported in the median number of days per week that people undertook 30 minutes or more moderate-intensity exercise other than walking (p=0.009); the mean overall Lifescripts physical activity score did not increase significantly.[258]

Discussion

To our knowledge this is the first published study examining the clinical effects from a comprehensive primary CVD prevention intervention delivered by community pharmacists. It facilitates systematic development of a complex intervention by establishing whether or not such an intervention might produce sufficient health benefit to warrant progression to an RCT. It also provides valuable information on feasibility and identifies that patients with higher baseline risk might benefit to a greater extent from the intervention than low-risk patients.

Table 9.3. Health behaviours at baseline and 6 months follow-up assessment

	N	Overall at baseline	Overall at 6 months	Change since baseline	P-value (change)
Adherence					
Overall number (%) nonadherent (Morisky scale)	67	26 (38.8)	15 (22)	–11 (–16)	0.001
Number (%) who forget to take medicine	67	21 (31.3)	12 (18)	–9 (–13)	0.004
Number (%) who are careful about taking medicine	67	67 (100)	67 (100)	0	NA
Number (%) who stop medicine if feeling better	67	6 (9)	4 (6)	-2 (-3)	0.63
Number (%) who stop medicine if feeling worse	67	3 (5)	0 (0)	-3 (-5)	0.25
Smoking status					
Number (%) current smokers	67	6 (9)	4 (6)	-2 (-3)	0.16
Diet					
Mean (95% CI) overall diet score, range 0 to 130.	59	83.8 (78.8 – 88.8)	93.5 (90.2 – 96.7)	9.6 (6.2 – 13.1)	<0.001
Median (IQR) fruit and vegetable score (0 to 20)†	67	16 (11 – 18)	16 (13 – 18)	1 (0 – 1.5)	0.30
Median (IQR) saturated fats and total fats score	62	36 (28 – 40)	38 (35 – 42.5)	4.5 (2.5 – 6)	<0.001
Median (IQR) fibre score (0 to 30)	67	20 (10 – 20)	20 (20 – 20)	0 (0 – 1.5)	0.05
Median (IQR) added salt score (0 to 20)	65	10 (10.0 – 20)	15 (10–20)	2.5 (0.5 – 4)	<0.001
Median (IQR) omega-3 fatty acid intake (0 to 10)	67	7.5 (5 – 7.5)	7.5 (5 – 10)	0 (0 – 0.5)	0.03
Physical activity					
Median (IQR) 'Lifescripts' physical activity score	67	6 (3 – 9)	6 (4 – 9)	1 (0 – 1.50)	0.02
Alcohol intake					
Median (IQR) AUDIT C score (recommended score 0 – 3)	67	1 (1 – 2)	1 (1 – 2)	0 (0 – 0)	0.53

† IQR = interquartile range

Our findings suggest that a CVD prevention program delivered by community pharmacists program is feasible to implement and has potential clinical benefits for participants. Participants achieved an estimated absolute risk reduction of 1.7% over five years, equivalent to a proportional risk reduction of 25%. Absolute benefits to those with moderate-high baseline CVD risk scores were 2.6 times greater than those with low risk scores, which is in keeping with previous studies.[217]

Clinical improvements were accompanied by several improvements to individual risk factors and self-reported health behaviours including medication adherence. The extent of improvements to CVD risk observed compare favourably with the pooled effects of previous multiple risk factor interventions for primary prevention observed by Ebrahim, et al.[142] Results are consistent with many RCT studies evaluating cardiovascular health benefits from pharmacist-led multiple risk factor interventions for patients with diabetes and established CVD,[136,137,272] although some RCTs indicating a lack of benefit suggest further research is required.[273] Pharmacists have long held an evidence-based role in the identification, prevention and management of individual cardiovascular risk factors, and there is reasonable evidence of their ability to screen for absolute CVD risk.[233,266,274] Recently published meta-analyses of pharmacist care for the management of lipids, hypertension and smoking cessation provide further compelling evidence of a beneficial impact for individual risk factors.[275] The Asheville pharmacy program for management of hypertension and lipid disorders demonstrated a sustained reduction in the incidence of cardiovascular events at six years.[276] Given these patient benefits, it is important to provide evidence such as

this supporting multiple risk factor interventions by pharmacists in this population. As primary CVD prevention adopts an absolute risk framework internationally, this evidence will be critical for the profession to retain a central role in this area.[91,183,233,252,268,269,274]

The extent of clinical improvement observed in this study may reflect the equal focus with lifestyle modification given to medicine management and particularly medication adherence. Ebrahim et al. note that optimising pharmacological management is a key attribute of effective primary prevention, yet this remains absent from most evaluated models of care.[142] Given the widespread evidence–treatment gaps relating to pharmacological management for CVD risk factors, it seems logical to consider medicine use for any primary prevention intervention program.[274-277] Incorporating a theoretical framework for behavioural change that was effective in similar populations may also have been beneficial; the existence of such frameworks are largely undocumented by most primary prevention studies.[125,142,242]

Nonetheless, certainty of health benefits will only be demonstrated if this intervention is tested in an adequately powered RCT and compared against usual care. Single-cohort studies such as this cannot account for the potential effect of regression to the mean, where natural variation in measured risk for extreme cases potentially (and misleadingly) indicates significant improvements to health status. This is particularly a risk for blood pressure, which is subject to regular fluctuation. However, blood pressure improvements for our study were very similar to the intervention arm of the (currently unpublished) HAPPY RCT, which used a similar protocol for data collection. The HAPPY study demonstrated a

significant improvement when compared with control group patients. Sustainability of the benefits should also be evaluated with longer follow-ups. Equally, it is important to acknowledge that some of the observed benefit may have been derived by facilitating appropriate referral to other health professionals. The loss to follow up of three individuals might potentially have resulted in overstated mean benefits from the intervention.

Results suggest that full RCT investigation of potential benefits from this intervention is warranted. An RCT would also enable economic analysis of the intervention, much needed for primary prevention.[142] The few economic evaluations available for such interventions suggest a focus on higher-risk individuals may be warranted; although the absolute reduction for low risk participants was less than half that achieved for high risk participants, it is sufficient to merit further investigation of cost-effectiveness in this group.

Program adherence was very satisfactory, with 86% of participants completing the full program where recommended following baseline assessment. In comparison, studies involving similar participants who received a comparable diabetes prevention intervention in primary care have reported 43% and 57% attending all six sessions;[125,242] this may reflect satisfaction with the intervention, shorter session durations, convenience of community pharmacy locations, or the benefits of using a health professional with whom participants had existing relationships. It might also reflect some recruitment bias on the part of pharmacists who may have felt more comfortable recruiting patients perceived as motivated to participate.

Several study limitations are acknowledged, including the absence of a control group to confirm that clinical and behavioural improvements can be attributed to the intervention; this is especially relevant for self-reported lifestyle measures where social desirability bias may have influenced participant responses.[278] Additionally, participants were recruited from a convenience sample and most were female. As stated previously, pharmacists may have preferentially recruited those perceived as more motivated, thus limiting the generalisability of findings to the general population. Although reasonably accurate, our point of care testing to establish lipid and glucose profile is less reliable than accredited laboratory testing.[279] Any future RCT evaluation should incorporate such laboratory-based outcome measures to validate point of care test results. The short period of follow up limits our insight into the sustainability of the intervention effect.

Conclusion

Community pharmacists are capable of effectively delivering tailored, multifaceted interventions to patients at risk of CVD. Rigorous RCT evaluation would confirm the validity of outcomes and cost-effectiveness of such an intervention.

Acknowledgements

The authors thank Professor Graham Giles of the Cancer Epidemiology Centre of The Cancer Council Victoria, for permission to use the Dietary Questionnaire for Epidemiological Studies (Version 2), Melbourne: The Cancer Council Victoria, 1996. We would also like to acknowledge the contributions of the community and accredited consultant pharmacists in this study.

Funding disclosure

This project, and KM's position at institution (2) was funded by the Australian Government Department of Health and Ageing as part of the Fourth Community Pharmacy Agreement through the Fourth Community Pharmacy Agreement Grants Program managed by the Pharmacy Guild of Australia.

Conflict of interest statement

The authors declare that there are no conflicts of interest. The project was initiated and analysed by the investigators.

PHASE THREE. THE POTENTIAL FOR QUALITY IMPROVEMENT PROCESSES TO IMPROVE MANAGEMENT OF HYPERTENSION IN EVERYDAY PHARMACY PRACTICE

Background to the research

It has been clearly established from published RCTs and meta-analysis studies that pharmacists can deliver effective interventions for CVD prevention.[136,169,171,172,275,280-282] The previous chapter added to the body of knowledge by demonstrating the capacity for pharmacists to deliver multiple risk factor interventions (MRFIs) specifically for the primary prevention of CVD. A public health benefit will be achieved when interventions with clear evidence of benefit becomes common practice in the 'real world'. It is often assumed that translation of clear evidence into clinical practice will occur naturally once dissemination of research findings and amendment of clinical practice guidelines have occurred. In fact this scenario is the exception.[283,284]

A growing awareness by healthcare providers that limited uptake of beneficial innovations is commonplace in practice has stimulated interest in implementation research. Defining implementation as 'efforts designed to get best practice

findings and related products into use via effective change/uptake/adoption interventions', implementation research is concerned with the identification of interventions targeted at the health organisation or individual healthcare provider to stimulate adoption of evidence-based practice.[285] This is distinct from research seeking to develop new treatments or models of care for patients, which predominates healthcare research.

There are three broad elements of implementation research:[285]

1. establishing barriers and enablers to uptake of evidence-based practice by healthcare providers
2. adaptation of the evidence-based practice to meet the needs of local practitioners and health systems
3. implementation of the tailored strategy and evaluating uptake.

A reasonable amount of literature describing evidence-practice gaps has been published, and barriers and facilitators to implementing evidence-based practice in community pharmacy.[286-294] However, explicit testing of adapted intervention processes and their effects on pharmacist uptake of evidence-based care is rare.

I was confident from my literature review and through investigations detailed in the previous chapter that community pharmacists can, under the correct conditions, deliver interventions that improve the management of CVD risk factors. There are a number of pharmacist-reported barriers to implementation or adaptation of practices during routine care that will lead to improved patient health. These include:[289,295-297]

- being too busy already

- fearful of GP reaction if it is perceived to encroach on their professional 'turf'
- lacking knowledge
- not seeing particular interventions as pharmacists' core role
- lack of financial incentive/existence of financial disincentives

There is consequently significant reason to suspect that pharmacists, like other health professionals, are unlikely to adopt new practices as a matter of course. We chose to examine the potential for improving the nature and extent of key cardiovascular health interventions by community pharmacists following the introduction of quality improvement processes.

The project

A project entitled 'Controlling Hypertension through Innovation in Primary Care' (CHIP C) was developed to test the feasibility of improved usual care following quality improvement interventions in community pharmacy. This was designed as a prospective RCT, where health professionals were randomly assigned to receive one of three different levels of support for the introduction of brief interventions by pharmacists – 'usual care', 'limited support' and 'comprehensive support'. Randomisation of workplaces rather than individuals was undertaken to avoid intervention contamination. Support options included:

1. **Registration with a BP awareness program** (all three groups). All pharmacies with a participating pharmacist were enrolled in the 'Know your numbers' BP awareness program run by the National Stroke Foundation.[173] This provided pharmacists with a free BP monitor and

patient information leaflets, as well as promotional materials and a manual for operating a BP measurement station in their pharmacy.

2. **Provision of guidelines for the management of high BP** (limited and comprehensive support groups). Both the intervention group and the limited support groups were provided with copies of the 2008 hypertension management guidelines produced by the National Heart Foundation of Australia.[78]
3. **Online training module** (comprehensive support group). Intervention group pharmacists were provided with access to a free online professional development module around hypertension management in the context of overall CVD risk. In particular, the training distilled down the generic hypertension guidelines provided to define potential brief interventions for pharmacists. Training was also framed around specific pharmacy scenarios (e.g. how to identify target group patients based on dispensary records). Recommendations for counselling were based on the HAPA model to promote patient motivation to follow through. This identifies the need to address patient perceptions of personal susceptibility if they do not follow advice, perceptions about the benefits of treatment, and beliefs about their personal capacity to change (self-efficacy).[126] An online format was chosen so that rural practitioners in particular were not disadvantaged by the location of training.
4. **Engagement in quality improvement cycle**, incorporating audit and feedback process (comprehensive support group). Pharmacists in the comprehensive support group had access to an online portal

(password-protected) designed to provide ongoing information and motivation to pharmacists. Discussion groups were put in place to allow sharing of ideas for intervention; their local participating GPs were also provided access to allow multidisciplinary input. Regular clinical updates were provided (e.g. new evidence for hypertension management), as was feedback on patient surveys conducted at baseline. These surveys identified current areas where patient self-management and treatment inertia could be addressed, and were designed to inform where pharmacists should focus their efforts. Alongside this, individual pharmacies were provided feedback on audits of hypertension management undertaken, to give them an understanding of how they were performing in relation to other participants.

This section of results documents two major aspects of the research:

- A baseline survey of patients describing current support from health professionals, and self-management practices; and
- An examination of the effects of this quality improvement program on sustained delivery and documentation of clinical interventions over the eight month period of evaluation. The original aim was to describe changes to patient-reported outcomes between the three groups. However, an insufficient number of responses were received at follow-up to allow any confidence in the analysis. Hence we changed the aim of this research to be a documentation of the sustainability of quality improvement

activities in community pharmacy that depend on pharmacist documentation of activities.

Theoretical framework for this intervention

For Phase III, the process of implementation adhered very closely to Grol and Wensing's model for health professional behaviour change, and I described the use of this model at an international conference in 2009. The key steps in this model are as follows:[298]

1. *Orientation.* This involves stimulating participant interest and awareness in the innovation. This was achieved through extensive networking, through working with the National Stroke Foundation to promote uptake, and by personally visiting participants in their pharmacies to discuss.

2. *Insight*. The target group of health professionals must begin to understand the required interventions, and must develop an appreciation about how their current practice deviates from an ideal situation. This was achieved by taking existing national (multidisciplinary) guidelines and developing recommendations that were specific pharmacist practices. Feasibility of implementing these measures was discussed with participants.

3. *Acceptance*. Pharmacists must be convinced it is a valuable exercise, and they must feel positive about changing practice. Local general practitioners were asked to endorse this activity, as they are key local opinion leaders for pharmacists. In addition, the activities were accredited with professional development points, so that pharmacists could directly link implementation of new practices to their professional reaccreditation

requirements. Finally, the project was linked to the National Stroke Foundation's *Know your numbers* blood pressure awareness program to heighten perceived legitimacy of involvement by pharmacists, and public acknowledgment of their efforts.

4. *Change*. Promoting adoption in practice and demonstrating the value of change. Multiple intervention components are described as a means of promoting change (e.g. online professional development, data feedback, discussion forums), and data was collected to attempt to demonstrate that this was improving hypertension management for patients.

5. *Maintenance*. Integrate changes to practices into an ongoing routine, and embed within organisations. This was probably attempted less rigorously than the previous phases because of difficulty in getting participants to this point. While attempts were made locally to work as groups, results of the study did identify the participation of individuals rather than workplaces as a key barrier to embedding new practices.

Phase Three also applied adult learning principles in its attempts to translate guideline recommendations into pharmacy practice.[299] The comprehensive intervention group's professional development was problem-based (using pharmacy scenarios), built on their experience, and promoted active involvement. Learning was self-directed, with multiple suggestions for approaches to delivering patient-level interventions, and feedback was provided.

Within the learning materials, the Theory of Planned Behaviour was also engaged as a framework for presenting materials.[300] Interventions options were presented

in a manner that developed positive attitudes regarding the importance of practice changes (describing the potential benefit and population need), by addressing subjective norms (incorporating with the *Know your numbers* program to make it seem like a standard expectation, and by directly identifying pharmacist responsibilities for blood pressure management), and by improving perceptions of self-efficacy (by showing how to identify patients likely to benefit from an intervention, by distilling guidelines down to several brief and relevant interventions, and by ensuring that local GPs endorsed the activity).

My role in this research

This project was undertaken as part of a National Institute of Clinical Studies – National Prescribing Service Quality Use of Medicines Fellowship 2008-2010 - now known as NHMRC Translation into Practice (TRIP) Fellowships. I was principal investigator for the project, which involved leading all aspects of the project, including:

1. Developing the concept and research design, and putting together a research team;
2. Drafting a successful fellowship grant application, with input from co-investigators;
3. Specifying the study protocol and project plan, and managing project personnel; and
4. Analysis of data and writing of the interim and final reports to the funding body, and manuscripts for peer review included in this thesis.

For both manuscript chapters, I undertook the majority of the work from conception through to writing and analysis, with input from other investigators being sought once complete drafts were prepared. I consulted a statistician on some minor issues during preparation of these drafts.

Declarations from co-authors for the two papers emanating from this project are available in Appendix 1.

Chapter 10. Management of Hypertension in Primary Care will Benefit from Basic Additional Health Professional Interventions

Citation details:

Mc Namara KP, Dunbar JA, Marriott JL, Reddy P. Management of hypertension in primary care will benefit from basic additional health professional interventions [unpublished].

Co-author declarations confirming the nature of my involvement are detailed in Appendix 1.

Background

The average risk of mortality due to cardiovascular disease (CVD) halves for every 20 mmHg reduction in systolic blood pressure (BP),[18] hence the need to seek innovative methods to achieve such a reduction. Methods may include defining and implementing potential roles for pharmacists. Meta-analysis of pharmacist intervention studies demonstrates a reduction in systolic BP (SBP) that is 6.9 mmHg greater than in controls.[172] Given that the majority of treated hypertensive patients do not reach their target BP,[16,17] there are clearly potential public health benefits from optimising such pharmacist interventions.

Pharmacist programs to raise BP awareness and develop interventions are being expanded in Australia and elsewhere in recognition that their potential remains largely untapped.[173] Effective implementation of evidence into routine care is facilitated by substantiating the need for better clinical management from the health professionals' own patients.[301] While evidence–treatment gaps for hypertension have been well-researched, a thorough and empirical understanding of patient needs in primary care remains less clearly defined, both for pharmacists and other health professionals. Population-level epidemiological studies of cardiovascular risk (e.g. AUSDIAB, NHANES),[16,17,302] are useful to measure quality of population care but generally only allow broad inferences about quality of primary care.[303] Direct measures of individual patient care, usually via audit of medical documentation,[98] help by identifying the extent of clinical target achievement and undertaking of key processes. Such information is valuable but practice-based audits only partially reflect contemporary hypertension

management where responsibility is often shared by several medical and non-medical practitioners with varying degrees of coordination, and varying support for patient self-management. This environment may encourage both errors of omission and commission in treatment. With the absence of shared electronic records in most countries, the patient may often be the most reliable source of information about quality of overall hypertension management.

Patient surveys undertaken to date have helped to further understand current management, but have limitations. Those identified focussed either on single topics such as patient knowledge and awareness,[304] used qualitative (non-empirical) methods,[305,306] or recruited an internet-based convenience sample.[307] We are unaware of previous studies which directly surveyed representative samples of treated hypertensive patients in a clinical setting to develop a detailed understanding of hypertension management and self-management practices from the patient perspective.

The aim of this study was therefore to gain a more thorough understanding of overall clinician management and support for patient self-management of hypertension in primary care from the perspective of a treated hypertensive population. In doing so, we hoped to confirm and further understand key areas where primary health professionals, and in particular pharmacists, might intervene and support patients more intensively and to greatest effect.

Methods

The setting

Patient surveys were distributed by community pharmacists. Pharmacists involved had been recently recruited to a quality improvement program from community pharmacies across several rural and metropolitan regions of Victoria, Australia via direct approach, 'snowball' referrals by pharmacists already recruited, and professional newsletters. Overall, pharmacists from 27 of the 30 community pharmacies with continuing involvement in the overall program agreed to participate in distributing a survey to assess the current state of hypertension management (the remaining three withdrew from the overall program). Distribution commenced in March 2009 and continued for ten weeks. No quality improvement processes were initiated during this period.

Distribution of surveys

The 27 community pharmacies with participating pharmacists were provided with 40 surveys each, and manuals instructing them on correct distribution of the anonymous survey. Not all surveys were distributed.

Pharmacists were instructed that questionnaires should be handed out to patients who were (1) dispensed a medication routinely used for hypertension, and (2) prescribed this medication by one of the local doctors participating in the quality improvement program. These basic criteria were chosen because this information is routinely available in community pharmacies. A list of appropriate medicines and local participating doctors was provided.

Workflow and limitations of pharmacy software systems make the identification of a truly random sample of patients unfeasible. Instead, guidance was provided to accommodate issues around working hours and varying numbers of target patients between pharmacies. Pharmacists were requested to distribute specific quantities of questionnaires during specific time periods to promote a representative sampling frame:

- Attempt to distribute questionnaires on any day that one or more participating pharmacists are working
- Aim to distribute 3-6 questionnaires per day.
- If there are not sufficient numbers of eligible patients to distribute three per day, simply distribute the questionnaires to each eligible person.
- If there are generally more than ten eligible patients visiting the pharmacy on a typical day, attempt to distribute an equal number of questionnaires before and after the half-way point in pharmacy opening hours (e.g.1.30pm if open 9am-6pm, 3pm if open 9am to 9pm).
- If the maximum six questionnaires has not been distributed at the end of any day, those left over can be distributed during the following day in addition to that day's quota (if applicable).

Patients were deemed ineligible if the pharmacist was aware that the patient was using a BP-lowering medicine exclusively for a purpose other than hypertension; or if the patient was resident in an aged care facility and not dealing directly with the pharmacy for care.

Each questionnaire was accompanied by an explanatory statement and reply-paid envelopes. Questionnaires were returned to researchers directly by mail.

The survey instrument

The main purpose of this survey, undertaken within the quality improvement program, was to identify shortcomings in the current primary care management of hypertension where community pharmacists could feasibly intervene to help control BP. Content therefore focussed on clinical issues that directly affect BP control or which might otherwise improve cardiovascular risk, that are significant in terms of public health outcomes, for which there is reasonable evidence and acceptance of established or potential roles for community pharmacists. The following topics were identified from literature and practical experience as appropriate for examination:

1. Basic patient education and awareness of their BP and treatment targets
2. Antihypertensive medicines adherence
3. Intensity of treatment with antihypertensive therapy
4. Lifestyle modification

Basic demographic information was also collected and patients were also asked to identify the presence of any conditions that might affect their BP target. We did not look for pharmacists to measure patients' BP because of the likely negative impact of this requirement on achieving a representative sample; as a non-routine activity, pharmacists would be less likely to approach patients during busy periods if this additional task was necessary. Moreover, we were more interested in

establishing quality of hypertension management than distribution of BP values. Anybody reporting impaired kidney function, diabetes or a history of CVD was assumed to have a lower BP target recommended by Australian guidelines (<130/80 mmHg).[78] Those without such conditions were assumed to have targets of 140/90 mmHg or lower. The survey was piloted using lay people and pharmacists to establish face and content validity. Adherence was measured using the 4-item Morisky Medicines Adherence Scale (MMAS).[257]

Sample size and statistical analysis

This survey was being used to provide baseline data for subsequent quality improvement interventions by pharmacists. The sample size was chosen to detect patient-reported changes to their BP management in these pharmacies after completion of the interventions. Population means and proportions were calculated using PASW Statistics 17.0 software®, as were confidence intervals around means. Confidence intervals for proportions were calculated at the 95% level using the Agresti-Coull interval. Fisher's exact tests were used to test for the significance of differences between proportions in two groups. Individuals for whom a diagnosis of hypertension and/or treatment for BP control could not be confirmed were excluded from analysis.

This study was approved by the relevant human research ethics committees at Monash University, Victoria and Flinders University of South Australia.

Results

Responses were received from twenty four of the twenty seven pharmacies, with 215 surveys returned. Two hundred and four patients (95%) reported either having a medical diagnosis of hypertension or using medication to treat BP, or both.

Patient characteristics

The majority of respondents attended pharmacies in metropolitan areas (58%, 95% CI 52 – 65%). Two thirds were aged 65 years or more (68%, 61 – 74%), and 41% (34 – 48%) were aged 75 years or more. Less than half the respondents were males (45%, 39 – 52%).

Common conditions warranting reduced BP targets according to Australian guidelines[78] – diabetes, a history of established CVD or a cardiovascular event, or impaired kidney function– were reported by 45% (38 – 52%) of respondents (Table 10.1). One quarter of respondents reported a history of arrhythmia. Most (88%, 82 – 92%) were able to administer their own medicines without assistance.

Table 10.1. Proportion (%) of respondents with significant co-morbidities of interest

	Number (n=201*)	**Percent**	**95% confidence interval**
Diabetes	33	16	12 – 22%
Stroke	7	4	2 – 7%
Transient ischaemic attack	19	10	6 – 14%
Coronary heart disease	50	25	19 – 31%
Impaired kidney function	15	8	5 – 12%
Any of the above conditions (conferring lower BP target)	**90**	**45**	**38 – 52%**
Arrhythmia	47	23	18 – 30%

* Not all respondents provided the required information

Monitoring of patient blood pressure

Overall, three quarters of respondents (78%, 72 – 83%) had their BP measured in the preceding month, and 99% (96– 100%) within the past year. Almost all respondents reported that a doctor had measured their BP over the previous six months (Table 10.2); indeed, doctors were the most recent source of BP measurement for 76% (70 – 81%) of patients.

Table 10.2 demonstrates that substantial proportions of respondents were also engaging in additional methods of BP monitoring and one in four respondents was self-monitoring. Some patients with uncontrolled BP commented that pharmacists monitored their BP at regular intervals between GP visits. Occasional 'other' opportunities for measurement came from blood donation clinics and gyms.

Table 10.2. Sources of BP measurement over the past six months

	Proportion (%, 95% CI) reporting BP monitoring		
	Confirmed high CVD risk	**No high risk conditions***	**Overall**
Doctor	98 (93 – 100)	99 (94 – 100)	99 (96 – 100)
Pharmacist	13 (8 – 21)	5 (2 – 12)	10 (6 – 14)
Other pharmacy staff	7 (4 – 14)	2 (0 – 8)	5 (3 – 9)
Nurse	27 (19 – 36)	16 (10 – 25)	22 (17 – 28)
Self-monitored	24 (17 – 33)	23 (15 – 32)	23 (18 – 30)
Other	4 (1 – 9)	3 (1 – 10)	4 (2 – 7)
N†	90	111	201

* Arrhythmia or any condition which confers a lower blood pressure target
† Not all respondents provided the required information

Patient-reported awareness and control of blood pressure

A majority (63%, 56 – 69%) were able to report both elements (systolic and diastolic) of their most recent BP measurement, while a further 4% (2 – 7%) reported only the systolic reading. The distribution of self-reported systolic measurements is reported in Table 10.3.

Table 10.3. Self-reported most recent blood pressure measurements

BP target		**Percent (95% CI) reporting each systolic blood pressure category**				
	n	**<130 mmHg**	**130-139 mmHg**	**140-159 mmHg**	**160-179 mmHg**	**≥180 mmHg**
<130/80 mmHg*	61	38 (27 – 50)	31 (21 – 44)	26 (17 – 39)	5 (1 – 14)	0 (0 – 7)
<140/90 mmHg*	70	24 (16 – 36)	30 (21 – 42)	33 (23 – 45)	13 (7 – 23)	0 (0 – 6)
Overall†	131	31 (23 – 39)	31 (23 – 39)	30 (23 – 38)	9 (5 – 16)	0 (0 – 3)
		Percent (95% CI) reporting each diastolic blood pressure category				
	n	**< 80mmHg**	**80-89 mmHg**	**90-99 mmHg**	**100-109 mmHg**	**≥ 110 mmHg**
<130/80 mmHg*	58	66 (53 – 77)	29.3 (19 – 42)	5 (1 – 15)	0 (0 – 7)	0 (0 – 7)
<140/90 mmHg*	66	52 (40 – 63)	33 (23 – 45)	11 (5 – 21)	5 (1 – 13)	0 (0 – 7)
Overall†	124	58 (49 – 66)	31.5 (24 – 40)	8 (4 – 14)	2 (1 – 7)	0 (0 – 4)

* Patients are defined as having the lower target (<130/80 mmHg) if they self-report diabetes, kidney function impairment or a history of cardiovascular disease). Otherwise the less stringent target was applied (<140/90 mmHg).
† Not all participants in the 'overall' category provided the required information for subgroup analysis

Patient awareness of hypertension status in relation to target

Two in five (42%, 36 – 53%) of 125 participants with full knowledge of their last self-reported BP measurement indicated BP measurements that met guideline-

indicated targets[14] – less than 130/80 mmHg if diabetes, kidney impairment or existing CVD was identified, otherwise less than 140/90 mmHg. A further 14% (10 – 23%) of all reported BP measurements were borderline controlled, that is, neither parameter was above target but one or both elements were exactly on the target measure. Those identified as having a lower target BP (less than 130/80 mmHg) were significantly less likely to report achieving their target. One in three of these participants (31%, 21 – 44%) were clearly below target measurements compared with more than half (53%, 41 – 63%) of those with a higher target (p=0.018, 2-tailed

Fisher's exact test). The majority (60%, 45% – 74%) of those who undertook home BP monitoring (HBPM) and reporting a BP measurement were at target, compared with one in three (32%, 22% – 42%) of those not self-monitoring but able to report a BP measurement (p=0.004, 2-tailed Fisher's exact test).

One third of all respondents (36%, 30 – 43%) reported knowing their target BP, while a further 20% (15 – 27%) were 'uncertain'. Among the 56% (49 – 63%) of overall patients indicating potential knowledge of their BP target, 86% (78 – 91%) actually provided a systolic BP target and 83% (75 – 89%) provided a diastolic BP target. Most of the stated targets – 80% (71 – 87%) of systolic BP targets, 93% (86 – 97%) of diastolic BP targets, and 78% (69 – 86%) overall – were in agreement with guidelines.[14] BP measurements at guideline targets were reported by 67% (55 – 77%) of the 67 patients reporting both a BP measurement and target, compared with 48.2% (35.7 – 61.0%) of the 56 patients reporting their BP measurement but no target (p=0.043, 2-tailed Fisher's exact test).

Overall, 22% (17 – 28%) reported keeping a record of their BP readings, a characteristic significantly associated with better knowledge of BP. Almost all (98%, 87 – 100%) of this group could report their last BP measurements (systolic and diastolic) compared with 53% (45 – 61%) of those who did not record this information ($p<0.001$, 2-tailed Fisher's exact test). Likewise, 55% (40 – 69%) of the group who recorded measurements could report their target BP, compared with 30% (23 – 38%) of those who did not record ($p=0.006$, 2-tailed Fisher's exact test). Documentation of BP is significantly associated with use of HBPM, being undertaken by 57% (42 – 71%) of those who use HBPM compared with 11% (6 – 16%) of those who do not ($p<0.001$, 2-tailed Fisher's exact test). Within the group who documented BP measurements, the prevalence of target BP knowledge was 72% (54 - 90%) for those who use HBPM compared with 29% (8 – 51%) for those who did not ($p=0.011$, 2-tailed Fisher's exact test).

Adherence to medicines

Overall, 15% (10 – 20%) reported some nonadherence with antihypertensive medicines based on the 4-item MMAS.[257] The main reason for nonadherence was forgetting to take the medicines (12%, 8 – 17%).

Best use of drug therapy

Two in five patients (41%, 35 – 48%) used monotherapy to control their BP. Overall, one in four (24%, 18 – 30%) patients reported changes to prescribing of their antihypertensive medicines (dose, change or addition of drug, etc) over the previous six months to improve BP control. One in three (34%, 23 – 47%) self-reporting BP measurements above guideline target indicated such a change to therapy. One in six respondents (16%, 12 – 22%) indicated never having changes

made, or being unsure of this ever happening. Among this subgroup with no changes, 39 % (19 – 55%) of the 18 patients for whom information is available self-reported uncontrolled BP, and a further 22% (9 – 46%) borderline control.

Antihypertensive classes used most commonly as monotherapy were ACE inhibitors (40%, 30 –51%) and angiotensin receptor antagonists (43%, 32 – 53%). Beta blockers (BBs, 10%, 5 – 19%) were more commonly used than calcium channel blockers (8%, 3 – 16%). Seven of the eight patients taking BB monotherapy were using atenolol. Diuretics and other agents (e.g. vasodilators) were not used by any respondent as antihypertensive monotherapy.

Support from health professionals

Table 10.4 describes support recalled by patients in medicines and lifestyle management. The GP was the most commonly identified source of counselling on hypertension-related issues relating to medicines use, medicines adherence and lifestyle modification. Pharmacists provided a reasonable proportion of counselling in all areas of management, but other health professionals did not appear to have a prominent role in management of this condition. The proportion of participants reporting pharmacist support was relatively constant across the various issues of medicines use and lifestyle modification.

Overall, it would appear that about half of all patients received regular counselling about lifestyle, but counselling on medicines issues and adherence was less frequent. When patients were asked what further support health professionals might provide, 56 patients provided a range of comments. The majority indicated satisfaction with current management, but suggestions for improvement also

emerged. Common themes involved increasing access and more frequent BP monitoring, better communication between their health professionals, improved written and verbal advice about their BP generally and treatment/medication issues in particular. No specific recommendations for improved lifestyle management were made.

Table 10.4. Proportion reporting discussions on key hypertension treatment issues over the past six months

Counselling topic	**Percent (95% CI) self reporting advice in the last 6 months†**			
	Doctor	**Pharmacist**	**Other health professional**	**Any health professional**
Drug-induced hypertension (n=192)	17 (12 – 23)	10 (7 – 16)	3 (1 – 6)	22 (17 – 28)
Importance of medicines adherence (n=190)	40 (33 – 47)	13 (9 – 19)	3 (1 – 6)	44 (37 – 51)
Optimising medicines use (n=183)	26 (20 – 33)	10 (7 – 16)	3 (1 – 6)	31 (25 – 38)
Identification of important lifestyle issues (n=187)*	52 (45 – 59)	11 (7 – 16)	6 (3 – 10)	59 (52 – 66)
Options to address important lifestyle issues (n=189)	49 (42 – 56)	9 (6 – 14)	6 (4 – 11)	56 (48 – 63)

* n = 186 for the option 'any health professional advice' (missing data)
† Not all respondents answered this question

Discussion

In this study, evidence–treatment gaps and opportunities for improved care are identified. Three fifths of patients treated with antihypertensive medicines self-report BP measurements above the targets indicated for them by guidelines, and regular monitoring and interactions with health professionals do not appear to ensure intensive lifestyle and drug treatment of uncontrolled BP. Key findings suggest that the need to improve delivery of fundamental messages around BP

targets and recording BP measurements remains relevant. The lack of patient knowledge and awareness is consistent with other studies.[304,308]

It is disappointing to note that despite regular monitoring of patients with uncontrolled BP, the motivation to enact regular treatment changes until BP is controlled appears lacking. Current guidelines recommend treatment changes be considered if previous changes have not had a satisfactory effect within 4-6 weeks;[78] findings suggest these changes occur far less frequently, and support previous evidence in Australia and internationally of therapeutic inertia for hypertension.[101,309,310] Therapeutic inertia is also evident in this study from the high proportion receiving monotherapy as treatment and failure to regularly discuss drug treatment with many patients. It is interesting to note how many respondents were aware that they had uncontrolled BP. Explanations may include a failure to perceive mildly-elevated BP as a cause for concern, or a lack of empowerment among hypertensive patients during consultations with health professionals.[306] Health professionals should more actively discuss the importance of BP control with patients. Recent Australian guidelines for hypertension management,[78] supported by widely-publicised clinical evidence,[311,312] recommend substitution of atenolol where used as monotherapy for hypertension. Our findings of persistent use of atenolol monotherapy merit further research investigation and greater awareness among health professionals.

The value of self-monitoring BP in a variety of settings – especially at home – has been well established and it is encouraging to note the frequent use of other health professionals and self-monitoring as a source of additional BP information.[78,313,314] Our findings support these studies and point to increased

patient awareness and self-management in the HBPM subgroup that may help to deliver this benefit. This is one of the few studies examining these perspectives of HBPM use in primary care. Prevalence of home BP monitoring among respondents (24%) is reasonably similar to findings from British (17%)[315] and Singaporean studies (24%)[316] of hypertensive patients undertaken in primary care, but is around half that recorded in US primary care surveys (40 – 55%).[317,318] This suggests substantial scope for increased patient uptake facilitated by healthcare professional recommendations. HBPM better predicts cardiovascular risk and is also associated with reduced likelihood of the terminal digit preference (rounding of BP measurements), thus facilitating more accurate recording of BP trends.[319,320]

The positive relationship between self-documentation of BP and improved BP awareness suggests this simple step should be encouraged by healthcare professionals. A large number of patients reported BP measurements exactly at the target thresholds for systolic BP and diastolic BP. This suggests a significant degree of rounding of results resulting in inaccurate trends over time. Use of HBPM appears to be strongly associated with increased likelihood of recording BP measurements.

The finding that just 15% were not adherent to their BP medicines probably underestimates the overall scale of nonadherence in primary care. Previous studies of antihypertensive adherence suggest the extent of missed doses lie around 50% at 12 months after initiation.[59,321] This discrepancy may reflect the fact that our survey did not target those who did not persist with medicines use and subsequently may not present for prescriptions at a pharmacy. Likewise, those who take ‘drug holidays’ (extended periods without use) will present for

prescriptions at their pharmacy less frequently and are therefore less likely to have been approached to participate in this survey. Most of the 14% identified are likely to engage in day to day nonadherence, which has previously been identified as being a minority component of overall nonadherence.[59] This explanation is plausible in light of similar levels of nonadherence reported in a recent US internet survey of patients currently taking antihypertensive medicines.[307]

In Australia, doctors can claim government reimbursement to develop formal management plans for individuals with chronic conditions such as hypertension. Self-management, patient education and referral to other health professionals (including practice nurses and pharmacists) are key components of such a plan. It is disappointing to see the availability of such mechanisms has not led to a more comprehensive and patient-centred approach to care, even among high risk patients.

Limitations of this study

This study possibly underestimates the true extent of treatment gaps for hypertension management if the participating GPs and pharmacists are more proactive in terms of BP management. In addition, certain patients who should also have had lower BP targets than attributed may not been identified due to complexity of self reporting:[78]

- Patient's whose reported last BP measurement was taken via HBPM.
- Patients without a history of CVD, diabetes or kidney disease who are at high risk of primary CVD onset due to the combined effects of several risk factors.

- Patients with severe kidney impairment

Objective recording of BP measurements by health professionals and obtaining a thorough medical history would have provided a more accurate picture of the extent of BP control among respondents. There is evidence, however, that self-reported BP measurements are reasonably accurate.[321] Any objective measurements would have required a significantly more intensive application of resources and patient time, or consent to contact doctors for their medical history. This would potentially have reduced recruitment and willingness to participate, and would unnecessarily compromise the anonymity of patients.

The block distribution sampling method was pragmatic but risked selection bias. Based on previous Australian studies of hypertensive patients, these respondents do seem generally representative of the treated population when key factors such as average age, percentage female, proportion with controlled BP, use of different antihypertensive drug classes, and proportion taking monotherapy care are considered.[16,17]

Pharmacists and GPs appear to provide the majority of medicines and lifestyle advice for treated hypertensive patients, but there is significant room for improvement. It is disappointing that less than half of patients have the importance of medicines adherence reinforced, given that overall nonadherence to medicines (incorporating non-persistence with use) with antihypertensives is around 50%.[58,59] Patient comments suggest some demand for extra patient education on the condition and treatment. It is equally disappointing to note the large proportion of respondents – many with significant cardiovascular co-

morbidities who report failure to receive regular support with lifestyle modification. In most developed countries, pharmacists interact with treated hypertensive patients on a monthly basis at the point of dispensing. This suggests much greater scope for supporting patients than is currently reported. Recognition of advice on each key area examined by about 10-15% of respondents suggests a reasonable degree of activity already and at least basic knowledge among pharmacists about key areas of management.

Conclusions

Therapeutic inertia, irregular lifestyle advice and poor education of patients with treated hypertension seem to exist despite close monitoring by health professionals and is highly prevalent even in patients who know their current BP is above target. Although the representativeness of this patient sample can be questioned, findings nonetheless point strongly towards issues in practice that should be addressed. If anything, these results may underestimate the true extent of gaps in care. Health professionals could dramatically improve hypertension management if they ensure proper patient education, regularly review the adequacy of current medicines, and promote use of HBPM by patients.

Acknowledgments

This project was undertaken as part of a Quality Use of Medicines Fellowship supported by the National Prescribing Service and NHMRC National Institute of Clinical Studies.

Financial support

This project was undertaken as part of a Quality Use of Medicines Fellowship awarded to author KM supported by the National Prescribing Service and NHMRC National Institute of Clinical Studies.

Conflict of interest statement

The authors declare that there are no conflicts of interest. The project was initiated and analysed by the investigators.

Chapter 11. The Feasibility of Practice Audit as Part of a Sustained Quality Improvement Program in Community Pharmacy: Lessons from a Hypertension Control Program

Citation details:

Mc Namara KP, Marriott JL, Dunbar JA. The feasibility of practice audit as part of a sustained quality improvement program in community pharmacy: lessons from a hypertension control program [unpublished].

Co-author declarations confirming the nature of my involvement are detailed in Appendix 1.

Introduction

Blood pressure (BP) is the second-leading biomedical contributor to the adult burden of disease internationally.[248] This burden is made significantly worse by several evidence–treatment gaps that pervade healthcare systems globally.[97-100,277,322] The benefits of integrating pharmacist involvement within general practice and wider primary care management to optimise care of patients with hypertension are well-established via systematic review of RCT evidence.[169,171,172,282] Recent Australian clinical trials are consistent with this international literature suggesting beneficial pharmacist interventions.[136,323]

Unfortunately, there are marked differences between RCT and usual practice environments for community pharmacists in most countries. RCT interventions have generally involved several lengthy consultations per patient and BP monitoring; most healthcare systems do not fund ongoing structured interventions by community pharmacists, rendering such an intensive intervention financially unviable for the profession. Second, these RCTs have been concerned with proof of concept, asking pharmacists to recruit small numbers (often less than 10) and to intervene for a time-limited period. Where evaluations of programs to enhance BP management during routine pharmacist care exist, they do indicate some success, but these are generally observational study designs, evaluating short-term programs to raise BP awareness, and not sustained programs aiming to engage pharmacists more broadly in hypertension management.[134,173] Hence, it should not be assumed that pharmacists are applying BP management skills to their full potential.

In general practice, continuous quality improvement (CQI) collaboratives have substantially improved the management by that profession of CVD risk factors including BP for entire practice populations.[324-326] Published literature examining similar efforts to improve and sustain the quality of cardiovascular care in community pharmacy remains scarce. Documenting and measuring care processes constitute a prerequisite for clinical CQI processes so that performance feedback can be provided. Hence we need to establish if this is possible in community pharmacy practice. The aim of this study is to examine the feasibility of sustainably auditing community pharmacist interventions for hypertension management using a paper-based system.

Methods

Background to methods

The methods engaged sought to examine the feasibility of a CQI model that could subsequently be implemented using currently available infrastructure and resources. In addition to providing quantitative data describing activities over time, the authors also provide a narrative account of interactions with participating pharmacists to try and explain factors associated with declining participation in audit activities.

Setting and participants

In order to examine general feasibility, we sought to recruit pharmacists working in diverse community pharmacy settings to participate in a quality improvement program. Several recruitment methods were applied in order to achieve this. There

was a mixture of purposive and convenience sampling methods, with ongoing monitoring to ensure a diversity of pharmacy types:

1. General advertisement to individuals via professional newsletters
2. Personal approaches to pharmacists in certain large and small rural centres
3. Specific targeting of pharmacists working in pharmacies of two corporate groups advocating involvement to their staff.
4. Personal approaches to a small number of pharmacists, previously involved in BP awareness programs, by National Stroke Foundation

Colleagues of recruited pharmacists were also encouraged to become involved as a means of promoting workplace-wide involvement in CQI initiatives. A maximum of sixty pharmacists was sought from metropolitan and regional areas. Local GPs were contacted and recruited to the project as a means of encouraging multidisciplinary collaboration, but with no specific expectations about their involvement. Data collection for the CQI processes was limited to those patients presenting with prescriptions for antihypertensive medication written by local participating doctors.

Data collection for quality improvements

As for most countries, quality of care indicators are not documented in Australian community pharmacy. Documentation of patient care episodes is almost entirely limited to dispensing information, and electronic health records have yet to be implemented in primary care. In effect, there are no existing mechanisms to electronically record or extract information about patient care processes, and

paper-based documentation of care remains the only feasible method for obtaining such data. All pharmacists were asked to undertake the following as a means of gauging baseline characteristics and intervention rates for their practices:

1. At baseline and six months, distribute patient questionnaires provided to a representative sample of treated hypertensive patients attending a participating doctor. This examined patient self-management and patient-reported support from health professionals for their hypertension management. A maximum of 40 questionnaires was distributed per community pharmacy on both occasions.
2. For a four week baseline period, count the number of patients presenting with prescriptions for antihypertensive medication from participating doctors. This was used to establish an estimate of the target group size.
3. At baseline, each pharmacy with participating pharmacists was asked to provide basic information about their workplace.
4. From baseline until eight months, document interventions and advice provided to target group patients. At the end of each month, pharmacists were also asked to estimate the number of interventions that they did not document.

The intervention

After a 10-week baseline data collection period, the community pharmacies in which participating pharmacists worked were first stratified into 'high' or 'low' performing based on the number of interventions delivered per 100 eligible treated hypertensive patients per full-time equivalent pharmacist. Within these

two strata, pharmacies were then randomised to one of three groups, with all pharmacists in a workplace then allocated to the same group. Groups received different levels of quality improvement support (see Figure 11.1):

1. Group 1 (usual care) were enrolled into an existing two-week BP awareness campaign ('Know your numbers'[KYN]) only. This targeted all pharmacy patients, regardless of hypertension status or GP, and provided pharmacists with promotional and educational materials, a BP monitor and a manual to guide them in running a BP station. Pharmacists were asked to run this program for a two-week period in May 2009.
2. Group 2 (Limited support) participated in KYN, were provided with national guidelines for management of high BP, and a two-page (A4) laminated summary of key patient-level interventions for pharmacists.
3. As well as the above interventions, Group 3 (comprehensive support) also received an online BP management training module focussed on the role of the pharmacist, in particular highlighting six brief counselling interventions identified from national BP guidelines as appropriate for treated hypertensive patients, and which were within the scope of usual pharmacist. Written feedback on performance and online forums for reflective learning and quality improvement were also provided. Participating GPs indicating a desire for project involvement were alerted to their pharmacists' intervention group status and provided access to the online quality improvement forum.

To ensure the examination of a likely 'real world' experience, all three intervention strategies were developed to be feasible with minimal additional resources if implemented on a wider scale. In keeping with this approach, researcher engagement with practitioners was limited to a maximum of one or two face-to-face meetings to explain and encourage the intervention, and checking progress by phone no more frequently than every four to six weeks. The purpose of phone calls was to briefly remind pharmacists to submit data and check their continued involvement; they were not designed to be motivational. When it became apparent that participation was waning for a number of pharmacists, I made a point of enquiring about any difficulties with implementation if relevant pharmacists were not forthcoming, and noted responses.

