Compliance with lipid-lowering medications following diagnosis of coronary heart disease by angiography: a prospective cohort study

Submitted by

Sandra N. McKellar OAM, RN, BN, Dip. Man., J.P. (C. Dec.)

A thesis submitted in partial fulfilment of the requirements of the degree of

Master of Nursing Research

School of Nursing & Midwifery
Faculty of Health Sciences

Australian Catholic University
Research Services
Locked Bag 4115,
Fitzroy, Victoria 3065
Australia

08/03/2010

The work presented in this thesis is, to the best of my knowledge and belief, original and my own work, except as otherwise acknowledged in the text, having not been submitted, either in whole or part, for a degree at this or any other university.

SANDRA NORMA McKELLAR

8th March, 2010

ACKNOWLEDGEMENTS

Many individuals have assisted the progression and completion of this work; to them all, I am indebted. In particular, I gratefully acknowledge the guidance and supervision of Professor Paul Fulbrook, Professor of Nursing, School of Nursing and Midwifery, Australian Catholic University (McAuley, Banyo). I am also extremely grateful to Helen Callum, Yvonne Connolly, Julanne Hatcher, Gregg McDougall, Jan McKenzie, Linda Preston, Matthew Pullen and Paul Vandersee, all of the HeartWise Health Services Program, for their tolerance, and support in relation to their manager's academic pursuits. I am especially indebted to Debbie Lennon from The Wesley Research Institute for her timely tutorials on the intricacies of SPSS data analysis.

Above all other acknowledgements, I thank my husband and our children for their sustaining love. To my husband, John, my sincere thanks for your encouragement, guidance and exceptional contribution, with reading and critiquing this research from a professional-academic-writing perspective. To my children, Fiona, Kirstin and Cameron, for whom I am truly blessed, I thank you for your belief, encouragement and inspiration.

CONTENTS

CHAPTER 2

ABBREVIATIONS

Abbreviations employed in the following text encompass the following:

AHA	**American Heart Association**
AIHW	**Australian Institute of Health and Welfare**
CABG	**Coronary artery by-pass graft**
CAD	**Coronary artery disease**
CHD	**Coronary heart disease**
CSANZ	**Cardiac Society of Australia and New Zealand**
CVD	**Cardiovascular disease**
LLM	**Lipid lowering medication**
NHFA	**National Heart Foundation of Australia**
OCR	**Outpatient cardiac rehabilitation**
WHO	**World Health Organization**

ABSTRACT

Aims: The aim of this research study was to measure the length of time that coronary heart disease patients remain compliant with lipid lowering medications and, if they ceased taking their medications, to investigate the reasons why.

Scope: The research was designed as a prospective cohort study, enrolling 120 randomly selected patients who were diagnosed with coronary heart disease by angiography and followed up for one year. Individual participants were followed up, via monthly telephone interviews, for a twelve-month period, using standardised questionnaires.

Conclusions: At month twelve, all subjects reported compliance with lipid lowering therapy. This result was unexpected and inconsistent with previous research that reported compliance rates averaging 50% within twelve months after therapy initiation. Although not within the scope of the study, several factors may have been influential in determining this 100% compliance to lipid lowering medications. Nearly half of the sample surveyed stated that the most important factor was the health benefit of lipid lowering medication. All subjects were prescribed lipid lowering medication prior to discharge from hospital. Current guidelines from the National Heart Foundation of Australia now specify this, whereas, prior to 2003, this was not the case. This may be the principal factor that accounts for the significant disparity between the results of this investigation and previous studies. Another explanation may embrace the fact that, because all patients were privately insured, they placed a higher personal value on healthcare that had been "paid for", as opposed to receiving "free" healthcare in the public hospital system.

CHAPTER 1

INTRODUCTION

The setting for this study was a large tertiary referral private hospital with a comprehensive cardiovascular diagnostic and management service. All of the study participants had been angiographically diagnosed with coronary heart disease (CHD) and were discharged from hospital on lipid lowering medication (LLM).

The purpose of this introductory chapter is to examine the prevalence of cardiovascular disease (CVD) and CHD and to establish the place of LLM as a specific treatment within this context.

This chapter provides an Australian and global overview of the impact of CVD with particular emphasis on CHD. It is presented under sub-headings, to provide an historical perspective of the disease prevalence, contributing pathophysiological features and available diagnostic measures. In addition, treatment guidelines and treatment options including revascularisation techniques and medical management leading to secondary prevention initiatives are discussed.

Cardiovascular disease

Documentation by leading agencies, such as the World Health Organization (Vita-Finzi, 2008), the National Heart Foundation of Australia (Vos & Begg, 2007; NHFA & CSANZ, 2005, 2007), the American Heart Association (Thom et al., 2008), the European Society of Cardiology (Graham et al. 2007), the British Heart Foundation (Allender, Peto, Scarborough, Boxer & Rayner, 2007) and the Australian Bureau of Statistics (Pink, 2008), suggests that more people worldwide are now surviving, rather than dying from, CVD. However, these agencies acknowledge that CVD continues to be the leading cause of death globally, generating a high level of ongoing concern for health agencies around the world. For example, heart and circulatory system disease in Europe and the European Union are the main cause of death annually in these regions, with CHD and stroke accounting for the majority of CVD deaths (Mackay & Mensah, 2004). It was estimated by Vita-Finzi (2008) that, in 2005, 17.5 million people worldwide died from CVD. This figure, according to the author, represents a massive 30% of all global deaths. Vita-Finzi (2008) also claimed that, of the 17.5 million deaths due to CVD, in excess of 7 million people worldwide died from CHD.