Figure 11.1. Quality improvement support provided to participating pharmacists

Pharmacist Group	**Comprehensive support**	**Limited support**	**'Usual' care**
KYN Patient campaign	×	×	×
Education	×	Limited	
Guidelines	×	×	
Quality improvement cycle	×		
Survey/audit feedback	×		

Data collection and analysis

We experienced declining rates of intervention documentation by pharmacists over time, and insufficient numbers of patient survey responses at six months. Final numbers were not sufficient to reliably ascertain or comment upon the

significance of intensive CQI support on the quality of pharmacist support for patient management of hypertension. Subsequently we redefined our aim to explore the feasibility and acceptability of CQI in community pharmacy and factors influencing sustained documentation of activities.

A triangulation approach was used to establish findings. Sources of data were as follows:

1. Audit data for patients prescribed antihypertensive therapy (AHT) by participating GPs. This was returned on a monthly basis by pharmacists, and consisted of a summary sheet of monthly activity and individual counselling intervention forms.
2. Registration logs for the KYN program – detailing patient interventions by participating KYN pharmacies over a two-week period. We saw this as an indicator of the preparedness of the individual pharmacies to implement a structured intervention program in practice.
3. Patient questionnaires distributed at baseline and follow-up
4. Baseline pharmacy data identified above (target patient group count and pharmacy information)
5. Written accounts by KM of phone conversations (described above) with pharmacists discussing CQI activities.

Activity was analysed for pharmacies rather than individual pharmacists, because coordination of documentation was organised at a pharmacy rather than an

individual level. Pharmacy activity levels were categorised on a monthly basis into to one of four categories:

Level One	Continued, active involvement: returns monthly summary statement of activity, and completes at least one detailed intervention audit forms
Level Two	Passive involvement: returns monthly summary statement of activity, but does not document individual interventions
Level Three	Functionally inactive: no longer returns documentation, but continues to verbally commit involvement
Level Four	Formally withdrawn: confirms the pharmacy will no longer continue involvement

Quantitative analysis was used to understand trends with respect to maintenance of quality improvement activity. This analysis was performed using SPSS version 19.0 (SPSS Inc., Chicago Ill., USA). Univariate comparisons between groups were conducted using chi-square test for equal proportion (or Fishers exact tests where numbers were small) and reported as percentages (n) or as percentages (95% CI). Continuous normally-distributed variables were compared using student t-tests and reported as means (95% confidence interval) while non-parametric data were compared using Wilcoxon rank-sum tests, and reported as medians [interquartile range]. Spearman's coefficient was used to test the correlation between performance in the short-term KYN audit with performance in the more sustained audit of interventions for treated patients. Thematic content analysis of phone conversation records was applied to the question of barriers and

facilitators affecting sustained CQI efforts, and pharmacist reflections on personal motivation to persist.

This project was approved by the relevant human ethics committees at Monash University and Flinders University.

Results

Recruitment and participation levels

Fifty-eight pharmacists from 30 pharmacies were initially recruited, with half (15/30) from metropolitan areas. Seventeen of these pharmacies belonged to two chains where management gave explicit endorsement to participate. Of the remainder, six were recruited via direct approach from researchers, four responded to our advertisement and the final two were previous KYN participants approached on our behalf by organisers.

Of these initial 30 pharmacies, two withdrew prior to commencement and a further three withdrew prior to completion of the ten-week baseline data collection phase. Four of the five withdrawn pharmacies were from regional areas. Twenty-four of the 25 remaining pharmacies provided some baseline information about their pharmacies. The majority of these pharmacies had one (9/24) or two (10) participating pharmacists, with the remaining five having between three and six participants. When combined, participating pharmacists accounted for a median of 72% (IQR 56 – 91%) of pharmacist-hours worked in their respective pharmacies. Participants' pharmacies dispensed one or more AHT prescriptions from consenting GPs on a median of 81 (IQR 39 – 141) occasions over the four-week baseline period.

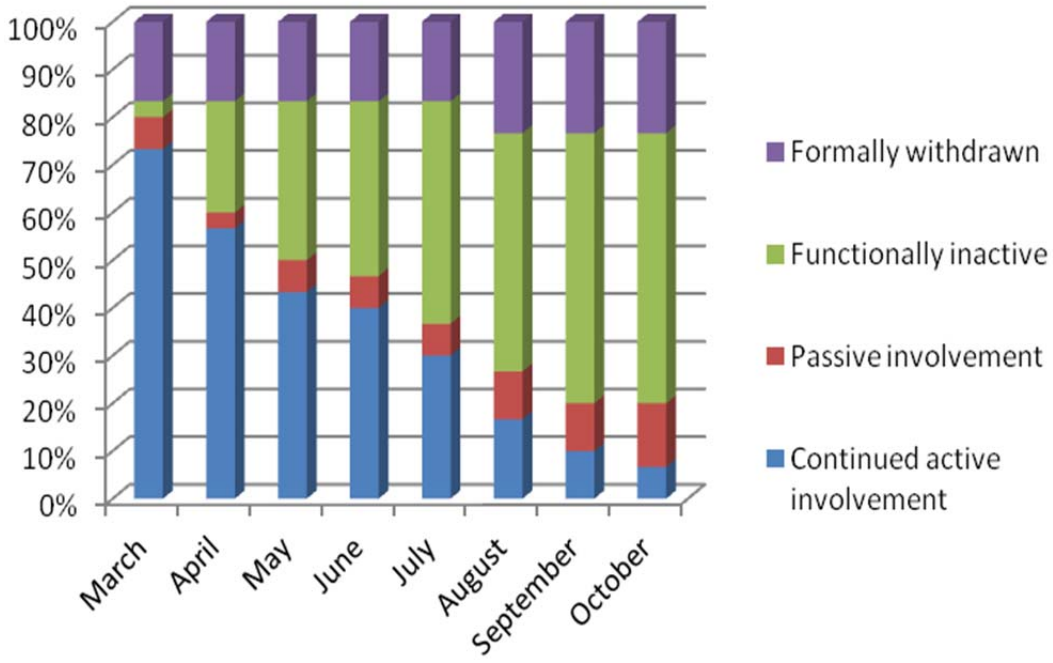
During the two-week KYN BP awareness campaign in May, nine of the 25 remaining pharmacies did not return any data on interventions. The remaining 16 pharmacies screened a median of 66 (IQR 21-104), and a total of 1110 patients. Including non-returning pharmacies, the median number screened was 21 (0-99). The patients screened were majority (69%) female, and 443 (41%) were aged over 65 years. Median BP for the 1083 measurements recorded was 135/80, with 500 (45%) being classified as high (≥140/90 mmHg), and a further 380 (35%) as high-normal (130-139/80-89 mmHg). Thirty eight percent of patients indicated an existing diagnosis of hypertension.

Persistence by the 30 pharmacies with the ongoing clinical audit is presented in Figure 11.2. Twenty-two pharmacies (73% of those initially registered) maintained level one activity in the first month of audit (March 2009), undertaking and documenting interventions undertaken. The proportion of pharmacies participating at this level steadily declined to 57% in April, 43% in May, 30% in July, and 17% August. Despite the continual decline in performance level, just two pharmacies formally withdrew from the program after commencement. Instead, researchers observed a continual growth in the number of functionally inactive (level three) pharmacies, rising from just one pharmacy (3%) at one month to a majority (57%) after eight months. Baseline survey responses were received from patients (n=215) attending twenty two of the twenty five pharmacies involved throughout the baseline data collection period. Participants from all twenty five pharmacies indicated a willingness to distribute follow up questionnaires after the program, but only 55 responses were received.

Among the 25 pharmacies participating in KYN, a moderate correlation was observed between the number of BP measurements logged during the brief KYN campaign and the number of months for which level one or level two participation in the CHIP C audit was sustained (R=0.332, p=0.105).

The large majority of participating pharmacists not providing audit data expressed a desire to persist with the project, even if the option of withdrawing from the project was raised by researchers. A number of pharmacists openly expressed feelings of guilt at not having performed better, and indicated on one or more occasions that they would make more of an effort. Generally speaking, these commitments did not result in improved adherence to the audit.

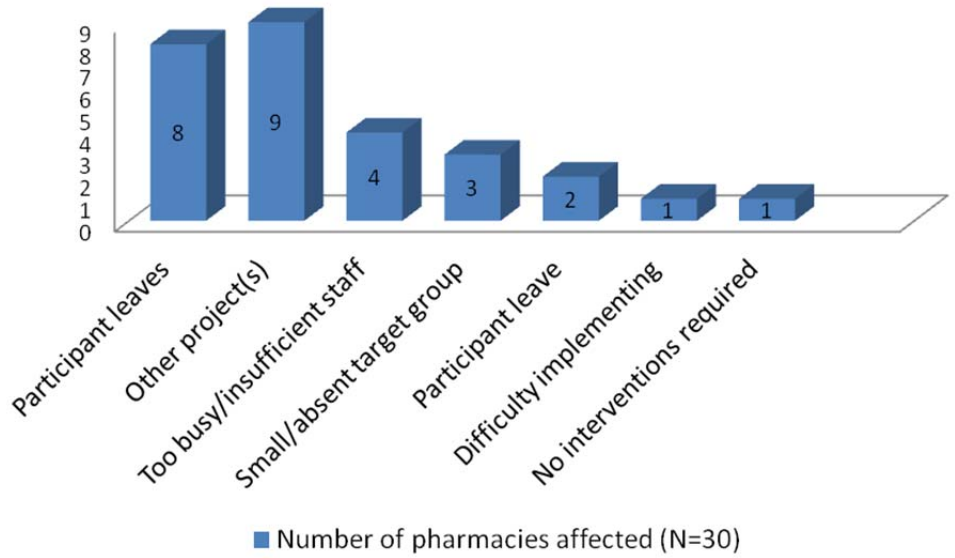
Figure 11.2. Pharmacist persistence with audit documentation process.



Barriers to sustained, active participation

Several themes emerged from discussions with pharmacists regarding self-reported reasons for withdrawal or inadequate audit participation (see Figure 11.3). Relocation or resignation of a participating pharmacist, on most occasions the pharmacist coordinating the project, was a decisive factor for almost one in three pharmacies. Three of these eight pharmacies were from one pharmacy chain. These pharmacies experienced a domino effect whereby the departure of one pharmacist led to pharmacists in the other pharmacies being relocated to cover resulting staff shortages. Relocated pharmacists, with various challenges in their new positions, did not assume the same responsibility for the project at their new positions, and participation subsequently faltered. Overall, most pharmacist departures were internal relocations with their own chain rather than resignations. Several further pharmacies were affected by work pressure resulting from periods of extended leave by a colleague working in their pharmacy, or from taking extended leave themselves.

Figure 11.3. Self-reported barriers to sustainability of the intervention and audit



Participation with other initiatives in their pharmacy proved an equally prevalent barrier to sustained involvement with this quality improvement process. These initiatives were varied in nature and the workload involved was often portrayed as onerous. Initiatives included pharmacy refurbishments, assuming additional management responsibilities, and engaging with other research projects. This final factor was relatively common, reflecting the fact that a number of Commonwealth-funded research and implementation projects began rolling out shortly after this quality improvement initiative. Participants reported general difficulty in managing multiple projects at once due to pressure of work.

There were several additional minor themes expressed by participants. A small number indicated they simply had too much work or insufficient staff without mentioning the presence of precipitating factors such as those described above. A couple of further participants felt that restricting the activity to patients from their local participating GPs made the cohort and the number of required interventions too small, or made it difficult to remember to intervene. Some participants admitted to forgetting about the audit. One pharmacy was unable to confirm a meeting with their local GPs to discuss the project despite the GP surgery being co-located with the pharmacy, and had to withdraw from the project as a result.

The researchers hypothesised that the amount of data required for documentation might have been contributing to suboptimal performance, and investigated this via an email to all participants, followed by enquiries over the phone to several individuals. All responses suggested this was not a contributor to low rates of intervention documentation. We streamlined the audit form anyway as a precaution but there was no observed impact on performance.

Discussion

Our findings provide a novel insight into the feasibility of implementing audit processes for the purpose of clinical CQI in community pharmacy programs. On one hand, they illustrate the willingness in principle of many community pharmacists to participate in programs addressing public health concerns, and considerable effort by the majority during a short-term program. On the other hand, they also suggest an ongoing and substantial decline in the level of audit participation over time. Participants indicated that pressure of work, departure or relocation of staff, annual leave and the burden associated with other project-type activity were key drivers of poor sustainability for this model of CQI.

The observed trend in audit adherence should be interpreted with caution. It does not necessarily mean pharmacists were delivering fewer valid or relevant interventions - we don't know to what extent this represents a decline in interventions versus a decline in documentation over time. Equally, pharmacists might have sought to intervene with all relevant patients (or a subgroup they perceived to require interventions) on just a single occasion, and hence they would naturally intervene less with time.

Regardless, the difficulty experienced in documenting proof of ongoing, high quality usual care represents a serious challenge to a profession struggling to consolidate its role in multidisciplinary primary care.[295,297] The few recent studies measuring integration of new evidence-based practices into the community pharmacy environment also suggest disappointing effects on quality of population-level cardiovascular care by pharmacists.[160,327] Prokhorov et al.

undertook a group-randomised RCT to see if a two-hour continuing education session would increase delivery of evidence-based smoking cessation activities by primary care physicians and community pharmacists with patients.[160] Changes to practice, assessed via exit interviews with both general practice and community pharmacy patients at 6 and 12 months, found significantly increased physician screening activity for smoking cessation, but no change among pharmacists.

A Dutch cluster randomised trial seeking to implement patient education programs in pharmacies over 12-months was also disappointing.[327] In a similar concept to our trial, the control and intervention pharmacist groups received varying levels of support (written manual only vs. intensive support) to facilitate statin therapy education to patients on the first and second occasion of dispensing. Ultimately there was no difference in performance between the two groups of pharmacies. Overall, just half of participating pharmacies in both groups reported education provision at first statin dispensing. Overall, just one in six new statin users, and one in eight presenting for a second prescription, ended up receiving this education despite the legal and ethical requirements for education. Neither of these trials indicated any financial incentive for pharmacists as part of the intervention.

Findings from these implementation trials are at odds with meta-analyses and phase three RCTs demonstrating significant improvements for BP, smoking cessation, lipid disorders and HbA1c concentrations following pharmacist interventions.[169,171,172,275] These phase three RCTs largely occur under idealised conditions where pharmacists are intensively supported, patient numbers are limited, interventions limited in duration, and pharmacist activities are

remunerated. They test the theoretical potential of the community pharmacist rather than their capacity to deliver interventions under the current community pharmacy working conditions that prevail. Our results may provide the basis for a more detailed understanding of the apparent discord in previous research into CVD risk factor management by community pharmacists.

Mounting evidence from the fields of psychology, economics and general practice support our concern that a substantial decline in targeted voluntary interventions may indeed have occurred.[328,329] The interventions we recommended to pharmacists are essentially acts of altruism, public-spirited interventions that go beyond the minimum requirements of keeping one's job or ensuring reimbursement.[328,329] Studies in various settings suggest that altruism wanes with passing time if appropriate financial or social incentives do not exist.[329,330] They will also wane if tasks competing for participants' time are seen to provide greater financial advantage, or where the costs of the altruistic act are perceived as exceeding the rewards of altruism by too great a margin.[328]

The revenue-raising potential of dispensing, disease state management programs, and various other activities creates a perverse disincentive against devoting resources towards quality improvement initiatives for routine care in the absence of any reimbursement. The 'Quality Outcomes Framework' for quality improvement in UK general practice is a highly relevant example of this phenomenon.[331] When introduced, this program of financial incentives resulted in sustained, above-trend improvements for many quality of care indicators linked with reimbursement. However, average performance for several further indicators without linked remuneration appear to have deteriorated.[331] This raises two issues

in pharmacy: first the obvious potential of financial incentives, but also the need to ensure that any financial incentives introduced would not create a perverse incentive to reduce other important activities. For example, a funded program promoting medicines-related interventions might reduce enthusiasm for important screening activities.

Identified barriers to sustainability related very strongly to workload fluctuations and continuity of staff (Figure 11.3). There may be merit to pharmacy management, researchers and other stakeholders first undertaking objective workload and capacity assessments before committing pharmacies to substantive activities over extended periods. In particular, mechanisms for coping with increases in workload or loss of staff might be beneficial as part of any risk management strategy for significant initiatives. If anything, our data suggests that disruptions to staffing are very common and pharmacies should be prepared not just in terms of finding replacement personnel, but also in terms of having systems in place to ensure continuity of various professional programs.

Our findings indicate that holistic programs supporting the entire work setting, and addressing practice- and system-level barriers, are required for effective implementation of CQI in community pharmacy. Current professional support mechanisms for improving quality of care might be excessively weighted towards education programs in isolation.

In Australia, the recent Fifth Community Pharmacy Agreement, a funding agreement for community pharmacy signed subsequent to this study, introduced several programs with financial incentives.[332] This includes the Clinical

Interventions Program which encourages pharmacist documentation of interventions during routine care. Electronic platforms for documentation and recall of these interventions have also become available. These are important drivers of practice change and further research should be undertaken to understand how they can be used to encourage systematic, evidence-based care. It was also interesting to note the correlation between short-term and long-term adherence to audit activities. Confirmation of this relationship and attributes affecting poor performance could be very useful. It would allow selective recruitment of pharmacies for programs with scarce resources, and might also enable earlier interventions with pharmacies at risk of not performing well.

Importantly, the pharmacies involved in CHIP C are quite similar in patient profile and performance to those in the overall KYN pharmacy.[173] In KYN about one quarter of pharmacies did not return data and the median number of patients screened per pharmacy was 25. Moreover, the patient demographics were similar, and the average BP and proportion with previous diagnosis of hypertension was almost identical. This suggests the pharmacies in our study were quite representative of pharmacies who partake in such programs. KYN is currently being rolled out on a permanent basis in pharmacies across Queensland, Australia, with an added diabetes risk screening component. The understanding provided by our study of barriers to sustained implementation might help to avoid repetition in future.

There are limitations to this study. As mentioned, it is difficult to ascertain the contribution of changing intervention rates to the declining rate of intervention documentation. Self-reported barriers to sustainability and widespread expressions

of desire to continue involvement may not be comprehensive or entirely accurate. A degree of socially desirable responsiveness may exist – that is, there may have been a desire not to offend the authors by suggesting flaws in the program as being responsible, or to portray a sense of disinterest in quality improvement or professional activities without any perceived incentive. Overall, this is an exploratory study in a field that has not been well-investigated in community pharmacy. While it does not conclusively identify the causes of poor sustainability, the study highlights several potential factors that require further investigation.

Chapter 12. Discussion

Summary of thesis findings

Findings from the research and literature review undertaken for this thesis add to our understanding of the public health burden imposed by CVD in Australia, and the potential for community pharmacists to contribute to primary care management of CVD risk factors. This thesis presents a cohesive body of work which initially explores the reasons for poor control of CVD risk. Then it examines a population-level rationale for pharmacist involvement with primary care programs to prevent and manage CVD, before finally testing the likely efficacy of pharmacist interventions.

Identification that current management of hypertension, lipid disorders and smoking – key CVD risk factors – was suboptimal across the three rural populations surveyed provided a context for the thesis rather than acting as a focus per se. Chapters 3–5, and Chapter 10 suggest that lack of lack of patient awareness of hypertension and lipid disorders are prevalent; and, treatment and professional support is inadequate when risk factors are identified. The examination of patients receiving intensive lifestyle support in general practice to reduce their risk of CVD and diabetes (Chapter 7) provided a more detailed perspective. Many participants had outstanding medication needs post-

intervention that were not addressed. Knowing that the patients' own GPs were involved in the intervention process and aware of the results suggests that usual primary care is somewhat prone to therapeutic inertia. Such insights provided further arguments for additional preventative health intervention strategies. An examination of the Wimmera population survey data in Chapter 6 indicated there was some justification for community pharmacists contributing to such strategies. We found that this profession was frequently accessed by individuals with uncontrolled risk factors, and increasingly so as CVD risk increased.

The remainder of the thesis examined the feasibility of implementing two markedly different models of care for CVD preventative in community pharmacy: first, a traditional disease management model attempting to provide comprehensive care to individuals for primary prevention of CVD (Chapters 8–9); second, a clinical quality improvement program to increase the provision of brief and evidence-based interventions to the pharmacists' patient population being treated for hypertension (Chapters 10–11). The former model was demonstrated to have substantial potential, reducing the average estimated CVD risk by 25%; the latter model was found not to be feasible in its current form and probably ineffectual in the long-term, but a process evaluation allowed some understanding of how future models might be shaped for greater sustainability.

The strengths and weaknesses of individual studies have been discussed within the chapters, as have their implications. When we consider the thesis as a cohesive body of work, there are some additional limitations to acknowledge. While the population-level studies added valuable perspectives on the use of pharmacists by individuals with CVD risk factors (Chapter 6), the absence of a concurrent

urban/metropolitan comparator group or previous literature on the subject hinders our ability to generalise to an entire population. Likewise, patients examined post-lifestyle intervention (Chapter 7) constituted a very specific group of rural patients with an elevated risk of diabetes. The practices involved were possibly more progressive than others in some respects given that they were participating in a clinical trial for diabetes prevention. We should not assume that other patient groups, and other practices, have evidence-treatment gaps to the same extent. In addition, data were self-reported by patients and not validated against practice records, so nonadherence may have influenced results. Doses were not recorded, and so we were only able to look at initiation and cessation of therapy, and not dose adjustments that may have occurred.

The intervention studies undertaken also had several limitations in terms of wider implementation. First and foremost was the inability in either study to establish the efficacy of the intervention against a control group. In Phase Two, PAART CVD did not have the budget to recruit control patients, while in Phase Three, declining levels of documentation in CHIP C rendered any analysis of changes to quality of care unreliable. The majority of PAART CVD patients were Anglo-Celtic and from rural areas, and therefore somewhat unrepresentative of the Australian population. This may also reflect greater ease of implementation in rural areas, and the need for modified models of care in metropolitan centres to aid recruitment and GP collaboration.

What novel ideas have been generated by this research?

Many of the limitations highlighted above stem from the exploratory nature of the research. It is simply not feasible for one thesis to answer every outstanding

question about the feasibility of community pharmacists involvement with CVD prevention programs. However, I do believe it is reasonable to claim that several aspects of this thesis have advanced the scientific knowledge base surrounding the topics of investigation.

This thesis explored the feasibility of implementing CVD prevention programs in community pharmacy. The extent to which our understanding of this proposition has broadened can be objectively assessed using established public health logic models. Logic models guide the systematic collation of evidence to determine the likelihood that a particular public health initiative will be successful. By inference, they also provide a rational retrospective framework against which the relevance and novelty of findings can be appraised. Such a framework is equally useful to discuss findings because the feasibility of implementing CVD prevention programs in community pharmacy is a multifaceted issue and with varying considerations for different patient groups, pharmacy settings, environmental influences and intervention types. Rather than generate extensive, and possibly more conclusive, data on a narrow aspect of feasibility for a defined context, I sought to understand how feasibility, as a broad set of concepts, might vary as does the context for intervention. It was a pragmatic approach that explored quite different interventions in Phases II and II that were equally valid from a theoretical perspective. Discussing the findings within a framework that defines the parameters of feasibility will help to frame the relative merits of findings in this regard.

The PRECEDE-PROCEED model, designed to develop health promotion programs, stipulates eight phases of evaluation and is one of the most widely

advocated models for health program development.[333,334] Before considering the implications of this thesis for future practice and research, I will first identify, using this framework, the key findings that might inform future research and policy regarding development of community pharmacy prevention programs.

The PRECEDE acronym in this model signifies the 'Predisposing, Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation', and encapsulates four planning phases for assessment prior to implementation. These phases should precede the intervention phase and are dealt with in the early results chapters outlining the epidemiology and cardiovascular health needs of various population cohorts:

Phase One identifies an end-desired result required by the community. As a Federally mandated National Health Priority in Australia with enormous health, social and economic implications, I believe the prevention of CVD can legitimately be accepted as a desirable outcome from the perspective of the Australian community and did not require further investigation.[335]

Phase Two determines the various factors that act as barriers in achieving the desired outcome. Findings from this thesis substantially added to our knowledge in this area. The population research in Chapters 3–5 has added to our knowledge of evidence-treatment gaps for key CVD risk factors in rural Australia. This includes the need for improved risk factor screening and education, and more intensive treatment if a risk factor is diagnosed. In addition, the consumer survey detailed in Chapter 10 established gaps in support currently provided to patients with hypertension by key primary healthcare professionals. These can justifiably

be seen as factors influencing CVD risk based on the following conclusions from literature:

- Current primary care systems allow persistent and widespread therapeutic inertia for the management of CVD risk factors.[98 97,99,100] Findings explored the nature and extent of these in rural areas.
- More regular interactions with patients encourage greater motivation towards healthier behaviours on the part of the individual.[132,141,336] Hence an identification of patient groups with opportunities for increased interaction with pharmacists can help to guide future interventions.
- Both pharmacists and GPs can deliver effective therapeutic interventions to promote improved cardiovascular health behaviours.[275] It is therefore reasonable to assume that the extent of support provided to patients is related to the quality of their care.[337,338]

Phase Three seeks to identify the predisposing, enabling, and reinforcing factors that can affect the behaviours, attitudes, and environmental factors given priority in Phase Two. The CHIP C baseline survey (Chapter 10) added to our understanding of the cardiovascular health behaviours (e.g. attitudes to pharmacist care) and reinforcing factors (e.g. low levels of regular lifestyle support, therapeutic inertia) affecting hypertension management for community pharmacy patients. Conversely, the Wimmera population study in Chapter 6 explored enabling factors (i.e. frequent use of primary healthcare professionals) among patients with uncontrolled CVD risk.

As mentioned in chapter 6, use of community pharmacy by patients with cardiovascular needs have not been described before from a population perspective. The many screening studies conducted in community pharmacy have a patient self-selection bias in this regard, and may not be representative of the overall pharmacy population.[134,173,266] Likewise, this is the first study to compare the relative frequency with which individuals at elevated risk of CVD use these two health professionals. Pre-existing frequent use of pharmacy services by at-risk individuals can be seen as a substantial enabler for patient access to interventions, and may reduce the appointment burden for patients receiving additional care. The literature review also identified the absence of alternative comprehensive primary prevention models and shortage of medical workforce in primary care as predisposing factors for consideration of a pharmacy based model.[165,166]

Phase Four considers the administrative and policy factors affecting the scope of what can be implemented. While not a core consideration of the thesis, the outcomes observed for the PAART CVD (Chapter 9) and CHIP C programs (Chapter 11), and resulting barrier analysis in CHIP C, gave insight into the likely efficacy of these contrasting models. While pharmacists appeared competent to deliver a comprehensive disease management intervention, there were difficulties with incorporating the principles into routine practice. Chapter 11 explores reasons why a sustained quality improvement approach might not be feasible in the absence of incentives and a system approach to implementation. Such an approach must engage pharmacy management to ensure adequate and ongoing workforce capacity at a practice level, and adequate incentive at a practitioner level. The feasibility and efficacy of clinical audit and other CQI interventions

activities in community pharmacy remains quite unexplored by academics, hence these findings present a basis for further work in this area.

The PAART CVD study published protocol also provided a detailed description of the theoretical principles and practical considerations underpinning many intervention attributes. These features were based on a review of best-practice literature for CVD prevention and the structures of existing primary care programs in Australia.

The PROCEED acronym represents the 'Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development', and provides a framework for implementation of intervention models over the four final phases. We will consider the PAART CVD and CHIP C studies with reference to this framework:

Phase Five considers aspects of the intervention design and implementation affecting outcomes. While this was a not a head-to-head study of the relative efficacy of the two intervention studies undertaken, it seems reasonable to argue that the disease state management approach was much more effective in getting pharmacists to deliver sustained care to patients and to document care. The likely reasons for this are elaborated upon in Chapter 11, and most likely stem from a departure from the ideal care environment as one progresses from disease state management towards quality improvement trials. A reasonable performance by the majority of CHIP C pharmacies in the two-week 'Know your numbers' BP screening program and in early phases of the overall CHIP C program suggest

goodwill in the profession and reasonable prospects for short-term programs, but insufficient capacity to sustain the effort.

Further evidence to this effect is provided from the HAPPY RCT subsequently undertaken to examine the role of community pharmacists in improving adherence to antihypertensive therapy.[323,339] The candidate (KM) was an investigator for this trial. It involved a very comparable group of pharmacies to CHIP C, and KM delivered or wrote much of the pharmacists' training. HAPPY had considerably more resources available for care in the intervention group (e.g. SMS reminders, free BP monitors for patients) and focussed only on interventions that would improve adherence. However, there was significant overlap with the CHIP C intervention regarding essential aspects of patient education and counselling, and documentation requirements were considerably less for CHIP C.

Ultimately, protocol adherence for the disease state management HAPPY RCT was much better than CHIP C and a significant improvement to BP was observed in the HAPPY intervention group compared with the control group. It suggests that features such as mandated patient appointments and counselling activities, specified patient quotas, mandatory reporting, contractual arrangements with management and financial incentives may have a substantial effect on uptake of interventions by health professionals. This is in keeping with general health literature indicating the effects of incentives, disincentives, and performance targets on quality of care, and the diminishing benefits from altruistic behaviour with time, i.e. a range of system changes acting together.[331,340,341] Continued reliance on voluntary health promotion activities by community pharmacists is therefore very likely to produce suboptimal performance.

Phase Six examines process evaluation to ensure the intervention was actually delivered as planned. The CHIP C project has identified substantial barriers that negatively affect the sustained delivery of innovative, evidence-based practices in everyday community pharmacy. The extent of negative effects incurred from personnel changes and taking on other large projects concurrently was unexpected. The CHIP C project has also aided our understanding of process evaluation in community pharmacy by examining the feasibility of sustained quality of care audits. We identified that a very common approach used for audit of quality of care in other health settings – asking practitioners to summarise treatment in patient notes – may not be appropriate in the current pharmacy environment. Equally, the degree of compliance with this voluntary activity appears to diminish as the duration progresses, making it unsuitable in its current format for longitudinal audit or CQI. The final report for PAART CVD (Appendix 3) provides insight into the process of care delivery that has not been reported for this thesis.

Phase Seven assesses the impact of the intervention on the key behavioural or environmental factors required to change in producing the desired outcome. PAART CVD quite clearly measured changes to important health behaviours that would affect patients' risk of CVD. The study demonstrated significant overall improvements to diet, specific dietary domains, cardiovascular medicines adherence and adoption of weight loss diets. Smoking prevalence was too low to demonstrate significant improvements, while non-significant improvements to physical activity were observed. The impact on health behaviours is regularly overlooked in pharmacist-intervention trials relating to CVD. As primary

prevention models are a novel area of research in pharmacy, establishing improvements to several health behaviours targeted by the intervention lends support to the notion that the intervention was instrumental in deriving an improved CVD risk profile.

CHIP C attempted to change health professional behaviour. Results are inconclusive due to the decline in documentation. However, the evidence suggests an initial effort to improve practice was not sustained by most participants.

Phase eight asks whether the desired outcomes were achieved for target groups. The PAART CVD study was the first to test the potential of a comprehensive primary prevention intervention by pharmacists (Chapter 9). The target group was aged 50-74 years, taking medication for lipid disorders or hypertension but without any history of CVD or diabetes. This group achieved a 25% reduction in their risk of CVD, suggesting considerable potential for future implementation. The algorithm used to assess risk has been validated via prospective cohort studies; hence it is reasonable to assert a link with real health outcomes.[63] Ultimately this intervention would need to be tested (via RCT or similar methods) in order to confirm efficacy.

CHIP C did not measure health outcomes. It instead sought to demonstrate the potential for improved patient health by measuring proxy indicators relating to patient self-management, awareness and support from health professionals. Our primary source of information was from patient surveys of these issues. Unfortunately an insufficient number of follow-up patient surveys were received to allow a meaningful assessment of changes to quality of care.

In summary, this thesis addressed our understanding of the feasibility of implementing CVD prevention programs in primary care in several respects. From a planning and justification perspective, it identified new perspectives on population need in rural Australia for additional responses to CVD risk issues, and identified a population-level argument for considering community pharmacists' potential role. In terms of implementation, it provided evidence that this role could extend to pharmacists engaging with quite complex primary prevention models of care. It also identified that the current model of routine care provided by community pharmacy appears unsuitable to sustained, high-quality clinical support programs on a population level.

How do the findings contribute to existing knowledge in this field?

The population health surveys added to the jigsaw of population epidemiology in Australia by focusing on a rural population. Previous Australian studies of population cardiovascular risk have tended to under-represent rural areas, or not include them at all.[16,342,343] This has led to some uncertainty in Australia and internationally about the links between CVD mortality and rurality.[344] It is inappropriate to assume the needs of rural populations are similar to metropolitan areas, given the range of environmental, socioeconomic and demographic differences. Research outcomes can act as an advocacy tool for encouraging increased funding for health services and health research, and for shaping local health service priorities.[345]

We found that the CVD risk factor status reported by our rural populations in Victoria and South Australia were similar to that of metropolitan centres. And yet, mortality rates from CVD in Australia remain consistently higher in rural and

remote areas.[75] If this does not stem from risk factor differences (as has been suspected), treatment rather than prevention might be a key determinant of this urban-rural differential. Access to acute and secondary prevention cardiac services is worse for rural Australia when compared with urban and metropolitan areas.[104,346,347] Furthermore, recruitment of many health professionals to rural communities remains a challenge.[166] These dilemmas suggest that rural health services need to optimise their use of existing health professionals, and ensure a strong focus on preventative care.

An important aspect of addressing preventative health needs in these communities is to ensure that new models of care being introduced are suited to implementation in low-resource settings where the risk of CVD mortality and morbidity is higher.[348] This lends further support to use of community pharmacies, which are accessible in most Australian communities.[349] Previous research examining frequency of use of pharmacies has not examined groups with CVD risk factors or existing CVD. With rare and limited exceptions,[163] there exists very little data to describe the use of community pharmacy by groups with elevated CVD risks. The findings from Chapter 6 allow a much more detailed understanding of appropriate target groups for cardiovascular health interventions involving pharmacists.

Current control rates for hypertension and cholesterol in Australia were demonstrated to be on a par with metropolitan areas of Australia. The Greater Green Triangle Risk Factor Studies also demonstrated the comparably high prevalence of obesity and contributing poor health behaviours in the rural populations involved.[6,23,180] Overall, the prevalence of these chronic disease risk factors, and the scale of evidence–treatment gaps for their management, are on a

par with comparable developed countries.[1,2,350-352] There exists an urgent need to improve population risk profiles in light of steadily increasing rates of obesity, and consequently diabetes, against a backdrop of an ageing western society.[3] Modelling from the US, supported by trends over the past few years in Australia and several other countries, predicts that the increasing obesity epidemic will cause decades of cardiovascular health gains made since the 1960s to plateau or even reverse.[3,353,354] Health systems will struggle to afford treatment for cardiovascular events if the cardiovascular risk of populations cannot be improved.

The need to deal with a looming crisis in cardiovascular health is widely acknowledged, and will require a balanced approach with strategies to intervene both with overall populations and with high-risk individuals. Because most cardiovascular incidents occur in the large majority of individuals with relatively low risk, population-level interventions can have a major effect on the total number of events. Typical population measures include taxes on salt and alcohol, or building health-promoting environments (e.g. cycle lanes) so that risk for the whole population shifts lower.[267,355] Conversely, it becomes less effective and cost-effective to deliver resource-intensive interventions at an individual level to those with low CVD risk.[142]

The role of health professionals becomes more important and cost-effective for higher risk individuals, including those with established risk factors or a history of CVD.[142] The PAART CVD model for the primary prevention of CVD potentially reduced CVD risk by one quarter in patients with CVD risk factors and could serve as the basis for a pharmacy intervention program. Confirmation of efficacy

and cost-effectiveness for this intervention requires an RCT. In particular, there is considerable need for more cost-effectiveness data for primary prevention programs in order to establish value for money.[142] To date, economic evaluations have measured the impact of interventions that lack a medicines management component.[142] This is despite antihypertensive and lipid-lowering medicine use being highly cost-effective components of CVD prevention.[142,145] The cost-effectiveness of paying pharmacists to deliver screening programs should also be investigated. Most pharmacy screening programs for BP are voluntary, and may deliver suboptimal screening rates. By paying pharmacists, the overall cost per pharmacy might increase but the cost per patient screened might actually decrease if there was an incentive to deliver more interventions.

An economic analysis will also be highly beneficial for establishing if the rationale for extending routine primary prevention care beyond general practice is legitimate.[249] While community pharmacists might prove they can deliver an effective intervention, they may further need to justify why that intervention should not simply be integrated into existing nursing or allied health services. Existing funding mechanisms for practice nurses in particular would already allow implementation of such a program and they have demonstrated considerable potential in the area of CVD prevention; hence a convincing argument identifying the unique contribution of pharmacists may be required to advocate for alternative funding models.[356,357] Equally, hybrid models which allowed each professional to contribute where they are strongest might be the preferred model. This approach appears to be the most successful model for CVD prevention programs involving pharmacists.[159,282]

In addition to considerations of efficacy and cost-effectiveness, it is essential from both an equity and a needs perspective that any models developed and implemented on a broader level are equally feasible in metropolitan, rural and remote areas. With the medical primary care workforce in rural Australia expected to be considerably under-strength for the foreseeable future,[165,166] a multidisciplinary approach with less rigid professional practice boundaries appears to be the only sustainable solution. The PAART CVD model, by focusing on a broad range of CVD risk factors, also has the potential to be adapted for other patient groups – in particular, patients with established CVD, diabetes, or at high risk of diabetes will have very similar needs.

Achievement of national goals for cardiovascular health will, however, require a more concerted and sustained national focus on prevention. Individual models of care such as PAART CVD might form part of these efforts, but they are not substitutes for multifaceted strategies. As discussed in the literature review, treatment inertia is common in primary care and is a major contributor to the evidence–treatment gaps for CVD risk factors.[358] [359] [99] While this remains a global phenomenon, notable exceptions provide us with good reason to argue that long-term, intensive national programs can deliver improvements. Multidisciplinary and often multisectoral collaboration appear to be at the heart of these successful programs.

In Canada, improvements to average population BPs between 1992 and 2009 have spectacularly outperformed other developed countries.[360] The proportion with hypertension who achieved BP below 140/90 mmHg increased from 13% to 65% in that seventeen year period. More intensive screening and treatment appear to be

key factors in this improvement. This is evident from improvements in the proportion with hypertension who were aware of their condition (from 57% to 83%) and the proportion with hypertension receiving treatment (from 30% to 79%). Certainly the GGT RFS hypertension study suggested that the treatment gap in rural Australia is not closing at this rate. The authors of this study do not make definitive conclusions about the reasons for such improvements, but suggest annual updates to guidelines accompanied by regular continuing education to health professionals might be important for maintaining BP control at the forefront of health professionals consciousness, and thus preventing treatment inertia.[361]

The Canadian Hypertension Education Program (CHEP, http://www.hypertension.ca/chep-recommendations), which develops these national guidelines for hypertension management and associated national rollout, has also been credited with playing a significant role in this success story. In addition to the above measures, they have a specific implementation taskforce for guidelines with 40 members from many health professions including pharmacy. This taskforce ensure a pervasive message across health professions including tailored guidelines and education programs. CHEP involvement of multiple disciplines in guideline development may also aid greater engagement outside medicine and by the public.[361]

Australia can lay claim to leading international efforts in tobacco control, with some of the lowest prevalence rates in the world. Use among adults declined from 35% in 1980 to 20% in 2001, and at current rates will reduce to 14% by 2020.[362,363] Tobacco use is somewhat unique among CVD risk factors with respect

to the chemical dependency involved. Many of the gains made in cessation rates are associated with legislation to make smoking less affordable and less convenient (e.g. workplace bans). Concerted regulation and other policies, multidisciplinary engagement and education have also played a key role, alongside mass media campaigns for public education.

Current Australian programs for hypertension and lipid control are perhaps not as intensive or comprehensive as these two examples in several respects. Let us consider the theme of research for this thesis – the role of pharmacists in CVD prevention – as an example. There is no indication in national clinical guidelines for hypertension, cholesterol, obesity, or related health behaviours describing what role pharmacists should play, or might play.[26,30,39,45,78,91] The same is true for many other key health professions. In the case of pharmacists, this is despite ample evidence of their potential to deliver effective interventions to reduce CVD risk.[159,169,171,172]

This is at odds with the Canadian program where pharmacists and other health professionals contribute to guideline development, and have tailored guidelines and associated continuing education programs for individual professions. Modeling suggests that if we optimise the management of lipids, smoking and hypertension in high-risk individuals, we can reduce the onset of CVD events in Australian adults by 13%.[182] International studies also suggest large benefits.[364] Australia needs to adopt more comprehensive national strategies based on these models if we are to achieve these goals.

Cardiovascular health policy initiatives at a societal level need to be matched by efforts from the pharmacy profession if pharmacists are going to play an active role in future national preventative health initiatives. Convincing all major stakeholders that *pharmacy has an essential role to play* will be a considerable challenge to the profession, but is absolutely necessary. These stakeholders are both external and internal to the profession, and early engagement is important. Their involvement from the outset will facilitate them taking ownership of increasing pharmacy's role and help to develop a mutually agreed vision for CVD prevention.

Much of the preventative health reform process is driven and funded by government policy.[335,365-368] In this respect, community pharmacy is notably absent from many key recent national health policies and reports such as the National Medicines Policy, the National Preventative Health Strategy (and 'Taking Preventative Action', the Federal government's official response), the National Primary Care Strategy and the National Chronic Disease Strategy.[335,365-368] Even the National Strategy for Quality Use of Medicines fails to specify a role for pharmacists.[369] By comparison, the National Primary Care Strategy and 'Taking Preventative Action' both commit to substantial funding, training and collaboration for general practice, practice nurses and nurse practitioners.[367,368] Hopefully the pharmacy profession's inclusion in the National Health and Hospital Reform Commission's final report will mark the beginning of a more integrated approach to pharmacy services.[162] Public funding for community pharmacy services is largely restricted to provisions made within the Community Pharmacy Agreement (CPA).[332] While the most recent Fifth CPA has seen the

introduction of several professional service programs, they are not explicitly linked with wider public health initiatives and do not directly incentivise stronger multidisciplinary collaboration with pharmacy. This siloed approach to funding may restrict integration of community pharmacists and optimisation of its preventative healthcare potential.

UK policy is somewhat more advanced than Australia in this regard, and might serve as a useful model for progress given the similarities of pharmacy practice. The Department of Health recognises in its most recent white paper for public health in England that '*community pharmacies are a valuable and trusted public health resource*'.[370] Key preventative health roles are clearly identified for community pharmacy, linked to a multidisciplinary and public health context, and funded for implementation (£2.3bn in 2009/2010). Moreover, it confirms the key role of public health agencies in commissioning services from pharmacy based on the outcome of population needs assessments. However, we should also learn from the UK experience of implementation, not just the proposals for change. Even in a supportive policy environment there has been criticism, often from the medical profession, that more should be done to promote multidisciplinary engagement, reduce duplication of services, and enhance continuity of care.[265,371] The value for money of decentralised primary care has also been questioned, but is difficult to estimate.[371] Such criticism and uncertainty underscores the political as well as clinical need for careful planning and comprehensive clinical and economic evaluation of expanded pharmacy scope of practice.

Several other countries including the UK, Canada, Germany, Switzerland and New Zealand have successfully developed a public health platform for pharmacy

services, particularly in the area of policy reform and pharmaceutical care remuneration.[372-375] It has been suggested that the major reform occurring generally in healthcare, the central involvement of community pharmacy in these reforms from a very early stage, development of a clear pharmacy services strategy by government, and representation for the profession within government by a Chief Pharmaceutical Officer, have all acted as key facilitators for policy successes in the UK.[374] Conversely, failure of representative professional organisations to actively advocate for pharmacist roles with clear evidence may contribute to policy inertia.[376] The separation of pharmacist dispensing and professional services may also be important as a means of eliminating potential conflicts of interests.[375]

The medical profession, and in particular general practice, will also be a key moderator of the extent to which community pharmacist services for CVD prevention and other areas are integrated with the broader primary care. First, pharmacists deeply value good relationships with local GPs and many would be reluctant to implement new programs without their approval.[295,297] They are the health profession with whom pharmacists generally have most contact for patient care, and who write the prescriptions that lead to the majority of income for most pharmacies. Second, medical practitioners are the most influential profession in terms of health policy decision-making.[377] Third, current models for coordinated chronic disease prevention and management in primary care in Australia have GPs acting as gatekeeper to patients accessing other publicly subsidised health services.[378] Fourth, it is not unreasonable to claim that the general public, or a large proportion thereof, embraces their GP as the primary advocate for

negotiating an increasingly complex health system on their behalf. Failure to secure reasonable medical endorsement of new pharmacy services will therefore result in unnecessary barriers at a patient, practice and policy level.

GP surveys indicate mixed views about the pharmacy profession's potential roles in primary care.[295,297] While there is support to varying degrees from many medical organisations, arguments abound that pharmacy service initiatives are designed simply as cheap alternatives to GP care that have insufficient underpinning evidence and threaten to fragment care.[265,371,379,380] There is a recurring concern that community pharmacists are excessively driven by commercial interests (the 'shopkeeper role'), have conflicts of interests associated with increasing corporatisation, cannot provide private counselling facilities and do not have adequate training or primary care integration to deliver on many of the proposed role extensions.[286,381] Indeed, some GPs have been identified as collaborating preferentially with independent rather than corporate pharmacies due to concerns about corporate pharmacy.[381] It is uncertain whether or not such GPs are equally resistant to corporatisation within their own profession, given the ethical concerns this raises.[378] It may be that the product-oriented nature of community pharmacy exposes these issues to a greater extent, and therefore needs to be addressed more strongly by this profession.

Although concerns expressed by medical commentators generally focus on patient outcomes, it is unwise to ignore the potential importance of unspoken perceived threats to GP status and income as a driver of medical opposition to pharmacy services. One study from the UK went so far as to conclude that many GPs who accommodated and welcomed extended pharmacist roles 'discriminated carefully'

and only encouraged supporting roles for pharmacists.[297] As a general rule, most GPs are happy for pharmacists to engage in supporting technical roles (e.g. compliance checking, provision of medicines information, and counselling on use of medicines), but often become hesitant about chronic disease management and prevention roles (e.g. screening, prescribing, advising on drug selection).[295,297] More thorough process evaluations in future pharmacy intervention trials may be required to demonstrate that outcomes are derived from clinical activities rather than technical aspects of care or a Hawthorne effect.[382]

Even when patients from a Canadian trial felt care had been improved by pharmacist intervention for lipid management, GPs were concerned it undermined their special relationship with patients.[383] This is at odds with the experience of the PAART CVD and CHIP C projects in this thesis. We encountered no resistance to such initiatives. Very early engagement with general practice and clear explanations of the purpose of the research may have assisted with this process. Alternatively, participating pharmacists may have engaged with GPs whom they felt were open to such initiatives. Regardless, it appears that a substantial evidence base for new models of care such as PAART CVD is warranted in order to appease medical concerns. This should not only examine health outcomes, but also the economic impacts and effects on GP income and coordination of care.

The geographical isolation of the community pharmacist from the GP, negative previous interprofessional interactions, complex administrative protocols, lack of remuneration or a general lack of interest in collaboration can all act as barriers to GP-pharmacist collaboration.[294,384] Despite such barriers, there are increasing

examples of community pharmacists and GPs collaborating effectively.[282,385-387] The scope of professional interaction with pharmacists, and the related concepts of communication, trustworthiness and role specification, all appear to be significant determinants of effective collaboration between these two professions.[294,381,386,388] A prospective study after initiation of formal collaborations between community pharmacists and GPs in the US suggested that their prior level of professional interaction at baseline and GP-reported trustworthiness accounted for 35% of variation in the stage of development of collaborations between the two professions.[386] Interestingly, role specification for pharmacists was seen as an important predictor of collaboration success at baseline for this study, but not at three months after formal collaboration commenced.[386] Because many of these pharmacists already collaborated with physicians to some extent at baseline, the importance of different approaches to relationship initiation remain unexplored. This evidence suggests that effective formal collaborations can be achieved between GPs and community pharmacists at a practice level if they build on existing relationships, and have clearly defined roles and communication strategies in place. Prerequisites to sustained collaboration will include remuneration systems and protocols with minimal administrative complexity.

As end-users, consumers are another key stakeholder group that must be convinced to embrace community pharmacist-delivered CVD prevention services. Peterson et al. have specifically investigated the views of a random telephone sample of 505 Australian households about what they perceive as an appropriate role for pharmacists.[239] It suggested quite divided public opinion on the topic.

About half thought pharmacists capable of screening for BP or diabetes, but a minority believed them capable of performing testing for cholesterol. Low participation rate for this study and screening out of individuals who had not visited a pharmacy in the previous month may positively bias these results.[239] Conversely, cheaper point of care cholesterol testing equipment has allowed an increasing number of Australia pharmacies to offer this service since the survey was carried out in 2005 – it would be interesting to see if public attitudes have changed as a result of exposure to a service they did not equate with a pharmacy setting.

A small majority in that survey indicated they would use each of these three testing or screening services if available through community pharmacies. Respondents indicated a similar likelihood of using such services if offered by nurses, but almost all indicated willingness to be screened where offered by a doctor. In contrast, the majority did not agree that pharmacists were capable of diagnosing conditions. Interestingly, only 25% identified quality of service and 14% the knowledge of staff as a reason for using their community pharmacy of choice.[239] This suggests that the profession must do more to convince the public it can effectively provide CVD prevention and management services. Supporting this argument is Australian and international research indicating significantly increased willingness to pay for pharmacist care where perceptions of pharmacists' abilities and the likely healthcare benefits are higher.[389,390]

International studies confirm poor communication from the profession at a practice level about the merits of pharmaceutical care services, and poor understanding by pharmacists of the types of services the consumer will value.[391]

Given the public apathy towards community pharmacist skills indicated above, it would appear the profession needs to convey the benefits of professional pharmacy services far more effectively.

Despite this, evidence from the UK suggests pharmacy is particularly useful for improving uptake of screening services among ethnic minorities and more deprived areas.[266,392] This might be partially explained by extended pharmacy opening hours and free consultation without appointment. It may also stem from a belief that pharmacists are less daunting that other health professionals.[393] We should be mindful then in developing disease state management approaches to pharmacy services not to diminish those positive attributes of access and acceptability associated with contemporary care.

A broader review of international literature describing consumer views also suggest varying public enthusiasm for extended community pharmacy involvement prevention and management of CVD, and expanded roles more generally.[239,296,394] Varying levels of service quality during routine care may contribute to views that pharmacists are not competent to deliver extended services such as CVD risk screening.[327,395] This may in fact contribute to observed low *expectations* that pharmacists will provide high quality counselling services.[396] While most patients report *satisfaction* with usual pharmacy care in studies included in a systematic review,[397] the focus of these surveys appears to examine the quality of service rather than the quality of care. They may in fact not understand that pharmacists have the training and legal requirements to provide more comprehensive care.

Public opinion may have shifted towards favouring extended pharmacy health information and screening services over the past few years, with increasing exposure to services from pharmacists.[173,266,398,399] While professional stakeholders might rely more on scientific evaluations, the most effective way to convince the general public that pharmacists should deliver CVD prevention services might be to adopt a more professional and patient-centred approach to everyday practice. It is here, rather than during disease state management services, that most people interact with pharmacists.

The pharmacy profession itself might just be the hardest stakeholder to engage in the change process, at least in a unified manner. Community pharmacy has for many years been described as 'at a crossroads',[292] half-heartedly embracing counselling-based services but unable to free itself from a fee-for-product model of care. This is perhaps not surprising given the number of vested interests that stand to gain or lose from a fundamental shift in pharmacy reimbursement mechanisms. In particular, the Pharmaceutical Society of Australia (profession's peak body) and the Pharmacy Guild of Australia (pharmacy owners' guild) have openly criticised each other's handling of negotiations with the government about the future funding of pharmacy services and pharmaceutical products.[400] A lack of consensus between two of the profession's most powerful organisations makes the future profoundly less certain. This may also reduce the willingness of external stakeholders to engage in this environment. It also diminishes the certainty required for investments in skills development and service infrastructure by pharmacists.

At a grassroots level, both nationally and internationally, community pharmacists seem divided about what type of profession they want. Pharmacists have a general appreciation of their potential public health role incorporating screening, health promotion and medicines management, but many are more comfortable with a more restricted role focussed on provision of medicines information.[296] In a systematic review of the topic, variation in the desired role appears to occur within and between countries, and also varied according to the clinical area.[296] Most surveys revealed positive attitudes towards smoking cessation services, but less confidence in providing counselling about alcohol consumption or weight management. A survey of Scottish pharmacists found that about one in three pharmacists were not confident that they could effectively facilitate behavioural change in patients.[289] Moreover, a separate UK survey suggests pharmacists themselves don't believe they have a mandate to do medicines management.[295] This calls into question the confidence with which many pharmacists would engage in a multifaceted intervention such as that proposed by PAART CVD.

These findings may, however, reflect pharmacists' personalities more than their skill levels. Successive clinical trials have demonstrated pharmacists' capacity to deliver combined lifestyle and medicines management interventions.[169,250,280,282] A lack of confidence may then partially represent an underestimate of pharmacists' own clinical skills, a perception among pharmacists identified across several international studies.[295] Even if this is the case, it should not be ignored. Rather than exerting a benign influence, negative attitudes towards skill level has been found to significantly reduce the likelihood of pharmacists implementing more complex patient interventions.[287] It could be speculated that the isolation from

pharmacist colleagues and low levels of engagement with other professions contribute to unrealistic and daunting impressions about the skills required to contribute to an interprofessional team. This is an area that is under-investigated, and greater insight might reassure pharmacists about their suitability for extended roles in chronic disease prevention and management.

If this limited literature on the topic is to be believed, a lack of confidence is endemic across the community pharmacy workforce. In fact, it has led one commentator to question whether in fact Canadian pharmacists really want to advance practice towards a chronic disease prevention model, given the failure of several steps taken to overcome the barriers to progress cited by pharmacists.[291] It is hypothesised that a culture of lacking confidence encourages pharmacists to 'fly under the radar' and avoid responsibilities beyond the dispensing of medicines. Pharmacists may also struggle with the concept of decision-making in 'less than textbook perfect' conditions as they transition from a highly standardised and protocol-driven dispensing/compounding tradition.[291] Austin et al. conducted an innovative piece of qualitative research where pharmacists who subsequently studied medicine were asked to comment on the differences in culture. Participants commented on the relative sense of 'powerlessness' and career limitations imposed by pharmacy, compared with the status and expansiveness associated with medicine.[401] It could be speculated that claims in the literature of limited professional ambition and a lack of leadership are in fact just symptoms of a learned helplessness.[401]

It would be very depressing and also quite remiss of me to end my thesis at this point. Much of this discussion has highlighted the challenges, shortcomings and

barriers faced by the profession. I focussed on them because the first step towards initiating practice change is to identify that the current scenario is not desirable.[301,402] With this job done, it is equally important to articulate the capacity for this profession to change. It must be remembered that the delivery of cognitive services in community pharmacy is in its infancy. It was only in the 1960s that clinical pharmacy began to emerge in hospitals from the ashes of a diminishing compounding role and subsequent need to reorient the profession. In the 1990s a pharmaceutical care model was widely adopted by the profession, with a remit to 'the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life.' [403,404] This was embraced by community pharmacy and in the short time since then the profession has substantially expanded the scope for professional services.

From a CVD prevention point of view, the ability for pharmacists to deliver meaningful and effective interventions is beyond question. There is now convincing evidence of effectiveness from multiple RCTs for their involvement with diabetes, heart failure, smoking cessation, lipid management, and hypertension – although there is considerable heterogeneity between many studies in the various meta-analyses.[159,169-172,275,281] The profession has taken cardiovascular risk screening from pilot evaluation through to large scale, ongoing programs in several countries that result in improved patient care.[134,173,266] The findings from this thesis adds to quite limited and generally inconclusive literature describing community pharmacist interventions for behavioural interventions addressing diet, physical activity, alcohol use and weight loss.[133,135,405-407] Further research establishing community pharmacists' potential in this regard is perhaps

the next major area requiring thorough RCT evaluation in order to fully understand community pharmacists' capacity to deliver multifaceted interventions for CVD prevention.

The journey towards improving the quality of routine cardiovascular care in community pharmacy began even more recently. The CHIP C project is one of just a handful of similar studies, all undertaken in the past five to ten years, looking specifically at the quality improvement needs of community pharmacy in the area of CVD prevention – or any clinical area for that matter. We are beginning to develop a more complex understanding of the profession beyond the more established barriers to implementation such as lack of time, confidence or remuneration.[408] Prokhorov and colleagues' examination of multidisciplinary smoking cessation programs involving community pharmacy allowed us to identify the need to develop unique models to facilitate behavioural change in pharmacy for brief interventions.[160] Van de Steeg-van Gompel C and colleagues identified very similar barriers in pharmacies to CHIP C (Chapter 11), suggesting environmental factors at play rather than intrinsic faults in the proposed methods of these two studies.[327] This suggests great comparability of 'usual care' and significant potential for shared learning between the two health systems.

Despite the absence of improved clinical performance, it was nonetheless interesting to note the success in the Dutch lipid study associated with a single 'tick the box' to indicate a standardised intervention had been delivered.[327] This suggests that more onerous intervention documentation may be a limiting factor when it comes to sustainability of participation, despite the denials of CHIP C participants. In the area of sleep disorders, Van de Steeg-van Gompel and

colleagues actually managed to significantly increase pharmacists' provision of letters recommending discontinuation of long-term benzodiazepine use to patients.[409] Despite not improving the primary outcome – a reduction in drug use – it points to the fact that pharmacists require extremely brief and simple interventions in order to sustain programs. While the advantages of simple interventions are well established in implementation research, it would appear that pharmacists who are not remunerated for services may require briefer interventions than those delivered by other health professions involved in quality improvement trials. Providing a choice of interventions to pharmacists in CHIP C along with an online education module might have been too complicating.[410]

CHIP C added to this emerging field by documenting for the first time the rate at which pharmacist participation dwindled, and the potential for identifying potentially weak performers through their short-term performance. It also identified previously undocumented practice- and system-level influences that negatively affected the performance of individual community pharmacies.

The future for this type of quality improvement research in community pharmacy might be accelerated if we can build on the experiences of related mainstream pharmacy practice research. For example, difficulties with intervention documentation might be overcome by using 'mystery shoppers', which has been extensively used for quality assurance purposes in community pharmacy.[411] The use of exit interviews by Prokhorov et al. also yielded reliable data.[160] This would overcome the requirement for pharmacist documentation. As mentioned earlier, developing a culture of high quality care and raising patient expectations of

pharmacists might be the key to ensuring further reimbursable care programs, and clear acknowledgment by government of pharmacists' role within primary care.

Some promising developments have occurred in Australia to assist quality improvement. As part of the Fifth Community Pharmacy Agreement, the federal government agreed in 2011 to fund several generic Practice Incentive Payments for pharmacists to provide and document clinical interventions and cognitive services during usual care.[332] Medicines use reviews and several other interventions are also funded. These new interventions are largely unproven and generic in nature, and not explicitly linked to wider multidisciplinary strategies. Recently developed electronic platforms to assist with documentation of these interventions, alongside the various financial incentives now available, may help to overcome some of the barriers related to lack of reimbursement and potential documentation issues identified in this thesis. There are no clear requirements for a high quality intervention stipulated, simply to document that the process has been undertaken. There is a clear need at this stage for pharmacists to be provided with substantial implementation assistance, and for rigorous evaluation of the effectiveness and cost-effectiveness of these new programs.

Future research interventions should incorporate and evaluate efforts to improve pharmacists' perceptions of their own skills, patient expectations of community pharmacists, relationships with general practitioners, and the general working environment for pharmacists beyond the intervention. Strategies need to be tested to raise public confidence and expectations in the profession, and to raise the profession's own confidence and expectations of itself to improve quality of care.

Much research also needs to be performed in order to understand the policy and workplace conditions that lead to improved community pharmacist performance.

Anecdotally, I am aware of individual pharmacy chains in Australia who use systems for monitoring pharmacist performance, and incentive structures to encourage good performance. However, published research remains scarce, and scaled-up projects examining a variety of pharmacy settings are required. Large-scale American programs have commenced and may yield valuable information.[412] Clearer public health policy and clinical practice guidelines describing priorities for pharmacy services would stimulate enhanced engagement of the pharmacy profession at a national and local level. It may also facilitate the necessary financial incentives required to justify investment in expanded services by the profession.

Research published since my initial submission points to the potential of intensively supporting the implementation of simple interventions in routine practice to improve performance.[413] Routine interventions in community pharmacy appear to require minimal documentation and concise counselling roles, and maximising outcomes within these confines needs to be examined. If we broaden the focus of research methods to include pharmacist-, patient- and practice-level determinants of implementation, and restrict clinical interventions to what is absolutely feasible, we may in fact see that significant improvements to the quality of cardiovascular care being delivered by community pharmacists is entirely feasible.

Appendices

Appendix 1. Co-author declarations

Co-author Declaration: Associate Professor Michael Bailey

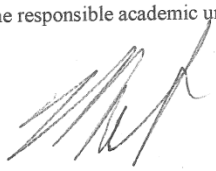
Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press].*	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date:** 1/2/12

Name: MICHAEL BARLEY.

Page **2** of **2**

Co-author Declaration: Dr Andrew Baird

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Chapman A, Bunker S, Dunbar A, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural Smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 15%. I did not play any significant part in project design, implementation or data collection.

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: [signature] **Date:** 22 MARCH 2012

Name: ANDREW BAIRD

Page **2** of **2**

Co-author Declaration: Dr Stephen J Bunker

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, Detection and Treatment of Hypertension in Rural Australia; the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medical Journal* 2008;38(12):879-886	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 10-15%. I did not play any significant part in project design, implementation or data collection.
Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management. *Medical Journal of Australia* 2010; 192: 127-132	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages through to submission • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was about 10%. I did not play any significant part in project design, implementation or data collection.
Chapman A, Bunker S, Dunbar A, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural Smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information

Manuscript details	Involvement of candidate
	My overall contribution to preparation of this manuscript was 15%. I did not play any significant part in project design, implementation or data collection.
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press].*	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: S. Bunker **Date:** 31 Jan 2012

Name: DR. STEPHEN BUNKER

Co-author Declaration: Ms Anna Chapman

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Chapman A, Bunker S, Dunbar A, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural Smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 15%. I did not play any significant part in project design, implementation or data collection.

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: A Chapman **Date:** 2/2/2012

Name: ANNA CHAPMAN

Co-author Declaration: Professor James A Dunbar

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, Detection and Treatment of Hypertension in Rural Australia; the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medical Journal* 2008;38(12):879-886	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 10-15%. I did not play any significant part in project design, implementation or data collection.
Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laatikainen TK. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management. *Medical Journal of Australia* 2010; 192: 127-132	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages through to submission • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was about 10%. I did not play any significant part in project design, implementation or data collection.
Chapman A, Bunker S, Dunbar A, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural Smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information

Page 1 of 5

Manuscript details:	Involvement of candidate
	My overall contribution to preparation of this manuscript was 15%. I did not play any significant part in project design, implementation or data collection.
Mc Namara KP, Dunbar JA, Philpot B, Marriott JL, Reddy P, Janus ED. The potential of pharmacists to help reduce the burden of poorly managed cardiovascular risk. *Australian Journal of Rural Health [In Press].*	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (jointly with Benjamin Philpot) • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was about 70%. I also advised on amendments to the data collection form that allowed this manuscript to be written. Apart from that I did not play any significant part in project design, implementation or data collection.
Mc Namara K, Philpot B, Janus ED, Dunbar JA. Greater Green Triangle Diabetes Prevention Program: remaining treatment gaps in hypertension and dyslipidaemia. *Australian Journal of Rural Health* 2010; 18: 43-44.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (jointly with Benjamin Philpot) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 65%. I advised on amendments to data collection that allowed this manuscript to be written. Apart from that I did not play any significant part in project design, implementation or data collection.
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As

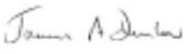
Manuscript details	Involvement of candidate
disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press].*	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).
Phase Three research	
Mc Namara KP, Dunbar JA, Marriott JL. Management of hypertension in primary care will benefit from basic health professional interventions [unpublished].	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was 75%. As principal chief investigator I initiated the project and led all aspects of development including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting.
Mc Namara KP, Marriott JL, Dunbar JA, Reddy P. The feasibility of practice audit as part of a sustained quality improvement	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages

Manuscript details	Involvement of candidate
program in community pharmacy: lessons from a hypertension control program [unpublished].	• Analysis and interpretation of data • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was 80%. As principal chief investigator I initiated the project and led all aspects of development including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting.

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date: 21 March 2012**

Name: Prof James A Dunbar

Page 5 of 5

Co-author Declaration: Mr Gregory Duncan

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press].*	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date:** 14/3/12

Name: Gregory Duncan

Page **2** of **2**

Co-author Declaration: Ms Jill Finch

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: JE Finch **Date:** 02 - 02 - 2012

Name: JILLIAN ELIZABETH FINCH

Page **2** of **2**

Co-author Declaration: Dr Johnson George

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press]*.	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date:** 31/01/12

Name: JOHNSON GEORGE

Page 2 of 2

Co-author Declaration: Dr Sami Heistaro

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, Detection and Treatment of Hypertension in Rural Australia; the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medical Journal* 2008;38(12):879-886	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 10-15%. I did not play any significant part in project design, implementation or data collection.
Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management. *Medical Journal of Australia* 2010; 192: 127-132	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages through to submission • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was about 10%. I did not play any significant part in project design, implementation or data collection.

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: [signature] **Date:** 3 FEB, 2012

Name: SAMI HEISTARO

Page 2 of 2

Co-author Declaration: Ms Helen Howarth

Declaration by Kevin Mc Namara ("the candidate") regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press]*.	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: [signature] **Date:** [date]

Name: [name]

Page 2 of 2

Co-author Declaration: Dr Shane Jackson

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press]*.	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date:** 31/1/2012

Name: SHANE JACKSON

Co-author Declaration: Professor Edward D Janus

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, Detection and Treatment of Hypertension in Rural Australia; the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medical Journal* 2008;38(12):879-886	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 10-15%. I did not play any significant part in project design, implementation or data collection.
Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management. *Medical Journal of Australia* 2010; 192: 127-132	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages through to submission • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was about 10%. I did not play any significant part in project design, implementation or data collection.
Chapman A, Bunker S, Dunbar A, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural Smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information

Manuscript details	Involvement of candidate
	My overall contribution to preparation of this manuscript was 15%. I did not play any significant part in project design, implementation or data collection.
Mc Namara KP, Dunbar JA, Philpot P, Marriott JL, Reddy P, Janus ED. The potential of pharmacists to help reduce the burden of poorly managed cardiovascular risk. *Australian Journal of Rural Health [In Press]*.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (jointly with Benjamin Philpot) • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was about 70%. I also advised on amendments to the data collection form that allowed this manuscript to be written. Apart from that I did not play any significant part in project design, implementation or data collection.
Mc Namara K, Philpot B, Janus ED, Dunbar JA. Greater Green Triangle Diabetes Prevention Program: remaining treatment gaps in hypertension and dyslipidaemia. *Australian Journal of Rural Health* 2010; 18: 43-44.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (jointly with Benjamin Philpot) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 65%. I advised on amendments to data collection that allowed this manuscript to be written. Apart from that I did not play any significant part in project design, implementation or data collection.
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As

Page 2 of 4

Manuscript details	Involvement of candidate
disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press].*	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: EDJ **Date:** 3/4/12

Name: E.D. JANUS

Page 4 of 4

Co-author Declaration: Dr Annamari Kilkinnin

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, Detection and Treatment of Hypertension in Rural Australia; the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medical Journal* 2008;38(12):879-886	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 10-15%. I did not play any significant part in project design, implementation or data collection.
Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management. *Medical Journal of Australia* 2010; 192: 127-132	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages through to submission • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was about 10%. I did not play any significant part in project design, implementation or data collection.

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: **Date: 16/2/2012**

Name: Annamari Lundqvist (neé Kilkkinen)

Page 2 of 2

Co-author Declaration: Adjunct Professor Tiina Laatikainen

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, Detection and Treatment of Hypertension in Rural Australia; the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medical Journal* 2008;38(12):879-886	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 10-15%. I did not play any significant part in project design, implementation or data collection.
Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management. *Medical Journal of Australia* 2010; 192: 127-132	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages through to submission • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was about 10%. I did not play any significant part in project design, implementation or data collection.
Chapman A, Bunker S, Dunbar A, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural Smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information

Manuscript details	Involvement of candidate
	My overall contribution to preparation of this manuscript was 15%. I did not play any significant part in project design, implementation or data collection.

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date:** 9th Feb 2012

Name: Tiina Laatikainen

Co-author Declaration: Associate Professor Jennifer L Marriott

Declaration by Kevin Mc Namara ("the candidate") regarding his contribution to the manuscripts presented in this thesis:

Manuscript details:	Involvement of candidate
Phase One Research	
Mc Namara KP, Dunbar JA, Philpot B, Marriott JL, Reddy P, Janus ED. The potential of pharmacists to help reduce the burden of poorly managed cardiovascular risk. *Australian Journal of Rural Health [In Press].*	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (jointly with Benjamin Philpot) • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was about 70%. I also advised on amendments to the data collection form that allowed this manuscript to be written. Apart from that I did not play any significant part in project design, implementation or data collection.
Phase Three research	
Mc Namara KP, Dunbar JA, Marriott JL. Management of hypertension in primary care will benefit from basic health professional interventions [unpublished].	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was 75%. As principal chief investigator I initiated the project and led all aspects of development including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting.
Mc Namara KP, Marriott JL, Dunbar JA, Reddy P. The feasibility of practice audit as part of a sustained quality improvement program in community pharmacy: lessons from a hypertension control program [unpublished].	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data • Submission of manuscript and drafting/coordination of revisions

Page 1 of 3

Manuscript details:	Involvement of candidate
	My overall contribution to the manuscript was 75%. As principal chief investigator I initiated the project and led all aspects of development including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting.

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date: 12 March 2012**

Name: A/Prof Jennifer Marriott

Page 3 of 3

Co-author Declaration: Ms Liz Morabito

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: [signature] **Date:** 3/2/12

Name: Elizabeth (Liz) Mordarski

Page 2 of 2

Co-author Declaration: Dr Sharleen O'Reilly

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press]*.	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: Sharleen O'R **Date:** 1/2/2012

Name: SHARLEEN O' REILLY

Page 2 of 2

Co-author Declaration: Mr Benjamin Philpot

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, Detection and Treatment of Hypertension in Rural Australia; the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medical Journal* 2008;38(12):879-886	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 10-15%. I did not play any significant part in project design, implementation or data collection.
Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management. *Medical Journal of Australia* 2010; 192: 127-132	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages through to submission • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was about 10%. I did not play any significant part in project design, implementation or data collection.
Chapman A, Bunker S, Dunbar A, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural Smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information

Manuscript details	Involvement of candidate
	My overall contribution to preparation of this manuscript was 15%. I did not play any significant part in project design, implementation or data collection.
Mc Namara KP, Dunbar JA, Philpot B, Marriott JL, Reddy P, Janus ED. The potential of pharmacists to help reduce the burden of poorly managed cardiovascular risk. *Australian Journal of Rural Health [In Press]*.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (jointly with Benjamin Philpot) • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was about 70%. I also advised on amendments to the data collection form that allowed this manuscript to be written. Apart from that I did not play any significant part in project design, implementation or data collection.
Mc Namara K, Philpot B, Janus ED, Dunbar JA. Greater Green Triangle Diabetes Prevention Program: remaining treatment gaps in hypertension and dyslipidaemia. *Australian Journal of Rural Health* 2010; 18: 43-44.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (jointly with Benjamin Philpot) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 65%. I advised on amendments to data collection that allowed this manuscript to be written. Apart from that I did not play any significant part in project design, implementation or data collection.
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As

Page 2 of 5

Manuscript details	Involvement of candidate
disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).
Mc Namara KP, O'Reilly S, Dunbar J, Bailey MJ, George J, Peterson GM, Jackson SL, Janus ED, Bunker S, Duncan G, Howarth H. A pilot study evaluating multiple risk factor interventions by community pharmacists to prevent cardiovascular disease. *The Annals of Pharmacotherapy [In Press]*.	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (with significant input from Michael Bailey) • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was 70-75%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and interpretation, and reporting (with the exception of stakeholder interviews).
Phase Three research	
Mc Namara KP, Dunbar JA, Marriott JL. Management of hypertension in primary care will benefit from basic health professional interventions [unpublished].	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was 75%. As principal chief investigator I initiated the project and led all aspects of development including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting.
Mc Namara KP, Marriott JL, Dunbar JA, Reddy P. The feasibility of practice audit as part of a sustained quality improvement	I led all aspects of this project and manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages

Manuscript details	Involvement of candidate
program in community pharmacy: lessons from a hypertension control program [unpublished].	• Analysis and interpretation of data • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was 75%. As principal chief investigator I initiated the project and led all aspects of development including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting.

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date:** 10/2/2012

Name: BENJAMIN PHILPOT

Co-author Declaration: Professor Prasuna Reddy

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Mc Namara KP, Dunbar JA, Philpot B, Marriott JL, Reddy P, Janus ED. The potential of pharmacists to help reduce the burden of poorly managed cardiovascular risk. *Australian Journal of Rural Health [In Press]*.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Analysis and interpretation of data (jointly with Benjamin Philpot) • Submission of manuscript and drafting/coordination of revisions My overall contribution to the manuscript was about 70%. I also advised on amendments to the data collection form that allowed this manuscript to be written. Apart from that I did not play any significant part in project design, implementation or data collection.

Page 1 of 2

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: Praguna Reddy **Date:** 20 March 2012

Name: PRAGUNA REDDY

Co-author Declaration: Professor Phil Tideman

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, Detection and Treatment of Hypertension in Rural Australia; the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medical Journal* 2008;38(12):879-886	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 10-15%. I did not play any significant part in project design, implementation or data collection.
Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management. *Medical Journal of Australia* 2010; 192: 127-132	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages through to submission • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was about 10%. I did not play any significant part in project design, implementation or data collection.

Page 1 of 2

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date:** 9/2/12

Name: DR PHILIP A TIDEMAN

Co-author Declaration: Ms Rosy Tirimacco

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Janus ED, Bunker SJ, Kilkkinen A, **Mc Namara K**, Philpot B, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, Detection and Treatment of Hypertension in Rural Australia; the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medical Journal* 2008;38(12):879-886	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 10-15%. I did not play any significant part in project design, implementation or data collection.
Janus ED, Tideman P, Dunbar J, Kilkinnen A, Bunker SJ, Philpot B, Tirimacco R, **Mc Namara K**, Heistaro S, Laaitikainen TK. Hypercholesterolaemia in Rural Australia: Prevalence and Treatment Gaps in Evidence Based Cardiovascular Risk Management. *Medical Journal of Australia* 2010; 192: 127-132	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages through to submission • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was about 10%. I did not play any significant part in project design, implementation or data collection.

Page 1 of 2

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: [signature] **Date:** 8/2/12

Name: Rosy Tirimacco

Co-author Declaration: Ms Peta Trinder

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase Two research	
Mc Namara KP, George J, O'Reilly S, Jackson SL, Peterson GM, Howarth H, Bailey MJ, Duncan G, Trinder P, Morabito L, Finch J, Bunker S, Janus E, Emery J, Dunbar, J. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010, 10:264.	I led all aspects of this manuscript, including: • Concept and design of the study • Writing of manuscript from draft stages • Submission of manuscript and drafting/coordination of revisions My overall contribution to preparation of this manuscript was about 70%. As principal chief investigator, I initiated and led all aspects of the project including conceptualisation, grant application, design and implementation, data management, statistical analysis and reporting (with the exception of stakeholder interviews).

Page 1 of 2

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature: P. Trinder **Date:** 1/2/12

Name: PETA TRINDER

Co-author Declaration: Professor Erkki Vartiainen

Declaration by Kevin Mc Namara ('the candidate') regarding his contribution to the manuscripts presented in this thesis:

Manuscript details	Involvement of candidate
Phase One Research	
Chapman A, Bunker S, Dunbar A, Philpot B, **Mc Namara K**, Baird A, Vartiainen E, Laatikainen T, Janus ED. Rural Smokers: a prevention opportunity for GPs. *Australian Family Physician* 2009 (30);5:352-356.	As part of the working group that drafted the initial versions of this manuscript, the nature of my contribution was in the following areas: • Concept and design of manuscript • Writing of manuscript from draft stages • Guiding and interpreting analysis • Specific advice on medication issues, and data management for medication information My overall contribution to preparation of this manuscript was 15%. I did not play any significant part in project design, implementation or data collection.

Page 1 of 2

Declaration by co-author

The undersigned hereby certify that:

1. the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors;
2. they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. there are no other authors of the publication according to these criteria; and
5. potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit.

Signature:  **Date:** 9.2.2012

Name: EKKEI VARTIAINEN

Appendix 2. Study protocol for Greater Green Triangle Risk Factor Studies

Protocol for non-communicable disease risk factor surveys

Greater Green Triangle

Limestone Coast Risk Factor Study

2004

Contents:

Annexes:

1 BACKGROUND

The Integrated Cardiac Assessment regional network (*i*CAR*net*) was established in rural South East of South Australia in 2001 to address the inequity of cardiac health outcomes between metropolitan and rural areas. *i*CAR*net*'s mission is "to improve outcomes for patients with Chest Pain, Acute Coronary Syndrome and other acute cardiac presentations through delivery of evidence-based Cardiac Care in Primary Care, particularly in regional, rural and remote settings". To date, information on the region's risk factor profile is lacking so the contribution of risk factors to the differential cardiovascular outcomes between urban, rural and remote areas is unknown.

The Greater Green Triangle University Department of Rural Health (GGT UDRH) is developing a public health program to tackle the health burden of non-communicable diseases (NCD), especially cardiovascular diseases (CVD), diabetes and cancer among the rural population. The overall aim is to concentrate on population-based approaches and community participation to reduce the major chronic disease risk factors, and to improve the related health behaviour among the population in the Greater Green Triangle area.

Continuing surveillance of levels and patterns of risk factors is of fundamental importance to planning and evaluation of preventive activities. Health monitoring provides a powerful tool to define disease burden, identify populations at the highest risk and determine the prevalence of health risks. Risk factor data is needed to:

- provide ongoing or routine prevalence estimates of NCD risk factors,
- track health trends over time,
- develop targeted programs, policy and legislation,
- evaluate program and policy progress and success, and
- demonstrate progress in meeting global or national health objectives.

Information on the risk factor profile and its changes in the population can also be effectively utilized in raising the awareness of health and health risks in the population.

Currently very little data on CVD or diabetes prevalence, especially their risk factors or underlying health behaviour is available for rural areas in Australia. Some information for the Greater Green Triangle area is available through Victorian Population Health surveys and South Australian Monitoring and Surveillance System. However, in these surveys, which are mainly computer assisted telephone interview (CATI) surveys, the sampling has been done at the state level and the database at local level is too small to allow detailed analysis. These databases contain only self-reported information and only provide useful information about health behaviour, use of health services and self reported data on illnesses and symptoms. They do not provide accurate information on physiological or biological risk factors such as blood pressure or cholesterol.

2 AIM OF THE SURVEY

The aim of the survey is to provide data on cardiovascular and other NCD risk factors among the population in the Greater Green Triangle area. Data can be utilized in the planning of community-based prevention programs. A further aim of the survey is to test the methodology of the risk factor surveys for future implementation of periodical health monitoring.

3 TARGET POPULATION

The target population of the survey is all 25 to 74 years old persons living in the Southeast of South Australia in year 2004. The age of the subjects will be defined according to December 31, 2004 (2004 – birth year), so selected subjects are born between 1930 and 1979.

4 SAMPLING

The sample size for the survey is 1000 persons and the sampling unit is an individual. The sample is drawn from electoral lists as a stratified random sample. Stratification will be made according to gender and ten year age groups. Exceptionally, the age group of 25-44 will be considered as one strata.

Age	**Men**	**Women**
25-44	125	125
45-54	125	125
55-64	125	125
65-74	125	125
Total	500	500

The name, sex, age, address, postal code and telephone number of the selected persons will be recorded in the sample database. A separate survey code will be given to each of the selected subjects. The questionnaires and blood samples are identified using this code.

5 TIMETABLE

Year	Month	Activity
2004	Feb-Apr	planning of the survey preparating survey protocol and questionnaire
	May-June	sampling
	May-June	procuring of equipment preparing other material
	May-June	Preparating databases and data entry programmes
	May-June	Recruiting nurses
	June	Training field workers
	June	Conducting small pilot study (included in the training)
	June-July	Sending invitation letters to participants
	Aug-Sep	Conducting field work (data collection)
	Aug-Oct	Performing laboratory analyses
	Sep-Oct	Entering data
	Nov-Dec	Checking data
	Dec-Jan	Analysing data and reporting

6 SURVEY COORDINATION

Steering Committee

The Steering Committee (SC) includes representatives from GGT UDRH and Flinders medical Centre. The Final Study protocol, recruitment of personnel and budgets need to be approved by the SC members. The Committee is also responsible for overseeing the legal and ethical issues. Regular Committee meetings would be held approximately once a month.

Project Working Group (PWG)

The project working group is responsible for managing all the practical issues of survey implementation. This include recruiting the personnel, preparing the protocols and other material needed for survey implementation (such as questionnaires, guides), taking care that the required equipment is available, organizing laboratory analyses and transferring of samples, preparing the data recording systems and database, keeping contact with survey sites and survey teams, organizing training of the personnel etc.

The PWG reports the activities carried out to the SC via the project coordinator. PWG will organize short working meetings as needed (approximately twice a month).

Fieldwork teams

Fieldwork is carried out by 2 survey teams assisted by local personnel. Each team includes two nurses. Local assistants are recruited locally for each survey site. Nurse 1 takes the physical measurements and Nurse 2 is responsible for blood sampling and field laboratory duties. Assistants can assist the team by introducing the survey protocol to the clients and helping them to complete the questionnaires and consent letters.

Steering Committee Members:

Edward Janus
Phil Tideman
James Dunbar
Tiina Laatikainen
Rosy Tirimacco

Survey Coordinating Team:

Tiina Laatikainen, Project Coordinator

Rosy Tirimacco, Coordinator for Laboratory Analyses

Lucinda Franklin, Field work Coordinator

IT person/ data manager

Secretary

Contact information for the Steering Committee and the Project Working Group is attached as annex 2.1.

Fieldwork teams:

List of study nurses is attached as annex 2.2.

7 DATA COLLECTION METHODS

The data collection follows closely the recommendations of the WHO MONICA project (protocol available at: http://www.ktl.fi/publications/monica/index.html) and the European Union European Health Risk Monitoring (EHRM) project (recommendations and protocol available from: http://www.ktl.fi/ehrm/).

7.1. Fieldwork organisation

Randomly selected participants are invited to a health check organized at specific survey sites. Three rooms are required for the purposes of the survey. List of survey sites and contact information are attached as annex 2.3. Survey team will spend 1 to 10 days in each survey site depending on how many participants from each region have been selected for the sample. After the main survey period one additional survey date will be conducted in some central survey sites to organize health checks to participants who were unable to attend during the survey period, or who were later contacted by the project secretary after missing their first given appointment.

The invitation to the health check will be sent by mail to each randomly selected participant and will include a pre-reserved appointment time. Two reply card will be included with the letter of invitation. The first confirms the participation in the survey and includes an option where participants can request that we contact them to reschedule the appointment time. The other card will indicate refusal. Participants are also given an opprotunity to contact the project secretary via a toll free (1800) number to arrange a more suitable appointment time. The patient information sheet and survey questionnaire will be included in this first mail out and participants are asked to complete the questionnaire prior to attending the health check.

Field work days will start at 8.00 am. Participants are scheduled at 10-15 minute intervals, and the survey time for each participant is approximately 30 min (15 min for physical measurements + 15 min for blood sampling). The last participant each day will be scheduled to arrive at 12.00 noon. All participants are asked to arrive after fasting (for at least 12 hours). The structure of a survey day timetable is attached as annex 2.4.

7.2. Division of tasks and order of the measurements at survey sites

Each team will include three workers: Nurse 1, Nurse 2 and an Assistant. Nurse 1 will carry out the physical measurements, Nurse 2 will be responsible for field laboratory and the Assistant will help both the participants and nurses with administrative duties.

Project secretary

The project secretary will update the timetables for field survey days and inform the survey teams of any changes. All survey teams will have their original timetables. The secretary will distribute updated timetables each day for the following day's appointments by email/fax to survey sites. If a survey team does not receive its' daily timetable, they can contact the project secretary and update the original timetables over the telephone. An example of a daily timetable is attached as annex 2.5.

Local assistant

At each survey site, the Assistant will check participants' identities and contact information and record potential changes to the survey diary. The Assistant will introduce participants to the contents of the survey and ask participants to complete the consent form. The Assistant will ensure that the take-home questionnaire has been completed, and will follow-up with participants if required. The Assistant will maintain contact with the project coordinator and the project secretary, and is able to assist the study nurses if required.

Nurse 1 (anthropometric measureement, blood pressure measurement)

Nurse 1 will be based in a quiet room at each survey site. She will introduce herself and her tasks to the participant and ask her/him to take off shoes and remove heavy outer garments (jackets, pullovers, jeans, belts). Nurse 1 will then carry out the physical measurements in the following order:

1. Arm circumference measurement
2. First measurement of blood pressure
3. Pulse measurement
4. Second measurement of blood pressure
5. Height measurement
6. Weight measurement
7. First measurement of waist
8. First measurement of hip
9. Second measurement of waist

10. Second measurement of hip

Following the physical measurements Nurse 1 will give feedback to the participant and guides the participant to blood sampling. More detailed instruction for measurement protocol and calibration of equipment is attached as annex 2.6.

The approximate timing for these measurements is: introduction to participant 2 (min), blood pressure measurement 5 (min), height and weight 2 (min), waist and hip 3 (min), feedback and guidance to next survey point 3 (min) = 15 minutes.

Nurse 2 (blood sampling and separation)

Nurse 2 will take the blood samples, centrifuges them and separates the serum samples. Blood will be drawn from the left arm of the subject to fill three 10 ml vacuum tubes (one 10 ml serum gel tube, one 10 ml EDTA plasma tube, one 10 ml Lithium heparin tube). Samples will be centrifuged and separated at the survey site being to the Flinders Medical Centre Laboratory for analysis.

Blood samples will be drawn in the following order:

1. Tube A (10 ml gel serum tube)
2. Tube B (10 ml Lithium heparin tube)
3. Tube C (10 ml EDTA plasma tube)

After the blood is drawn the following steps are taken:

Tube A (S11)

1. Tube is allowed to clot at 20-24 ° C for at least 20-30 minutes.
2. Blood is centrifuged at least within one hour after blood collection.
3. Blood is span in centrifuge for 10 minutes at 1500-1600 G.
4. The serum is promptly separated from clot or cells and transferred to clean transfer tubes. Each sample is divided to three equal aliquots (ss21, ss22, ss23) to smaller transfer tubes.

Tube B (F12)

1. The tube will be inverted 8 times toward the stopper immediately after draw (while the next tube is filling up).
2. Blood is centrifuged at least within 30 minutes after blood collection.
3. Blood is span in centrifuge for 10 minutes at 1500-1600 G.
4. The serum is promptly separated from clot or cells and transferred to three clean transfer tubes. Each sample is divided to one 1.5 ml aliquot (fp24) to 5 ml transfer tube and two 1.0 ml aliquots (f25, f26) to smaller transfer tubes.

Tube C (P13)

1. The tube will be inverted 8 times toward the stopper immediately after draw.
2. Tube is opened and the first 0.5 ml aliquot of whole blood is diverted to tube b20, which goes for Hb1Ac analyses.
3. Tube is closed with a stopper.
4. Blood is centrifuged as soon as possible after blood collection.
5. Blood is span in centrifuge for 10 minutes at 1500-1600 G.
6. The plasma is promptly separated from clot or cells and transferred to clean transfer tubes. Each sample is divided to three 1.0 ml aliquots (p27, p28, p29) to small transfer tubes.

All tubes are clearly marked with a sticker including the subject's survey code and an aliquot code indicating the further use of the aliquot (see the chart 1).

As tube A will need clotting time and tube C should be centrifuged as soon as possible after sampling, it is recommended that all the tubes will be centrifuged 20-25 (min) after sampling. After a sample is drawn an alarm clock will be set to 20 (min) and centrifuging should start immediately after the alarm.

After separation of serum, the transfer tubes will be placed in special storage boxes and should be frozen immediately to -20°C. Samples will be divided to transfer boxes so that Box 1 will include b20 (HbA1c) samples and Box 2 will include ss21, ss22 and ss23 (storage) samples, Box 3 will include f25 and f26 (storage) samples and Box 4 will include p27, p28 and p29 (storage) samples (see chart 2). Samples fp24 (fp-gluc) will be packed to small ice boxes (Box 5) with log sheets describing the content. Frozen samples will be transferred to Flinders University after the fieldwork period is completed. Samples should not be thawed during transportation. More detailed protocol for laboratory procedures is attached as annex 2.7.

7.3. Questionnaire

The survey questionnaire will be sent to participants together with the invitation. Participants will be asked to complete the questionnaire before attending the health check. The Assistant at the survey site will provide assistance with the completion of the questionnaire if required (for example, if participants have difficulty understanding a question or want to ask questions about the survey). If a participant leaves the questionnaire at home, she/he will be asked to complete another one at the survey site. Questionnaires will be labelled with the participant's survey code. The last page of the questionnaire will be used for recording the physical measurements. The survey questionnaire is attached as annex 2.8.

7.4. Anthropometric measurements

Height measurement

Height will be measured in all participants except wheelchair-bound individuals or persons who have difficulty standing. Height is measured by stadiometer attached to the wall or using a measuring rod attached to the scale. Before each measurement the height rule attached to the wall will be checked by pulling the head piece against floor and checking the reading.

Participants will be asked to remove their shoes and hair ornaments. The participant will be asked to stand with his/her back to the height rule. The back of the head, back, buttocks, calves and heels should be touching the upright rule, standing with feet together. The top of the external auditory meatus should be level with the inferior margin of the bony orbit (cheek bone). The participant will be asked to look directly ahead. The head piece of the stadiometer will be lowered so that the hair is pressed flat. Height will be recorded to the resolution of the height rule (1mm). If the participant is taller than the person taking the measure, the measurer should stand on a platform so that he/she can properly read the height rule at eye-level.

If the particpant is excluded from the height measurement, the reason is recorded in the questionnaire.

Weight measurement

Weight should be measured in all participants except wheelchair-bound individuals or persons who have difficulty standing steady. Weight will be measured by a beam-balance scale.

The scale will be placed on a hard-floor surface. It is important to verify that the surface on which the scale is placed is horizontal. After placing the scale on the floor it will be tested in order to check that it gives the zero value.

Participants will be asked to remove their heavy outer garments and shoes, empty pockets and remove heavy belts and items. The participant will stand in the centre of the platform, with weight evenly distributed to both feet. Weight will be recorded to the resolution of the scale (0.1 kg).

Waist measurement

The waist will be measured with a plastic tailor's measuring tape (length 3 meters). The length of the tape is checked every second week against the height rule. If the measuring tape is streched it should be replaced.

Waist circumference will be measured at a level midway between the lower rib margin and the iliac crest with a tape around the body in a horizontal position. Participants will be asked to remove their clothes, except for light underwear. Tight clothing, including belt, should be loosened and the pockets emptied. The measurer should sit at a side of the participant in order to watch the tape at eye level. Participant should be standing with their feet fairly close together (about 12-15 cm apart) with their weight equally distributed to each leg. Participants will be asked to breathe normally and the reading of the measurment will be taken at the end of gentle exhaling. The measurment tape should be held firmly in the horizontal position. Measurments will be recorded according to the resolution of the tape.

Hip measurement

Hip circumference will be measured as the maximal circumference over the buttocks. The measurement procedure is the same as for waist measurement with exception for tape position.

7.4. Blood pressure measurement

Blood pressure will be measured with a simple mercury sphygmomanometer. Normally a standard cuff size 14 x 40 cm will be used. If participant's arm circumference is much more than 35 cm, a larger cuff is used. Blood pressure will be measured in sitting position after at least 5 minutes rest. The sleeve of shirts, blouses etc should be rolled up so that the upper arm is bare. The remaining garments should not be constrictive and the blood pressure cuff should not be placed over garments.

Measurments will be taken in a sitting position so that the arm and back are supported. Participant's feet will be resting firmly on the floor, not dangling. Measurement will be taken from the right arm. The arm should be resting on the desk so that the antecubital fossa is levelled with the heart and the palm is facing up.

The cuff should be placed on the right arm and its bottom edge should be 2-3 cm above the antecubital fossa, allowing sufficient room for the bell of the stethoscope. The top edge of the cuff should not be restricted by clothing.

Two measurments will be taken one minute apart. A 30 second pulse will be measured between the measurments. If the two readings differ by more than 10 mmHg systolic or 6 mmHg diastolic, a third measurment will be made.

Procedure of the pulse rate and blood pressure measurement

1. The manometer will be placed so that the scale is at eye-level and the column perfectly vertical. The mercury column should be at level 0.
2. The subjects radial pulse will be palpated. The cuff will be inflated 30 mmHg higher than where the radial pulse disappears.
3. The brachial pulse will be located and the bell of the stethoscope will be placed immediately below the cuff at the point of maximal pulsation.
4. The cuff will be deflated at a rate of 2 mmHg per second until the first Korotkoff sound is heard. After that the cuff is deflated not faster than 2 mmHg per heart beat.
5. The first appearance of a clear, repetitive tapping sound (Korotkoff Phase 1) will be recorded as the systolic pressure. The disappearance of repetitive sounds (Phase 5) will be recorded as the diastolic pressure.
6. The measurments will be recorded to the nearest 2 mmHg so that the systolic pressure is the first sound heard and the diastolic is the first sound not heard.
7. After first measurement the cuff should be properly deflated.
8. The radial pulse will be counted for 30 seconds and recorded in the questionnaire.
9. The second blood pressure measurement will be made at least one minute apart after the first one.

7.5. Non-participants

If a participant contacts the project secretary either by phone or using the reply card to inform them that he/she is not able to attend the health check, the non-participation will recorded in the daily timetables. If the participant informs about his/her refusal to the survey team by phone, a permission to contact him/her later to carry out a short telephone interview will be asked. If the particpant returns the reply paid card indicating refusal, he/she can only be contacted if she/he has stated so in the card. If the participant does not arrive at the survey site and has not contacted the project secretary or sent back a card indicating refusal, a sent out of a follow-up letter will be made. For telephone interviews a shortened version of the main survey questionnaire will be used.

7.6. Feedback

Each participant will be provided feedback, both at the survey site and on completion of the survey as soon as laboratory analyses are completed. Nurse 1 will provide feedback from the anthropometric and blood pressure measurements. Results from the laboratory tests will be sent by mail to all participants. In the feedback letter interpretation of results will be explained. If any abnormalities are found either in the measurements or laboratory tests, the participants will be adviced to contact their GP.

8. EQUIPMENT

Equipment	**No**	Model **or other important details**
Sample and protocols:		
Sample lists		
Protocols for measurements and field laboratory		
Timetables for field working days		
Questionnaires:		
Questionnaires	1200	
Consent letters	1000	
Measurement equipment:		
Mercury sphygmomanometer	3	Cuff size about 14 x 40 cm
Stethoscope	3	With both bell and diaphragm
Stadiometer	3	At least 200 cm
Beam balance scale	1	
Digital scale (bathroom scale)	2	
Measuring tapes	6	At least 200 cm
Portable stands for sphygmomanometers	2	
Other equipment:		
Stopwatch	2	
Blood sampling:		
10 ml gel vacuum tubes for serum sampling	1000	
10 ml vacuum EDTA tubes	1000	
10 ml vacuum Litium Heparin tubes	1000	
Needles	1000	20 – 22 G
Disposable pipettes or pipettes with changeable apex	3000	One for each type of blood sample
Vacutainer holders	6	
Tourniquet	4	
Disinfection swabs	1000	
Micropore tape	10	
Adhesive dressing	1000	
Rubber gloves	4 pack	
Pillow or other support	2	
Sparate stoppers for opended vacuum tubes	100	

and non-vacuum tubes		
Tubes for transferring serum and plasma	9 000	9 per each participant
Needle disposal box	4	
Centrifuge	1-2	Capapable of 3000g, if gel tubes used, centrifuge should have swinging bucket rotor
Timer	8	
Racks for tubes	6+6	
Special boxes for tube transfer and storage	70	Different sizes for different tubes
Labels with identification codes (survey codes)	1000	
Freezer	1-2	Possibility to use some freezer at survey site
Disinfection handwash liquid	6	
Office equipment:		
Tape (adhesive)	4	
Pencils	100	
Scissors	4	
Paper		
Mailing material (envelopes etc)		
Transfer:		
Ice boxes	4	
Packing material		
Dry ice		

9. DATA RECORDING AND MANAGEMENT

Sample data will be stored separately form the survey data. Sample data includes personnal information (name, address, birthdate, sex, telephone number, survey code, participation, reason for non-participation). Sample data is originally received from the electoral rolls. The information on participation and non-participation will be recorded later. The sample database will be secured and a password will be needed to use the database.

All self-reported data will be collected through the survey questionnaire. Questionnaires will not include names or other personal data. Each questionnaire will be labelled with a sticker including the survey code. Results of the physical measurements will also be recorded in the questionnaire (last page). Questionnaires will be sent to the GGT UDRH and the data will be entered in the database using Microsoft Access programme. Data recording instructions

are attached as annex 2.9. Observations will be identified using survey codes given to each participant. Any personal information will not recorded in the questionnaire database.

Data of laboratory analyses will be sent electronically to GGT UDRH as excel files. Survey codes will be used to identify samples. No personal information will be transferred with results of the laboratory analyses.

Data on non-participants will be recorded into separate questionnaires and entered using Microsoft Access programme to a separate database (non-participants questionnaire database).

Questionnaire data, laboratory data and data on non-participants will be linked to one dataset using the survey code (observation code). No personnal information will be recorded in the survey database.

Annex 2.1

Contact List for Limestone Coast Risk Factor Study

Title	First Name	Surname	Position	Phone	Fax	Mobile	Email
Professor	James	Dunbar	Steering committee	03 5563 3315	03 5563 3144	0407 725 157	james.dunbar@greaterhealth.org
Ms	Lucinda	Franklin	Field work coordinator	03 5563 3525	03 5563 3144	0417 358 478	lucinda.franklin@greaterhealth.org
Professor	Edward	Janus	Steering committee	03 5381 9168	03 5381 9357 03 5571 2141	0409 700 675	januse@netspace.net.au
Doctor	Tiina	Laatikainen	Project coordinator	03 5563 3549	03 5563 3144	0400 920 609	tiina @deakin.edu.au tiina.laatikainen@greaterhealth.org
Mrs	Anna	Philpot	Research assistant	03 5563 3574	03 5563 3144	0408 613 061	anna.kao@greaterhealth.org
Mr	Richard	Sager	Research fellow	03 5563 3565	03 5563 3144	0412 341 622	richard.sager@greaterhealth.org
Doctor	Phil	Tideman	Steering committee	08 8404 2001	08 8404 2150	0438 500 415	phil.tideman@fmc.sa.gov.au
Ms	Rosy	Tirimacco	Coordinator for laboratory analysis	08 8404 2027	08 8404 2150	0412 749 418	rosy.tirimacco@flinders.edu.au

Flinders Medical Centre
Bedford Park, South Australia 5042

Greater Green Triangle University Department of Rural Health (GGT UDRH)
PO Box 423, Warrnambool, Victoria 3280

Hamilton Office
Foster Street, Hamilton, Victoria 3300

Annex 2.2

Field Workers and Contact Information

First Name	Surname	Responsibility	Survey Site	Contact Address	Phone	Email
Elaine						
Karen						
Josie						
Kate						
Chris						
Christine						
Karalyn						

Survey sites and contact information

Town	Survey site	Address	Contact person	Telephone/fax	Additional notes
Mount Gambier	Mount Gambier Hospital	Wehl St, Mount Gambier SA, 5290		(08) 8721 1200	
Penola	Penola & District Hospital	18 Church St, Penola SA, 5277		(08) 8737 2311	
Millicent	Millicent Hospital	Mt Gambier Rd, Millicent SA, 5280		(08) 8733 0100	
Kingston	Kingston Soldiers Memorial Hospital	Young St, Kingston SA, 5275		(08) 8767 0222	
Naracoorte	Naracoorte Health Service	Jenkins Tce, Naracoorte SA, 5267		(08) 8762 8100	
Lucindale	Lucindale Community Health Centre	Musgrave Ave, Lucindale SA, 5272		(08) 8766 2656	OPEN MON. & THURS. PM ONLY
Bordertown	Bordertown Memorial Hospital	23 South Terrace, Bordertown SA, 5268		(08) 8752 9000	
Keith	Keith & District Hospital	Hill Ave, Keith SA, 5267		(08) 8755 1555	
Robe	Robe Community Health Centre	Smillie St, Robe SA, 5276		(08) 8768 2012	

Timetable for inviting the participants

7.50 *
8.00 N
8.10 N
8.20 N
8.30 N
8.40 N
8.50 *
9.00 N
9.10 N
9.20 N
9.30 N
9.40 N
9.50 *
10.00 coffee break
10.20 N
10.30 N
10.40 N
10.50 *
11.00 N
11.10 N
11.20 N
11.30 N
11.40 N
11.50 *

N = normal appointment time, timetabelled beforehand
* = spare time (can be given out by the project secretary, when contacted by the participant)

18 timetabelled appointments / day
→ for 1000 participants 11 survey weeks are needed + some extra days (appr 1/survey site) for reminder rounds → 12 survey weeks

With 70 % participation rate there will be 12-13 participants/day
→ 4 participants/working hour → creates a bit more flexibility and recess times to the timetable

Example of a Daily Time Table

Town: Mount Gambier
Survey Site: Mount Gambier Medical Clinic
Site Address: 12 Gambier Street, Mount Gambier, SA
Telephone / Fax: 08 8444 6636 / 08 8444 6637
Survey Day and Date: Monday, 19 July 2004

* = spare time slots

Time	Name of Participant & Contact Details	Survey Code	Notes
08:00	Mr Simon Jones 9 Crest Crescent, Mt. Gambier SA 5290	***Adhere "Survey code Label" here***	
08:10	Mr Steven Gillies 1/31 Union Road Mt. Gambier SA 5290	***Adhere "Survey code Label" here***	
08:20	Mrs Jane Sigmond 223 High Street Mt. Gambier SA 5290	***Adhere "Survey code Label" here***	
08:30	Mr Charlie Milligan 77 Monty Road Mt. Gambier SA 5290	***Adhere "Survey code Label" here***	
08:40	Miss Katie Fischer 11/73 Sunset Boulevard Mt. Gambier SA 5290	***Adhere "Survey code Label" here***	
08:50 *	Ms Jamie Lee 12 Serenity Street Mt. Gambier SA 5290	***Adhere "Survey code Label" here***	Rescheduled appointment on 16 July with Project Secretary by phone. Mob: 0408 912 313

NB. Actual Daily Time Table will include time slots up to 11:50

Protocol for anthropometric and blood pressure measurements

In the Limestone Coast Risk Factor Survey the anthropometric measurements are done in the following order:

1. Arm circumference measurement
2. First measurement of blood pressure
3. Pulse measurement
4. Second measurement of blood pressure
5. Height measurement
6. Weight measurement
7. First measurement of waist
8. First measurement of hip
9. Second measurement of waist
10. Second measurement of hip

1. Arm circumference measurement

Equipment needed:

- Measuring tape

Calibration of equipment:

The measuring tape needs to be changed regularly as the plastic tape stretches easily in heavy use. The length of the measuring tape is checked with the length rod (metallic) at least after every two weeks. If the tape is stretched it should be replaced.

Measurement procedure:

The measurement should be made on the right arm whenever possible. The subject should remove outer garments and all other tight clothes. The sleeve of shirts, blouses etc should be rolled up so that the upper right arm is bare. The remaining garments should not be constrictive.

The subject's arm should be resting on the desk. The greatest circumference of the upper arm is measured, with the arm relaxed. The measurement is read to the nearest half centimeter. The reading is recorded on the last page of the survey questionnaire (question 2).

2. Blood pressure measurement

Equipment needed:

- Sphygmomanometer
- Stethoscope
- Cuffs (two different sizes)

Calibration of equipment:

The sphygmomanometer is checked every day. Before the measurements the mercury column of the sphygmomanometer should be at zero. The mercury column should fall smoothly when the cuff is deflated and the column should latch properly into vertical position. Equipment failing in the testing has to be replaced.

After every measurement it is important to deflate the cuff properly by pressing it firmly with both hands and to ensure that the mercury column return back to the zero level.

Preparation for measurement:

Before the blood pressure measurement begins the following conditions should be met:
1. Subjects should abstain from eating, drinking, smoking and taking drugs that affect the blood pressure one hour before measurement
2. Because a full bladder affects blood pressure, it should have been emptied
3. Painful procedures and exercise should not have occurred within one hour
4. Subject should have been sitting quietly for about 5 minutes
5. Subject should have removed outer garments and all other tight clothes. The sleeve of shirts, blouses etc. should have been rolled up so that the upper right arm is bare. The remaining garments should not be constrictive and the blood pressure cuff should not be placed over the garment.
6. Blood pressure should be measured in a quiet room with comfortable temperature.
7. The time of day should have been recorded to the last page of the survey questionnaire (question 1).
8. The blood pressure measurer should have written her code to the survey questionnaire (will be recorded on the last page, next to the blood pressure question).

Position of the subject and arm:

Measurements are taken in sitting position so that the arm and back are supported. Subject's feet should be resting firmly on the floor, not dangling. If the subject's feet do not reach the floor, a platform should be used to support them.

The measurement is made on the right arm whenever possible. The subject's arm should be resting on the desk so that the antecubital fossa (a triangular cavity of the elbow joint that contains a tendon of biceps, the median nerve and the brachial artery) is at the level of the heart and palm is facing up. The subject must always feel comfortable.

Selection and placement of the cuff:

The basic cuff (alternative adult, 13.5 x 36 cm) is used if the arm circumference is less or equal to 36 cm. The bigger cuff (17 x 38 cm) is used if the arm circumference is over 36 cm.

The cuff should be placed on the right arm so that its bottom edge is 2-3 cm above the antecubital fossa, allowing sufficient room for the bell of the stethoscope. The top edge of the cuff should not be restricted by clothing.

Stethoscope

The bell of the stethoscope should be used because it gives clearer sounds than the diaphragm.

Procedure of the pulse rate and blood pressure measurement

1. The radial pulse is palpated and checked to determine it is regular.
2. The manometer should be placed so that the scale is at eye level, and the column is perfectly vertical. The subject should not be able to see the column of the manometer.
3. The brachial pulse is located and the bell of the stethoscope is place immediately below the cuff at the point of maximal pulsation. If it is not possible to feel the brachial pulse, the bell of the stethoscope should be placed over the area of the upper arm immediately inside the biceps muscle tendon. The bell should not touch the cuff, rubber or clothing.
4. Determining the peak inflation level:
   - The mercury column has to be at 0 level
   - The subject's radial pulse is again palpated
   - The cuff is inflated and the level of the top of the meniscus of the mercury column is noted at the point when the radial pulse disappears.
   - The peak inflation level is determined by adding 30 mmHg to the pressure where the radial pulse disappeared
5. The cuff is then deflated at a rate of 2 mmHg per second.
6. The pressure should be reduced steadily at this rate until the occurrence of the systolic level at the first appearance of a clear, repetitive tapping sound (Korotkoff Phase 1) and diastolic level at disappearance of repetitive sounds (Phase 5) have been observed. Then the cuff should be rapidly deflated by fully opening the valve of the inflation bulb. ***Note:*** There may be a brief period (auscultatory gap) between systolic and diastolic pressure, when no Korotkoff sounds are heard. Therefore 2 mmHg/second deflation should be continued until the diastolic blood pressure is definitely established. If Korotkoff sounds persist until the cuff is completely deflated, a diastolic blood pressure of 0 should be recorded.
7. The measurement is recorded in the questionnaire (last page question 3) to the nearest 2 mmHg. If the top of the meniscus falls half way between two markings, the marking immediately above is chosen. The subject is not told the blood pressure values at this point.
8. Wait one minute to allow redistribution of blood in the forearm then take a second measurement by repeating the steps 6-8. While waiting the 30 second pulse is measured. The subject should not change position while waiting.

9. If the second measurement differs more than 10 mmHg systolic or 6 mmHg diastolic from the first measurement a third measurement is made after waiting another minute.
10. After all the measurements, the subject may be told the measurement values.

3. Pulse measurement

Equipment

A stopwatch or a timer is needed for the pulse measurement.

Pulse measurement procedure

Pulse is measured between the first and second blood pressure measurements. The radial pulse is palpated from the right arm of the subject and the pulse rate is counted for 30 seconds. The rate is recorded in the last page of the questionnaire (question 3).

4. Height measurement

Equipment needed:

- Measuring rod mounted on balanced beam scale or wall mounted stadiometer with movable head piece

Setting up and calibration of equipment:

If height is measured with the measuring rod attached to the scale no further set-up procedures are required. However, it should be verified that the upper part of the measuring rod is straight and vertical (i.e. not bent and curved).

If height is measured by a stadiometer, the height rule is taped vertically to the hard flat wall surface with the base at floor level. The wall may not have a baseboard molding.

At the beginning and in the middle of each examination day, the height rule should be checked and corrected if the error is greater than 2 mm. The wall mounted stadiometer is checked by pulling the head piece towards the floor when the reading in the stadiometer should be 0.

Measurement procedure:

Height is measured from all participants, except wheelchair bound individuals, persons who have difficulty standing steady or straight and participants with hairstyle or head dress that can not be removed and that prevents proper use of the height measuring equipment (e.g. turban).

1. Participants are asked to remove their shoes, heavy outer garments, and hair ornaments.

2. The participant is asked to stand with his/her back to the height rule. The back of the head, back, buttocks, calves and heels should be touching the upright, feet together. The top of the external auditory meatus (ear canal) should be level with the inferior margin of the bony orbit (cheek bone). The participant is asked to look straight.
3. The head piece of the stadiometer or the sliding part of the measuring rod is lowered so that the hair is pressed flat.
4. Height is recorded to the resolution of the height rule (i.e. nearest millimeter) on the last page of the survey questionnaire. If the participant is taller than the measurer, the measurer should stand on the platform so that she/he can properly read the height rule.

Exceptions

If the participant is taller than the scale of the height rule, no height measurement should be made and this fact, together with the upper limit of the height rule, should be recorded in the data collection form.

Self-reported data is not acceptable, even if the participant is immobile or refuses to have his/her height measured.

5. Weight measurement

Equipment needed:

- Balanced beam scale

Setting up and calibration of equipment:

The scale should be placed on a hard-floor surface. It should be verified that the surface is horizontal.

The scale needs to be calibrated at the beginning of each examination day. The scale is balanced with both sliding weights at zero and the balance bar aligned.

Measurement procedure:

Weight is measured from all participants, except pregnant women, wheelchair bound individuals, persons who have difficulty standing steady.

1. The participant is asked to remove their heavy outer garments (jacket, coat, trousers, skirts, etc.) and shoes. If subject refuse to remove trousers or skirt, at least make them empty their pockets and record the fact in the data collection form.
2. The participant stands in the center of the platform, weight distributed evenly to both feet. Standing off-centre may affect measurement.

3. The weights are moved until the beam balances (the arrows are aligned).
4. The weight is recorded on the last page of the questionnaire to the resolution of the scale (the nearest 0,1 kg).

Exceptions

If the participant is heavily overweight, i.e. weights more than the upper limit of the scale, this fact should be noted in the data collection form, together with the upper limit of the scale.

Self-reported data is not acceptable, even if the participant is immobile or refuses to have his/her weight measured.

6. Waist and hip circumference measurement

Equipment needed:

- Measuring tape

Calibration of equipment:

The measuring tape needs to be changed regularly as the plastic tape stretches easily in heavy use. The length of the measuring tape is checked with the length rod (metallic) at least after every two weeks. If the tape is stretched it should be replaced.

Waist measurement procedure:

Waist circumference should be measured at a level midway between the lower rib margin and iliac crest with the tape all around the body in horizontal position.

1. The participant is asked to remove their clothes, except for light underwear. If this is not possible, for example due to cultural reasons, the alternative is to measure the circumference on the subject without heavy outer garments (jacket, coat, trousers, skirts, etc.) and record this fact in the data collection form. Tight clothing, including the belt, should be loosened and the pockets emptied.
2. The measurer should sit at the side of the participant in order to have a clear view to the readings in the tape.
3. Participants should be standing with their feet fairly close together (about 12-15 cm apart) with their weight equally distributed to each leg. Participants are asked to breathe normally; the reading of the measurement should be taken at the end of gentle exhaling. This will prevent subject from contracting their abdominal muscles or from holding their breath.
4. The measuring tape is held firmly, ensuring its horizontal position. The tape should be loose enough to allow the observer to place one finger between the tape and the subject´s body.
5. Measurements are recorded to the nearest half centimeter.

Exceptions

If the participant is heavily overweight, i.e. waist circumference exceeds the length of the tape, this fact should be noted in the data collection form, together with the maximum length of the tape.

Self-reported data is not acceptable, even if the participant is immobile or refuses to have his/her waist measured.

Hip measurement procedure:

Hip circumference should be measured as the maximal circumference over the buttocks.

1. The participant is asked to remove their clothes, except for light underwear. If this is not possible, for example due to cultural reasons, the alternative is to measure the circumference on the subject without heavy outer garments (jacket, coat, trousers, skirts, etc.) and record this fact in the data collection form. Tight clothing, including the belt, should be loosened and the pockets emptied.
2. The measurer should sit at the side of the participant in order to have a clear view to the readings in the tape.
3. Participants should be standing with their feet fairly close together (about 12-15 cm apart) with their weight equally distributed to each leg. Participants are asked to breathe normally..
4. The measuring tape is held firmly, ensuring its horizontal position. The tape should be loose enough to allow the observer to place one finger between the tape and the subject´s body.
5. Measurements are recorded to the nearest half centimeter.

Exceptions

If the participant is heavily overweight, i.e. hip circumference exceeds the length of the tape, this fact should be noted in the data collection form, together with the maximum length of the tape.

Self-reported data is not acceptable, even if the participant is immobile or refuses to have his/her waist measured.

Protocol for field laboratory

1. Safety issues

- Eating is not permitted in field laboratory
- Nurses working in the field laboratory should use laboratory overalls
- Tables should be kept clean and wiped regularly each day with a sterilizing agent. If any blood is spattered in the laboratory the stain should be wiped with spirit.
- Plastic gloves should be used both in blood sampling and handling. If personnel drawing blood samples are not used to using gloves they should wash their hands between all the subjects.
- The needle is released from the adapter directly into the needle disposal box. Needles should never be re-sheathed after use. The disposal boxes should not be allowed to become overfull as this increases potential hazard.

2. Needle stick injuries

In the event of a needle stick injury, seek immediate advice from the local health personnel responsible for advising in situations with risk of communicable diseases. The ´first aid´ instructions in the event of a needle stick injury are:

1. Do not panic. Make sure that injury does not happen again.
2. Clean the possible infected area:
    a. Rinse with substantial amount of water
    b. Do not squeeze wounded area
    c. If you have blood on eczema or on puncture wound, place a patch with alcohol (at least 70%) over it for two minutes
3. Contact the local health personnel responsible for infectious diseases to get further instructions.

3. Special situations

If the subject loses consciousness or feels dizzy during the blood sampling, it should be discontinued. The subject should be asked to place his/her head between their knees. He/she should subsequently be asked to lie down.

If the participant has an illness or other condition that prevents the sampling following the protocol, the sample should be drawn following participants instructions concerning the procedure (arm, position) and amount of samples drawn. Any exceptions should be recorded to the questionnaire.

If the participant is pregnant, the principle is that the all samples are drawn normally. However, it is good to ask the participant whether she is anemic. If her serum hemoglobin is less than 110, only two first samples are drawn. If her serum hemoglobin is less than 100, the samples are drawn only if the participant wishes this to be done. Any exceptions from normal protocol need to be recorded to the protocol.

If there are any problems in the blood flow during the blood taking (e.g. collapsing vein), the procedure should be discontinued and an attempt should be made on the other arm. If that also fails, no further attempts should be made. The result of blood collection should be recorded in the last page of the questionnaire (question 9).

4. Preparation of patients before the sample collection

Fasting

As fasting glucose and triglycerides are to be measured, the samples will be collected after a fasting period. The participants are invited to attend the survey after fasting at least 12 hours. However, for fasting glucose measurement, fasting of four hours is sufficient and for triglycerides 10 hours fasting is sufficient. Fasting for too long can cause changes in energy metabolism with implications for blood triglycerides, therefore the fasting should not be longer than 14 hours.

Every participant needs to be asked the length of time that they fasted. This is to be recorded in the last page of the survey questionnaire (question 7).

Previous infections

Participants are also asked about probable severe infections during the last week, as these may affect the CRP analyses. If the participant has had any infection with fever or infection that needed treatment with antibiotics, it needs to be recorded in the last page of the questionnaire (question 8). Mild flu (without fever) and equivalent needs not to be recorded.

Position of the subject and the arm used for blood collection

The position of the subject and any procedures carried out with participant before blood collection can influence the equilibration of the concentrations of blood components and thus can have affect on different laboratory measures i.e. cholesterol values.

The samples should be drawn in a sitting position. The participant should remain in sitting position for 15 minutes prior to blood collection. If the sampling needs to be done with the participant lying down, the fact should be recorded to the questionnaire.

It is recommended that the blood should not be collected from the arm that is used for blood pressure measurement i.e. should be collected from the left arm. If the blood needs to be collected from the right arm the reason should be recorded to the questionnaire.

5. Equipment and consumables

All consumables needed in the laboratory are listed to the laboratory consumables table. At the beginning of the survey, each team is to check that they have all the consumables and equipment needed. The consumables and equipment should be stored in a place, which is not cold or humid. The store should be checked regularly to determine if they have a suitably supply to ensure that they do not soon run out. More consumables are ordered through project management centre (GGT UDRH).

Sampling equipment

- Vacuum tubes 3/person (1 gel serum tube, 1 EDTA tube, 1 litium heparin tube)
- Needles
- Adapter
- Needle disposal box
- Torniquet
- Desinfection swabs
- Adhesive dressing
- Micropore tape
- Pillow
- Pillow case
- Blueys

Equipment needed in blood handling

- 5 ml transfer tubes 2/person
- 1.5 ml transfer tubes 8/person
- Pasteur pipettes

Other equipment

- Racks
- Boxes for transferring samples
- Timers

- Cold packages
- Ice boxes
- Freezer

6. Stickers

Every participant is given a set of stickers (2 x 20) by the project assistant. The running number in the sticker sets is not pre-linked with the participants, so any set of stickers can be taken from the pile. The sticker set has two identical parts. The upper part is to be used for the questionnaires and tubes during the survey day and the lower part needs to be saved for future use when storing and transferring the samples.

The first sticker (Q1) is fastened to the survey questionnaire. The second sticker (Q2) will be fastened to the daily timetables. The rest of the stickers are for laboratory use.

Laboratory stickers in the sticker sheet follow the order of tubes presented in the chart describing the dividing of samples (see chart 1). The stickers from the upper part are to be fastened to sampling and transferring tubes following the chart. Stickers need to be fastened to the tubes vertically, so that the barcode can be read.

The stickers from the lower part are used for the log sheets when transferring the samples to Flinders Medical Centre. The log sheets have a 10 x 10 table, each cell indicating one location in the sample storage boxes. A sticker corresponding to each sample needs to be fastened to a cell in a log sheet representing a place in the box.

7. Blood samples

Three samples will be drawn from each participant. Blood samples will be drawn in the following order:

1. Tube A (10 ml gel serum tube)
2. Tube B (10 ml litium heparin tube)
3. Tube C (10 ml EDTA plasma tube)

8. Sampling

All tubes needed for each patient will be advanced placed in the racks following the instructions in chart 1. To avoid confusion only tubes for one participant should be set to each rack. Tubes **should not** be labelled before sampling as the vacuum in the tube might be damaged.

Sampling procedure:

- Blood samples are taken from the vein in antecubital fossa
- During the sampling the arm should rest on a pillow and any clothes constricting the arm should be removed
- The phlebotomist sets the tourniquet around the upper arm of the subject
- The proper vein is searched by inspecting and palpating

- The injection site is sterilized
- The vein can be anchored by placing the thumb about two centimeters below the vein and pulling gently to make the skin taut. However, the vein should not be stretched.
- The needle, beveled upwards, should be pushed smoothly and quickly in to the vein, to minimize the possibility of hemolysis as a result of vascular damage
- Immediately after the insertion, the tourniquet should be released to minimize the effect of hemoconcentration
- The first tube is placed to the adapter
- After the first tube has filled up, the phlebotomist changes the next tube to the adapter
- While the second tube is filling up the phlebotomist inverts the first tube 8 times towards the stopper
- Each three sampling tubes need to be inverted 8 times towards the stopper while the next tube is filling up
- After all the samples are taken, the needle is pulled off and an adhesive dressing is placed on the insertion site
- Needle should immediately be released to the needle disposal box
- After sampling the question 9 at the last page of the questionnaire needs to be filled in. All exceptions in the procedure need to be recorded as well.
- Before the subject leaves the field laboratory, all the tubes should be labeled. That can be done while the participant is pressing firmly the insertion site to avoid the formation of hematoma

9. Handling of samples

After the blood is drawn the following steps needs to be taken for each sample:

Tube A (S11)

1. Tube is allowed to clot at 20-24 ° C for at least 20-30 minutes.
2. Blood is centrifuged at least within one hour after blood collection.
3. Spin blood in centrifuge for 10 minutes at 1600 G.
4. The serum is promptly separated from clot or cells and transferred to clean transfer tubes. Each sample is divided to three equal aliquots (ss21, ss22, ss23) to smaller transfer tubes.

Tube B (F12)

1. The tube will be inverted 8 times toward the stopper immediately after draw (while the next tube is filling up).
2. Blood is centrifuged at least within 30 minutes after blood collection.
3. Spin blood in centrifuge for 10 minutes at 1600 G.
4. The serum is promptly separated from clot or cells and transferred to three clean transfer tubes. Each sample is divided to one 1.5 ml aliquot (fp24) to 5 ml transfer tube and two 1.0 ml aliquots (f25, f26) to smaller transfer tubes.

Tube C (P13)

1. The tube will be inverted 8 times toward the stopper immediately after draw.
2. Tube is opened and the first 0.5 ml aliquot of whole blood is diverted to tube b20, which goes for Hb1Ac analyses.
3. Tube is closed with a stopper.
4. Blood is centrifuged as soon as possible after blood collection.
5. Spin blood in centrifuge for 10 minutes at 1600 G.
6. The plasma is promptly separated from clot or cells and transferred to clean transfer tubes. Each sample is divided to three 1.0 ml aliquots (p27, p28, p29) to small transfer tubes.

Clotting time

Serum samples needs to have at least 20 minutes time to clot before spinning. The temperature should be at least 20°C, because gel viscosity changes in colder temperature. Plasma samples do not need clotting time. Sodium fluoride tube should be centrifuged as soon as possible after sampling and the separated plasma should be transferred to transfer tubes and frozen/cooled immediately. However, all the samples are centrifuges after 20 minutes from sampling, as it is more practical and minimizes the risk to mix-up the samples. It is important that the time before spinning ***does not exceed 30 minutes*** as the values of fasting glucose are easily affected.

Procedure after sampling:

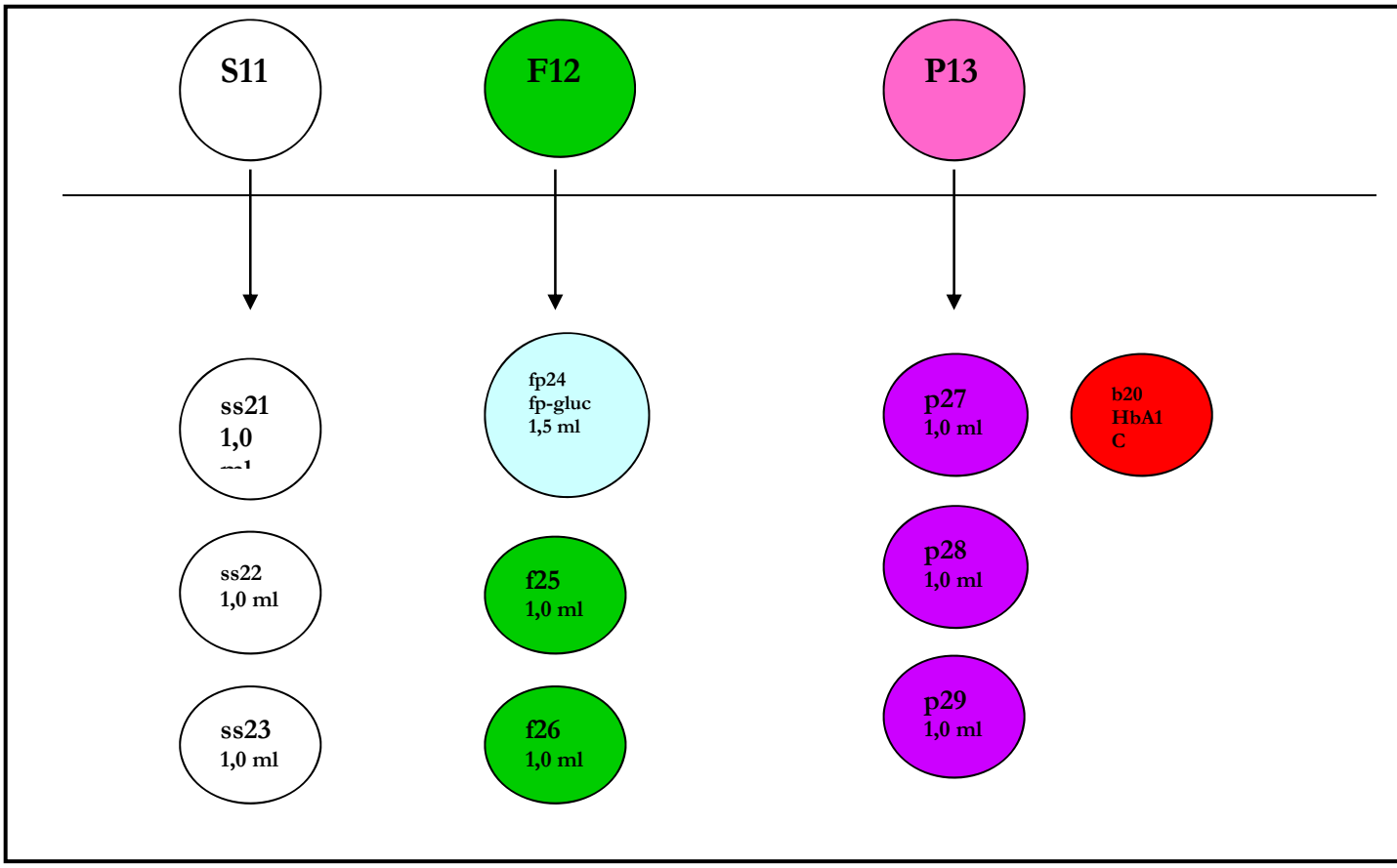
- Timer is set on to alarm after 20 minutes
- The tube C (P13) is opened and 0,5 ml of blood is diverted to tube b20
- Tube b20 is placed to storage box 1 and frozen/cooled immediately
- Tube C (P13) is closed with stopper and all the samples are allowed to stand for 20 minutes
- After the timer alarms the samples are put into the centrifuge
- All the samples are spun in centrifuge at 1600G, which means 3200 rpm with Hettich Rotofix 32 centrifuge. Spinning time is set to 11 minutes (has 10 minutes effective spinning time). After spinning time the centrifuge need some time for braking, so the time needed for spinning of a set of samples is altogether about 12 minutes.
- After spinning the serum tubes should be inspected carefully to check that the gel surface is straight, the layers are properly separated, there are no red cells above the gel surface, there are no fibrin filaments in the sample and the sample is not coagulated after the centrifugation.
- The serum/plasma from each tube should be promptly separated from clot or cells and diverted to transfer tube following chart 1. A separate pipette is used for each blood sample.
- All the transfer tubes are placed to sample transfer boxes following the chart 2.
- Samples fp24, f25 and f26 needs to be cooled/frozen immediately. In Mount Gambier the storage boxes of these samples (box 3 and box 5) are kept in freezer and the other team keeps these boxes in ice box with cold packages.
- Also all the other samples are frozen/cooled as soon as possible.

10. Storage and transfer of the samples

All the samples should be frozen/cooled immediately after separation of serum/plasma. In Mount Gambier the samples are put directly to the freezer. The circulating team cools the samples in ice boxes with cold packages and puts them into freezer after each survey day as soon as possible. Care has to be taken to check the freezers daily that the temperature in freezers is cold enough to keep the samples properly frozen.

After one storage box is filled, the log sheet needs to be completed using the stickers from lower part of the sticker set. The samples are transported frozen to Flinders Medical Centre approximately every second week according to separate timetable agreed with Rosy Tirimacco. Samples should be packed properly, so that they do not thaw during the transport.

Chart 1. Dividing the samples



S Vacuum gel-serum tube 10 ml
F Litium Heparin tube 10 ml
P EDTA-plasma tube 10 ml
b transfer tube for whole blood aliquot for HbA1c analyses 0.5 ml
ss transfer tubes for serum storage aliquots 1.0 ml each
fp transfer tube (5 ml) for 1.5 ml plasma aliquot for fasting glucose analyses
f transfer tubes for serum aliquots from litium heparin plasma samples 1.0 ml each
p transfer tubes for EDTA-plasma aliquots 1.0 ml each

Chart 2. Dividing the aliquots to transfer and storage boxes

Storage boxes

Box 1		Box 2	
b20	0.5 ml	ss21	1.0 ml
		ss22	1.0 ml
		ss23	1.0 ml
		f25	1.0 ml
		f26	1.0 ml
		p27	1.0 ml
		p28	1.0 ml
		p29	1.0 ml

Transfer boxes

Box 5 (5 ml tubes)	
fp24	1.5 ml

Australian Government
Department of Health and Ageing

The Pharmacy Guild of Australia

Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD):

Final report

Researchers: Kevin Mc Namara (Principal Investigator), Dr Stephen Bunker, Prof James Dunbar, Gregory Duncan, Prof Jon Emery, Helen Howarth, Dr Johnson George, Dr Shane Jackson, Prof Edward Janus, Dr Sharleen O'Reilly, Prof Gregory Peterson

THE RESEARCH AND DEVELOPMENT PROGRAM IS FUNDED BY THE AUSTRALIAN GOVERNMENT DEPARTMENT OF HEALTH AND AGEING
AS PART OF THE FOURTH COMMUNITY PHARMACY AGREEMENT

Acknowledgement

We would like to acknowledge the excellent work of Peta Trinder and Jill Finch (Research Assistants), Liz Morabito (Project Officer, Monash University), Kimbra Fitzmaurice (Research Manager, University of Tasmania) and Tonie Miller (Research Assistant) throughout this project.

We are also grateful to:

- Associate Professor Michael Bailey, Department of Epidemiology and Preventive Medicine, Monash University, for undertaking the statistical analyses associated with the project
- Jenny McDowell (Monash University) for coordinating the editing and compilation of the final report
- the Project Steering Group Committee for their valuable contributions
- the pharmacists and pharmacy staff involved in the project for their input and commitment to the project
- the consultant pharmacists for their preparation of the baseline patient clinical reports
- the patients, for their time and their feedback
- Peter Merrilees (Point of Care Diagnostics) and Anna Chapman (Monash University) for their contribution to the comprehensive training of the research assistants.

The authors thank Professor Graham Giles of the Cancer Epidemiology Centre of The Cancer Council Victoria, for permission to use the Dietary Questionnaire for Epidemiological Studies (Version 2), Melbourne: The Cancer Council Victoria, 1996.

.

This report was produced with the financial assistance of the Australian Government Department of Health and Ageing. The financial assistance provided must not be taken as endorsement of the contents of this report.

The Pharmacy Guild of Australia manages the Fourth Community Pharmacy Agreement Research & Development which supports research and development in the area of pharmacy practice. The funded projects are undertaken by independent researchers and therefore, the views, hypotheses and subsequent findings of the research are not

Acronyms

AUDIT	Alcohol Use Disorders Identification Test
BMI	body mass index
BP	blood pressure
CES-D 10	Center for Epidemiologic Studies Short Depression Scale
CHD	coronary heart disease
COACH	Coaching patients On Achieving Cardiovascular Health
CVD	cardiovascular disease
DALYs	Disability Adjusted Life Years
DPP	Diabetes Prevention Project
GGT	Greater Green Triangle
GP	General Practitioner
HAPA	Health Action Processes Approach
HIPS	Health Improvement and Prevention Study
HDL	high density lipoprotein
HMR	Home Medicines Review
IQR	interquartile range
LDL	low density lipoprotein
MONICA	MONItoring of CArdiovascular events
NHMRC	National Health and Medical Research Council
NHS	National Health Service
RA	research assistant
SE	standard error
SNAP Guidelines	Smoking, Nutrition, Alcohol and Physical Activity Guidelines
TABS	Tool for Adherence Behaviour Screening
TC	total cholesterol
TG	triglycerides
WHO	World Health Organization

Glossary

absolute cardiovascular risk	probability of a cardiovascular event occurring in a defined time period
anthropometric	relating to dimensions of the human body E.g. weight, height, waist
antihypertensive	blood pressure lowering
antiplatelet	prevent the formation of blood clots
biomedical factors	physiological parameters. E.g. blood pressure, lipid profile
cardiovascular disease	any disorder affecting the ability of the heart or blood vessels to function normally
cardiovascular event	a severe or acute condition relating to the heart or blood vessels, including the following: myocardial infarction, stroke, transient ischaemic attack, peripheral vascular disease, angina and congestive heart failure
co-morbidity	the presence of one or more conditions (or diseases) in addition to a primary disease or disorder
coronary heart disease	a condition of the heart caused by narrowing of the blood vessels that supply the heart muscle
diastolic BP	the pressure in the arteries when the heart is at rest
dyslipidaemia	abnormal blood lipid (fat) levels
familial hypercholesterolaemia	a genetic disorder causing dyslipidaemia
high density lipoprotein (HDL) cholesterol	a type of lipoprotein, commonly referred to as 'good' cholesterol; high blood levels are thought to decrease the risk of heart disease
hypertension	high blood pressure
low density lipoprotein (LDL) cholesterol	a type of lipoprotein, commonly referred to as "bad" cholesterol; high blood levels are thought to increase the risk of heart disease
medicines adherence	the extent to which a person takes their medicine in accordance with recommendations from a health professional
myocardial infarction	commonly known as a "heart attack"; it is the death or damage of a part of the heart muscle due to insufficient blood supply to the heart muscle
primary care	essential healthcare made available in the community as the first contact in the medical management of a condition
systolic BP	the pressure in the arteries when the heart contracts
triglycerides	the most common type of fat in the body, it is found in the blood and fat tissue; high levels are linked to heart disease

Table of contents

Background and Rationale

Cardiovascular disease in Australia

Cardiovascular disease (CVD) is an enormous health problem in Australia, second only to cancer in terms of its burden on society. According to official statistics[1] CVD accounts for 18% of the disease burden in Australia, and in 2005, 35% of all Australian deaths could be attributed to CVD.

There is a cluster of highly prevalent cardiovascular risk factors which can be controlled or avoided: tobacco smoking, hypertension, overweight and obesity, physical inactivity, dyslipidaemia (high cholesterol), poor nutrition and diabetes. In an Australian context, the significance of these cardiovascular risk factors on a population level is exacerbated by high – and in some cases increasing – prevalences,[2] and numerous evidence–treatment gaps in their prevention, treatment and management.[3 4-9 10 11 12 13 14 15]

Addressing cardiovascular risk

Evidence-based Australian guidelines identify best-practice clinical management for all of the major CVD risk factors described above,[8 11 16 17 18 19 20 21] and relevant Australian and international evidence-based guidelines exist for overall cardiovascular risk management.[22] These documents all have condition-specific assessment and management recommendations, but share several general themes regarding treatment recommendations:

- A patient's overall CVD risk must be considered, not just the individual risk factor.
- Lifestyle modification should be implemented for at-risk patients regardless of the decision to treat with medicines.
- Net benefits of using medicines to treat risk factors are relative, and increase with increasing CVD risk levels. As a general rule, lifestyle modification should therefore be attempted before prescribing medicines for patients with lesser risk, with longer periods of trialling lifestyle modification as the risk gets lower.
- Antiplatelet use is considered to have a net beneficial effect in appropriate patients where the risk of heart disease is greater than 1% per annum.[23]
- Adherence to prescribed medicines and lifestyle recommendations is a great challenge in all areas of CVD prevention.

Current Australian programs to address cardiovascular risk

There is a paucity of research into the management of multiple risk factors for primary prevention of CVD in Australian primary care. The trial 'Prevention of vascular disease in general practice: Health Improvement and Prevention Study' (HIPS) [24] may provide some evidence for clinical management in general practice. The 'Greater Green Triangle 'Diabetes Prevention Project' (GGT DPP) [25] addresses the full spectrum of care from identification of at-risk patients through to risk management in diabetes primary prevention (which has similar treatment goals to CVD prevention). The GGT DPP was cost effective and achieved a 40% reduction in the risk of progression to type II diabetes and a 16% reduction in overall cardiovascular risk.

While many successful or potentially successful models of care exist which reduce CVD risk to some extent in Australian primary care, we could find no evidence of any widely implemented primary prevention program in Australian primary care – pharmacy, general practice or other – explicitly designed to be systematic, evidence-based and comprehensive, and to incorporate all of the following important issues:

- prior training of health professionals in accordance with national evidence-based guidelines
- assessment of patient cardiovascular risk using a Framingham-based equation
- assessment of both health behaviours and medicines use
- incorporation of both lifestyle modification and medicines management interventions
- explicit consideration of medicines adherence and lifestyle adherence by the patient
- patient-centred approach to interventions
- adoption of a proven theoretical framework for patient behavioural change
- consideration of measures to facilitate multidisciplinary involvement where necessary.

Adherence

Medicines adherence is a particularly important factor to consider in cardiovascular risk factor management. The 'Australian National Blood Pressure Study' (ANBP-2) of 4,000 older people with

hypertension demonstrated that persons adhering to antihypertensive medicines regimens were significantly less likely to experience a cardiovascular event.[26] Unfortunately, about half of patients stop taking antihypertensive and lipid-lowering medicines within one year of commencement – one in five will not even collect a second month or repeat prescription. [27] [28] [29] Despite the importance of medicines adherence in CVD prevention, it was not stated to be a feature of any of the identified Australian programs previously mentioned.

Evidence for pharmacist management of multiple risk factors

Numerous clinical trials have also demonstrated the capacity of community pharmacists to impact positively on individual CVD risk factors such as dyslipidaemia, smoking, and hypertension. [30] [31] [32] [33] [34] More recent evidence suggests that pharmacy can also play a clinically effective role in the management of multiple cardiovascular risk factors.[35] Clifford et al.[36] examined the effects of a pharmaceutical care program on vascular risk factors in Australian diabetic patients. The intervention achieved significant improvements in HbA1c (–0.5% difference), systolic blood pressure (BP) (–14 mmHg) and diastolic BP (–7 mmHg). In the US, Lee et al.[37] also demonstrated significantly improved systolic BP, medicine adherence and medicine persistence following pharmacist interventions. Emerson et al.[35] demonstrated the clinical effectiveness of general practitioner (GP)–pharmacist collaborations in Australia for multiple CVD risk management. A 13% relative risk reduction in coronary heart disease (CHD) likelihood was achieved in the multifaceted intervention group – it is unclear as to the relative contributions of the pharmacists, GPs and other health professionals in delivering interventions.
In summary, no other widely available programs in primary care comprehensively and equally address: medicine use, medicine adherence, lifestyle modification and adherence to relevant national guidelines. It was therefore highly important to test the clinical and practical feasibility of implementing a comprehensive disease management program for primary CVD prevention in community pharmacy.

Research objective and research questions

The research objective is to develop and assess a model of care for the primary prevention of CVD in community pharmacy. Research questions are as follows:

1. Does such a pharmacy-based intervention successfully deliver health promotion and medication management messages to patients?
2. Is the nature of such an intervention acceptable to patients?
3. Can the proposed intervention complement and assist general practitioners in patient care?
4. Can the proposed intervention be implemented within the current community pharmacy structure?
5. Do clinical outcomes from such a program justify the funding of a large-scale randomised controlled trial to assess the clinical effectiveness of the intervention?

Methodology

Pharmacy recruitment and training

Ten community pharmacies participated; five from Melbourne and rural southwest Victoria, and five from Hobart and rural southern Tasmania. All pharmacies involved had a private counselling area. To participate in the project, one or more pharmacists from each participating pharmacy attended training over an evening plus one full day. Training focused on developing generic skills such as health promotion and assessment of CVD risk, and evidence-based approaches to management of individual biomedical, anthropometric and lifestyle-related risk factors (Annex 3.1 Training Overview). All training, including training materials, was consistent with relevant national guidelines.

Patient recruitment

Each pharmacy was asked to recruit a maximum of ten eligible patients. The patient recruitment steps were as follows:
1. Pharmacists who had undertaken the project training conducted an initial screening for potential participants. Patients were provisionally eligible if they met the following criteria:

- aged 50–74 years
- taking either a prescribed cholesterol-lowering medication or antihypertensive, or both
- no history of a cardiovascular event or established CVD.

Interested patients who met the above criteria were invited to complete an expression of interest form.
2. When the research team received a patient expression of interest to participate, they conducted a formal assessment of patient eligibility by phone. This process involved reviewing the initial criteria for assessment (age, CVD medicine use, CVD history), and also the following additional exclusion criteria: previously diagnosed diabetes**,** target organ damage, history of cardiovascular event or established CVD, cognitive impairment, dependent/reliant on a carer or living in a residential aged care facility, recent inpatient hospitalisation, non-English speaking, living more than 40 km from the pharmacy, Home Medicines Review (HMR) in the past 12 months.
3. If a patient was deemed eligible, approval was sought by the RA to contact the patient's GP to give them the opportunity to declare patients inappropriate for the intervention. Prior to the baseline assessment patients were advised that best results for cholesterol and blood glucose levels would be obtained if they fasted 12–16 hours prior to testing, and to take their medications as normal on the day of clinical assessment. See Annex 3.2 for more details.

Baseline assessment

Patients could choose to be interviewed by the RA at their home or at the pharmacy if the pharmacy had a suitably private area for the assessment.
The following baseline anthropometric and biomedical information was collected:

- BP, weight, height, waist and hip circumference, all in accordance with documented protocols used for the Greater Green Triangle Chronic Disease Risk Factor Surveys.[2] The BP protocol was amended to allow for use of an automated monitor (Omron 1A1B).
- cholesterol and blood glucose levels via finger-prick testing and use of a Cholestech LDX® Analyzer: RAs were trained in its use in accordance with official manufacturer protocols.

The remainder of the assessment consisted of an interviewer-administered questionnaire. This questionnaire, which included several validated survey instruments, covered a range of health indicators:

- demographic and social information, including some questions based on the WHO MONICA (MONItoring of CArdiovascular events) protocol,38 as adapted for the Greater Green Triangle Chronic Disease Risk Factor Studies (GGT RFS)2
- brief patient medical history and family history of CVD events
- current medicines' details
- adherence to current medicines' advice using the Tool for Adherence Behaviour Screening (TABS)39 and the Morisky 4-item scale40
- smoking, physical activity and weight management status – including some screening questions from the Lifescripts program41 and questions from surveys used by the GGT RFS2
- quality of cardiovascular diet, based on adherence to the Dietary Guidelines for Australian Adults (2003).42 The dietary scoring tool used a number of questions from the National Nutrition Survey 1995,43 and Cancer Council of Victoria Food Frequency Questionnaire43
- screening for excess alcohol consumption using the AUDIT C tool44
- screening for depression using the Center for Epidemiological Study of Depression Scale (CES-D)45
- quality of life measure, assessed using the SF-12v2 Health SurveyTM. 46

The RA was responsible for supplying the information collected to a consultant pharmacist for review. If the RA identified any risk factors requiring urgent attention at the point of baseline assessment (e.g. severe hypertension), they were required to arrange appropriate medical care. The patient also provided written consent to the RA to share the clinical information with other health professionals and to allow the consultant pharmacist to contact patients directly if further information was required to complete the review being performed.

Consultant pharmacist review

Two consultant accredited pharmacists (one in each state) reviewed the patient baseline assessment data and prepared a patient-specific clinical report (Annex 3.3) for the community pharmacist to use. Each report outlined the following: the patient's estimated overall CVD risk and individual risk factor status; the patient's adherence to CVD medicines; suggestions for the patient's medicines management; patient's adherence to lifestyle guidelines and motivation to change; suggestions for any improvements in adherence to various evidence-based guidelines for risk factor management. [8 11 16 17 18 19 20 21 22]

Overall 5-year CVD risk was estimated using the New Zealand Cardiovascular Risk Equation.[22] This calculation was made based on data collected about the patient's age, gender, blood pressure, lipid profile and smoking status. An extra 5% was added to the patient's calculated risk if the patient had one or more of these extra risk factors not fully accounted for by the risk equation: obesity (BMI≥30), family history of heart disease, certain ethnic groups (Maori, Aboriginal or Torres Strait Islander, Indian subcontinent, Pacific Islander), or familial hypercholesterolaemia.[22]

A 13-item questionnaire was developed addressing dietary quality in this study population as there is currently no validated tool available. The questionnaire used previously-validated questions relating to the nutrients of concern for primary prevention of CVD.[42 43] Responses for each item were scored between zero (least healthy response option) and 10 (healthiest option) – consistent with the developing literature in this area of diet research. This scoring allowed for an overall diet score to be generated ranging from 0 to 130. Overall quality of dietary intake was reported to the community pharmacist using the following arbitrary cut-offs:

Diet score	Interpretation
104–130	High level (80% or more) compliance with CVD dietary guidelines
78–103	Medium level (60–80%) compliance with CVD dietary guidelines
77 or less	Low level (59% or less) compliance with CVD dietary guidelines

This score allows a good estimate of the level of adherence to key diet-related behaviours. Constituent elements of the questionnaire also allowed development of sub-scales for assessment of fruit and vegetable intake, saturated fat and total fat intake, omega-3 fatty acid intake, fibre intake and salt intake.

The consultant pharmacist also assessed 'at risk' conditions which would require prompt GP attention: a CES-D10 score greater than 10 may indicate depression;[45] random plasma glucose level above 11.0 mmol/L may indicate diabetes;[12] and patients were advised to see their doctor within two weeks if systolic BP was 160–179 mmHg or diastolic BP was 100–109 mmHg (unless the doctor was obviously aware already; higher blood pressure required immediate referral by the RA at baseline assessment if unaddressed). Community pharmacists were not trained or asked to make interventions related specifically to diabetes or mental health issues, but were alerted to any suboptimal assessment results in these areas necessary to facilitate GP input with the patient.

The consultant pharmacist provided the report to researchers for documentation, and it was then forwarded to community pharmacist. After receiving the consultant pharmacist report, the community pharmacist arranged a meeting with the patient and prioritised the issues for baseline counselling. The report contained summaries for the pharmacist to forward to the GP (Annex 3.3) and patient (Annex 3.4). GP input for each patient was invited. If a patient's overall risk score was 5% or less they were advised to discuss with their pharmacist the likely benefit of continuing with the intervention. The decision to continue treatment was left to the pharmacist and the patient.

Intervention interviews by the pharmacist in the pharmacy

The project was designed to use the community pharmacist to educate patients and raise their awareness of CVD prevention, empowering patients to take a more proactive role in cardiovascular risk self-management. The Health Action Processes Approach[47] was adopted as a framework for the community pharmacy intervention. This advocates two distinct stages in facilitating change to patient behaviour. The first is patient motivation to change behaviour through mobilisation of risk perception, self efficacy, and outcome expectation, the second is ongoing assistance in intention formation, goal setting, planning, feedback and relapse prevention.

Participating community pharmacists conducted five sessions with each patient at monthly intervals (see Annex 3.5 for an outline of sessions). Sessions usually occurred at the community pharmacy during regular patient visits but were managed as a follow-up phone call when necessary. The pharmacist detailed each patient session in a structured document which contained appointment records, a checklist of objectives, an overview of discussion points, patient referrals, and written goals and strategies. Written goals and strategies were also provided to the patient (Annex 3.6).

An understanding of the overall risk of CVD allowed the patient and pharmacist an objective understanding of the urgency of treatment. As stated, low risk patients (scoring less than 5% risk over 5 years), were given the option of withdrawing from the intervention if it was felt there was little to be gained. Identifying patients as either moderate or high risk allowed pharmacists to better advise the patient about the need for immediate changes to their prescribed medicines, or the advisable trial period for lifestyle modification.

After the first session, the community pharmacist shared these results with the patient's nominated GP to ensure proper coordination of care. They were required to forward the GP copy of the assessment report

and report any pertinent issues arising from their discussions with or personal knowledge of the patient. This allowed the GP to have formal input into the treatment goals and coordination of care.

Second assessment

After the five community pharmacist–patient intervention sessions (about six months after the baseline assessment), a follow-up assessment was arranged with the RA. A clinical report compiled by the RA, with a summary of the first and second assessment results (Annex 3.7), was forwarded to the pharmacist, GP and patient.

Stakeholder evaluation

After the 6-month intervention, anonymous satisfaction surveys were posted to patients, pharmacists and GPs, regardless of their persistence or level of involvement with the program (Appendices 3.8 – 3.10). A covering letter, explanatory statement and reply-paid envelope were included.

Data storage

With respect to privacy, confidentiality and document de-identification, data was treated and retained in a manner consistent with the requirements of the university ethics committees and the Victorian, Tasmanian and Commonwealth legal requirements. Data reporting was undertaken in a manner that maintained anonymity of individual patients, participating pharmacists and GPs.

Statistical analysis

Analysis was performed using SAS software, version 9.2 (SAS Institute Cary, NC, USA). Univariate comparisons between groups were conducted using chi-square test for equal proportion (or Fishers exact tests where numbers were small) and reported as percentages (n). Continuous normally distributed variables were compared using student t-tests and reported as means (standard error) while non-parametric data were compared using Wilcoxon rank-sum tests and reported as medians (interquartile range). Pairwise differences between pre and post values were calculated using paired t-tests for normally distributed data, and Wilcoxon sign rank tests for non-normally distributed data. To account for the large number of comparisons made, we have used a reduced 2-sided p-value of 0.01 to indicate clear statistical significance.
Where data for one or more cases is missing when calculating a statistic, a new denominator will be specified.

Results

Baseline characteristics of recruited patients

Demographic profile

Basic demographic information for the 70 recruited patients is presented in Table 1. Fifty-one participants (73%) were women. The average patient age was 60.5 +/–1.4 years. There was a higher average age among rural participants (61.6 +/–1.9 years) compared with metropolitan participants (58.5 +/–1.8 years; p= 0.03).
Sixty-three (90%) participants were Australian born. Two participants (3%) self-identified as Aboriginal or Torres Strait Islander, and one as Maori. No other participants were recruited who reported an ethnic background associated with increased cardiovascular risk compared with the general Australian population. The majority of participants (65%) cited their highest level of education as secondary school year 7–10 or below. Almost half (31/70, 44%) had a concession card. Participants aged 60 years and over were more likely to have a concession card compared with younger participants (25/38, 65% vs. 6/32, 18%; p<0.001), as were rural patients (25/46, 54%) compared with metropolitan patients (6/24, 25%; p= 0.02). Rural participants were significantly more likely to claim an Australian background (43/46, 93%) than their metropolitan counterparts (16/24, 66%; p=0.003). Almost one half reported that a first or second degree relative (living or dead) had experienced CHD before the age of 60 years.

Table 1. Baseline demographic features of participants

Baseline demographic features	Overall (n=70)

Number (%) women	51 (73)
Average age (years)	60.5
Number (%) aged 60 years plus	38 (54)
Ethnic background	
Number (%) of Aboriginal or Torres Strait Islander ethnic background	2 (3)
Number (%) with Australian background	59 (84)
Number (%) with 'other' high CVD risk ethnic background	1 (1)
Average number of years full-time education	11.3
Number (%) of participants recruited from Victorian pharmacies	30 (43)
Number (%) recruited from rural pharmacies	46 (66)
Number (%) with a concession card	31 (44)
Number (%) reporting family history of premature coronary heart disease before age 60 years	31 (44)

Use of health services

On average these participants had visited their community pharmacy six times in the six months prior to initial assessment, more than for any of the other commonly used health professionals examined. This compares with an average of two visits to GPs, and zero visits to a medical specialist. One participant reported a single visit to a dietitian in the same period, and just six patients reported visiting a specialist nurse.

Baseline cardiovascular risk

A summary of the baseline cardiovascular risk of participants is shown in Table 2. The average baseline risk of CVD onset over the next five years was 6.66 +/–1.52% overall, 10.81 +/–2.34% for men and 5.11 +/–0.80% for women ($p<0.001$) according to the New Zealand risk equation ('calculated risk', excluding factors such as family history, ethnicity, obesity). When additional factors were accounted for ('total risk'), the absolute risk was an average 9.59 +/–1.18% overall, 13.44 +/–2.84% for men and 8.15 +/–1.06% for women ($p<0.001$). Overall, 7/70 participants (10%) were at high or very high total risk of CVD (≥ 15% over five years). A further 23 (33%) had a moderate (10–15%) level of total risk. With gender as a contributor to risk, a much higher proportion of men (6/19, 31%) compared with women (1/51, 2%) were at a high total risk of CVD at baseline ($p<0.001$). Likewise, those participants aged 60 years and over had higher median calculated risk scores (7.70%, IQR 5.10–9.20% vs. 3.80%, IQR 2.70–6.10%; $p<0.001$), and total risk scores (10.40%, 7.80–13.30% vs. 7.80%, 4.75–10.4%; $p=0.009$) when compared with those aged less than 60 years.

Mean total cholesterol and LDL-cholesterol concentrations were 4.94 mmol/L and 2.84 mmol/L, (mean total:HDL ratio 4.37 +/–0.51 mmol/L). The average BP, at 138 mmHg systolic and 86 mmHg diastolic, was bordering on mildly hypertensive (140/90 mmHg or greater). Men had significantly lower HDL (good) cholesterol than women ($p<0.001$) and on average were below the recommended minimum level of 1 mmol/L. Most participants were either overweight or obese, with an average BMI of 30 and an average waist circumference in excess of 96 cm.

Multivariate analysis of risk factors examined the impact of individual risk factors in their contributions to overall risk. Seven risk factors were found to be significantly associated with CVD risk profile (Table 3) but this does not necessarily imply a causal relationship. The seven variables could explain 70% of the variation in risk score. The most important was gender (men had a risk score on average 4 points higher), which could explain 21.5% of the variation, followed by smoking status and systolic blood pressure.

Table 2. Participants' baseline cardiovascular risk profile

	N	Women	Men	Overall (0 mths)	P (gender)
Cardiovascular risk					
Mean (SE) 'total' 5-year CVD risk (%)	70	8.15 (0.53)	13.44 (1.42)	9.59 (0.61)	<0.001
Number (%) with total risk ≥ 15% over 5 years	70	1(2)	6 (31)	7 (10)	<0.001
Number (%) with 10–15% total risk over 5 years	70	15 (29)	8 (42)	23 (33)	0.31
Number (%) with <10% total risk over 5 years	70	35 (68)	5 (26)	40 (57)	0.001
Mean (SE) 'calculated' 5-year CVD risk (%)	70	5.11 (0.40)	10.81 (1.17)	6.66 (0.53)	<0.001
Lipid profile					
Mean (SE) total cholesterol (mmol/L)	70	4.96 (4.43–5.74)∞	4.37 (4.18–4.83)∞	4.94 (0.113)	0.02
Mean (SE) LDL cholesterol (mmol/L)	66	2.90 (0.11)	2.67 (0.09)	2.84 (0.87)	0.26
Mean (SE) HDL cholesterol (mmol/L)	70	1.38 (0.05)	0.99 (0.08)	1.28 (0.05)	<0.001
Median (IQR) triglycerides (mmol/L)	70	1.41 (1.02–2.15)	1.34 (0.92–1.74)	1.39 (1.01–2.13)	0.39
BP					
Mean (SE) systolic BP (mmHg)	70	136.62 (2.46)	140.57 (3.8)	137.70 (17.32)	0.40
Mean (SE) diastolic BP (mmHg)	70	85.52 (1.30)	86.63 (1.56)	85.83 (8.70)	0.64
Number (%) with uncontrolled BP (≥ 140/90 mmHg)	70	24 (47)	12 (63)	36 (51)	0.23
Random blood glucose					
Mean (SE) concentration (mmol/L)	70	5.21 (0.12)	5.61 (0.25)	5.32 (0.95)	0.12
Anthropometric measures					
Mean (SE) weight (kg)	70	73.3 (66.1–86.1)∞	89.9 (81.6–98.2)∞	81.94 (19.09)	0.001
Mean BMI	70	30.19 (1.02)	29.76 (1.04)	30.08 (6.67)	0.81
Number (%) with BMI ≥ 30 (obese)	70	19 (37)	7 (36)	26 (37)	0.97
Average waist circumference (cm)	70	92.25 (84.10–99.50)	98.45 (94.15–111.35)	NA	NA
Number (%) with recommended waist circumference (women <84 cm, men < 90 cm)	70	12 (23)	1 (5)	13 (19)	0.08
Average hip circumference (cm)	70	110.26 (2.38)	105.27 (1.49)	NA	NA

∞ Median (interquartile range) and Sign rank p-values are quoted because distribution of values obtained is non-parametric

Table 3. Multivariate analysis of individual CVD risk factor contributions to overall baseline risk

Patient risk factor	Partial R-square	Parameter estimate	Standard error	P-value
Male gender	21.48%	4.10	0.90	<0.001
Current smoker	10.12%	6.55	1.29	<0.001
Systolic blood pressure	11.41%	10.99	0.02	<0.001
BMI	12.30%	0.20	0.06	0.001
HDL cholesterol	6.64%	–3.93	0.97	<0.001
Age	4.57%	0.22	0.06	0.001
Total cholesterol	3.65%	1.11	0.40	0.007

Medical history

Participants reported an average of 4.1 (+/–0.5) health conditions overall, including high BP (62/70, 89% of patients) and lipid disorders (39/70, 56%). Eight patients (11%) reported one other treated cardiovascular health issue. Other common areas of treatment were musculoskeletal (71%), digestive (33%), neurological (17%), psychological (16%), respiratory (16%), and metabolic/endocrine or nutritional (7%). Unsurprisingly, patients aged 60 years or more reported a greater median number of chronic conditions (4, IQR 3–5) compared with younger patients (3, IQR 3–4; p=0.024).

Use of medicines

Patients used a median of 3 (IQR 2–4) prescribed medicines (considers active ingredients of combination products separately). The median number of medicines taken was lower for those aged under 60 years (3, IQR 2–4), than for those aged 60 years and over (4, IQR 3–5; p=0.01); the average number of medicines used overall was 5.74 +/–0.63, significantly greater for women (4, IQR 3–6) than for men (6, IQR 5–7; p=0.008). Most participants (62/70, 89%) used one or more antihypertensive medicines, and those being treated were using a median of 2 (IQR 1–2) antihypertensive medicines. A majority of participants (39/70, 56%) were prescribed medicines for lipid disorders – on average taking one lipid-lowering medicine (IQR 1–1).Twelve patients (17%) were taking aspirin, 27 patients (39%) were using fish oil, two (3%) were using potassium supplements and four (5.7%) were using smoking cessation therapy. The median number of cardiovascular medicines was two (IQR 2–3).

Adherence to cardiovascular medicines

Overall 29 participants (41%) were identified as nonadherent using the Morisky scale (see Table 4).[40] The most common reason for nonadherence was sometimes forgetting to take the medicines (34.3%). This was despite all 70 patients reporting their medicines regimen complexity as 'very simple' (68, 97.1%) or 'simple' (2, 2.9%).

Adherence to guidelines for a healthy lifestyle

Mean adherence score for diet was just 84 +/–5 out of a maximum 130 (Table 5), Fifteen percent (9/60) scored 104 or greater. Mean scores for all subcategories of diet were between 50% and 75% of the maximum. The mean score of 37.5 +/–2.8 for saturated fat and total fat intake among metropolitan participants was significantly higher than for rural participants (31.7 +/–2.7; p=0.008).

The median AUDIT-C score screening for excessive alcohol intake was 2 (IQR 1–4), with 61% reporting a score inside the desirable range of 0–3. Most people reported never taking six or more standard alcoholic drinks on a single occasion, although those aged under 60 years (median 'never', IQR 'never'–'less than monthly') may have been more inclined (median 'never', IQR 'never'–'never'; p=0.02). When they drank, men reported consuming a larger median number of alcoholic drinks ('0–2', IQR '0–2' to'3–4') than women (median '0–2', IQR '0–2' to '0–2;'p=0.002), and there was also a trend towards men being more likely to consume six or more alcoholic drinks more frequently (median 'never', IQR 'never'–'less than monthly' [men] vs. 'Never', IQR 'never'–'never' [women]; p=0.01).

Table 4. CVD medicines adherence and general management of medicines

	N (0 mths)	Women n=51	Men n=19	Overall 0 mths	P (gender)
Medication adherence					
Number (%) nonadherent (Morisky scale)	70	22 (43)	7 (36)	29 (41)	0.63
Number (%) who forget to take medicines	70	19 (37)	5 (26)	24 (34)	0.39
Number (%) 'always careful' about taking medicines	70	51 (100)	19 (100)	70 (100)	1.00
Number (%) who stop taking medicines if they feel better	70	5 (9)	1 (5)	6 (9)	0.55
Number (%) who stop taking medicines if they feel worse	70	2 (3)	1 (5)	3 (4)	1.00
Medicines management (median [IQR])					
I have strict routines for using my regular medicines? 1(never) to 5 (always)	70	5 (5–5)	5 (5–5)	5 (5–5)	0.42
I keep my medicines close to where I need to use them? 1 (never) to 5 (always)	70	5 (5–5)	5 (5–5)	5 (5–5)	0.56
I ensure I have enough medicines so I don't run out? 1 (never) to 5 (always)	70	5 (5–5)	5 (5–5)	5 (5–5)	0.75
I strive to follow the instructions of my doctors? 1 (never) to 5 (always)	70	5 (5–5)	5 (5–5)	5 (5–5)	0.028
I get confused about my medicines? 1 (never) to 5 (always)	70	1 (1–1)	1 (1–1)	1 (1–1)	0.16
I make changes in the recommended management to suit my lifestyle? 1 (never) to 5 (always)	70	1 (1–1)	1 (1–1)	1 (1–1)	0.67
I put up with my medical problems before taking any action? 1 (never) to 5 (always)	69	3 (1–3)	1.5 (1–3)	3 (1–3)	0.11
I alter my recommended management based on how I am feeling? 1 (never) to 5 (always)	70	1 (1–1)	1 (1–1)	1 (1–1)	0.72

The average physical activity score (6.24 +/–1.02) exceeded the recommended minimum of 5, and was higher for men than for women (8.21 vs. 5.50, p=0.02). Just 9% (6 participants) were current smokers. Five of the six (83%) had previously been advised to quit by their current GP and three of the six (50%) had previously been advised to quit by their pharmacist. All six had previously made some attempt to do so, with a median time since their last attempt of 9 (IQR 6–36) months. Half of the participants (46%) were ex-smokers who had quit a self-reported average of 24 years prior to baseline assessment.

Quality of life/depression

Most (87%) participants did not screen positive for depression. The mean CES-D score of 4.52 +/–0.96 was less than half of the positive screening threshold score of ten. Median scores were significantly higher for Tasmanian participants (5, IQR 2–7) compared with Victorian participants (2, IQR 0–4; p=0.003). Quality of

life scores were established using the SF-12[46] but can only provide meaningful interpretation relative to follow-up scores.

Table 5. Baseline adherence to recommended health behaviours

Baseline risk: clinical parameters	N (0 mths)	Women (n=51)	Men (n=19)	Overall 0 mths	P (gender)
Smoking status					
Number (%) current smokers	70	5 (9)	1 (5)	6 (9)	0.55
Number (%) ex-smokers	70	20 (39)	12 (63)	32 (46)	0.07
Number (%) who never smoked	70	26 (51)	6 (32)	32 (46)	0.19
Diet					
Mean (SE) overall diet score, range 0 (no adherence)–130 (maximum adherence)	61	84.35 (2.82)	82.33 (5.27)	83.86 (2.48)	0.73
Mean (SE) fruit and vegetable score (range 0 to 20)	70	15.11 (0.54)	14.52 (1.06)	14.96 (0.49)	0.59
Mean (SE) saturated fat and total fat intake score (0 to 50)	64	33.93 (1.31)	33.05 (1.78)	33.70 (1.07)	0.72
Median (IQR) fibre score (0 to 30)	69	20 (10–20)	17 (10–20)	20 (10–20)	0.47
Median (IQR) salt score (0 to 20)	68	10 (10–20)	15 (8–20)	10 (10–20)	0.71
Mean (SE) omega 3 fatty acid intake (0 to 10)	70	6.71 (0.38)	7 (0.53)	6.79 (0.31)	0.69
Physical activity					
Mean (SE) Lifescripts physical activity score	70	5.50 (0.53)	8.21 (1.12)	6.24 (0.51)	0.02
Alcohol intake*					
Median (IQR) AUDIT C alcohol intake score*	70	2 (1–4)	3 (1–6)	2 (1–4)	0.15

* Based on AUDIT-C screening tool, scores of 0–3 are considered low risk.

Changes to CVD risk after 6 months

Overall cardiovascular risk

Overall, 67 patients were assessed both at baseline and at 6 months follow-up. Using the basic New Zealand CVD risk equation (calculated risk)[48] in isolation, the intervention delivered an absolute risk reduction of 1.66%, equivalent to a relative risk reduction of 24.4 +/–9.3%. Mean total cardiovascular risk scores reduced to 8.03% (see Table 6), a statistically significant mean absolute risk reduction of 1.58 +/–0.73% (p <0.001), and relative risk reduction of 16.4 +/–0.7%. The percentage of participants whose total risk score was less than 10% significantly increased in absolute terms by 11/67 (16%) to 49/67 (73%; p=0.003). Mean absolute reduction in calculated risk for those with a baseline risk of 10% or greater was –2.56 +/–1.21%, significantly more than the median –0.96 +/–0.48% for those with risk less than 10% (p=0.01).

Changes observed in overall CVD risk were the result of improvements across several biomedical and anthropometric contributing factors (Table 6). Overall systolic and diastolic BPs reduced by considerable margins, systolic BP by a median of 7 mmHg (p<0.001) and diastolic BP by a mean of 5 mmHg (p<0.001). There was a statistically significant drop of 21% (14/67) in the absolute proportion of all participants measured with uncontrolled BP (p=0.001). There was a significantly greater reduction in diastolic BP among Tasmanian participants compared with Victorian participants (diastolic BP –7.21 +/–2.82 mmHg vs. –1.85 +/–3.02 mmHg; p=0.01).

Mean total:HDL cholesterol ratio reduced by 0.197 +/–0.42 (p=0.04). Total cholesterol reductions were greater for participants with baseline cholesterol greater than 5.5 mmol/L (–0.69 +/–0.56 mmol/L vs. 0.0 +/–0.07 mmol/L; p=0.001). Statistically significant reductions in hip circumference were accompanied by median overall reductions in waist circumference of 1 cm (IQR –4.25– +1.8cm; p=0.01). Participants with baseline total cardiovascular risk of 10% or greater had a significantly greater reduction in median waist circumference (–4.0 cm, –5.3– –0.2) compared with those of a lesser baseline risk (0.2, –2.4– +2.0; p=0.003).

Multivariate analysis was undertaken to ascertain the contribution of key risk factors to the change in estimated total CVD risk. Partial R-square (RSq) values indicated the proportion of risk change attributable to individual factors (table 7). Three variables were independent predictors of the risk reduction, namely overall systolic BP (RSq =28%), total cholesterol (RSq =11%), and HDL cholesterol (RSq =13%). Overall these three variables could explain 52% of the risk reduction. Smoking, diastolic BP and BMI were not significant predictors (p>0.4, RSq <0.4%). There was insufficient power to independently assess the impact of lifestyle modification factors.

Medicines use and adherence

The small numbers involved meant that it was not possible to detect the significance of any changes to medicines used for individual conditions or classes of medicine. There were minor increases in the median total number of regular prescription medicines (+0, IQR 0–1; p=0.02). Self-reported medicines adherence (assessed using the Morisky scale) dramatically improved over the 6 months, with the number reporting any form of nonadherence almost halving to just one in five people at follow-up (Table 8). The most noticeable gains were derived from a significant reduction in the proportion of people who sometimes forget to take medicines. There were improvements to other responses but their interpretation is limited by the small numbers involved. No significant changes were noticed to responses on the TABS scale.

Changes to lifestyle factors affecting CVD risk

Two of the six smokers at baseline reported quitting in the 6 months (Table 9). Given the small number of remaining smokers, it is not feasible to make meaningful interpretation of data. Improvements were seen in all the key domains of a cardiovascular health-promoting diet, as well as the overall diet quality. There was a statistically significant increase of 9.4 +/–3.5 in mean dietary quality score (p<0.001), as well as significant reductions in saturated fat and total fat intake (p<0.001), and in salt use (p<0.001). These gains were accompanied by improvements in fibre intake (p=0.02). Median increases to overall diet scores were greater for those with baseline scores less than 104 (+10, 5–18 vs. –5, –8– –4; p<0.001).

Table 6. Summary of changes to CVD risk parameters after 6 months

	Overall results at 6 months	N (6 mths)	N (pairs)	Change since baseline	P (change)
Cardiovascular risk					
Mean (SE) 'total' 5-year CVD risk (%)	8.03 (0.51)	67	67	–1.58 (0.36)	<0.001
Number (%) with total risk ≥ 15% over 5 years	3 (5)	67	67	–4 (–6)	0.04
Number (%) with 10–15% total risk over 5 years	15 (22)	67	67	–7 (–10)	0.05
Number (%) with <10% total risk over 5 years	41 (73)	67	16	+11 (+16)	0.002
Mean (SE) 'calculated' 5-year CVD risk (%)	4.1 (2.5–7.0)*	67	67	–1.66 (0.32)	<0.001
Lipid profile					
Mean (SE) total cholesterol (mmol/L)	4.78 (0.11)	67	67	–0.16 (0.10)	0.09
Mean (SE) LDL cholesterol (mmol/L)	2.67 (0.09)	61	61	–0.159 (0.09)	0.08
Mean (SE) HDL cholesterol (mmol/L)	1.30 (0.05)	67	67	+0.02 (–0.17–0.21)∞	0.43
Median (IQR) triglycerides (mmol/L)	1.782 (0.13)	67	67	–0.1 (–0.47–0.42)**	0.98
BP					
Mean systolic BP (mmHg)	126.45 (15.68)	67	67	–7 (–18.5– –1)∞	<0.001
Mean diastolic BP (mmHg)	80.77 (9.50)	67	67	–4.98 (1.079)	<0.001
Number (%) with uncontrolled BP (≥ 140/90 mmHg)	20 (29.9)	67	67	–14 (–21)	0.001
Random blood glucose					
Mean (SE) concentration (all, mmol/L)	5.42 (0.11)	67	67	0.05 (–0.4–0.61)∞	0.31
Anthropometric measures					
Mean (SE) weight (kg)	80.09 (2.21)	67	67	–0.4 (–2.40–1.00)∞	0.05
Mean BMI	29.32 (6.37)	67	67	–0.15 (–0.94–0.34)∞	0.05
Number (%) with BMI ≥ 30 (obese)	23 (34.3)	67	67	0 (0)	1.00
Median waist circumference (men, cm)	98.5 (94.2–111.4)	18	18	–2 (–4.8–0.4)	0.27
Average waist circumference (women, cm)	92.3 (84.1–99.5)	49	49	–0.7 (–4.0–2.0)	0.27
Number (%) meeting recommended waist circumference (women 84 cm, men 90 cm)	17 (25.4)	67	67	+4 (+6)	0.22
Mean hip circumference (SE)(cm)	106.7 (1.6)	67	67	–1.75 (0.6)	0.003

* This statistic is non-parametric and 4.1 (2.5–7.0) represents the median (interquartile range).
** Paired differences had a non-parametric distribution despite normally-distributed baseline and follow-up values, causing reduced median TG despite increased mean.
∞ Median (IQR) and Sign rank p-values have been used because the distribution of values is non-parametric.

Table 7. Multivariate analysis of individual CVD risk factor contributions to estimated total CVD risk change*

Patient risk factor	Partial R-square	Parameter estimate	Standard error	P-value
Systolic blood pressure	28.3%	0.12	0.02	<0.001
Diastolic blood pressure	0.22%	– 0.02	0.04	0.60
Smoking status	0.36%	0.95	1.31	0.47
Body Mass Index	0.01%	0.02	0.06	0.91
Total cholesterol	10.7%	1.51	0.37	0.001
HDL cholesterol	12.9%	-4.29	1.11	<0.001

No significant changes to alcohol consumption patterns were in evidence from the data. Overall, 44/66 (67%) of the participants reported receiving dietary advice from health professionals in the 12 months prior to follow-up, representing a significant absolute increase of 46% (30/66) compared with baseline (p<0.001).The proportion of people reporting specific dietary habits for weight reduction more than doubled in 6 months, significantly increasing in absolute terms by 13.4% (9/67) to 22.4% (15/67; p=0.002). Absolute increases in the proportion of high-risk individuals (+7/29, +24%) reporting a weight loss diet were 5 times those observed for lower risk individuals (+2/38, +5%; p=0.03).

Table 8. Self-reported medicines adherence at 6 months follow-up (Morisky scale)

	Overall (6 months)	N (6 months)	N (pairs)	Change since baseline	P (change)
Medication adherence					
Overall number (%) nonadherent (Morisky scale)	15 (22)	67	67	–11 (–16)*	0.001
Number (%) who forget to take medicines	12 (18)	67	67	–9 (–13)*	0.004
Number (%) 'always careful' about taking medicines	67 (100)	67	67	0	NA
Number (%) who stop taking medicines if they feel better	4 (6)	67	67	0 (0–0)	0.63
Number (%) who stop taking medicines if they feel worse	0 (0)	67	67	0 (0–0)	0.25

* The distribution of values used to calculate this figure is non-parametric. A mean is being used instead of a median to allow for easier interpretation

Participants self-rated physical fitness was measured on a 5-point scale from 1(very good) to 5 (very bad), and significantly improved (decreased) at follow-up by a mean 0.36 points to 2.49 (p<0.001). This was supported by the Lifescripts physical activity screening score[41] which indicated a mean increase of 0.87 +/–0.82 points (p=0.04) and a small but significant increase of 0 (IQR 0–2) in the median number of times per week that people undertook moderate-intensity exercise other than walking (p<0.001). There was an increase in the proportion reporting professional physical activity advice, rising in absolute terms by14/67 (21%) to 26/67 (39%; p=0.04).

Mental health and quality of life

Both the proportion who screened negative for depression (86%) and the median CES-D score (4) remained virtually unchanged. Also, there were no significant changes to quality of life measures following the 6-month reassessment.

Pharmacists supporting patient cardiovascular health

Overall, 54 of the 69 patients (78%) for whom information is available attended all five sessions. Six (9%) of the 70 patients opted not to complete all five sessions, three of these following recommendations after baseline assessment that they had low CVD risk and may not benefit. The first session required 34 minutes on average, while the remaining four meetings averaged 16–22 minutes. The average total time taken was 108 minutes.

Provision of educational material was documented for 52 patients (74%). Of these patients, 41 (79%) received written materials on physical activity, 45 (87%) received diet-related materials, and 49 (94%) received material related to cholesterol reduction.

Table 9. Health behaviours at follow-up

	Overall (6 months	N (6 mths)	N (pairs)	Change since baseline	P (change)
Smoking status					
Number (%) current smokers	3 (6)	67	67	0 (0–0)∞	0.50
Diet					
Mean (SE) overall diet score, range 0 to 130.	92.90 (1.63)	64	55	+9.38 (1.77)	<0.001
Mean (SE) fruit and vegetable score (0 to 20)	15.54 (0.42)	67	67	+0.55 (0.47)	0.24
Mean (SE) saturated fat and total fat intake score (0 to 50)	37.91 (0.84)	64	58	+4.52 (0.90)	<0.001
Median (IQR) fibre score (0 to 30)	20 (20–20)	67	66	+1.71 (0.72)∞	0.02
Median (IQR) salt score (0 to 20)	15(10–20)	67	65	+2.72 (0.70) ∞	<0.001
Mean (SE) omega 3 fatty acid intake (0 to 10)	7.23 (0.32)	67	67	+0.47 (0.23)	0.05
Physical activity					
Mean (SE) 'Lifescripts' physical activity score	7.22 (0.59)$^{\alpha}$	67	67	+0.866 (0.41)	0.04
Alcohol intake					
Median (IQR) AUDIT C score (recommended score 0 – 3)	2 (1–4)	67	67	+0.00	0.54

∞ Mean (SE) have been used because the distribution of values obtained when baseline data was subtracted from the follow-up data is parametric α The distribution of data is non-parametric, but the mean and standard error are presented in place of the median and interquartile range to improve interpretability.

Table 10 outlines the major areas of lifestyle and medicines-related recommendations made to patients throughout the intervention period, and pharmacists' perceptions of patient success in following recommendations. Most patients received both dietary and physical activity advice. One quarter of patients received a medicines adherence intervention and a further quarter of patients were advised on some other aspect of medicines use. Pharmacists reported largely positive outcomes to these interventions, most notably in the areas of medicines use, medicines adherence and weight management. Fourteen patients (14/69, 22%) had documented referrals to other health professionals.
Thirteen patients (13/60, 22%) opted for some changes to suggested goals, including four patients (out of six) who declined to pursue smoking cessation, three who wanted to modify their diet goal(s), eight who wanted to modify their physical activity goal(s), and one patient who wanted to modify a goal related to alcohol consumption. At the end of the intervention pharmacists indicated that of the 53 patients for whom pharmacist competence has been documented, they felt competent in treating 50/53 patients (94%). Factors affecting pharmacist perceptions of competence to treat individual patients mainly focussed on insufficient knowledge about diet (2 patients), exercise (1 patient), patient motivation (1 patient) and dealing with expert patients (2 patients).

Table 10. Treatment recommendations by pharmacists and pharmacist-perceived patient success

Area of recommendation	Number (%) of participants receiving recommendation	N_1	Number (%) achieving success*	N_2
Medication adherence	17 (27)	63	16 (100)	16
Other medicines strategies	16 (25)	63	15 (100)	15
Diet	58 (91)	64	51 (94)	54
Weight management	15 (23)	64	10 (100)	10
Alcohol intake	11 (18)	63	8 (80)	10
Physical activity	56 (88)	64	44 (88)	50
Smoking cessation	3 (5)	63	1 (33)	3
BP monitoring	1 (2)	65	1 (100)	1

N_1 Number of patients for whom documentation of recommendation (or no recommendation) is available
N_2 Number of patients receiving the pharmacist recommendation and for whom the pharmacist has indicated, whether or not the recommendation was successfully adopted
* 'Success' was decided by the pharmacist, and was defined as the patient having reached the stated goal or having made some progress towards this.

Satisfaction surveys

Patient attitudes to the service

The 70 participating patients were mailed anonymous postal surveys; one survey was returned unopened and there were 49 respondents from the remaining 69 (71% response rate). There was almost unanimous patient support for delivery of such a program in community pharmacies, with 48/49 (98%) respondents indicating the suitability of this location for such a service. In addition, 37 out of 41 (90%) respondents felt that this should be a routine service provided by community pharmacists (eight participants [16%] had no opinion). A large majority of respondents (29/48, 60%) rated the overall program as excellent, and a further 17 (35%) rated it as good. Just two referred to it as 'average' and none rated it as 'poor'.
Attitudes were highly positive to potential project benefits. On a scale from zero (strongly disagree) to 10 (strongly agree), mean values were 8.6 (this was a valuable service), 8.3 (increased patient interest in heart health), 8.0 (made patient aware of other support and information services), 5.6 (actual increase in services accessed), 6.6 (improved management of medicines). Eighteen from 43 participants (42%) gave a score between 9.5 and 10 to suggest that they saw a very strong benefit from the project as being able to better manage their medicines.
The majority of patients indicated that they had increased regular exercise (31/49, 63%), lost weight (28, 57%) and improved their diet (37, 76%). Thirteen (27%) indicated other lifestyle changes. Two of the six smokers indicated that they had ceased smoking. More than one in four (14, 29%) had commenced a new medicine, and a further three (6%) had medicines ceased or a dose decreased.
Ninety-four percent (29/31) of patients who received GP feedback about the process said it was positive and a further 18 patients (37%) reported no GP feedback about the process. Forty-six respondents (94%) reported receiving feedback from their treating pharmacist about their progress, all of which was positive.

When asked what they would pay for such a service, 17/44 respondents (39%) indicated they would not pay, while 9/44 (20%) suggested just $1–5 per visit, 9/44 (20%) suggested $5–10 and a further 9/44 (20%) suggested in excess of $10.

Pharmacists

All 12 participating pharmacists (six Victorian, six Tasmanian) responded to an anonymous postal survey. There was agreement on the program quality, with seven (58%) describing it as 'excellent' and the remaining five (42%) as 'good' (choices were excellent, good, fair or poor). They were first asked to indicate agreement on a scale from zero (strongly disagree) to ten (strongly agree) to seven statements about how well they felt the service was implemented (Table 11). Responses were generally very positive in terms of the service quality. In fact, at least 75% of respondents gave a score of 7.5 or greater for the six questions relating to these issues.

The lowest level of agreement was for the statement suggesting that GPs gave positive input to the process. All 12 pharmacists felt that community pharmacy was a good place to conduct this type of program. Seven out of nine respondents felt that community pharmacies should routinely provide this service (two felt it should not be routine; an additional three were unsure). When asked how much they felt patients would be willing to pay for such a service, the median response was just $1–5 per visit; responses ranged from nothing to $6–10 per visit.

Table 11. Pharmacist attitudes towards the value of the PAART CVD service

Statements (n=12)	Mean	Standard error of mean	Number 'unsure'
I found this to be a valuable service provided to my patients	8.1	0.6	0
I found that my patients were more interested in their cardiovascular health after the project	7.8	0.6	1
This is a valuable service to promote the professional activities of pharmacy	8.4	0.6	0
I found this research project professionally satisfying	8.1	0.6	0
I found this to be a valuable service for my pharmacy business	7.5	0.6	0
On the whole feedback from GPs was positive	5.8	0.5	2
On the whole feedback from patients was positive	8.0	0.6	0

The main barriers to implementing this project were seen as difficulty recruiting patients (five comments), and obtaining meaningful input from GPs (four comments). Three pharmacists found delivering the service to be time-consuming. When asked for additional considerations if rolling the service out as a full professional pharmacy service, four pharmacists indicated that adequate financial remuneration would necessary to run this as a proper professional service. Two comments posed the need for more training (especially to support diet and exercise advice).

Five pharmacists found GP involvement helpful, four were unsure and three felt it did not help. The main reason for negative responses was a lack of GP feedback, cited by five respondents. A couple of other pharmacists felt that seeking GP input was too time-consuming. Conversely, two pharmacists indicated that this collaboration made patients more willing to engage in the process and ask for information; two commented on positive patient feedback about this approach; two commented that it was valuable in promoting interprofessional activity; and one commented that this process reduced GP workload.

General practitioners

Twelve of the 41 treating GPs (29%) responded to our anonymous postal survey. Six of the seven GPs (86%) who offered an opinion felt that community pharmacies were a good place to conduct this type of program (a further four had no opinion); just two of the 11 respondents (18%) agreed with the statement 'I don't believe that this is an appropriate role for a pharmacist". No GP indicated that the service was intrusive on their practice. Three doctors commented positively on the detailed reports received about patient assessment, and the promotion of evidence-based practice. Six GPs gave an overall service rating – four thought it was 'good' and two 'average'. Three did not recall being actively involved in the project.

Discussion

Using the Framingham-based New Zealand cardiovascular risk score,[48] the relative risk of primary onset of CVD was reduced by 24% over a 6-month period (16% when adjusted for other major factors). Several risk factors were improved – most notably BP – but also a number of health behaviours, including improved adherence to medicines, diet and physical activity. Patients were highly satisfied with the service and their health improvements, and reported substantial benefits in their cardiovascular health knowledge. High-risk patients appeared to benefit more than other patients.

Overall study outcomes suggest that community pharmacists could contribute significantly to the management of multiple CVD risk factors and help to substantially reduce overall CVD risk. These are important findings because managing individual CVD risk factors in isolation – established standard practice in pharmacy and other professions – is no longer considered best practice for good CVD risk management.[49] Importantly, results also suggest that this project provides a feasible model for wider implementation in community pharmacy and for a new professional service implementable under a community pharmacy agreement framework. Pharmacists felt that the program benefited patients and was worthwhile continuing. One of the key limitations noted by both patients and pharmacists was the difficulty in engaging with GPs during the process.

Recruitment

Participant exclusion criteria, the patient profile of some participating pharmacies, and other practice-related issues might have contributed to recruiting less than the anticipated 80–100 patients. Greater female representation has been found for this and other Australian community pharmacy preventive health projects.[50] [51] Given the greater CVD risk associated with male gender,[23] [52] it is important for programs of this type to develop strategies to encourage male participation. Once recruited, nearly all participants remained in the program. Success in retaining patients may be partly due to the convenience of attending sessions while collecting prescriptions.

Comparison with existing knowledge

Ebrahim et al. conducted a systematic review and meta-analysis of outcomes for interventions that manage multiple CVD risk factors for the primary prevention of CVD.[53] This review of 39 trials demonstrated pooled odds ratios for total and CHD mortality of 0.96 (95% confidence interval [CI] 0.92 to 1.01) and 0.96 (95% CI 0.89 to 1.04) respectively; weighted mean reduction in systolic BP of 3.6 mmHg (95% CI –3.9 to –3.3), and a reduction in diastolic BP of 2.8 mmHg (95% CI –2.9 to –2.6); total cholesterol reduction of an average 0.07 mmol/L, (95% CI –0.08 to –0.06 mmol/L); net reduction in smoking prevalence of 24%. The PAART CVD trial results compare favourably with these figures, and also with the Australian GGT DPP which achieved CVD relative risk reductions of 16% among high-risk pre-diabetic patients in general practice.[25]

A couple of pharmacist-led cardiovascular risk reduction studies have been identified. The SCRIP trial intervention group experienced a (10-year) CVD absolute risk reduction of 0.9%.[30] However, the predominant focus was on controlling lipid levels, and eligibility was restricted to individuals with high-level baseline CVD risk (>30% over 10 years). This limited benefits to those with reasonably elevated cholesterol, and limited potential benefits to this group by not adopting a broader treatment approach. Emerson et al.[35] demonstrated an absolute risk reduction of 2.3% (over 10 years) through a multiple CVD risk factor management project for patients in rural New South Wales. There was no indication of how a patient-centred approach, health promotion strategies or the use of particular behavioural change strategies may have been integrated into the model of care. Both studies appear to have included patients with a history of heart disease into Framingham-based risk calculations. *These equations are validated only in populations free from CVD, and our study may be the first to assess changes to estimated risk in such a population following pharmacist intervention.* [54]

Our findings complement positive clinical outcomes from the Fremantle Diabetes Study[36] in suggesting that Australian community pharmacists are capable of running a structured and comprehensive CVD management service to reduce CVD risk. By reproducing a CVD risk reduction similar to the Diabetes Prevention Project (DPP) run in Victoria[25] this project further supports development of the Health Action Processes Approach (HAPA) health promotion model in Australian primary care. It is interesting to note that improvements in CVD risk were significantly associated with blood pressure reductions in our study, whereas the DPP intervention appeared to have little effect on blood pressure despite substantial improvements to other risk factors.

Adherence

The extent of self-reported nonadherence at baseline in our study (41%) is similar to that reported in previous cardiovascular adherence studies.[27 29 55]

Subjects who adhere to their medication regimen are significantly less likely to experience cardiovascular events than nonadherent subjects,[26] hence the importance of this issue being addressed. Measures of self-reported adherence such as the Morisky scale and TABS give valuable information about nonadherence reasons and adherence barriers. Such information would have allowed practitioners in our study to meaningfully address nonadherence, although the scale of improvement – an almost 50% reduction – requires further confirmation. This is well above the adherence change reported by other intervention studies (–3% to 25%).[56 57] Differences in adherence measures might partly explain this.

Interventions for improving cardiovascular medications adherence could be categorised as (1) simplification of drug regimens, (2) patient information and education (3) patient care intensification, or (4) complex behavioural interventions, such as group sessions.[56] Our study focused on improvements through patient education. Future studies for improving medication adherence in patients with cardiovascular conditions should investigate how to better facilitate other effective strategies such as regimen simplification, reminder systems and group education.

Lifestyle modification

Findings of improvements to diet following intervention are consistent with evidence that health professional interventions can produce moderate effects.[58 59 60] Reliability of self-reported physical activity has been questioned previously, although self-reporting still remains the most common measure.[61] HDL-cholesterol levels from our study remained unchanged over the 6-month period, but would normally be expected to increase somewhat if exercise levels had increased. Patient evaluations suggest that patients were more informed about cardiovascular health and about how to access CVD support following the intervention. This supports evidence from follow-up assessments that health behaviours had improved, and that the interventions brought about intrinsic improvements to patient self-efficacy in preventing CVD. Our findings that patients support a pharmacist role in CVD prevention confirms a previous study of consumer views.[62]

Implications for practice

The model of care delivered appears very promising for its positive impact on patient health and the feasibility of implementing it into practice. All three surveyed stakeholder groups reported satisfaction with the process, and with pharmacists having a CVD prevention role. Pharmacists have demonstrated their ability and potential impact in delivering important health messages and interventions. The high proportion of patients (29%) who report commencing new medicines suggests this intervention may help address widespread treatment inertia in CVD prevention.[63]

An expanded role for community pharmacists should be considered as part of the National Service Improvement Framework for Heart, Stroke and Vascular Disease.[64] The wider implementation of such a service in community pharmacy would also help the profession to develop a model of care that meets the proposed National Primary Care Strategy principles of evidence-based chronic disease management, patient self-management of chronic disease, supporting GPs, improved access to other health professionals and the promotion of preventive health.[65] The role of community pharmacy role in primary prevention of CVD is gaining some attention. The ability for pharmacists to screen for CVD has already been demonstrated in Australia,[51] and there is some evidence internationally that use of Framingham-based risk assessment tools by community pharmacists is quite feasible.[66] Most notably, a national community pharmacy roll-out is planned in the UK for a CVD risk assessment and intervention program. While the fundamental rationale for UK community pharmacy involvement is acknowledged by government, medical concerns about the lack of evidence for the effectiveness of such a strategy and how best to integrate such a program into mainstream have been voiced. [67] Such programs are inherently multidisciplinary in nature and hence it is essential to carry out appropriate research so policymakers and other professions are convinced of the need for mainstream integration of new pharmacy services.

The pharmacist satisfaction surveys identified a small number of very important barriers that would need to be overcome in order to achieve wider implementation, most notably the time taken to deliver the service, difficulty with participant recruitment and adequate remuneration. Development of such a service would need to carefully consider the remuneration required for such a service. It required an average 108 minutes of community pharmacist's time, in addition to time spent collecting and reviewing baseline and follow-up data, and is unlikely to be widely adopted unless financially viable.

Areas for further research

The major area for further research is the consolidation of these results via a randomised controlled trial. As outlined above, the promising health benefits demonstrated should be retested alongside a control group and patients should be followed-up for a longer time period to ensure sustainable health outcomes. Undertaking the trial within more pharmacies and with greater statistical power through increased patient numbers would enable greater confidence regarding generalisability of findings and the impact of the intervention on individual CVD risk factors and health behaviours.

Some GPs' involvement in the process fell short of patient and pharmacist expectations, and mechanisms to improve GP involvement should be examined. Options may include developing reimbursable Medicare item numbers for pharmacists undertaking this service as part of a general practice management plan. Involvement of GP organisations and academic detailers may also help to raise the profile of such a service locally. Similarly, some pharmacists expressed the need for further training or support in diet and lifestyle modification areas. Formal referral to or support options from dietetic, physiotherapy or other relevant expertise may help a number of patients to further improve health outcomes.

With some further training, community pharmacists are capable of undertaking all aspects of the patient care process described. In order to facilitate ease of implementation by minimising unnecessary demands on community pharmacist time, the need for their direct involvement in certain service aspects should be investigated before any wider roll-out. Clinical data collection at baseline and follow-up has been standardised according to a protocol and might be undertaken by another suitably trained pharmacist, pharmacy technician or other health professional. Similarly, baseline clinical reports may be prepared by any suitably trained pharmacist. The necessity of using an accredited consultant pharmacist is uncertain. To implement a similar service in the real world, community pharmacists could be paid to organise and undertake the entire process from patient identification through to follow-up assessment, while having the option of delegating clinical assessment and reporting to appropriately trained professionals. Identifying appropriate patients for treatment and delivering advice to them should remain the treating community pharmacist's responsibility. Several options exist for other health professional involvement; these might be accessed either via the GP, through formal involvement with each patient, or by allocating a budget to individual pharmacists for certain referrals or support.

Given the growing number of professional pharmacy programs, issues should be examined around pharmacist, patient and community factors that impact on recruitment success. Cost-effectiveness also needs to be established for providing this service through the community. Given the relatively brief intervention (on average, less than two hours) – compared with GGT DPP[25] – it may be worth investigating if a more intensive pharmacist intervention could deliver even better results.

Limitations

A number of methodological limitations exist to this study, largely owing to the trial's short duration and uncontrolled nature. Sustainability of patients' health benefits need to be tested beyond six months to ensure that reduction in clinical risk actually delivers a subsequent reduction in adverse cardiovascular events. Clinical trials examining lifestyle interventions often deliver only a short term behavioural change in patients. Intervention results need to be compared with a control group to fully distinguish intervention benefits from potential changes to CVD risk in the normal course of events had the participants gone untreated, or from observer bias. A similar control group would also establish the extent to which it was the pharmacist input that brought about the clinical changes as opposed to other health professionals who were involved in the care of these patients. Likewise, there is a risk that participants who volunteered for this study were already motivated to reduce their CVD risk and would have done so regardless of pharmacist input. The control group examined by Emerson et al.[35] had a relatively unchanged overall risk at 16 months, suggesting that such a population is unlikely to naturally improve their CVD risk level. Conversely, a risk exists of observing declining BPs as a result of habituation to patient BP self-measurement.[53] This would favour positive results if it occurred in the PAART CVD trial.

It is also possible that certain beneficial clinical effects of behavioural change may only emerge over time, as happened in the Multiple Risk Factor Intervention trial (MRFIT) after 10 years.[68] Likewise, the full effects of pharmacological therapy in the areas of BP management and blood cholesterol reduction are generally seen within 2–4 years.[69] Although the New Zealand risk score used[48] is unvalidated for use with patients taking medicines for CVD risk factors, the equation is commonly used for such patients. As with many studies examining lifestyle change, there was substantial reliance on self-reported rather than objective measures of change. While our primary outcome did not depend on such self-reports, most outcomes related to key health behaviours such as diet and physical activity were based on such reports. The small sample size limits our ability assess the impact of this intervention on individual risk factors. The significance of gains made to risk factors such as smoking cessation, cholesterol profiles and waist circumference cannot be established. A small sample size also limited the extent to which findings in

relation to individual population subgroups at high risk of CVD could be assessed (e.g. ethnic minorities, obese patients, males). Future studies should be powered to enable more detailed analysis of clinical and demographic subgroups to be performed.

Conclusion

As prevalence of CVD and chronic disease continues to rise in the face of an ageing and more sedentary population, Australian society needs to focus more on preventive health services that reduce the healthcare burden by reducing evidence–treatment gaps in primary prevention of CVD. To our knowledge this study represents one of the first attempts in Australia by any health profession to develop and implement a formal care model for delivering a broad approach to primary prevention of CVD. These and other findings suggest a potentially substantial public health benefit if a 24% relative risk reduction for the primary onset of CVD can be achieved. Stakeholder feedback suggests this is a very practical model for implementation.

Wider implementation of such a service would also help to place community pharmacists at the forefront of efforts to underpin primary care with evidence-based practice, a patient-centred approach, a preventive health focus and engagement with other health disciplines. Generic skills would be developed by pharmacists in important areas of chronic disease management such as screening, improving medicines adherence and generating patient behavioural change. Pharmacists would also ensure a consistent and evidence-based approach to addressing chronic disease risk factors such as BP, dyslipidaemias, diet, weight management and smoking cessation. The benefits of such a service would extend to improved management for a number of non-cardiovascular conditions with the same common risk factors.

References

1. Australian Institute of Health and Welfare. National Drug Strategy Household Survey: first results. Drug Statistics Series number 20. Cat. no. PHE 98. In: AIHW, editor. Canberra: AIWH, 2008.

2. Laatikainen T, Janus E, Kilkkinen A, Heistaro S, Tideman P, Baird A, et al. Chronic disease risk factors in rural Australia: results from the Greater Green Triangle Risk Factor Surveys. *Asia Pac J Public Health* 2009;21(1):51-62.

3. Briganti EM, Shaw JE, Chadban SJ, Zimmet PZ, Welborn TA, McNeil JJ, et al. Untreated hypertension among Australian adults: the 1999-2000 Australian Diabetes, Obesity and Lifestyle Study (AusDiab). *Med J Aust* 2003;179(3):135-9.

4. Janus ED, Bunker SJ, Kilkkinen A, Mc Namara K PB, Tideman P, Tirimacco R, Laatikainen TK, Heistaro S, Dunbar JA. Prevalence, detection and drug treatment of hypertension in a rural Australian population: the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medicine Journal* 2008;38(12):879-86.

5. Chapman RH, Benner JS, Petrilla AA, Tierce JC, Collins SR, Battleman DS, et al. Predictors of adherence With antihypertensive and lipid-lowering therapy. *Arch Intern Med* 2005;165(10):1147-52.

6. Cameron AJ, Welborn TA, Zimmet PZ, Dunstan DW, Owen N, Salmon J, et al. Overweight and obesity in Australia: the 1999-2000 Australian Diabetes, Obesity and Lifestyle Study (AusDiab). *The Medical Journal of Australia* 2003;178(9):427-32.

7. Janus ED, Laatikainen T, Dunbar JA, Kilkkinen A, Bunker SJ, Philpot B, et al. Overweight, obesity and metabolic syndrome in rural southeastern Australia. *The Medical Journal of Australia* 2007;187(3):147-52.

8. National Health and Medical Research Council. Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults. In: Department of Health and Ageing, editor. Canberra: Commonealth of Australia, 2003.

9. Manson JE, Willett WC, Stampfer MJ, Colditz GA, Hunter DJ, Hankinson SE, et al. Body weight and mortality among women. *N Engl J Med* 1995;333(11):677-85.

10. Australian Bureau of Statistics. National Health Survey 2004-2005. In: ABS, editor. Canberra 2006.

11. National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand. Position statement on lipid management-2005. *Heart, Lung and Circulation.* 2005;14:275-91.

12. Australian Centre for Diabetes Strategies. National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus. In: NHMRC, editor. Canberra 2001 (updated 2005).

13. Dunstan DW, Zimmet PZ, Welborn TA, de Courten MP, Cameron AJ, Sicree RA, et al. The rising prevalence of diabetes and impaired glucose tolerance. *Diabetes Care* 2002;25(5):829-34.

14. Australian Institute of Health and Welfare. Australia's Health 2008. Canberra, 2008.

15. Hickie IB. Responding to the Australian experience of depression. *Medical Journal of Australia* 2002;176(10 Suppl):S61-S62.

16. Zwar N, Richmond R, Borland R, Stillman S, Cunningham M, Litt J. Smoking Cessation Guidelines for Australian General Practice. In: Quit Australia, editor, 2004.

17. National Heart Foundation of Australia (National Blood Pressure and Vascular Disease Advisory Committee). Guide to management of hypertension 2008.

18. National Physical Activity Program Committee. Physical activity and energy balance: National Heart Foundation of Australia, 2007.

19. National Health and Medical Research Council. Dietary Guidelines for Australian Adults In: NHMRC, editor. Canberra 2003.

20. National Health and Medical Research Council. Australian Guidelines to Reduce Health Risks from Drinking Alcohol. In: NHMRC, editor. Canberra 2009.

21. Ellis PM, Smith DA. Treating depression: the beyondblue guidelines for treating depression in primary care. *Medical Journal of Australia* 2002;196((10 Suppl)):S77-S83.

22. New Zealand Guideline Group. The Assessment and Management of Cardiovascular Risk In: NZGG, editor, 2003.

23. Hung J. Aspirin for cardiovascular disease prevention. *Med J Aust* 2003;179(3):147-52.

24. Harris M, Lyle D, Davies GP, McKenzie S, Passey M, Heading G, Tzar C, Devlin L, Purcell K, Zwar N, Jayasinghe U, Wan Q, Amoroso C, Laws R. Prevention of vascular disease in general practice: Health Improvement and Prevention Study (HIPS). In: Centre for Primary Health Care and Equity, University of New South Wales website.

25. Laatikainen T, Dunbar JA, Chapman A, Kilkkinen A, Vartiainen E, Heistaro S, et al. Prevention of type 2 diabetes by lifestyle intervention in an Australian primary health care setting: Greater Green Triangle (GGT) Diabetes Prevention Project. *BMC Public Health* 2007;7:249.

26. Nelson MR, Reid C, Ryan P, Willson K, Yelland L, on behalf of the ANBP2 Management Committee. Self-reported adherence with medication and cardiovascular disease outcomes in the Second Australian National Blood Pressure Study (ANBP2). *Medical Journal of Australia* 2006;185 (9):487-89.

27. Simons L, Ortiz M, Calcino G. Persistence with antihypertensive medication: Australia-wide experience, 2004–2006. *Medical Journal of Australia* 2008;188(4):224-27.

28. Vrijens B, Vincze G, Kristanto P, Urquhart J, Burnier M. Adherence to prescribed antihypertensive drug treatments: longitudinal study of electronically compiled dosing histories. *BMJ* 2008;336(7653):1114-17.

29. Simons LA, Graham Levis, Simons J. Apparent discontinuation rates in patients prescribed lipid-lowering drugs. *Medical Journal of Australia* 1996;164(4):208-11.

30. Tsuyuki RT, Olson KL, Dubyk AM, Schindel TJ, Johnson JA. Effect of community pharmacist intervention on cholesterol levels in patients at high risk of cardiovascular events: the second study of cardiovascular risk intervention by pharmacists (SCRIP-plus). *The American Journal of Medicine* 2004;116(2):130-33.

31. Tsuyuki R, Johnson J, Teo K, Ackman M, Biggs R, Cave A, et al. Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP): a randomized trial design of the effect of a community pharmacist intervention program on serum cholesterol risk. *Annals of Pharmacotherapy* 1999;33(9):910-19.

32. Paulos CP, Nygren CEA, Celedon C, Carcamo CA. Impact of a Pharmaceutical Care Program in a Community Pharmacy on Patients with Dyslipidemia. *Annals of Pharmacotherapy* 2005;39(5):939-43.

33. Fahey T, Schroeder K, Ebrahim S, Glynn L. Interventions used to improve control of blood pressure inpatients with hypertension (Review). *Cochrane Database of Systematic Reviews*, 2006.

34. Sinclair HK, Bond CM, Stead LF. Community pharmacy personnel interventions for smoking cessation. *Cochrane Database of Systematic Reviews* 2004;Issue 1. Art. No.: CD003698. DOI: 10.1002/14651858.CD003698.pub2.

35. Emerson L, Krass I. A Collaborative, Interdisciplinary Evidence Based Approach to Reducing Coronary Heart Disease in Rural Areas. Canberra: Pharmacy Guild of Australia 2006.

36. Clifford RM, Davis WA, Batty KT, Davis TME. Effect of a pharmaceutical care program on vascular risk factors in type 2 diabetes. *Diabetes Care* 2005;28(4):771-76.

37. Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: A Randomized Controlled Trial. *JAMA* 2006:296.21.joc60162.

38. The World Health Organization MONICA Project (monitoring trends and determinants in cardiovascular disease): a major international collaboration. WHO MONICA Project Principal Investigators. *J Clin Epidemiol* 1988;41(2):105-14.

39. George J, Mackinnon A, Kong DCM, Stewart K. Development and validation of the Beliefs and Behaviour Questionnaire (BBQ). *Patient Education and Counseling* 2006;64(1-3):50-60.

40. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care* 1986;24(1):67-74.

41. Kinect Australia for the Lifescripts consortium. Lifescripts Practice Manual: Supporting Lifestyle Risk Factor Management in General Practice. Canberra Commonwealth of Australia, 2005.

42. National Health and Medical Research Council. Dietary Guidelines for Australian Adults: Commonwealth of Australia 2003.

43. McLennan W, Podger A. National Nutrition Survey: Nutrient Intakes and Physical Measurements Australia 1995. Canberra: Australian Bureau of Statistics1998.

44. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA, for the Ambulatory Care Quality Improvement Project. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. *Arch Intern Med* 1998;158(16):1789-95.

45. Radloff LS. The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement*, 1977, pp.385-401.

46. Ware JE, Kosinski M, Turner-Bowker DM, Gandeck B. *User's manual for the SF-12v2™ Health Survey*. Boston: Quality Metrics, 2007.

47. Schwarzer R. Modeling health behavior change: how to predict and modify the adoption and maintenance of health behaviors. *Applied Psychology* 2008;57(1):1-29.

48. Anderson KM, Odell PM, Wilson PW, Kannel WB. Cardiovascular disease risk profiles. *Am Heart J* 1991;121(1 Pt 2):293-8.

49. Ritz E. Total cardiovascular risk management. *The American Journal of Cardiology* 2007;100(3, Supplement 1):S53-S60.

50. Saini B, Filipovska J, Bosnic-Anticevich S, Taylor S, Krass I, Armour C. An evaluation of a community pharmacy-based rural asthma management service. *Australian Journal of Rural Health* 2008;16(2):100-08.

51. Hourihan F, Krass I, Chen T, Hourihan F, Krass I, Chen T. Rural community pharmacy: a feasible site for a health promotion and screening service for cardiovascular risk factors. *Australian Journal of Rural Health* 2003;11(1):28-35.

52. Ridker PM, Cook NR, Lee I-M, Gordon D, Gaziano JM, Manson JE, et al. A randomized trial of low-dose aspirin in the primary prevention of cardiovascular disease in women. *N Engl J Med* 2005;352(13):1293-304.

53. Ebrahim S, Beswick A, Burke M, Davey Smith G. Multiple risk factor interventions for primary prevention of coronary heart disease *Cochrane Database of Systematic Reviews* 2006;Issue 4. Art. No.: CD001561. DOI: 10.1002/14651858.CD001561.pub2.(Accessed online 05/06/2009 from www.cochrane.org).

54. Wilson PWF, D'Agostino RB, Levy D, Belanger AM, Silbershatz H, Kannel WB. Prediction of Coronary Heart Disease Using Risk Factor Categories. *Circulation* 1998;97(18):1837-47.

55. Simpson SH, Johnson JA, Biggs C, Biggs RS, Kuntz A, Semchuk W, et al. Practice-based research: lessons from community pharmacist participants. *Pharmacotherapy* 2001;21(6):731-9.

56. Schedlbauer A, Schroeder K, Peters TJ, Fahey T. Interventions to improve adherence to lipid lowering medication. *Cochrane Database Syst Rev* 2004(4):CD004371.

57. Haynes RB, Ackloo E, Sahota N, McDonald HP, Yao X. Interventions for enhancing medication adherence. *Cochrane Database Syst Rev* 2008(2):CD000011.

58. Brunner EJ, Rees K, Ward K, Burke M, Thorogood M. Dietary advice for reducing cardiovascular risk. *Cochrane Database of Systematic Reviews* 2007 (Issue 4. Art. No.: CD002128. DOI:10.1002/14651858.CD002128.pub3).

59. Twardella D, Merx H, Hahmann H, Wusten B, Rothenbacher D, Brenner H. Long term adherence to dietary recommendations after inpatient rehabilitation: prospective follow up study of patients with coronary heart disease. *Heart* 2006;92(5):635-40.

60. Pomerleau J, Lock K, Knai C, McKee M. Interventions Designed to Increase adult fruit and vegetable intake can be effective: a systematic review of the literature. *J. Nutr.* 2005;135(10):2486-95.

61. Sallis JF, Saelens BE. Assessment of physical activity by self-report: Status, limitations, and future directions. *Research Quarterly for Exercise and Sport* 2000;71(2):S1-14.

62. Peterson G, Jeff Hughes, Stewart K, Nation R, Scott S, Farris K, Jackson S, Fitzmaurice K, Gee P, Bereznicki L. Pharmacy Cardiovascular Healthcare Model. Canberra: Pharmacy Guild of Australia, 2005.

63. Guthrie B, Inkster M, Fahey T. Tackling therapeutic inertia: role of treatment data in quality indicators. *BMJ* 2007;335(7619):542-44.

64. National Health Priority Action Council (NHPAC). Improvement Framework for Heart, Stroke and Vascular Disease Risk. In: Government Department of Health and Ageing, editor. Canberra 2006. Accessed online from www.health.gov.au.

65. Department of Health and Ageing. Primary Health Strategy: Department of Health and Ageing website, accessed 24/06/2009 online from www.health.gov.au

66. Liu Y, Mentele LJ, McDonough RP, Carruthers KM, Doucette WR. Community pharmacist assessment of 10-year risk of coronary heart disease for union workers and their dependents. *Journal of the American Pharmacists Association* 2003;48(4):515-17.

67. Patel KC, Minhas R, Gill P, Khunti K. Vascular risk checks in the UK: strategic challenges for implementation. *Heart* 2009:hrt.2008.165035.

68. The Multiple Risk Factor Intervention Trial Research Group. Mortality rates after 10.5 years for participants in the Multiple Risk Factor Intervention Trial: findings related to a priori hypotheses of the trial. *JAMA* 1990;263(13):1795-801.

69. Collins R, MacMahon S. Blood pressure, antihypertensive drug treatment and the risks of stroke and of coronary heart disease. *Br Med Bull* 1994;50(2):272-98.

Appendices

Annex 3.1: Pharmacist Training – Timetable
Annex 3.2: Participant recruitment assessment pathway
Annex 3.3: GP copy of clinical assessment results (baseline)
Annex 3.4: Patient copy of clinical assessment results (baseline)
Annex 3.5: Intervention interviews by community pharmacist – Session Guide
Annex 3.6: Patient goal sheet
Annex 3.7: Clinical report (follow-up)
Annex 3.8: Patient evaluation
Annex 3.9: Pharmacist evaluation
Annex 3.10: GP evaluation

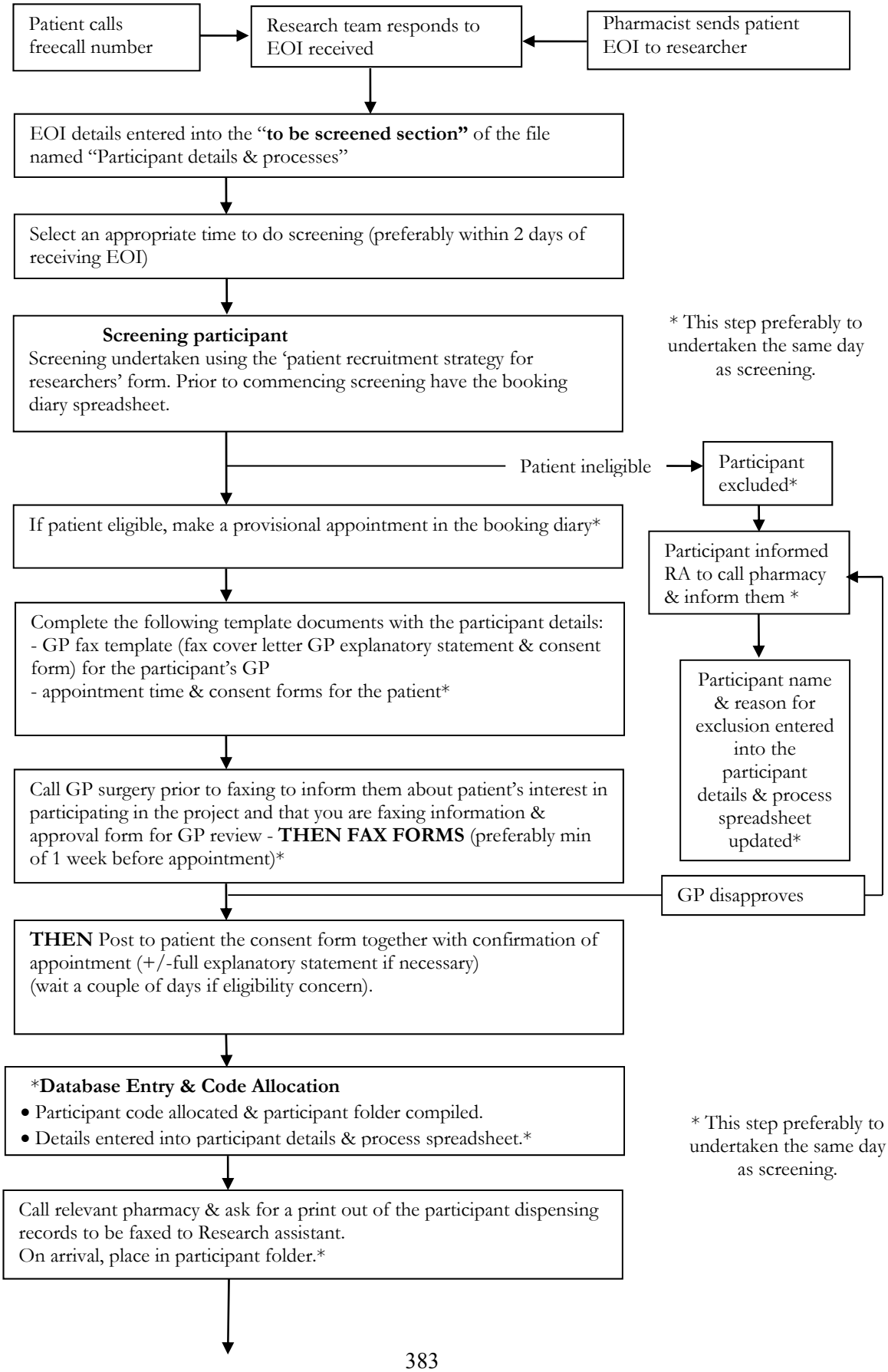
Annex 3.1:
Pharmacist Training – Timetable

Healthy Hearts in Pharmacy Project
Pharmacist Training – Timetable

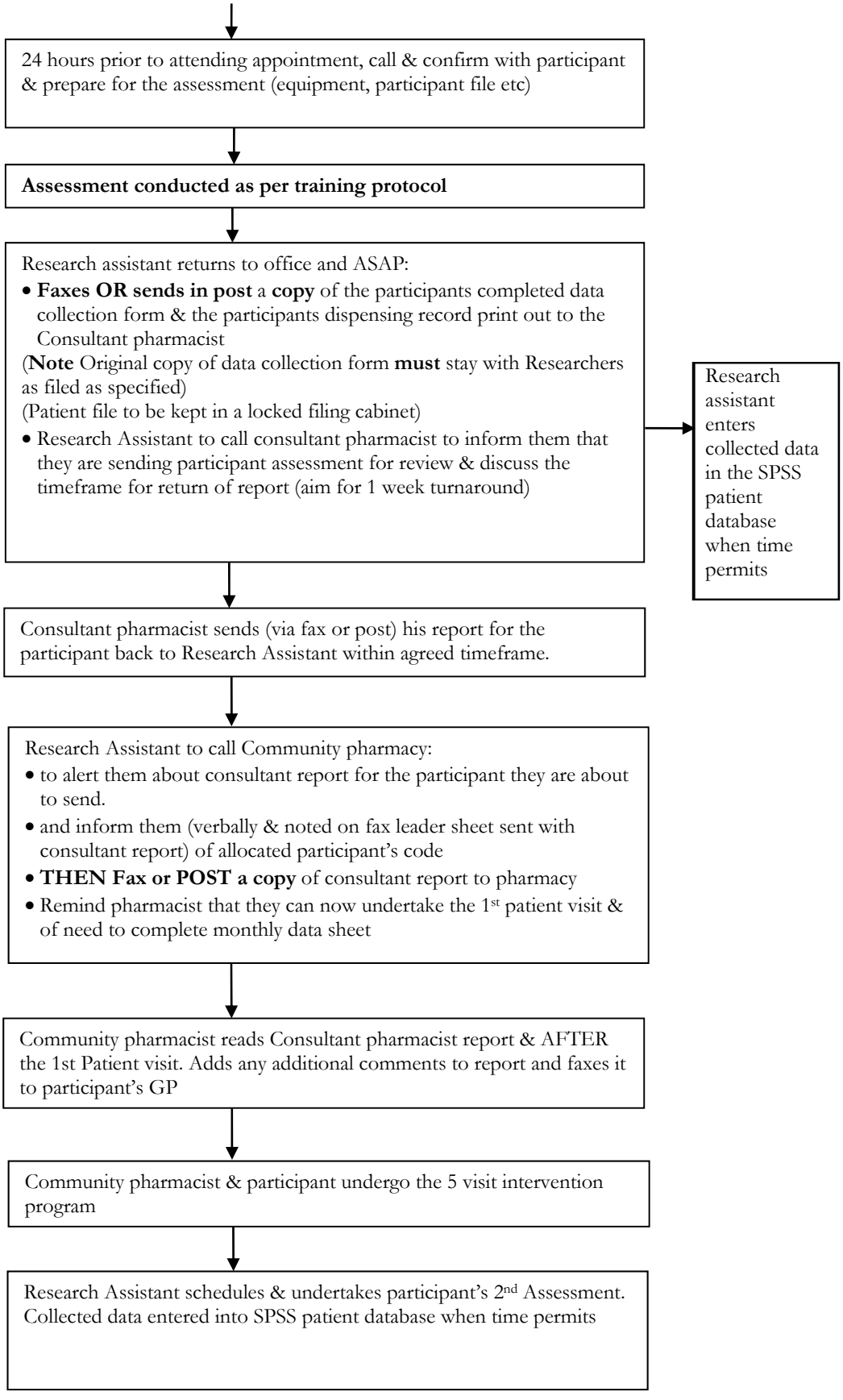
Topic	Duration
Overview of the "Healthy Hearts in Pharmacy Project"	40–60min
Healthy Hearts in Pharmacy & the health promotion model being used (motivational tools & behavioral change , using smoking cessation as the example) Communication with patients & GP's	60min
Patient recruitment process	15 min
Data collection process & content	25 min
Consultant Pharmacist report – Interpretation by participating pharmacists	15 min
Absolute Cardiovascular Risk & the Healthy Hearts in Pharmacy intervention strategy	15 min
Antiplatelets in primary care	10 mins
Smoking cessation and the Stages of Change	25 mins
Medication adherence: - identifying non-compliance (questions to ask) - Barrier to compliance - Management strategies	60 min
Hypertension & Cholesterol (workshop)	40 min
Reducing Cardiovascular risk – Diet & Activity (workshop)	60 min
Reducing Cardiovascular risk – alcohol, diabetes and depression	15 mins
Discussion and feedback	30 min

Annex 3.2:
Participant recruitment assessment pathway

Part 1: Patient recruitment & screening



Part 2: Assessment & reporting phase



THE END

Annex 3.3:
GP copy of clinical assessment results (baseline)

Dear Doctor <Insert name>

As you may be aware your patient, <Insert name and address, DOB> has been enrolled in the Healthy Hearts in Pharmacy Program which is a collaborative project between Monash University, University of Tasmania and the Greater Green Triangle University Department of Rural Health.

This program will target patients from community pharmacies who are being dispensed medications for high blood pressure or high cholesterol, but who have not had a cardiovascular event. Following the initial clinical assessment reported on in this document (including an examination of cholesterol, blood pressure, BMI and lifestyle risk factors), local community pharmacies will implement a support plan offering brief counselling sessions to patients on a monthly basis for six months. They will counsel medication use, medication adherence and lifestyle. We are happy to receive any input you feel is relevant.

Summary of clinical assessment and interpretation

Parameters	Result
Smoking status	
Total Cholesterol	
LDL Cholesterol	
HDL Cholesterol	
Triglycerides	
Blood Pressure	
Pulse	
Random Blood Glucose	
Age	
Height	
Weight	
BMI	
Waist	
Family History of CHD	
Overall cardiovascular risk (% risk of an event over the next five years)	

**Please note: The results from this assessment should be used as a guide only. Suboptimal fasting times can adversely affect lipid results – this patient fasted for (x) hours (optimal 12–16 hours). If you intend to commence and/or modify therapies as a result of this assessment we would advise that the results that we have obtained are repeated by your normal assessment mechanisms.*

Please find attached a current cardiovascular medication list for your patient:

Drug prescribed and dose	**Actual use of medication**

Medication adherence assessment

Suggestions by accredited pharmacist for implementation and/or follow-up	Additional comments by community pharmacist	Comments by GP on recommendations
Based on the information provided by the patient during the interview and using this patients dispensing history this patient was found to be at risk of suboptimal medication adherence. They expressed reservations about the long term use of these medications. Ongoing reinforcement regarding the benefits of these medications is required, and suboptimal medication adherence may be the reason they have not reached their target levels.		

Lifestyle, diet, alcohol, weight management and physical activity based suggestions

Suggestions by accredited pharmacist for implementation	Additional comments by community pharmacist	Comments by GP on recommendations
Diet Mrs Jones has a low level of compliance with a good cardiovascular diet. Through the Healthy Hearts program we will deliver education and motivation to improve her overall diet.		
Smoking As outlined above, Mrs Jones does want to cease smoking at some stage in the future. We should monitor this and encourage her to give up.		
Physical activity Mrs Jones does not perform adequate physical activity, she does ~30 minutes per week. I will encourage her to increase the exercise component to 30 minutes five times per week.		
Alcohol She does not drink any alcohol		
Weight management Her current BMI is 29kg/m2. I will encourage her through a program of diet and exercise to reduce her weight and therefore improve her BMI.		

Medication based suggestions for possible implementation

Suggestions for follow-up by accredited pharmacist	Additional comments by community pharmacist	Comments by GP on recommendations
Antiplatelet At her current level of cardiovascular risk over 5 years, if he does not have any other contraindications, the addition of an antiplatelet agent would appear to be beneficial		
Lipids At the time of the interview Mrs Jones' lipid profile was just on target for primary prevention. She does not qualify for PBS subsidised lipid lowering, however would benefit from lowering her lipids further through diet and lifestyle and increasing her HDL level.		

Ideal targets and suggested patient goals for the six month program:

1. **Aim to lose weight towards achieving a BMI of 25 and a waist circumference of <80cm.**
2. **Aim to lower total cholesterol levels to 5.5mmol/L and lower TG levels to <1.7mmol/L.**
3. **Aim to increase physical activity to at least 30 minutes on most days.**
4. **Improve diet further to an even better cardiovascular friendly diet.**

In the average person with your results, meeting these targets could help to lower the likelihood of a heart attack or other cardiovascular disease from an estimated (x)% to about (x)% chance over the next five years.

Appendix 3.4:
Patient copy of clinical assessment results (baseline)

Patient Copy of assessment results – Mrs Jones

Summary of clinical assessment and interpretation

Parameters	Result
Smoking status	
Total Cholesterol	
LDL Cholesterol	
HDL Cholesterol	
Triglycerides	
Blood Pressure	
Pulse	
Random Blood Glucose	
Age	
Height	
Weight	
BMI	
Waist	
Family History of CHD	
Overall cardiovascular risk (% risk of an event over the next five years)	

**Please note: The results from this assessment should be used as a guide only. Your cholesterol results may be inaccurate of you did not fast for 12–16 hours before being tested (your fast time= x hours)*

The following activities have been identified as suitable goals to help lower your heart disease risk over the six month program with your pharmacist. This program will help you to maximise the benefits and minimise the unnecessary inconvenience in achieving these goals.

1. **Aim to lose weight towards achieving a BMI of 25 and a waist circumference of <80cm.**
2. **Aim to lower total cholesterol levels to 5.5mmol/L and lower TG levels to <1.7mmol/L.**
3. **Aim to increase physical activity to at least 30 minutes on most days.**
4. **Improve diet further to an even better cardiovascular friendly diet.**

In the average person with your results, meeting these targets could help to lower the likelihood of a heart attack or other cardiovascular disease from an estimated (x)% to about (x)% chance over the next five years.

Annex 3.5:

Intervention interviews by community pharmacist – Session Guide

Intervention interviews by community pharmacist – Session Guide

Session 1. The pharmacist ensures patients accurately perceive their cardiovascular risk, and understand the importance of even minor improvements to risk factors. Discussions then focus around identifying realistic and attainable goals for expected health gains, based on the consultant pharmacist's report. Pharmacists recommend and facilitate a GP referral if:

- patients' 5-year CVD event risk was greater than 20% and their self-reported data suggested their GPs were unaware of overall risk or contributing factors
- a CVD drug therapy change was considered immediately necessary
- behavioural modification needs were too complex for the community pharmacist to manage
- GPs' specified additional criteria were met for referral based on local circumstances and resources.

Patients are given the Patient Copy of Clinical Assessment Results (baseline) (Appendix 3.3), a Patient Goal Sheet (Appendix 3.4) and appropriate education materials to take home. After the session, a clinical report copy, including any additional pharmacist notes, are forwarded to patients' GPs for comment.

Session 1 objectives:

1. Describe to patients how the program operates
2. Ensure patients understand the CVD risk issues, recommended targets, etc
3. Address any urgent issues identified during clinical assessment
4. Provide basic education materials if necessary
5. Communicate plan to the patients' GPs.

Session 2. Pharmacist and patients confirm goals, or reaffirm them if already set after Session 1. By Session 2 end, patients should have a set of written goals and an action plan for achieving them consisting of practical and realistic measures. Pharmacists should review any attempts already made to achieve goals and give practical feedback and motivation where possible. Any medication issues arising from Session 1 should have been resolved.

Session 2 objectives:

1. Clarify medication management strategy, if relevant to patients
2. Agree upon treatment priorities and goals with patients
3. Review patients' perceptions around their need and ability to change behaviours
4. Confirm/review strategies with patients; provide feedback if appropriate
5. Provide ongoing assistance in intention formation, goal setting, planning, feedback and relapse prevention.

Sessions 3–5. Continuous progress review. If changes have been made, pharmacist and patients establish how these can be sustained. Where problems arise or where patients lapse into less healthy behaviours, discuss alternative methods for achieving goals, or modify goals. Patients' progress is reviewed to assess

individual strategies. Relapse prevention becomes a key focus if goals are attained or patient circumstances change. If patients have difficulty with their goals and strategies in a particular area, the need for specific expert input is discussed (e.g. dietitian, exercise programs).

Session 3–5 objectives:

1. Assess patient progress
2. Review goals
3. Relapse prevention.

Annex 3.6:

Patient goal sheet

HEALTHY HEART ACTION PLAN

List your goals for this program (e.g. lose 5 kilos in weight, reduce total cholesterol to less than 5.5 mmol/L)

1.
2.
3.
4.
5.

Date	**Strategies for achieving my goals** (e.g. walk for 10 minutes at lunchtime; switch to low fat milk; reminder in diary to refill cholesterol prescription on time)	**How well have you done this month with your strategies?** 1=Not well; 2=fairly well; 3=very well!					
		Month 1	Month 2	Month 3	Month 4	Month 5	Month 6

Next appointment:

	Date	**Time**
Session 2		
Session 3		
Session 4		
Session 5		

Annex 3.7:
Clinical report (follow-up)

Your Assessment Results Explained

About your results
The suggested targets for your results in the table below may vary for different individuals. The figures we suggest are commonly used, but do not apply to everyone.

The results and targets below may also be different from those given to you by your pharmacist or GP on other occasions. There are often simple explanations for this. For example, using different testing equipment can affect results. Also, some measurements such as cholesterol or blood pressure can change regularly. If you have any queries about your results, please check with your pharmacist or GP.

Calculated cardiovascular risk
We calculate your cardiovascular risk (risk of heart disease) based on a formula which considers your smoking status, cholesterol levels, age, sex, and blood pressure. It indicates the percentage chance of having a serious heart problem over the next 5 years for the average person with the same characteristics.

This score is only an estimate of your risk. It is important to note that other issues can also have a significant impact on the risk of heart disease. Therefore, some changes you have made over the last six months may not be reflected in the final score. If you require further explanation about your risk of heart disease, please check with your pharmacist or GP.

Improvements in areas such as diet, weight, waist measurement, alcohol intake, aspirin use and exercise will lower your future risk of heart disease considerably but are not considered by the risk score. So if you have made positive changes in any of these areas, the final score may have underestimated the benefit of these changes to you. Please remember this and continue to keep up the good work.

Stay healthy in the future

We hope you have enjoyed the process and found it to be of benefit to your health. As you probably know, keeping your heart healthy is a lifelong process. You can achieve this by maintaining the healthy changes you have managed and by setting new goals in the future if needed. If you need advice about health issues we recommend that you discuss these with your pharmacist or GP.

On behalf of your pharmacist and the research team, thank you for participating in The Healthy Hearts Project. Your involvement in this project will help us to make important recommendations about how pharmacists can best support individuals who want to improve their heart health. Please do not hesitate to contact us if you have further questions about this project.

Kind regards

Kevin Mc Namara
Principal Researcher, Monash University.

Copy of Assessment Results

Patient Name

Summary of Assessment Results

Parameters	Result 1 00/00/08	Result 2 00/00/09	Suggested target results	Pharmacist Comments
Fasting hours			12–16 hours *Your cholesterol results and blood glucose result may be inaccurate if you did not fast for 12–16 hours before being tested*	
Total Cholesterol			Less than 5.0 – 5.5 mmol/L	
LDL Cholesterol			Less than 3.0–3.5 mmol/L *Sometimes referred to as "bad" cholesterol*	
HDL cholesterol			More than 1 mmol/L. *Sometimes referred to as "good" cholesterol*	
Triglycerides			Less than 1.7 mmol/L	
Blood Pressure			If diagnosed as high, reduce to at least 140/90 mmHg or further if possible. Less that 120/80 mmHg is considered 'normal'	
Random Blood Glucose			Less than 5.5 mmol/L	
Height				
Weight				
BMI			18.5–24.9 (lower if Asian/Indigenous Australian background)	
Waist			Less than 94 cm for males, less than 80 cm for females	
Family history of coronary heart disease				
Smoking status			Non-smoker and not exposed to smoke.	
Overall cardiovascular risk			**The % risk of a cardiovascular event over the next five years**	

Annex 3.8:
Patient evaluation

Healthy Hearts in Pharmacy

EVALUATION SURVEY FOR PATIENTS

Please answer the following questions. Honest feedback is important to evaluate the program. Please place a cross ***anywhere*** on the line or tick the box or provide with additional feedback as suggested. Thank you for your participation and support.

1. Do you think community pharmacies are a good place to do this type of program?

- ❑ Yes
- ❑ No
- ❑ I don't know/ I'm not sure

2. Do you think that all pharmacists should routinely provide this service?

- ❑ Yes
- ❑ No
- ❑ I don't know/I'm not sure

3. I found this to be a valuable service provided by my pharmacy.

Strongly agree — Strongly disagree — ☐ Unsure

4. I was more interested in my heart health after the project.

Strongly agree — Strongly disagree — ☐ Unsure

5. Participation in the project made me more informed about how to prevent heart disease through diet and lifestyle.

Strongly agree — Strongly disagree — ☐ Unsure

6. Participation in the project made me more aware of other support and information services available for heart disease prevention.

Strongly agree — Strongly disagree — ☐ Unsure

7. I have accessed more services for heart disease prevention as a result of participation in this project.

Strongly agree Strongly disagree ☐ Unsure

8. This project has helped me to better manage my medicines.

Strongly agree Strongly disagree ☐ Unsure

9. Since participating in the project I have: *(you may tick more than one)*

- ❑ Increased my regular exercise
- ❑ Lost weight
- ❑ Improved my diet
- ❑ Stopped smoking
- ❑ Made other lifestyle changes……
- ❑ Started a new medication…..…….

10. Feedback from my General Practitioner was positive.

- ❑ Yes
- ❑ No
- ❑ I don't know/I'm not sure

Please add any comments……...…… …. …… ……

11. Feedback from my pharmacist was positive.

- ❑ Yes
- ❑ No
- ❑ I don't know/I'm not sure

Please add any comments……..…… . …… ……

12. What do you think you would pay for this program?

- ❑ Nothing
- ❑ $1–5 per visit
- ❑ $6–10 per visit
- ❑ $11–20 per visit
- ❑ More than $20 per visit

13. Did you find the team-based approach using your pharmacist and General Practitioner for the management of your condition helpful?

- ❑ Yes
- ❑ No
- ❑ I don't know/I'm not sure

14. What do you think were the positives and negatives of this collaborative approach?

……
……
……
……
……
……
……
……

15. Overall, how would you rate the quality of the program?

- ❑ Excellent
- ❑ Good
- ❑ Average
- ❑ Poor

Any other comments about this program would be appreciated.

……
……
……
……
……
……
……
……
……
……
……
……
……
……

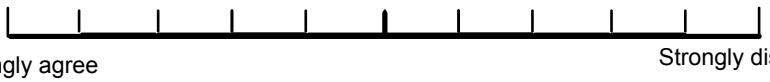
Annex 3.9:
Pharmacist evaluation

Healthy Hearts in Pharmacy

EVALUATION SURVEY FOR COMMUNITY PHARMACISTS

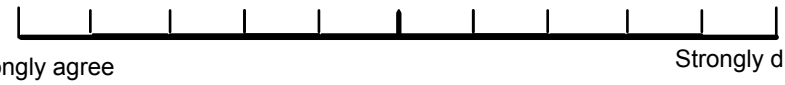
Please answer the following questions. Honest feedback is important to evaluate the program. Please place a cross ***anywhere*** on the line **OR** tick the box **OR** provide additional feedback as suggested. Thank you for your participation and support.

1. I found this to be a valuable service provided to my patient(s).



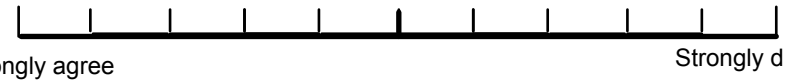
☐ Unsure

2. I found that my patient(s) showed more interest in their cardiovascular health after the project.



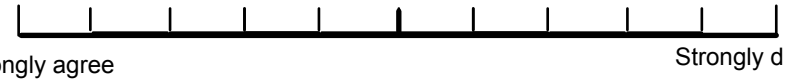
☐ Unsure

3. I found this to be a valuable service to promote the professional activities of pharmacy.



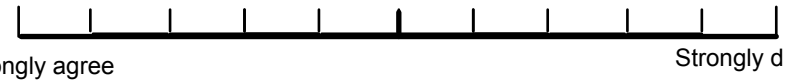
☐ Unsure

4. I found this research project professionally satisfying.



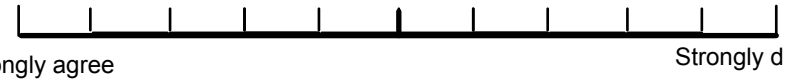
☐ Unsure

5. I found this to be a valuable service for my pharmacy business.



☐ Unsure

6. On the whole feedback from General Practitioners was positive.



☐ Unsure

7. On the whole feedback from patients was positive.

☐ Unsure

8. Do you think community pharmacies are a good place to conduct this type of program?

- ❑ Yes
- ❑ No
- ❑ I don't know/ I'm not sure

9. Do you think that all pharmacists should routinely provide this service?

- ❑ Yes
- ❑ No
- ❑ I don't know/I'm not sure

10. What do you think patients would pay for this program?

- ❑ Nothing
- ❑ $1–5 per visit
- ❑ $6–10 per visit
- ❑ $11–20 per visit
- ❑ More than $20 per visit

11. Did you experience any of the barriers and challenges listed below? *(you may tick more than one)*

- ❑ I don't believe this service is part of the role of a pharmacist.
- ❑ In my experience, General Practitioners were reluctant to participate or communicate.
- ❑ I had difficulty recruiting patients.
- ❑ I felt uncomfortable providing this form of professional pharmacy service.
- ❑ I felt under qualified or trained for this role.
- ❑ This service was too intrusive on my current practice.
- ❑ I found this type of service too time consuming.

Were there any other barriers and challenges that you experienced?

……
……

……
……

12. If this model were to become part of community pharmacy practice, what changes would have to be made for you to participate?

……
……

……
……

13. This service could be offered as part of a Home Medicines Review with community pharmacy participation. Do you think this could be a sustainable model?

……
……

……
……

14. Did you find the team-based approach using the pharmacist and General Practitioner for the management of your patient's condition helpful?

- ❑ Yes
- ❑ No
- ❑ I don't know/I'm not sure

15. What do you think were the positives and negatives of this collaborative approach?

……
……

……
……

……
……

16. Overall, how would you rate the quality of the program?

- ❑ Excellent
- ❑ Good
- ❑ Average
- ❑ Poor

Any other comments about this program would be appreciated. Thank you.

Annex 3.10:
GP evaluation

Healthy Hearts in Pharmacy

EVALUATION SURVEY FOR GENERAL PRACTITIONERS

Please answer the following questions. Honest feedback is important to evaluate the program. Please place a cross ***anywhere*** on the line **OR** tick the box **OR** provide additional feedback as suggested. Thank you for your participation and support.

1. I found this to be a valuable service provided to my patient(s).

Strongly agree — Strongly disagree — ☐ Unsure

2. I found that my patient(s) showed more interest in their cardiovascular health after the project.

Strongly agree — Strongly disagree — ☐ Unsure

3. On the whole feedback from correspondence was appropriate.

Strongly agree — Strongly disagree — ☐ Unsure

4. On the whole feedback from patients was positive.

Strongly agree — Strongly disagree — ☐ Unsure

5. Do you think community pharmacies are a good place to conduct this type of program?

- ❑ Yes
- ❑ No
- ❑ I don't know/ I'm not sure

6. Did you experience any of the barriers and challenges listed below? *(you may tick more than one)*

- ❑ I don't believe this service is part of the role of a pharmacist.
- ❑ This service was too intrusive on my current practice.
- ❑ I found this type of service too time consuming.

Were there any other barriers and challenges that you experienced?

……
……

……
……

7. This service could be offered as part of a Home Medicines Review with community pharmacy participation. Do you think this could be a sustainable model?

……
……

……
……

8. Did you find the team-based approach using the pharmacist and General Practitioner for the management of your patient's condition helpful?

- ❑ Yes
- ❑ No
- ❑ I don't know/I'm not sure

9. What do you think were the positives and negatives of this collaborative approach?

……
……

……
……

10. Overall, how would you rate the quality of the program?

- ❑ Excellent
- ❑ Good
- ❑ Average
- ❑ Poor

Any other comments about this program would be appreciated.

Appendix 4. Description of health behaviour terms and self-report scales used

A. Self-report scales used for health and health behaviour assessment

- AUDIT C is an internationally recognised brief intervention screening tool for alcohol misuse.[1]
- CES-D is a 10-item patient self-report scale used to screen for depression.[2]
- CVAR (Cardiovascular Absolute Risk) scores are an estimate of the probability of developing CVD over the next five years. These are calculated using validated Framingham algorithms based on demographics and key risk factor information.
- DQT (Diet Quality Tool) is a survey instrument used to assign a score indicating the quality of diet in terms of cardiovascular health.[3] The total score indicates overall diet quality, and there are subdomains for total and saturated fat, fibre, and added salt consumption.
- 'Lifescripts' is a lifestyle modification program endorsed by the Australian Department of Health and Ageing for use in primary care.[4] They recommend specific screening tools for physical activity, weight management and smoking, all of which were incorporated into this program for consistency with medical practitioners. Further information and online resources are available from http://www.health.gov.au/lifescripts.
- MMAS (Morisky Medicines Adherence Scale) is a 4-item survey used to assess medication adherence.[5]
- SF-12v2 is a 12-item scale used to measure quality of life for participants.[6]

- TABS (Tool for Adherence Behaviour Screening) is a patient survey used to assess behaviours in patients that are associated with adherence/nonadherence.[7]
- WHO MONICA (MONItoring of CArdiovascular events) is an internationally used survey protocol developed for monitoring of chronic disease risk factors and health behaviours at a population level. This was used as the basis for several clinical measures.

B. Model used to facilitate behaviour change by patients

HAPA (Health Action Process Approach) is a psychological model for facilitating health behaviour change. In general terms, it suggests that behaviour change is initiated through patient motivation, leading to an intention to change behaviour. Patient motivation is achieved by addressing issues around self-efficacy, risk perception and outcomes expectancy. Once intention to change is achieved, the patient must then be supported through implementation and maintenance of healthier behaviours through different processes such as action planning, goal-setting and relapse prevention.

References

1. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA, for the Ambulatory Care Quality Improvement Project. The AUDIT Alcohol Consumption Questions (AUDIT-C): An Effective Brief Screening Test for Problem Drinking. *Archives of Internal Medicine* 1998;158(16):1789-95.
2. Radloff LS. The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement* 1977 1:385-401.
3. O'Reilly S, McCann L. Development and validation of the Diet Quality Tool for use in cardiovascular disease prevention settings. . *Australian Journal of Primary Care* (In Press).
4. Kinect Australia for the Lifescripts consortium. Lifescripts Practice Manual: Supporting Lifestyle Risk Factor Management in General Practice. Canberra Commonwealth of Australia, 2005.
5. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Med Care* 1986;24(1):67-74.
6. Ware JE, Kosinski M, Turner-Bowker DM, Gandeck B. *User's manual for the SF-12v2™ Health Survey*. Boston: Quality Metrics, 2007.
7. George J, Mackinnon A, Kong DCM, Stewart K. Development and validation of the Beliefs and Behaviour Questionnaire (BBQ). *Patient Education and Counseling* 2006;64(1-3):50-60.

Bibliography

1. Yusuf S, Reddy S, Ounpuu S, Anand S. Global burden of cardiovascular diseases: part I: general considerations, the epidemiologic transition, risk factors, and impact of urbanization. *Circulation* 2001;104(22):2746-53.
2. Yusuf S, Hawken S, Ôunpuu S, Dans T, Avezum A, Lanas F, et al. Effect of potentially modifiable risk factors associated with myocardial infarction in 52 countries (the INTERHEART study): case-control study. *The Lancet* 2004;364(9438):937-52.
3. Capewell S, Flaherty M. What explains declining coronary mortality? Lessons and warnings. *Heart* 2008;94(9):1105-08.
4. Begg S, Vos T, Barker B, Stevenson C, Stanley L, Lopez AD. The Burden of Disease and Injury in Australia 2003. Canberra: Australian Institute of Health and Welfare, 2007.
5. Australian Institute of Health and Welfare. Australia's Health 2008. *Australia's Health series*. Canberra, 2008.
6. Laatikainen T, Janus E, Kilkkinen A, Heistaro S, Tideman P, Baird A, et al. Chronic disease risk factors in rural Australia: results from the Greater Green Triangle Risk Factor Surveys. *Asia Pacific Journal of Public Health* 2009;21(1):51-62.
7. Australian Institute of Health and Welfare. National Drug Strategy Household Survey: first results. Drug Statistics Series number 20. Cat. no. PHE 98. In: AIHW, editor. Canberra: AIWH, 2008.
8. Teo KK, Ounpuu S, Hawken S, Pandey MR, Valentin V, Hunt D, et al. Tobacco use and risk of myocardial infarction in 52 countries in the INTERHEART study: a case-control study. *The Lancet* 2006;368(9536):647-58.
9. Aldoori MI, Rahman SH. Smoking and stroke: a causative role. *BMJ* 1998;317(7164):962-63.
10. Mattson ME, Pollack ES, Cullen JW. What are the odds that smoking will kill you? *American Journal of Public Health* 1987;77(4):425-31.
11. Coleman T, Wynn A, Barrett S, Wilson A. Discussion of NRT and other antismoking interventions in UK general practitioners'

routine consultations. *Nicotine and Tobacco Research* 2003;5:163-8.
12. Humair J-P, Ward J. Smoking cessation strategies observed in videotaped general practice consultations. *American Journal of Preventive Medicine* 1998;14:71-2.
13. Stead LF, Bergson G, Lancaster T. Physician advice for smoking cessation. *Cochrane Database of Systematic Reviews* 2008(Issue 2. Art. No.: CD000165. DOI: 10.1002/14651858.CD000165.pub3.).
14. Vogt F, Hall S, Marteau T. General practitioners' and family physicians' negative beliefs and attitudes towards discussing smoking cessation with patients: a systematic review. *Addiction* 2005;100:1423-31.
15. Young D, Furler J, Vale M, Walker C, Segal L, Dunning P, et al. Patient Engagement and Coaching for Health: The PEACH study - a cluster randomised controlled trial using the telephone to coach people with type 2 diabetes to engage with their GPs to improve diabetes care: a study protocol. *BMC Family Practice* 2007;8(1):20.
16. Briganti EM, Shaw JE, Chadban SJ, Zimmet PZ, Welborn TA, McNeil JJ, et al. Untreated hypertension among Australian adults: the 1999-2000 Australian Diabetes, Obesity and Lifestyle Study (AusDiab). *Medical Journal of Australia* 2003;179(3):135-9.
17. Janus ED, Bunker SJ, Kilkkinen A, Mc Namara K, Philpot B, Tideman P, et al. Prevalence, detection and drug treatment of hypertension in a rural Australian population: the Greater Green Triangle Risk Factor Study 2004-2006. *Internal Medicine Journal* 2008;38(12):879-86.
18. Prospective Studies Collaboration. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. *The Lancet* 2002;360(9349):1903-13.
19. Hansson L, Zanchetti A, Carruthers SG, Dahlöf B, Elmfeldt D, Julius S, et al. Effects of intensive blood-pressure lowering and low-dose aspirin in patients with hypertension: principal results of the Hypertension Optimal Treatment (HOT) randomised trial. *The Lancet* 1998;351(9118):1755-62.
20. Jamerson K, Weber MA, Bakris GL, Dahlof B, Pitt B, Shi V, et al. Benazepril plus amlodipine or hydrochlorothiazide for hypertension in high-risk patients. *New England Journal of Medicine* 2008;359(23):2417-28.
21. The ALLHAT Officers, Coordinators for the ALLHAT Collaborative Research Group. Major outcomes in high-risk hypertensive patients randomized to angiotensin-converting enzyme inhibitor

or calcium channel blocker vs diuretic: the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT). *JAMA* 2002;288(23):2981-97.
22. Cameron AJ, Welborn TA, Zimmet PZ, Dunstan DW, Owen N, Salmon J, et al. Overweight and obesity in Australia: the 1999-2000 Australian Diabetes, Obesity and Lifestyle Study (AusDiab). *Medical Journal of Australia* 2003;178(9):427-32.
23. Janus ED, Laatikainen T, Dunbar JA, Kilkkinen A, Bunker SJ, Philpot B, et al. Overweight, obesity and metabolic syndrome in rural southeastern Australia. *Medical Journal of Australia* 2007;187(3):147-52.
24. Van Gaal LF, Mertens IL, De Block CE. Mechanisms linking obesity with cardiovascular disease. *Nature* 2006;444(7121):875-80.
25. Manson JE, Willett WC, Stampfer MJ, Colditz GA, Hunter DJ, Hankinson SE, et al. Body weight and mortality among women. *New England Journal of Medicine* 1995;333(11):677-85.
26. National Health and Medical Research Council. Clinical Practice Guidelines for the Management of Overweight and Obesity in Adults. In: Department of Health and Ageing, editor. Canberra: Commonealth of Australia, 2003.
27. Australian Bureau of Statistics. National Health Survey 2004-2005. In: ABS, editor. Canberra 2006.
28. National Physical Activity Program Committee. Physical activity and energy balance: National Heart Foundation of Australia, 2007.
29. Healy GN, Wijndaele K, Dunstan DW, Shaw JE, Salmon J, Zimmet PZ, et al. Objectively measured sedentary time, physical activity, and metabolic risk. *Diabetes Care* 2008;31(2):369-71.
30. National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand. Position statement on lipid management-2005. *Heart, Lung and Circulation.* 2005;14:275-91.
31. Chirovsky DR, Fedirko V, Cui Y, Sazonov V, Barter P. Prospective studies on the relationship between high-density lipoprotein cholesterol and cardiovascular risk: a systematic review. *Journal of Cardiovascular Risk* 2009;16(4):404-23.
32. Arsenault BJ, Rana JS, Stroes ESG, Després J-P, Shah PK, Kastelein JJP, et al. Beyond low-density lipoprotein cholesterol: respective contributions of non-high-density lipoprotein cholesterol levels, triglycerides, and the total cholesterol/high-density lipoprotein cholesterol ratio to coronary heart disease risk in apparently healthy men and women. *Journal of the American College of Cardiology* 2009;55(1):35-41.
33. El Harchaoui K, van der Steeg WA, Stroes ESG, Kuivenhoven JA, Otvos JD, Wareham NJ, et al. Value of low-density lipoprotein particle number and size as predictors of coronary artery

disease in apparently healthy men and women: the EPIC-Norfolk prospective population study. *Journal of the American College of Cardiology* 2007;49(5):547-53.

34. Gordon T, Castelli WP, Hjortland MC, Kannel WB, Dawber TR. High density lipoprotein as a protective factor against coronary heart disease: The Framingham study. *The American Journal of Medicine* 1977;62(5):707-14.
35. Sarwar N, Danesh J, Eiriksdottir G, Sigurdsson G, Wareham N, Bingham S, et al. Triglycerides and the risk of coronary heart disease: 10 158 incident cases among 262 525 participants in 29 western prospective studies. *Circulation* 2007;115(4):450-58.
36. Sprecher DL. Triglycerides as a risk factor for coronary artery disease. *The American Journal of Cardiology* 1998;82(12, Supplement 1):49U-56U.
37. Marks GC, Rutishauser IHE, Webb K & Picton P Key food and nutrition data for Australia 1990-1999. In: Australian Food and Nutrition Monitoring Unit, editor. Canberra: Department of Health and Ageing, 2001, as cited in Australia's Health 2008 (available at www.aihw.gov.au).
38. Trichopoulou A, Orfanos P, Norat T, Bueno-de-Mesquita B, Ocke MC, Peeters PH, et al. Modified Mediterranean diet and survival: EPIC-elderly prospective cohort study. *BMJ* 2005;330(7498):991-.
39. National Health and Medical Research Council. Dietary Guidelines for Australian Adults In: NHMRC, editor. Canberra 2003.
40. Brunner EJ, Rees K, Ward K, Burke M, Thorogood M. Dietary advice for reducing cardiovascular risk. *Cochrane Database of Systematic Reviews* 2007 (Issue 4. Art. No.: CD002128. DOI: 10.1002/14651858.CD002128.pub3).
41. Almdal T, Scharling H, Jensen JS, Vestergaard H. The independent effect of type 2 diabetes mellitus on ischemic heart disease, stroke, and death: a population-based study of 13 000 men and women with 20 years of follow-up. *Archives of Internal Medicine* 2004;164(13):1422-26.
42. Australian Centre for Diabetes Strategies. National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus. In: NHMRC, editor. Canberra 2001 (updated 2005).
43. Dunstan DW, Zimmet PZ, Welborn TA, de Courten MP, Cameron AJ, Sicree RA, et al. The rising prevalence of diabetes and impaired glucose tolerance. *Diabetes Care* 2002;25(5):829-34.
44. Shaw JE, Chisholm DJ. 1: Epidemiology and prevention of type 2 diabetes and the metabolic syndrome. *Medical Journal of Australia* 2003;179(7):379-83.

45. National Health and Medical Research Council. Australian Guidelines to Reduce Health Risks from Drinking Alcohol. In: NHMRC, editor. Canberra 2009.
46. Coulson CE, Williams LJ, Henry MJ, Berk M, Lubman DI, Brennan SL, et al. Patterns of alcohol use and associated physical and lifestyle characteristics according to new Australian guidelines. *Australian and New Zealand Journal of Psychiatry* 2010;44(10):946-51.
47. White SL, Polkinghorne KR, Cass A, Shaw JE, Atkins RC, Chadban SJ. Alcohol consumption and 5-year onset of chronic kidney disease: the AusDiab study. *Nephrology Dialysis Transplantation* 2009;24(8):2464-72.
48. Bunker SJ, Colquhoun DM, Esler MD, Hickie IB, David Hunt, Jelinek VM, et al. "Stress" and coronary heart disease: psychosocial risk factors. *Medical Journal of Australia* 2003;178(6):272-76.
49. Ellis PM, Smith DA. Treating depression: the beyondblue guidelines for treating depression in primary care. *Medical Journal of Australia* 2002;196((10 Suppl)):S77-S83.
50. Kilkkinen A, Kao-Philpot A, O'Neil A, Philpot B, Reddy P, Bunker S, et al. Prevalence of psychological distress, anxiety and depression in rural communities in Australia. *Australian Journal of Rural Health* 2007;15(2):114-19.
51. Hickie IB. Responding to the Australian experience of depression. *Medical Journal of Australia* 2002;176((10 Suppl)):S61-S62.
52. van Melle JP, de Jonge P, Spijkerman TA, Tijssen JGP, Ormel J, van Veldhuisen DJ, et al. Prognostic association of depression following myocardial infarction with mortality and cardiovascular events: a meta-analysis. *Psychosomatic Medicine* 2004;66(6):814-22.
53. Surtees PG, Wainwright NWJ, Luben RN, Wareham NJ, Bingham SA, Khaw K-T. Depression and ischemic heart disease mortality: evidence from the EPIC-Norfolk United Kingdom prospective cohort study. *American Journal of Psychiatry* 2008;165(4):515-23.
54. Van der Kooy K, van Hout H, Marwijk H, Marten H, Stehouwer C, Beekman A. Depression and the risk for cardiovascular diseases: systematic review and meta analysis. *International Journal of Geriatric Psychiatry* 2007;22(7):613-26.
55. Nicholson A, Kuper H, Hemingway H. Depression as an aetiologic and prognostic factor in coronary heart disease: a meta-analysis of 6362 events among 146 538 participants in 54 observational studies. *European Heart Journal* 2006;27(23):2763-74.
56. Nelson MR, Reid C, Ryan P, Willson K, Yelland L, on behalf of the ANBP2 Management Committee. Self-reported adherence with

medication and cardiovascular disease outcomes in the Second Australian National Blood Pressure Study (ANBP2). *Medical Journal of Australia* 2006;185 (9):487-89.
57. LaRosa JH, LaRosa JC. Enhancing drug compliance in lipid-lowering treatment. *Archives of Family Medicine* 2000;9(10):1169-75.
58. Simons L, Ortiz M, Calcino G. Persistence with antihypertensive medication: Australia-wide experience, 2004–2006. *Medical Journal of Australia* 2008;188(4):224-27.
59. Vrijens B, Vincze G, Kristanto P, Urquhart J, Burnier M. Adherence to prescribed antihypertensive drug treatments: longitudinal study of electronically compiled dosing histories. *BMJ* 2008;336(7653):1114-17.
60. Simons L, Balasubramaniam S, von Konigsmark M, Parfitt A, Simons J, Peters W. On the effect of garlic on plasma lipids and lipoproteins in mild hypercholesterolaemia. *Atherosclerosis* 1995;113(2):219 - 25.
61. Chapman RH, Benner JS, Petrilla AA, Tierce JC, Collins SR, Battleman DS, et al. Predictors of adherence with antihypertensive and lipid-lowering therapy. *Archives of Internal Medicine* 2005;165(10):1147-52.
62. Keys A, Mienotti A, Karvonen MJ, Aravanis C, Blackburn H, Buzina R, et al. The diet and 15-year death rate in the Seven Countries Study. *American Journal of Epidemiology* 1986;124(6):903-15.
63. Anderson KM, Odell PM, Wilson PW, Kannel WB. Cardiovascular disease risk profiles. *American Heart Journal* 1991;121(1 Pt 2):293-8.
64. Saaristo T, Peltonen M, Lindstrom J, Saarikoski L, Sundvall J, Eriksson JG, et al. Cross-sectional evaluation of the Finnish Diabetes Risk Score: a tool to identify undetected type 2 diabetes, abnormal glucose tolerance and metabolic syndrome. *Diabetes and Vascular Disease Research* 2005;2(2):67-72.
65. Porkka KVK, Raitakari OT, Leino A, Laitinen S, Rásänen L, Rónnemaa T, et al. Trends in serum lipid levels during 1980–1992 in children and young adults. *American Journal of Epidemiology* 1997;146(1):64-77.
66. Juonala M, Viikari JSA, Hutri-Kähönen N, Pietikäinen M, Jokinen E, Taittonen L, et al. The 21-year follow-up of the Cardiovascular Risk in Young Finns Study: risk factor levels, secular trends and east–west difference. *Journal of Internal Medicine* 2004;255(4):457-68.
67. Australian Institute of Health and Welfare. Australia's Health 2010. *Australia's Health series*. Canberra: AIHW, 2010:250.
68. Department of Human Services. Victorian Population Health Survey, 2007.

69. Crossley TF, Kennedy S. The reliability of self-assessed health status. *Journal of Health Economics* 2002;21(4):643-58.
70. Davis T, Fortun P, Mulder J, Davis W, Bruce D. Silent myocardial infarction and its prognosis in a community-based cohort of Type 2 diabetic patients: the Fremantle Diabetes Study. *Diabetologia* 2004;47(3):395-99.
71. Knuiman MW, Vu HT. Prediction of coronary heart disease mortality in Busselton, Western Australia: an evaluation of the Framingham, national health epidemiologic follow up study, and WHO ERICA risk scores. *Journal of Epidemiology and Community Health* 1997;51(5):515-19.
72. Adams RJ, Appleton S, Wilson DH, Taylor AW, Dal Grande E, Chittleborough C, et al. Population comparison of two clinical approaches to the metabolic syndrome. *Diabetes Care* 2005;28(11):2777-79.
73. Simons LA, Friedlander Y, McCallum J, Simons J. Risk factors for coronary heart disease in the prospective Dubbo Study of Australian elderly. *Atherosclerosis* 1995;117(1):107-18.
74. Dunstan D, Zimmett P, Welborn T. The Final Report of the Australian Diabetes, Obesity and Lifestyle Study (AusDiab). 2001.
75. Sexton PT, Sexton TLH. Excess coronary mortality among Australian men and women living outside the capital city statistical divisions *Medical Journal of Australia* 2000;172:370-74.
76. National Health and Medical Research Council. Dietary Guidelines for Australian Adults: Commonwealth of Australia 2003.
77. Zwar N, Richmond R, Borland R, Stillman S, Cunningham M, Litt J. Smoking Cessation Guidelines for Australian General Practice. Quit Australia, 2004.
78. National Heart Foundation of Australia (National Blood Pressure and Vascular Disease Advisory Committee). Guide to management of hypertension 2008 (updated 2009).
79. Sheridan SL, Viera AJ, Krantz MJ, Ice CL, Steinman LE, Peters KE, et al. The effect of giving global coronary risk information to adults: a systematic review. *Archives of Internal Medicine* 2010;170(3):230-39.
80. Torley D, Zwar N, Comino EJ , Harris M. GPs' views of absolute cardiovascular risk and its role in primary prevention. *Australian Family Physician* 2005;34(6):503-05.
81. Stampfer MJ, Hu FB, Manson JE, Rimm EB, Willett WC. Primary prevention of coronary heart disease in women through diet and lifestyle. *New England Journal of Medicine* 2000;343(1):16-22.

82. Djousse L, Driver JA, Gaziano JM. Relation between modifiable lifestyle factors and lifetime risk of heart failure. *JAMA* 2009;302(4):394-400.
83. Iestra JA, Kromhout D, van der Schouw YT, Grobbee DE, Boshuizen HC, van Staveren WA. Effect size estimates of lifestyle and dietary changes on all-cause mortality in coronary artery disease patients: a systematic review. *Circulation* 2005;112(6):924-34.
84. Chobanian AV, Bakris GL, Black HR, Cushman WC, Green LA, Izzo JL, Jr, et al. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: The JNC 7 Report. *JAMA* 2003;289(19):2560-71.
85. Blair SN, Kampert JB, Kohl HW, Barlow CE, Macera CA, Paffenbarger RS, et al. Influences of cardiorespiratory fitness and other precursors on cardiovascular disease and all-cause mortality in men and women. *JAMA* 1996;276(3):205-10.
86. Arnlov J, Ingelsson E, Sundstrom J, Lind L. Impact of body mass index and the metabolic syndrome on the risk of cardiovascular disease and death in middle-aged men. *Circulation* 2010;121(2):230-36.
87. Thun MJ, Peto R, Lopez AD, Monaco JH, Henley SJ, Heath CW, et al. Alcohol consumption and mortality among middle-aged and elderly U.S. adults. *New England Journal of Medicine* 1997;337(24):1705-14.
88. Sofi F, Cesari F, Abbate R, Gensini GF, Casini A. Adherence to Mediterranean diet and health status: meta-analysis. *BMJ*;337:673-79.
89. Tuomilehto J, Lindstrom J, Eriksson JG, Valle TT, Hamalainen H, Ilanne-Parikka P, et al. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. *New England Journal of Medicine* 2001;344(18):1343-50.
90. National Heart Foundation of Australia, Cardiac Society of Australia and New Zealand. Reducing Risk in Heart Disease In: NHFA, editor, 2007 (updated 2008)
91. National Vascular Disease Prevention Alliance. Guidelines for the assessment of absolute cardiovascular disease risk: National Heart Foundation of Australia. Downloaded 28 April 2010 from <http://www.heartfoundation.org.au/Professional_Information/General_Practice/Pages/AbsoluteRisk.aspx>, 2009.
92. Hung J. Aspirin for cardiovascular disease prevention. *Medical Journal of Australia* 2003;179(3):147-52.
93. De Berardis G, Sacco M, Strippoli GFM, Pellegrini F, Graziano G, Tognoni G, et al. Aspirin for primary prevention of

cardiovascular events in people with diabetes: meta-analysis of randomised controlled trials. *BMJ* 2009;339.
94. Barnett H, Burrill P, Iheanacho I. Don't use aspirin for primary prevention of cardiovascular disease. *BMJ* 2010;340.
95. Simpson RJ, Mendys P. The effects of adherence and persistence on clinical outcomes in patients treated with statins: a systematic review. *Journal of Clinical Lipidology* 2010;4(6):462-71.
96. Esler M, Schwarz R, Alvarenga M. Mental stress is a cause of cardiovascular diseases: from scepticism to certainty. *Stress and Health* 2008;24(3):175-80.
97. Sturm JW, Davis SM, O'Sullivan JG, Vedadhaghi ME, Donnan GA. The Avoid Stroke as Soon as Possible (ASAP) general practice stroke audit. *Medical Journal of Australia* 2002;176(7):312-6.
98. Webster RJ, Heeley EL, Peiris DP, Bayram C, Cass A, Patel Anushka A. Gaps in cardiovascular disease risk management in Australian general practice. *Med J Aust* 2009;191 (6): 324-29.
99. Owen AJ, Retegan C, Rockell M, Jennings G, Reid CM. Inertia or inaction? Blood pressure management and cardiovascular risk in diabetes. *Clinical and Experimental Pharmacology and Physiology* 2009;36(7):643-47.
100. Wan Q, Harris MF, Jayasinghe UW, Flack J, Georgiou A, Penn DL, et al. Quality of diabetes care and coronary heart disease absolute risk in patients with type 2 diabetes mellitus in Australian general practice. *Quality and Safety in Health Care* 2006;15(2):131-35.
101. Wong N, Wang SS, Lamoureux E, Wong TY, Tikellis G, Harper A, et al. Blood pressure control and awareness among patients with diabetes and hypertension attending a tertiary ophthalmic clinic. *Diabetic Medicine* 2009;26(1):34-39.
102. Walters DL, Aroney CN, Chew DP, Bungey L, Coverdale SG, Allan R, et al. Variations in the application of cardiac care in Australia. *Medical Journal of Australia* 2008;188(4):218-23.
103. Peiris DP, Patel AA, Cass A, Howard MP, Tchan ML, Brady JP, et al. Cardiovascular disease risk management for Aboriginal and Torres Strait Islander peoples in primary health care settings. *Medical Journal of Australia* 2009;191(6):304-09.
104. Clark RA, Eckert KA, Stewart S, Phillips SM, Yallop JJ, Tonkin AM, et al. Rural and urban differentials in primary care management of chronic heart failure: new data from the CASE study. *Medical Journal of Australia* 2007;186:441-45.
105. Heeley EL, Peiris DP , Patel AA , Cass A, Weekes A, Morgan C, et al. Cardiovascular risk perception and evidence–practice gaps in Australian general practice (the AusHEART study). *Med J Aust* 2010;192(5):254-59.

106. Orozco-Beltrán D, Gil-Guillen VF, Quirce F, Navarro-Perez J, Pineda M, Gomez-de-la-Cámara A, et al. Control of diabetes and cardiovascular risk factors in patients with type 2 diabetes in primary care. The gap between guidelines and reality in Spain. *International Journal of Clinical Practice* 2007;61(6):909-15.
107. Mosca L, Linfante AH, Benjamin EJ, Berra K, Hayes SN, Walsh BW, et al. National study of physician awareness and adherence to cardiovascular disease prevention guidelines. *Circulation* 2005;111(4):499-510.
108. Carroll K, Majeed A, Firth C, Gray J. Prevalence and management of coronary heart disease in primary care: population-based cross-sectional study using a disease register. *Journal of Public Health* 2003;25(1):29-35.
109. McBride P, Schrott HG, Plane MB, Underbakke G, Brown RL. Primary care practice adherence to National Cholesterol Education Program guidelines for patients with coronary heart disease. *Archives of Internal Medicine* 1998;158(11):1238-44.
110. Cacoub PP, Abola MTB, Baumgartner I, Bhatt DL, Creager MA, Liau C-S, et al. Cardiovascular risk factor control and outcomes in peripheral artery disease patients in the Reduction of Atherothrombosis for Continued Health (REACH) Registry. *Atherosclerosis* 2009;204(2):e86-e92.
111. Ampt A, Amoroso C, Harris M, McKenzie S, Rose V, Taggart J. Attitudes, norms and controls influencing lifestyle risk factor management in general practice. *BMC Family Practice* 2009;10(1):59.
112. Sheridan S, Shadle J, Simpson R, Pignone M. The impact of a decision aid about heart disease prevention on patients' discussions with their doctor and their plans for prevention: a pilot randomized trial. *BMC Health Services Research* 2006;6:121.
113. Beckett NS, Peters R, Fletcher AE, Staessen JA, Liu L, Dumitrascu D, et al. Treatment of hypertension in patients 80 years of age or older. *New England Journal of Medicine* 2008;358(18):1887-98.
114. Ogihara T, Saruta T, Rakugi H, Matsuoka H, Shimamoto K, Shimada K, et al. Target blood pressure for treatment of isolated systolic hypertension in the elderly: Valsartan in Elderly Isolated Systolic Hypertension Study. *Hypertension* 2010;56(2):196-202.
115. Amoroso C, Harris MF, Ampt A, Laws RA, McKenzie S, Williams AM, et al. The 45 year old health check: feasibility and impact on practices and patient behaviour. *Australian Family Physician* 2009;38(5):358-62.
116. Wechsler H, Levine S, Idelson RK, Schor EL, Coakley E. The physician's role in health promotion revisited - a survey of

primary care practitioners. *New England Journal of Medicine* 1996;334(15):996-8.
117. McAvoy BR, Kaner EF, Lock CA, Heather N, Gilvarry E. Our Healthier Nation: are general practitioners willing and able to deliver? A survey of attitudes to and involvement in health promotion and lifestyle counselling. *British Journal of General Practice* 1999;49(440):187-90.
118. Brotons C, Bjorkelund C, Bulc M, Ciurana R, Godycki-Cwirko M, Jurgova E, et al. Prevention and health promotion in clinical practice: the views of general practitioners in Europe. *Preventive Medicine* 2005;40(5):595-601.
119. Hart JT. Rule of halves: implications of increasing diagnosis and reducing dropout for future workload and prescribing costs in primary care. *British Journal of General Practice* 1992;42(116-119).
120. Jones S, Frager L. Community programs to improve cardiovascular health and cancer prevention: a preliminary review of programs in rural Australia. In: Australian Centre for Agricultural Health and Safety, editor. Accessed online 05/06/2009 from http://www.aghealth.org.au, 2008.
121. Vale M, Jelinek M, Best J, Dart A, Grigg L, Hare D, et al. Coaching patients On Achieving Cardiovascular Health (COACH): a multicenter randomized trial in patients with coronary heart disease. *Archives of Internal Medicine* 2003;163:2775 - 83.
122. Anderson D, Mizzari K, Kain V, Webster J. The effects of a multimodal intervention trial to promote lifestyle factors associated with the prevention of cardiovascular disease in menopausal and postmenopausal Australian women. *Health Care For Women International* 2006;27(3):238-53.
123. Woollard J, Burke V, Beilin LJ. Effects of general practice-based nurse-counselling on ambulatory blood pressure and antihypertensive drug prescription in patients at increased risk of cardiovascular disease. *Journal of Human Hypertension* 2003;17(10):689-95.
124. Halcomb E, Moujalli S, Griffiths R, Davidson P. Effectiveness of general practice nurse interventions in cardiac risk factor reduction among adults. *International Journal of Evidence-Based Healthcare* 2007;5(3):269-95.
125. Laatikainen T, Dunbar JA, Chapman A, Kilkkinen A, Vartiainen E, Heistaro S, et al. Prevention of type 2 diabetes by lifestyle intervention in an Australian primary health care setting: Greater Green Triangle (GGT) Diabetes Prevention Project. *BMC Public Health* 2007;7:249.

126. Schwarzer R. Modeling health behavior change: how to predict and modify the adoption and maintenance of health behaviors. *Applied Psychology* 2008;57(1):1-29.
127. Payne WR, Walsh KJ, Harvey JT, Livy MF, McKenzie KJ, Donaldson A, et al. Effect of a low–resource-intensive lifestyle modification program incorporating gymnasium-based and home-based resistance training on type 2 diabetes risk in Australian adults. *Diabetes Care* 2008;31(12):2244-50.
128. Chan LCK, Ware R, Kesting J, Marczak M, Good D, Shaw JTE. Short term efficacy of a lifestyle intervention programme on cardiovascular health outcome in overweight Indigenous Australians with and without type 2 diabetes mellitus. The healthy lifestyle programme (HELP). *Diabetes Research and Clinical Practice* 2007;75(1):65-71.
129. Baker A, Richmond R, Castle D, Kulkarni J, Kay-Lambkin F, Sakrouge R, et al. Coronary heart disease risk reduction intervention among overweight smokers with a psychotic disorder: pilot trial. *Australian and New Zealand Journal of Psychiatry* 2009;43(2):129-35.
130. Joubert J, Reid C, Barton D, Cumming T, McLean A, Joubert L, et al. Integrated care improves risk-factor modification after stroke: initial results of the Integrated Care for the Reduction of Secondary Stroke model. *Journal of Neurology, Neurosurgery, and Psychiatry* 2009;80(3):279-84.
131. Halbert JA, Silagy CA, Finucane PM, Withers RT, Hamdorf PA. Physical activity and cardiovascular risk factors: effect of advice from an exercise specialist in Australian general practice. *Medical Journal of Australia* 2000;173(2):84-87.
132. Artinian NT, Fletcher GF, Mozaffarian D, Kris-Etherton P, Van Horn L, Lichtenstein AH, et al. Interventions to promote physical activity and dietary lifestyle changes for cardiovascular risk factor reduction in adults: a scientific statement from the American Heart Association. *Circulation*;122(4):406-41.
133. Hourihan F, Krass I, Chen T. Rural community pharmacy: a feasible site for a health promotion and screening service for cardiovascular risk factors. *Australian Journal of Rural Health* 2003;11(1):28-35.
134. Krass I, Hourihan F, Chen T. Health promotion and screening for cardiovascular risk factors in NSW: a community pharmacy model. *Health Promotion Journal of Australia* 2003;14(2):101-07.
135. Emerson L, Krass I. A Collaborative, Interdisciplinary Evidence Based Approach to Reducing Coronary Heart Disease in Rural Areas. Canberra: Pharmacy Guild of Australia 2006.

136. Clifford RM, Davis WA, Batty KT, Davis TME. Effect of a pharmaceutical care program on vascular risk factors in type 2 diabetes. *Diabetes Care* 2005;28(4):771-76.
137. Krass I, Armour CL, Mitchell B, Brillant M, Dienaar R, Hughes J, et al. The Pharmacy Diabetes Care Program: assessment of a community pharmacy diabetes service model in Australia. *Diabetic Medicine* 2007;24(6):677-83.
138. Fanaian M, Laws R, Passey M, McKenzie S, Wan Q, Davies G, et al. Health improvement and prevention study (HIPS) - evaluation of an intervention to prevent vascular disease in general practice. *BMC Family Practice* 2010;11(1):57.
139. Eakin EG, Reeves MM, Lawler SP, Oldenburg B, Del Mar C, Wilkie K, et al. The Logan Healthy Living Program: a cluster randomized trial of a telephone-delivered physical activity and dietary behavior intervention for primary care patients with type 2 diabetes or hypertension from a socially disadvantaged community-rationale, design and recruitment. *Contemporary Clinical Trials* 2008;29(3):439-54.
140. Waters L, Reeves M, Fjeldsoe B, Eakin E. Characteristics of control group participants who increased their physical activity in a cluster-randomized lifestyle intervention trial. *BMC Public Health* 2011;11(1):27.
141. Brett T, Arnold-Reed D, Phan C, Cadden F, Walker W, Manea-Walley W, et al. The Fremantle Primary Prevention Study: a multicentre randomised trial of absolute cardiovascular risk reduction. *British Journal of General Practice* 2012;62(594):e22-e28.
142. Ebrahim S, Taylor F, Ward K, Beswick A, Burke M, Davey Smith G. Multiple risk factor interventions for primary prevention of coronary heart disease. *Cochrane Database of Systematic Reviews* 2011: Issue 1. Art. No.: CD001561. DOI:10.1002/14651858.CD001561.pub3.
143. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *The Lancet* 1993;342(8883):1317-22.
144. Michie S, Miles J, Weinman J. Patient-centredness in chronic illness: what is it and does it matter? *Patient Education and Counseling* 2003;51(3):197-206.
145. Vos T, Carter R, Barendregt J, Mihalopoulos C, Veerman L, Magnus A, et al. Assessing Cost-Effectiveness in Prevention (ACE–Prevention): Final Report. Melbourne: University of Queensland, Brisbane and Deakin University, 2010.
146. Rollnick S, Miller WR. What is Motivational Interviewing? *Behavioural and Cognitive Psychotherapy* 1995;23(04):325-34.

147. Bandura A. Health promotion by social cognitive means. *Health Education & Behavior* 2004;31(2):143-64.
148. Conner M, Armitage CJ. Extending the Theory of Planned Behavior: a review and avenues for further research. *Journal of Applied Social Psychology* 1998;28(15):1429-64.
149. Fisher EB, Brownson CA, O'Toole ML, Shetty G, Anwuri VV, Glasgow RE. Ecological approaches to self-management: the case of diabetes. *American Journal of Public Health* 2005;95(9):1523-35.
150. Hill-Briggs F, Gemmell L. Problem solving in diabetes self-management and control. *The Diabetes Educator* 2007;33(6):1032-50.
151. Katon W, Lin EHB, Von Korff M, Ciechanowski P, Ludman E, Young B, et al. Integrating depression and chronic disease care among patients with diabetes and/or coronary heart disease: The design of the TEAMcare study. *Contemporary Clinical Trials* 2010;31(4):312-22.
152. Shilts MK, Horowitz M, Townsend MS. Goal setting as a strategy for dietary and physical activity behavior change: a review of the literature. *American Journal of Health Promotion* 2004;19(2):81-93.
153. Laatikainen T, Philpot B, Hankonen N, Sippola R, Dunbar JA, Absetz Pilvikki, et al. Predicting changes in lifestyle and clinical outcomes in preventing diabetes:The Greater Green Triangle Diabetes Prevention Project. *Preventive Medicine* 2011 [In Press].
154. Brug J, Conner M, Harré N, Kremers S, McKellar S, Whitelaw S. The Transtheoretical Model and stages of change: a critique. *Health Education Research* 2005;20(2):244-58.
155. West R. Time for a change: putting the Transtheoretical (Stages of Change) Model to rest. *Addiction* 2005;100(8):1036-39.
156. Kraft P, Sutton SR, Reynolds HM. The transtheoretical model of behaviour change: Are the stages qualitatively different? *Psychology & Health* 1999;14(3):433-50.
157. Larabie LC. To what extent do smokers plan quit attempts? *Tobacco Control* 2005;14(6):425-28.
158. Pharmaceutical Society of Australia. National Competency Standards Framework for Pharmacists in Australia 2010. *Downloaded 13/05/2011 from* *http://www.psa.org.au/site.php?id=6783*.
159. Koshman SL, Charrois TL, Simpson SH, McAlister FA, Tsuyuki RT. Pharmacist care of patients with heart failure: a systematic review of randomized trials. *Archives of Internal Medicine* 2008;168(7):687-94.

160. Prokhorov AV, Hudmon KS, Marani S, Foxhall L, Ford KH, Luca NS, et al. Engaging physicians and pharmacists in providing smoking cessation counseling. *Archives of Internal Medicine* 2010;170(18):1640-46.
161. Carter BL, Rogers M, Daly J, Zheng S, James PA. The potency of team-based care interventions for hypertension: a meta-analysis. *Archives of Internal Medicine* 1748;169(19):1748-55.
162. National Health and Hospitals Reform Commission. A Healthier Future for all Australians - Final Report of the National Health and Hospitals Reform Commission. In: Department of Health and Ageing, editor. Canberra: Commonwealth of Australia, 2009.
163. Shiu J, Simpson S, Johnson J, Tsuyuki T. Quantifying opportunities to affect diabetes management in the community. *Canadian Pharmacists Journal* 2006;139(3):37-38.
164. Keleher H, Joyce MC, Parker R, Piterman L. Practice nurses in Australia: current issues and future directions. *Medical Journal of Australia* 2007;187(2):108-10.
165. Productivity Commission. Australia's Health Workforce, Research Report. Canberra: Productivity Commission, 2005.
166. Joyce CM, McNeil JJ, Stoelwinder JU. More doctors, but not enough: Australian medical workforce supply 2001-2012. *Medical Journal of Australia* 2006;184:441-46.
167. Tudor Hart J. The Inverse Care Law. *The Lancet* 1971;297(7696):405-12.
168. Australian Institute of Health and Welfare. Medical labour force 2008. Bulletin no. 82. Cat. no. AUS 131. In: AIHW, editor. Canberra, 2010.
169. Machado M, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to pharmacist interventions. Part I: systematic review and meta-analysis in diabetes management. *The Annals of Pharmacotherapy* 2007;41(10):1569-82.
170. Sinclair HK, Bond CM, Stead LF. Community pharmacy personnel interventions for smoking cessation. *Cochrane Database of Systematic Reviews* 2004;Issue 1. Art. No.: CD003698. DOI: 10.1002/14651858.CD003698.pub2.
171. Machado M, Nassor N, Bajcar JM, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to pharmacist interventions. Part III: systematic review and meta-analysis in hyperlipidemia management. *The Annals of Pharmacotherapy* 2008;42(9):1195-207.
172. Machado M, Bajcar J, Guzzo GC, Einarson TR. Sensitivity of patient outcomes to pharmacist interventions. Part II: systematic review and meta-analysis in hypertension management. *The Annals of Pharmacotherapy* 2007;41(11):1770-81.

173. Kilkenny MF, Johnson RR, Cadilhac DA, on behalf of the National Stroke Foundation. Feasibility of a pilot programme to increase awareness of blood pressure as an important risk factor for stroke in Australia. *International Journal of Stroke* 2010;5(5):344-50.
174. Lee JK, Grace KA, Taylor AJ. Effect of a pharmacy care program on medication adherence and persistence, blood pressure, and low-density lipoprotein cholesterol: a randomized controlled trial. *JAMA* 2006;296(21):2563-71.
175. Tsuyuki RT, Olson KL, Dubyk AM, Schindel TJ, Johnson JA. Effect of community pharmacist intervention on cholesterol levels in patients at high risk of cardiovascular events: the second study of cardiovascular risk intervention by pharmacists (SCRIP-plus). *The American Journal of Medicine* 2004;116(2):130-33.
176. Tsuyuki R, Johnson J, Teo K, Ackman M, Biggs R, Cave A, et al. Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP): a randomized trial design of the effect of a community pharmacist intervention program on serum cholesterol risk. *The Annals of Pharmacotherapy* 1999;33(9):910-19.
177. McLean DL, McAlister FA, Johnson JA, King KM, Makowsky MJ, Jones CA, et al. A randomized trial of the effect of community pharmacist and nurse care on improving blood pressure management in patients with diabetes mellitus: Study of Cardiovascular Risk Intervention by Pharmacists-Hypertension (SCRIP-HTN). *Archives of Internal Medicine* 2008;168(21):2355-61.
178. Vale MJ, Jelinek MV, Best JD, Dart AM, Grigg LE, Hare DL, et al. Coaching patients On Achieving Cardiovascular Health (COACH): a multicenter randomized trial in patients with coronary heart disease. *Archives of Internal Medicine* 2003;163(22):2775-83.
179. Anderson D, Mizzari K, Kain V, Webster J. The effects of a multimodal intervention trial to promote lifestyle factors associated with the prevention of cardiovascular disease in menopausal and postmenopausal Australian women. *Health Care for Women International,* 2006;27(3):238 - 53.
180. Vaughan C, Kilkkinen A, Philpot B, Brooks J, Schoo A, Laatikainen T, et al. Physical activity behaviours of adults in the Greater Green Triangle region of rural Australia. *Australian Journal of Rural Health* 2008;16(2):92-9.
181. Montgomerie A, Tideman P, Taylor A, Janus E, Philpot B, Tirimacco R, et al. An epidemiological analysis of risk factors: rural versus metropolitan– are there differences?: Population Research & Outcome Studies Unit - SA Health, Adelaide; and Greater Green

Triangle, University Department of Rural Health, Flinders University and Deakin University, 2010.
182. Vartiainen EA, Laatikainen T, Philpot B, Janus ED, Davis-Lameloise N, Dunbar JA. The projected impact of population and high-risk strategies for risk-factor control on coronary heart disease and stroke events. *Medical Journal of Australia* 2011;194(1):10-15.
183. World Health Organisation. WHO MONICA Project (monitoring trends and determinants in cardiovascular disease): a major international collaboration. WHO MONICA Project Principal Investigators. *Journal of Clinical Epidemiology* 1988;41(2):105-14.
184. Tolonen H, Kuulasmaa K, Laatikainen T, Wolf H. European Health Risk Monitoring project. Recommendation for indicators, international collaboration, protocol and manual of operations for chronic disease risk factor surveys, 2002. Accessed May 16 2007 from <http://www.ktl.fi/publications/ehrm/product2/title.htm>.
185. Australian Institute of Health and Welfare. Australia's Health 2006. Canberra: AIHW cat. no. AUS 73. Available from http://www.aihw.gov.au/publications/aus/ah06/ah06-c00.pdf, 2006.
186. World Health Organisation/International Society for Hypertension. Hypertension guidelines. *Journal of Hypertension* 1999;17:151-83.
187. National Heart Foundation of Australia. Hypertension management guide for doctors: NHFA, 2004.
188. Bennett S, Magnus P. Trends in cardiovascular risk factors in Australia. Results from the National Heart Foundation's Risk Factor Prevalence Study 1980-1989. *Medical Journal of Australia* 1994;161:519-27.
189. Greater Green Triangle University Department of Rural Health. Greater Green Triangle Risk Factor Study: Limestone Coast and Corangamite Shire Surveys Basic Report. In: Heistaro S, Janus E, Dunbar J, Laatikainen T, Kilkinnen A, editors. Warrnambool: Greater Green Triagle University Department of Rural Health 2007.
190. Australian Bureau of Statistics. 2001 Census Basic Community Profile. Canberra: ABS, 2001.Available at www.abs.gov.au [Accessed February 2007].
191. Australian Institute of Health and Welfare. Analysis of the 1980, 1983 and 1989 Risk Factor Prevalence Surveys, 1995 National Nutrition Survey and 1999–2000 Australian Diabetes, Obesity and Lifestyle (AusDiab) Study. Canberra: AIHW, 2007.

192. Whelton PK, He J, Appel LJ, Cutler JA, Havas S, Kotchen TA, et al. Primary prevention of hypertension. *JAMA* 2002;288(15):1882-88.
193. Brown CD, Higgins M, Donato KA, Rohde FC, Garrison R, Obarzanek E, et al. Body mass index and the prevalence of hypertension and dyslipidemia. *Obesity* 2000;8(9):605-19.
194. Smith WC, Lee AJ, Crombie IK, Tunstall-Pedoe H. Control of blood pressure in Scotland: the rule of halves. *BMJ* 1990;300(6730):981-83.
195. Kastarinen MJ, Antikainen RL, Laatikainen TK, Salomaa VV, Tuomilehto JO, Nissinen AM, et al. Trends in hypertension care in eastern and south-western Finland during 1982-2002. *Journal of Hypertension* 2006;24(5):829-35
196. Psaltopoulou T, Orfanos P, Naska A, Lenas D, Trichopoulos D, Trichopoulou A. Prevalence, awareness, treatment and control of hypertension in a general population sample of 26 913 adults in the Greek EPIC study. *International Journal of Epidemiology* 2004;33(6):1345-52.
197. Primatesta P, Brookes M, Poulter NR. Improved hypertension management and control. *Hypertension* 2001;38(4):827-32.
198. Hajjar I, Kotchen TA. Trends in prevalence, awareness, treatment, and control of hypertension in the United States, 1988-2000. *JAMA* 2003;290(2):199-206.
199. National Institute of Clinical Studies. Evidence-Practice Gaps Report Volume 2. Achieving optimal control of blood pressure. Melbourne: National Institute of Clinical Studies, 2005:34-35.
200. National Institute of Clinical Studies. Using evidence: using guidelines symposium. Barriers and enablers. In: NICS, editor, 2006 [cited 2007 May 16]. Available from URL: http://www.nhmrc.gov.au/nics/.
201. Wagner EH, Groves T. Care for chronic diseases. *BMJ* 2002;325(7370):913-14.
202. Wagner EH. Chronic disease care. *BMJ* 2004;328(7433):177.
203. National Primary Care Collaboratives. http://www.npcc.com.au, 2006 [cited 2007 May 16].
204. The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group. Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels. *New England Journal of Medicine* 1998;339(19):1349-57.
205. National Heart Foundation of Australia; Cardiac Society of Australia and New Zealand. Lipid management guidelines — 2001. *Medical Journal of Australia* 2001;175 (9 Supp):S57-88.

206. National Heart Foundation of Australia. Risk Factor Prevalence Study no. 1 -1980. Canberra, 1980.
207. National Heart Foundation of Australia. Risk Factor Prevalence Study no. 2 - 1983. Canberra: NHFA, 1983.
208. Risk Factor Prevalence Study Management Committee. Risk Factor Prevalence Study survey no. 3, 1989. Canberra: National Heart Foundation of Australia, Australian Institute of Health, 1990.
209. Dunstan D ZP, Welborn T, et al; on behalf of the AusDiab Steering Committee. Diabesity and associated disorders in Australia - 2000. The accelerating epidemic. The Australian Diabetes, Obesity and Lifestyle Study (AusDiab). Melbourne: International Diabetes Institute, 2001. http://www.diabetes.com.au/pdf/AusDiab_Report.pdf (accessed Sep 2007).
210. National Health and Hospitals Reform Commission. A healthier future for all Australians. Interim Report. In: Department of Health and Ageing, editor. Canberra: NHHRC, 2008. http://www.nhhrc.org.au/internet/nhhrc/publishing.nsf/Content/nhhrc-report (accessed Dec 2009).
211. Stocks N, Ryan P, Allan J, Williams S, Willson K. Gender, socioeconomic status, need or access? Differences in statin prescribing across urban, rural and remote Australia. *Australian Journal of Rural Health* 2009;17(2):92-96.
212. Janus ED, for the Hong Kong Cardiovascular Risk Factor Prevalence Study Steering Committee, editors. The Hong Kong Cardiovascular Risk Factor Prevalence Study 1995-1996. Hong Kong: University of Hong Kong, 1997.
213. Lam TH, Liu LJ, Janus ED, Bourke C, Hedley AJ. The relationship between fibrinogen and other coronary heart disease risk factors in a Chinese population. *Atherosclerosis* 1999;143(2):405-13.
214. Batty GD, Gale CR. Impact of resurvey non-response on the associations between baseline risk factors and cardiovascular disease mortality: prospective cohort study. *Journal of Epidemiology and Community Health* 2009;63(11):952-55.
215. Caggiula A, Mustad V. Effects of dietary fat and fatty acids on coronary artery disease risk and total and lipoprotein cholesterol concentrations: epidemiologic studies *American Journal of Clinical Nutrition* 1997;65((5 Suppl)):1597S-610.
216. Laatikainen T, Critchley J, Vartiainen E, Salomaa V, Ketonen M, Capewell S. Explaining the decline in coronary heart disease mortality in Finland between 1982 and 1997. *American Journal of Epidemiology* 2005;162(8):764-73.
217. Manuel DG, Kwong K, Tanuseputro P, Lim J, Mustard CA, Anderson GM, et al. Effectiveness and efficiency of different guidelines on

statin treatment for preventing deaths from coronary heart disease: modelling study. *BMJ* 2006;332(7555):1419.
218. Chen L, Rogers SL, Colagiuri S, et al. How do the Australian guidelines for lipid lowering drugs perform in practice? Cardiovascular disease risk in the AusDiab Study, 1999-2000 *Medical Journal of Australia* 2008;189:319-22.
219. Harris M, Zwar N. Care of patients with chronic disease: the challenge for general practice. *Medical Journal of Australia* 2007;187:104-07.
220. Jousilahti P, Vartiainen E, Pekkanen J, Tuomilehto J, Sundvall J, Puska P. Serum cholesterol distribution and coronary heart disease risk: observations and predictions among middle-aged population in eastern Finland. *Circulation* 1998;97(11):1087-94.
221. Collins D, Lapsley H. The costs of tobacco, alcohol and illicit drug abuse to Australian society in 2004/05. *National Drug Strategy Monograph Series no. 66*. Canberra: Department of Health and Ageing, , 2008.
222. Britt H, Miller GC, Charles J, et al. General practice activity in Australia 2006-07. *General practice series no. 21. Cat. no. GEP 21*. Canberra: Australian Institute of Health and Welfare, 2008.
223. Department of Human Services. Victorian Population Health Survey 2006. Victoria, 2006.
224. Department of Primary Industries and Energy, Department of Human Services and Health. Rural, Remote and Metropolitan Areas classification 1991 census edition. Canberra: AGPS, 1994.
225. Laatikainen T, Vartiainen E, Puska P. Comparing smoking and smoking cessation process in the Republic of Karelia, Russia and North Karelia, Finland. *Journal of Epidemiology and Community Health* 1999;53(9):528-34.
226. Tucker JS, Ellickson PL, Orlando M, Klein DJ. Predictors of attempted quitting and cessation among young adult smokers. *Preventive Medicine* 2005;41(2):554-61.
227. Chen K, Kandel DB. The natural history of drug use from adolescence to the mid-thirties in a general population sample. *American Journal of Public Health* 1995;85(1):41-47.
228. Chassin L, Presson CC, Rose JS, Sherman SJ. The natural history of cigarette smoking from adolescence to adulthood: demographic predictors of continuity and change. *Health Psychology* 1996;15(6):478-84.
229. Lancaster T, Stead L, Silagy C, Sowden A. Effectiveness of interventions to help people stop smoking: findings from the Cochrane Library. *BMJ* 2000;321(7257):355-58.

230. Department of Health and Ageing. Australian National Tobacco Strategy 2004–2009. Canberra: : Australian Government Department of Health and Ageing, , 2004.
231. The Royal Australian College of General Practitioners. Putting Prevention into Practice: Guidelines for the Implementation of Prevention in the General Practice Setting. 2nd edn. South Melbourne: RACGP, 2006.
232. Zwar N. Smoking cessation - What works? *Australian Family Physician* 2008;37(1/2):10-14.
233. Mangum SA, Kraenow KR, Narducci WA, Mangum SA, Kraenow KR, Narducci WA. Identifying at-risk patients through community pharmacy-based hypertension and stroke prevention screening projects. *Journal of the American Pharmaceutical Association* 2003;43(1):50-5.
234. Janus ED, Tideman P, Dunbar JA, Kilkinnen A, Bunker SJ, Philpot B, et al. Dyslipidaemia in rural Australia: prevalence, awareness, prevention and treatment gaps. *Medical Journal of Australia* 2010;192(3):127-32.
235. Macinko J, Starfield B, Shi L. The contribution of primary care systems to health outcomes within Organization for Economic Cooperation and Development (OECD) countries, 1970–1998. *Health Services Research* 2003;38(3):831-65.
236. Dent LA, Harris KJ, Noonan CW. Tobacco interventions delivered by pharmacists: a summary and systematic review. *Pharmacotherapy* 2007;27(7):1040-51.
237. Sunderland B, Burrows S, Joyce A, McManus A, Maycock B. Rural pharmacy not delivering on its health promotion potential. *Australian Journal of Rural Health* 2006;14(3):116-19.
238. Joyce AW, Sunderland VB, Burrows S, McManus A, Howat P, Maycock B. Community pharmacy's role in promoting healthy behaviours. *Journal of Pharmacy Practice and Research* 2007;37(1):42-4.
239. Peterson GM, Jackson SL, Hughes JD, Fitzmaurice KD, Murphy LE. Public perceptions of the role of Australian pharmacists in cardiovascular disease. *Journal of Clinical Pharmacy and Therapeutics* 2010;35(6):671-77.
240. Mott K, Eltridge F, Gilbert A, Lawson T, Vitry A, Rau D, et al. Consumer Experiences, Needs and Expectations of Community Pharmacy [internet] Canberra: Pharmacy Guild of Australia 2005 [cited 6 June 2011]; Available from: http://www.5cpa.com.au/sites/The_Guild/tab-Pharmacy_Services_and_Programs/Research_and_Development/Third%20Agreement/2005-501.page

241. Smith KB, Humphreys JS, Lenard Y, Jones JA, Prince V, Han GS. Still the doctor - by a country mile! Preferences for health services in two country towns in north-west New South Wales. *Medical Journal of Australia* 2004;181 (2):91-95.
242. Absetz PP, Valve RP, Oldenburg BP, Heinonen HP, Nissinen AMP, Fogelholm MS, et al. Type 2 diabetes prevention in the "real world": one-year results of the GOAL implementation trial. *Diabetes Care* 2007;30(10):2465-70.
243. Begg SJ, Vos T, Barker B, Stanley L, Lopez AD. Burden of disease and injury in Australia in the new millennium: measuring health loss from diseases, injuries and risk factors. *Medical Journal of Australia* 2008;188(1):36-40.
244. Fahey T, Schroeder K, Ebrahim S, Glynn L. Interventions used to improve control of blood pressure in patients with hypertension (Review). *Cochrane Database of Systematic Reviews*, 2006.
245. Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Mark P. Developing and evaluating complex interventions: new guidance: Medical Research Council, Downloaded 03/02/2012 from www.mrc.ac.uk/complexinterventionsguidance
246. Oakley A, Strange V, Bonell C, Allen E, Stephenson J. Process evaluation in randomised controlled trials of complex interventions. *BMJ* 2006;332(7538):413-16.
247. Campbell NC, Murray E, Darbyshire J, Emery J, Farmer A, Griffiths F, et al. Designing and evaluating complex interventions to improve health care. *BMJ* 2007;334(7591):455-59.
248. Lopez AD, Begg S, Bos E. Global Burden of Disease and Risk Factors. In: Lopez AD, Mathers CD, Ezzati M, Jamison DT, Murray CJL, editors. *Demographic and Epidemiological Characteristics of Major Regions, 1990–2001*. Oxford: Oxford University Press/World Bank 2006. Downloaded 28 April 2010 from http://files.dcp2.org/pdf/GBD/GBD.pdf.
249. Schwappach D, Boluarte T, Suhrcke M. The economics of primary prevention of cardiovascular disease - a systematic review of economic evaluations. *Cost Effectiveness and Resource Allocation* 2007;5(1):5.
250. Blenkinsopp A, Anderson C, Armstrong M. Systematic review of the effectiveness of community pharmacy-based interventions to reduce risk behaviours and risk factors for coronary heart disease. *Journal of Public Health* 2003;25(2):144-53.
251. New Zealand Guideline Group. The Assessment and Management of Cardiovascular Risk In: NZGG, editor, 2003, Downloaded 28 April 2010 from <http://www.nhf.org.nz/files/CVD_Risk_Full.pdf>. .

252. Graham I, Atar D, Borch-Johnsen K, Boysen G, Burell G, Cifkova R, et al. European guidelines on cardiovascular disease prevention in clinical practice: executive summary. *European Heart Journal* 2007;28(19):2375-414.
253. World Health Organisation. Prevention of cardiovascular disease: guidelines for assessment and management of total cardiovascular risk. Geneva: WHO, 2007.
254. Cholestech Corporation. Technical Brief: Clinical performance of the Cardiocheck PA and the Cholestech LDX System compared to a Clinical Diagnostic Laboratory Reference Method for the Determination of Lipid Profiles. Downloaded 28 April 2010 from http://www.cholestech.com/docs/ldx_accuracy/tbCardioChek.pdf. , 2002.
255. Santee J. Accuracy and precision of the Cholestech LDX System in monitoring blood lipid levels. *American Journal of Health-System Pharmacy* 2002;59(18):1774-79.
256. George J, Mackinnon A, Kong DCM, Stewart K. Development and validation of the Beliefs and Behaviour Questionnaire (BBQ). *Patient Education and Counseling* 2006;64(1-3):50-60.
257. Morisky DE, Green LW, Levine DM. Concurrent and predictive validity of a self-reported measure of medication adherence. *Medical Care* 1986;24(1):67-74.
258. Kinect Australia for the Lifescripts consortium. Lifescripts Practice Manual: Supporting Lifestyle Risk Factor Management in General Practice. Canberra Commonwealth of Australia, 2005.
259. McLennan W, Podger A. National Nutrition Survey: Nutrient Intakes and Physical Measurements Australia 1995. Canberra: Australian Bureau of Statistics, 1998.
260. Hodge A, Patterson AJ, Brown WJ, Ireland P, Giles G. The Anti Cancer Council of Victoria FFQ: relative validity of nutrient intakes compared with weighed food records in young to middle-aged women in a study of iron supplementation. *Australian and New Zealand Journal of Public Health* 2000;24(6):576-83.
261. Bush K, Kivlahan DR, McDonell MB, Fihn SD, Bradley KA, for the Ambulatory Care Quality Improvement Project. The AUDIT alcohol consumption questions (AUDIT-C): an effective brief screening test for problem drinking. *Archives of Internal Medicine* 1998;158(16):1789-95.
262. Radloff LS. The CES-D scale: A self-report depression scale for research in the general population. *Applied Psychological Measurement* 1977;1:385-401.

263. Ware JE, Kosinski M, Turner-Bowker DM, Gandeck B. *User's manual for the SF-12v2™ Health Survey*. Boston: Quality Metrics, 2007.
264. McNaughton SA, Dunstan DW, Ball K, Shaw J, Crawford D. Dietary quality is associated with diabetes and cardio-metabolic risk factors. *Journal of Nutrition* 2009;139(4):734-42.
265. Patel KC, Minhas R, Gill P, Khunti K. Vascular risk checks in the UK: strategic challenges for implementation. *Heart* 2009:hrt.2008.165035.
266. Horgan JMP, Blenkinsopp A, McManus RJ. Evaluation of a cardiovascular disease opportunistic risk assessment pilot ('Heart MOT' service) in community pharmacies. *Journal of Public Health* 2010;32(1):110-16.
267. Rose G. Sick individuals and sick populations. *International Journal of Epidemiology* 1985;14(1):32-38.
268. Mosca L, Benjamin EJ, Berra K, Bezanson JL, Dolor RJ, Lloyd-Jones DM, et al. Effectiveness-based guidelines for the prevention of cardiovascular disease in women-2011 update: a guideline from the American Heart Association. *Circulation* 2011;123(11):1243-62.
269. Mc Namara K, George J, O'Reilly S, Jackson S, Peterson G, Howarth H, et al. Engaging community pharmacists in the primary prevention of cardiovascular disease: protocol for the Pharmacist Assessment of Adherence, Risk and Treatment in Cardiovascular Disease (PAART CVD) pilot study. *BMC Health Services Research* 2010;10(1):264.
270. Greater Green Triangle University Department of Rural Health. Final Project Report: Greater Green Triangle Diabetes Prevention Project. Warrnambool. Accessed online at http://www.greaterhealth.org/media/resources/Final_DPP_Report_2006.pdf 2006.
271. O'Reilly S, McCann L. Development and validation of the Diet Quality Tool for use in cardiovascular disease prevention settings. . *Australian Journal of Primary Care* (In Press).
272. Taveira TH, Wu W-C, Martin OJ, Schleinitz MD, Friedmann P, Sharma SC. Pharmacist-led cardiac risk reduction model. *Preventive Cardiology* 2006;9(4):202-08.
273. The Community Pharmacy Medicines Management Project Evaluation Team. The MEDMAN study: a randomized controlled trial of community pharmacy-led medicines management for patients with coronary heart disease. *Family Practice* 2007;24(2):189-200.
274. Liu Y, Mentele LJ, McDonough RP, Carruthers KM, Doucette WR. Community pharmacist assessment of 10-year risk of coronary

heart disease for union workers and their dependents. *Journal of the American Pharmacists Association* 2003;48(4):515-17.
275. Santschi V, Chiolero A, Burnand B, Colosimo AL, Paradis G. Impact of pharmacist care in the management of cardiovascular disease risk factors: a systematic review and meta-analysis of randomized trials. *Archives of Internal Medicine* 2011;171(16):1441-53.
276. Bunting B, Smith B, Sutherland S. The Asheville Project: Clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia *Journal of the American Pharmacists Association.* 2008 48(1):23-31.
277. Wolf-Maier K, Cooper RS, Kramer H, Banegas JR, Giampaoli S, Joffres MR, et al. Hypertension treatment and control in five European countries, Canada, and the United States. *Hypertension* 2004;43(1):10-17.
278. Hebert JR, Clemow L, Pbert L, Ockene IS, Ockene JK. Social desirability bias in dietary self-report may compromise the validity of dietary intake measures. *International Journal of Epidemiology* 1995;24(2):389-98.
279. Stein JH, Carlsson CM, Papcke-Benson K, Einerson JA, McBride PE, Wiebe DA. Inaccuracy of lipid measurements with the portable Cholestech LDX Analyzer in patients with hypercholesterolemia. *Clinical Chemistry* 2002;48(2):284-90.
280. Tsuyuki RT, Fradette M, Johnson JA, Bungard TJ, Eurich DT, Ashton T, et al. A multicenter disease management program for hospitalized patients with heart failure. *Journal of Cardiac Failure* 2004;10(6):473-80.
281. Tsuyuki RT, Johnson JA, Teo KK, Simpson SH, Ackman ML, Biggs RS, et al. A randomized trial of the effect of community pharmacist intervention on cholesterol risk management: the Study of Cardiovascular Risk Intervention by Pharmacists (SCRIP). *Arch Intern Med* 2002;162(10):1149-55.
282. Carter BL, Ardery G, Dawson JD, James PA, Bergus GR, Doucette WR, et al. Physician and pharmacist collaboration to improve blood pressure control. *Archives of Internal Medicine* 2009;169(21):1996-2002.
283. Asch SM, McGlynn EA, Hogan MM, Hayward RA, Shekelle P, Rubenstein L, et al. Comparison of quality of care for patients in the Veterans Health Administration and patients in a national sample. *Annals of Internal Medicine* 2004;141(12):938-45.
284. McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, et al. The Quality of Health Care Delivered to Adults in the United States. *New England Journal of Medicine* 2003;348(26):2635-45.

285. Stetler C, Mittman B, Francis J. Overview of the VA Quality Enhancement Research Initiative (QUERI) and QUERI theme articles: QUERI Series. *Implementation Science* 2008;3(1):8.
286. Hughes CM, McCann S. Perceived interprofessional barriers between community pharmacists and general practitioners: a qualitative assessment. *British Journal of General Practice* 2003;53(493):600-06.
287. Muijrers PEM, Knottnerus JA, Sijbrandij J, Janknegt R, Grol RPTM. Pharmacists in primary care Determinants of the care-providing function of Dutch community pharmacists in primary care. *Pharmacy World & Science* 2004;26(5):256-62.
288. O'Loughlin J, Masson P, Dery V, Fagnan D. The role of community pharmacists in health education and disease prevention: a survey of their interests and needs in relation to cardiovascular disease. *Preventive Medicine* 1999;28(3):324-31.
289. Pfleger D, McHattie L, Diack H, McCaig D, Stewart D. Views, attitudes and self-assessed training needs of Scottish community pharmacists to public health practice and competence. *Pharmacy World & Science* 2008;30(6):801-09.
290. Pronk MC, Blom LT, Jonkers R, Rogers EM, Bakker A, de Blaey KJ. Patient oriented activities in Dutch community pharmacy: diffusion of innovations. *Pharmacy World & Science* 2002;24(4):154-61.
291. Rosenthal M, Austin Z, Tsuyuki RT. Are pharmacists the ultimate barrier to pharmacy practice change? *Canadian Pharmacists Journal* 2010;143(1):37-42.
292. Ross LA. Pharmacists as mid-level practitioners/providers. *The Annals of Pharmacotherapy* 2011;45(6):810-12.
293. Dunlop JA, Shaw JP. Community pharmacists' perspectives on pharmaceutical care implementation in New Zealand. *Pharmacy World & Science* 2002;24(6):224-30.
294. Bradley F, Elvey R, Ashcroft DM, Hassell K, Kendall J, Sibbald B, et al. The challenge of integrating community pharmacists into the primary health care team: A case study of local pharmaceutical services (LPS) pilots and interprofessional collaboration. *Journal of Interprofessional Care* 2008;22(4):387-98.
295. Bryant LJM, Coster G, Gamble GD, McCormick RN. General practitioners' and pharmacists' perceptions of the role of community pharmacists in delivering clinical services. *Research in Social and Administrative Pharmacy* 2009;5(4):347-62.
296. Eades C, Ferguson J, O'Carroll R. Public health in community pharmacy: A systematic review of pharmacist and consumer views. *BMC Public Health* 2011;11(1):582.

297. Edmunds J, Calnan MW. The reprofessionalisation of community pharmacy? An exploration of attitudes to extended roles for community pharmacists amongst pharmacists and General Practioners in the United Kingdom. *Social Science & Medicine* 2001;53(7):943-55.
298. Grol R, Wensing M. What drives change? Barriers to and incentives for achieving evidence-based practice. *Medical Journal of Australia* 2004;180(6):S57-60.
299. Bryan RL, Kreuter MW, Brownson RC. Integrating Adult Learning Principles Into Training for Public Health Practice. *Health Promotion Practice* 2009;10(4):557-63.
300. Ajzen I. The theory of planned behavior. *Organizational Behavior and Human Decision Processes* 1991;50(2):179-211.
301. Pathman D, Konrad T, Freed G, Freeman V, Koch G. The Awareness-to-Adherence Model of the steps to clinical guideline compliance: the case of pediatric vaccine recommendations. *Medical Care* 1996;34(9):873-89.
302. Gu Q, Paulose-Ram R, Dillon C, Burt V. Antihypertensive medication use among US adults with hypertension. *Circulation* 2006;113(2):213-21.
303. Guthrie B, Inkster M, Fahey T. Tackling therapeutic inertia: role of treatment data in quality indicators. *BMJ* 2007;335(7619):542-44.
304. Alexander M, Gordon NP, Davis CC, Chen RS. Patient knowledge and awareness of hypertension is suboptimal: results from a large health maintenance organization. *The Journal of Clinical Hypertension* 2003;5(4):254-60.
305. Sims J. What influences a patient's desire to participate in the management of their hypertension? *Patient Education and Counseling* 1999;38(3):185-94.
306. Bensing J, Tromp F, van Dulmen S, van den Brink-Muinen A, Verheul W, Schellevis F. Shifts in doctor-patient communication between 1986 and 2002: a study of videotaped General Practice consultations with hypertension patients. *BMC Family Practice* 2006;7(1):62.
307. Moser M, Franklin SS. Hypertension management: results of a new national survey for the Hypertension Education Foundation: Harris Interactive. *The Journal of Clinical Hypertension* 2007;9(5):316-23.
308. Miller NH, Berra K, Long J. Hypertension 2008—awareness, understanding, and treatment of previously diagnosed hypertension in baby boomers and seniors: a survey conducted by Harris Interactive on behalf of the Preventive Cardiovascular

Nurses Association. *The Journal of Clinical Hypertension* 2010;12(5):328-34.
309. Hyman DJ, Pavlik VN. Self-reported hypertension treatment practices among primary care physicians: blood pressure thresholds, drug choices, and the role of guidelines and evidence-based medicine. *Archives of Internal Medicine* 2000;160(15):2281-86.
310. Engel-Nitz NM, Darkow T, Lau H. Antihypertensive medication changes and blood pressure goal achievement in a managed care population. *Journal of Human Hypertension* 2010;24(10):659-68.
311. Carlberg B, Samuelsson O, Lindholm LH. Atenolol in hypertension: is it a wise choice? *The Lancet* 2004;364(9446):1684-89.
312. Dahlöf B, Devereux RB, Kjeldsen SE, Lyle PA, Zhang Z, Edelman JM. Atenolol as a comparator in outcome trials in hypertension: a correct choice in the past, but not for the future? *Blood Pressure* 2007;16(1):6-12.
313. Halme L, Vesalainen R, Kaaja M, Kantola I. Self-monitoring of blood pressure promotes achievement of blood pressure target in primary health care. *American Journal of Hypertension* 2005;18(11):1415-20.
314. Cappuccio FP, Kerry SM, Forbes L, Donald A. Blood pressure control by home monitoring: meta-analysis of randomised trials. *BMJ* 2004;329(7458):145.
315. Tyson MJ, McElduff P. Self-blood-pressure monitoring - a questionnaire study: response, requirement, training, support-group popularity and recommendations. *Journal of Human Hypertension* 2003;17(1):51-61.
316. Tan NC, Khin LW, Pagi R. Home blood-pressure monitoring among hypertensive patients in an Asian population. *Journal of Human Hypertension* 2005;19(7):559-64.
317. Viera AJ, Cohen LW, Mitchell CM, Sloane PD. Use of home blood pressure monitoring by hypertensive patients in primary care: survey of a practice-based research network cohort. *The Journal of Clinical Hypertension* 2008;10(4):280-86.
318. Pickering TG, Miller NH, Ogedegbe G, Krakoff LR, Artinian NT, Goff D. Call to action on use and reimbursement for home blood pressure monitoring: a joint scientific statement from the American Heart Association, American Society of Hypertension, and Preventive Cardiovascular Nurses Association. *Hypertension* 2008;52(1):10-29.
319. Tsuji I, Imai Y, Nagai K, Ohkubo T, Watanabe N, Minami N, et al. Proposal of reference values for home blood pressure measurement. *American Journal of Hypertension* 1997;10(4):409-18.

320. Stergiou GS, Voutsa AV, Achimastos AD, Mountokalakis TD. Home self-monitoring of blood pressure. *American Journal of Hypertension* 1997;10(4):428-33.
321. Johnson KA, Partsch DJ, Rippole LL, McVey DM. Reliability of self-reported blood pressure measurements. *Archives of Internal Medicine* 1999;159(22):2689-93.
322. Kotseva K, Wood D, De Backer G, De Bacquer D, Pyörälä K, Reiner Ž, et al. EUROASPIRE III. Management of cardiovascular risk factors in asymptomatic high-risk patients in general practice: cross-sectional survey in 12 European countries. *European Journal of Cardiovascular Prevention & Rehabilitation* 2010;17(5):530-40.
323. Stewart K, George J, Jackson S, Peterson G, Hughes J, Mc Namara K, et al. Increasing Community Pharmacy Involvement in the Prevention of Cardiovascular Disease:The HAPPY Trial Final Report: The Pharmacy Guild of Australia 2010.
324. Ornstein S, Jenkins RG, Nietert PJ, Feifer C, Roylance LF, Nemeth L, et al. A multimethod quality improvement intervention to improve preventive cardiovascular care. *Annals of Internal Medicine* 2004;141(7):523-32.
325. Ketola E, Sipilä R, Mäkelä M, Klockars M. Quality improvement programme for cardiovascular disease risk factor recording in primary care. *Quality in Health Care* 2000;9(3):175-80.
326. Wells KB, Sherbourne C, Schoenbaum M, Duan N, Meredith L, Unützer J, et al. Impact of disseminating quality improvement programs for depression in managed primary care. *JAMA* 2000;283(2):212-20.
327. Van de Steeg-van Gompel C, Wensing M, De Smet P. Implementation of patient education at first and second dispensing of statins in Dutch community pharmacies: the sequel of a cluster randomized trial. *BMC Health Services Research* 2011;11(1):313.
328. Fehr E, Fischbacher U. The nature of human altruism. *Nature* 2003;425:785-91.
329. Muller L, Sefton M, Steinberg R, Vesterlund L. Strategic behavior and learning in repeated voluntary contribution experiments. *Journal of Economic Behavior & Organization* 2008;67(3–4):782-93.
330. Jones R. Declining altruism in medicine. *BMJ* 2002;324(7338):624-25.
331. Doran T, Kontopantelis E, Valderas JM, Campbell S, Roland M, Salisbury C, et al. Effect of financial incentives on incentivised and non-incentivised clinical activities: longitudinal analysis of

data from the UK Quality and Outcomes Framework. *BMJ* 2011;342.
332. Australian Government/The Pharmacy Guild of Australia. The Fifth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia. Department of Health, Canberra, 2011.
333. Crosby R, Noar SM. What is a planning model? An introduction to PRECEDE-PROCEED. *Journal of Public Health Dentistry* 2011;71:S7-S15.
334. Green LW, Kreuter MW. *Health program planning: an educational and ecological approach*. 4 ed. New York; London: McGraw-Hill, 2005.
335. National Health Priority Action Council (NHPAC). National Chronic Disease Strategy. Canberra: Australian Government Department of Health and Ageing, 2006.
336. Ndumele CD, Baer HJ, Shaykevich S, Lipsitz SR, Hicks LS. Cardiovascular disease and risk in primary care settings in the United States. *The American Journal of Cardiology* 2011(0).
337. Ellerbeck EF, Mahnken JD, Cupertino AP, Cox LS, Greiner KA, Mussulman LM, et al. Effect of varying levels of disease management on smoking cessation. *Annals of Internal Medicine* 2009;150(7):437-46.
338. Morrison F, Shubina M, Turchin A. Encounter frequency and serum glucose level, blood pressure, and cholesterol level control in patients with diabetes mellitus. *Archives of Internal Medicine* 2011;171(17):1542-50.
339. Lau R, Stewart K, McNamara K, Jackson S, Hughes J, Peterson G, et al. Evaluation of a community pharmacy-based intervention for improving patient adherence to antihypertensives: a randomised controlled trial. *BMC Health Services Research* 2010;10(1):34.
340. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Quarterly* 2004;82(4):581-629.
341. Oxman AD, Thomson MA, Davis DA, Haynes RB. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *CMAJ* 1995;153(10):1423-31.
342. MacMahon S, Macdonald G, Blacket R. Plasma lipoprotein levels in treated and untreated hypertensive men and women. The National Heart Foundation of Australia Risk Factor Prevalence Study. *Arteriosclerosis, Thrombosis, and Vascular Biology* 1985;5(4):391-96.

343. Welborn TA, Dhaliwal SS, Bennett SA. Waist–hip ratio is the dominant risk factor predicting cardiovascular death in Australia. *Medical Journal of Australia* 2003;179(3):580-85.
344. Smith KB, Humphreys JS, Wilson MGA. Addressing the health disadvantage of rural populations: How does epidemiological evidence inform rural health policies and research? *Australian Journal of Rural Health* 2008;16(2):56-66.
345. Mc Namara K, Dunbar J, Reddy P, Philpot B, Vaughan C, Morgan M, et al. How population health data can help primary care services to improve population health - a rural case study. *SA Public Health Bulletin* 2009;6(2):21-25.
346. Clark RA, Driscoll A. Access and quality of heart failure management programs in Australia. *Australian Critical Care* 2009;22(3):111-16.
347. Coffee N, Turner D, Clark RA, Eckert K, Coombe D, Hugo G, et al. Measuring national accessibility to cardiac services using geographic information systems. *Applied Geography* 2012;34(0):445-55.
348. Kilkkinen A, Heistaro S, Laatikainen T, Janus E, Chapman A, Absetz P, et al. Prevention of type 2 diabetes in a primary health care setting: interim results from the Greater Green Triangle (GGT) Diabetes Prevention Project. *Diabetes Research and Clinical Practice* 2007;76(3):460 - 62.
349. Benrimoj SI, Frommer MS. Community pharmacy in Australia. *Australian Health Review* 2004;28(2):238-46.
350. Kearney PM, Whelton M, Reynolds K, Muntner P, Whelton PK, He J. Global burden of hypertension: analysis of worldwide data. *The Lancet* 2005;365(9455):217-23.
351. Kearney PM, Whelton M, Reynolds K, Whelton PK, He J. Worldwide prevalence of hypertension: a systematic review. *Journal of Hypertension* 2004;22(1):11-19.
352. Wild S, Roglic G, Green A, Sicree R, King H. Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. *Diabetes Care* 2004;27(5):1047 - 53.
353. Australian Institute of Health and Welfare. Cardiovascular disease mortality: trends at different ages. In: AIHW, editor. *Cardiovascular series no. 31. Cat. no.47*. Canberra: AIHW, 2010.
354. O'Flaherty M, Ford E, Allender S, Scarborough P, Capewell S. Coronary heart disease trends in England and Wales from 1984 to 2004: concealed levelling of mortality rates among young adults. *Heart* 2008;94(2):178-81.
355. Rose G. Strategy of prevention: lessons from cardiovascular disease. *British Medical Journal* 1981;282(6279):1847-51.

356. Voogdt-Pruis HR, Beusmans GHMI, Gorgels APM, Kester ADM, Van Ree JW. Effectiveness of nurse-delivered cardiovascular risk management in primary care: a randomised trial. *British Journal of General Practice* 2010;60(570):40-46.
357. Laurant M, Reeves D, Hermens R, Braspenning J, Grol R, Sibbald B. Substitution of doctors by nurses in primary care: Cochrane Database of Systematic Reviews, Issue 4. Art. No.: CD001271. DOI: 10.1002/14651858.CD001271.pub2., 2004.
358. Virani SS, Woodard LD, Chitwood SS, Landrum CR, Urech TH, Wang D, et al. Frequency and correlates of treatment intensification for elevated cholesterol levels in patients with cardiovascular disease. *American Heart Journal* 2011;162(4):725-32.e1.
359. Phillips LS, Twombly JG. It's time to overcome clinical inertia. *Annals of Internal Medicine* 2008;148(10):783-85.
360. McAlister FA, Wilkins K, Joffres M, Leenen FHH, Fodor G, Gee M, et al. Changes in the rates of awareness, treatment and control of hypertension in Canada over the past two decades. *Canadian Medical Association Journal* 2011.
361. McAlister FA, Feldman RD, Wyard K, Brant R, Campbell NRC. The impact of the Canadian Hypertension Education Programme in its first decade. *European Heart Journal* 2009;30(12):1434-39.
362. White V, Hill D, Siahpush M, Bobevski I. How has the prevalence of cigarette smoking changed among Australian adults? Trends in smoking prevalence between 1980 and 2001. *Tobacco Control* 2003;12(suppl 2):ii67-ii74.
363. Gartner CE, Barendregt JJ, Hall WD. Predicting the future prevalence of cigarette smoking in Australia: how low can we go and by when? *Tobacco Control* 2009;18(3):183-89.
364. Wong ND, Thakral G, Franklin SS, L'Italien GJ, Jacobs MJ, Whyte JL, et al. Preventing heart disease by controlling hypertension: impact of hypertensive subtype, stage, age, and sex. *American Heart Journal* 2003;145(5):888-95.
365. National Preventative Health Taskforce. Australia: The Healthiest Country by 2020 – National Preventative Health Strategy – the roadmap for action: Australian Government Department of Health and Ageing, 2009.
366. Department of Health and Ageing. National Medicines Policy. Canberra: DoHA, 2000.
367. Department of Health and Ageing. Taking Preventative Action – A Response to Australia: The Healthiest Country by 2020 – The Report of the National Preventative Health Taskforce. Canberra: Commonwealth of Australia, 2010.

368. Department of Health and Ageing. Building a 21st Century Primary Health Care System. Australia's First National Primary Health Care Strategy. Canberra: Commonwealth of Australia, 2010.
369. Department of Health and Ageing. The National Strategy for Quality Use of Medicines. Canberra: Commonwealth of Australia 2002.
370. Department of Health (UK). Healthy Lives, Healthy People: Our strategy for public health in England. London: Stationary Office, 2011.
371. Richardson E, Pollock AM. Community pharmacy: moving from dispensing to diagnosis and treatment. *BMJ* 2010;340.
372. Eickhoff C, Schulz M. Pharmaceutical care in community pharmacies: practice and research in Germany. *The Annals of Pharmacotherapy* 2006;40(4):729-35.
373. Guignard E, Bugnon O. Pharmaceutical care in community pharmacies: practice and research in Switzerland. *The Annals of Pharmacotherapy* 2006;40(3):512-17.
374. Scahill S, Harrison J, Carswell P, Shaw J. Health care policy and community pharmacy: implications for the New Zealand primary health care sector. *The New Zealand Medical Journal* 2010;123 (1317):41-51.
375. Stubbings J, Nutescu E, Durley SF, Bauman JL. Payment for clinical pharmacy services revisited. *Pharmacotherapy* 2010;31(1):1-8.
376. Truong K, Rosenthal M, Tsuyuki RT. Asleep at the wheel: Pharmacy practice research advocacy and knowledge translation by Canadian pharmacy organizations. *Canadian Pharmacists Journal* 2010;143(2):78-81.e1.
377. Lewis JM. Being around and knowing the players: networks of influence in health policy. *Social Science & Medicine* 2006;62(9):2125-36.
378. Catchlove BR. GP corporatisation: the why and the wherefore *Medical Journal of Australia* 2001;175:68-70.
379. British Medical Association, Press Release. BMA calls for urgent meeting with Patricia Hewitt on plans to extend prescribing powers. *Accessed 01/08/2011 from* http://web2.bma.org.uk/pressrel.nsf/wlu/STRE-6HZJ4X?OpenDocument&vw=wfmms.
380. McNamara S. Improve regulation in wake of 'Coke and fries' deal. MJA Insight 10/10/2011, accessed 13/01/2011 from www.mjainsight.com.au.
381. Bradley F, Ashcroft DM, Noyce PR. Integration and differentiation: a conceptual model of general practitioner and community pharmacist collaboration. *Research in Social and Administrative Pharmacy* 2012;8(1):36-46.

382. Wickstrom G, Bendix T. The "Hawthorne effect" - what did the original Hawthorne studies actually show? *Scandinavian Journal of Work, Environment & Health* 2000;26(4):363-67.
383. Lalonde L, Hudon E, Goudreau J, Bélanger D, Villeneuve J, Perreault S, et al. Physician-pharmacist collaborative care in dyslipidemia management: The perception of clinicians and patients. *Research in Social & Administrative Pharmacy* 2011;7(3):233-45.
384. Van C, Mitchell B, Krass I. General practitioner–pharmacist interactions in professional pharmacy services. *Journal of Interprofessional Care* 2011;25(5):366-72.
385. Muijrers PEM, Knottnerus JA, Sijbrandij J, Janknegt R, Grol R. Changing relationships: attitudes and opinions of general practitioners and pharmacists regarding the role of the community pharmacist. *Pharmacy World & Science* 2003;25(5):235-41.
386. Liu Y, Doucette WR, Farris KB. Examining the development of pharmacist-physician collaboration over 3 months. *Research in Social and Administrative Pharmacy* 2010;6(4):324-33.
387. Norton D, Measday J, Grenfell R, Mackay C, Teed A, Macdonald C. GP - pharmacist liaison: a rural case study. *Australian Family Physician*, 2003:1-2. Downloaded 04/11/2010 from http://www.racgp.org.au/afp/200303/20030301norton.pdf
388. Zillich AJ, McDonough RP, Carter BL, Doucette WR. Influential characteristics of physician/pharmacist collaborative relationships. *The Annals of Pharmacotherapy* 2004;38(5):764-70.
389. Hanna A, White L, Yanamandram V. Patients' willingness to pay for diabetes disease state management services in Australian community pharmacies. *International Journal of Pharmaceutical and Healthcare Marketing* 2010;4(4):339 -54.
390. Barner JC, Branvold A. Patients' willingness to pay for pharmacist-provided menopause and hormone replacement therapy consultations. *Research in Social and Administrative Pharmacy* 2005;1(1):77-100.
391. Assa-Eley M, Kimberlin CL. Using interpersonal perception to characterize pharmacists' and patients' perceptions of the benefits of pharmaceutical care. *Health Communication* 2005;17(1):41-56.
392. Lambert AM, Burden AC, Chambers J, Marshall T. Cardiovascular screening for men at high risk in Heart of Birmingham Teaching Primary Care Trust: the 'Deadly Trio' programme. *Journal of Public Health* 2011.

393. McNaughton R, Oswald N, Shucksmith J, Heywood P, Watson P. Making a success of providing NHS Health Checks in community pharmacies across the Tees Valley: a qualitative study. *BMC Health Services Research* 2011;11(1):222.
394. Iversen L, Mollison J, MacLeod TNN. Attitudes of the general public to the expanding role of community pharmacists: a pilot study. *Family Practice* 2001;18(5):534-36.
395. White L, Clark C. Stakeholders' views of service quality in community pharmacy: a qualitative study. *Health Marketing Quarterly* 2010;27(1):48-65.
396. Schommer JC. Patients' expectations and knowledge of patient counseling services that are available from pharmacists. *American Journal of Pharmaceutical Education* 1997;61(4):402-06.
397. Naik Panvelkar P, Saini B, Armour C. Measurement of patient satisfaction with community pharmacy services: a review. *Pharmacy World & Science* 2009;31(5):525-37.
398. Teh R, Chen T, Krass I. Consumer perspectives of pharmacist-delivered health information and screening services. *International Journal of Pharmacy Practice* 2001;9(4):261-67.
399. Volmer D, Bell JS, Janno R, Raal A, Hamilton DD, Airaksinen MS. Change in public satisfaction with community pharmacy services in Tartu, Estonia, between 1993 and 2005. *Research in Social and Administrative Pharmacy* 2009;5(4):337-46.
400. Kardachi G. We support 5CPA. *Australian Pharmacist* 2012;31(1):1.
401. Austin Z, Gregory PAM, Martin JC. Negotiation of interprofessional culture shock: the experiences of pharmacists who become physicians. *Journal of Interprofessional Care* 2007;21(1):83-93.
402. Grol R. Implementing guidelines in general practice. *Quality in Health Care* 1992;1:184-91.
403. Pearson GJ. Evolution in the practice of pharmacy—not a revolution! *Canadian Medical Association Journal* 2007;176(9):1295-96.
404. Hepler CD, Strand L. Opportunities and responsibilities in pharmaceutical care. *American Journal of Hospital Pharmacy* 1990;47:533-43.
405. Gordon J, Watson M, Avenell A. Lightening the load? A systematic review of community pharmacy-based weight management interventions. *Obesity Reviews* 2011;12(11):897-911.
406. Schwartz SM, Bansal VP, Hale C, Rossi M, Engle JP. Compliance, behavior change, and weight loss with orlistat in an over-the-counter setting. *Obesity* 2008;16(3):623-29.

407. Sheridan J, Stewart J, Smart ROS, McCormick R. Risky drinking among community pharmacy customers in New Zealand and their attitudes towards pharmacist screening and brief interventions. *Drug and Alcohol Review* 2012;31(1):56-63.
408. van Mil JWF, de Boer WO, Tromp TFJ. European barriers to the implementation of pharmaceutical care. *International Journal of Pharmacy Practice* 2001;9(3):163-68.
409. van de Steeg-van Gompel CHPA, Wensing M, De Smet PAGM. Implementation of a discontinuation letter to reduce long-term benzodiazepine use— a cluster randomized trial. *Drug and Alcohol Dependence* 2009;99(1–3):105-14.
410. Grilli R, Lomas J. Evaluating the message: the relationship between compliance rate and the subject of a practice guideline. *Medical Care* 1994;32(3):202-13.
411. Watson MC, Norris P, Granas AG. A systematic review of the use of simulated patients and pharmacy practice research. *International Journal of Pharmacy Practice* 2006;14(2):83-93.
412. Trapskin K, Johnson C, Cory P, Sorum S, Decker C. Forging a novel provider and payer partnership in Wisconsin to compensate pharmacists for quality-driven pharmacy and medication therapy management services *Journal of the American Pharmacists Association* 2009;49:642-51.
413. Patwardhan P, Chewning B. Effectiveness of intervention to implement tobacco cessation counseling in community chain pharmacies *Journal of the American Pharmacists Association* 2012;52:507-14.