In Australia, heart, stroke and vascular diseases kill more Australians than any other disease group, and accounted for 50,294 deaths (37.6% of all deaths) in 2002 (AIHW, 2004). Approximately 3.67

million Australians are affected by heart, stroke and vascular diseases and 1.1 million Australians are disabled long-term by CVD according to the Australian Institute of Health & Welfare, (AIHW), 2004. The prevalence of heart, stroke and vascular conditions increased by 18.2% over the last decade and the total burden of heart, stroke and vascular diseases is expected to increase over the coming decades, due to the aging Australian population, among whom these diseases are most common (AIHW, 2004).

Coronary heart disease – a brief Australian overview

CHD, also referred to as coronary artery disease (CAD) and atherosclerotic heart disease, is one manifestation of CVD and is a chronic disease process (Weinrauch, 2007). In Australia, according to the AIHW, in 1999-2000, there were 48,313 reported cardiac events in the 40-90 age group due to CHD (Mathur, 2002). This figure represented a daily average of 132 coronary events. Almost half (23,633) of these events were fatal, with 87% being out of hospital fatalities (Mathur, 2002). According to the AIHW report, one quarter of people who have a fatal myocardial infarct (MI) die within an hour of the onset of their first symptoms (Mathur, 2002).

Progressive Australian cardiovascular disease statistics show CHD was the underlying cause in the death of 25,439 Australians and the associated cause of death in a further 20,816 individuals (AIHW, 2005). Further evidence published by AIHW (2006) confirms that, today, more Australians are also surviving longer with a diagnosis of CHD, as opposed to a high non-survival rate, as was the case previously. Although Australian death rates from CHD over the past 30 years have declined by over 60%, the prevalence of CHD is still considered to be the major cause of morbidity and mortality in Australia (Pink, 2008).

The NHFA, in their revised report on cardiovascular disease in Australia for the year 2003 concluded that, despite a sustained decrease in CVD mortality in the last 30 to 40 years, CVD was still the leading cause of morbidity (Vos & Begg, 2007). More recent morbidity statistics on the prevalence of CHD in the Australian community indicate that 1.9% of the population or 367,000 individuals are living with CHD (defined predominantly as experiencing angina). This figure represents 1.3% of male and 0.9% of female Australians (AIHW, 2006).

Coronary heart disease – a global overview

In assessing CHD and its widespread occurrence, it is also necessary to consider statistical data from a number of countries apart from Australia, in order to fully appreciate the current global prevalence of this disease and to comprehend the projected magnitude of the health burden, especially if timely and efficient methods to improve outcomes are not implemented. For example, in the document *Preventing Chronic Disease, A Vital Investment,* which assessed global deaths from CHD by gender and age groups, it was revealed that, in 2005, 53% of men and 47% of women died (Vita-Finzi, 2008). Although suboptimal outcome data are reported from both developed and developing countries, Vita-Finzi (2008) has conceded that mortality from CHD is generally lower in developed countries. When the latter was compared to developing countries, the incidence of morbidity, however, was acknowledged as being difficult to measure (Vita-Finzi, 2008). Regardless of the challenges involved, agencies generally recognise the personal and economic burden associated with CHD morbidity (Vita-Finzi, 2008; Allender, Peto, Scarborough, Boxer and Rayner, 2007).

The multinational *Monitoring Trends and Determinants in Cardiovascular Disease* (MONICA) project, involving populations in 21 countries, from the mid-1980s to the mid-1990s, was unique in being the largest collaboration of its type ever undertaken (Tunstall-Pedoe, 2003). One objective of the MONICA project was to observe a population of 10 million men and women, aged 25 to 64 years, and measure prevalence, severity, progression and risk factors associated with CVD within different populations. The latest available CHD data published by Tunstall-Pedoe (2003), from the MONICA project, found a high incidence of coronary events in Northern, Central and Eastern Europe, with the highest event rate being in Glasgow (UK). Outcome data demonstrate that the coronary-event rate (per 100,000) in men was highest in Finland (North Karelia, 835) and lowest in China (Beijing, 81). For women, the highest event rate was in the UK (Glasgow, 265), and the lowest in Spain (Catalonia, 35) and China (Beijing, 35). These data represent results from 35 MONICA project populations (Tunstall-Pedoe, 2003).

However, Yusuf, Reddy, Ôunpuu and Anand (2001) have suggested that, for CHD, mortality for all developing countries will increase in the next two decades by 120% for women and 137% for men. Their predictions for the next two decades include a tripling of CHD and stroke mortality in Latin America, the Middle East, and even in sub-Saharan Africa. Those figures represent a rate of increase that exceeds that for any other region, except for Asian and Pacific Island countries. Contrastingly, the authors have also predicted an increase in more developed nations, largely attributable to an expansion of the population of older people at risk, ranging between 30% and 60% (Yusuf et al., 2001). Vita-Finzi (2008) has similarly predicted that, without appropriate initiatives to slow this trend, 11.1 million people globally will die from CHD in 2020.

In Europe, CHD is the most common cause of death, accounting for the deaths of one in five women (22%) and more than one in five men (21%) from the disease. In the European Union, the figures are similar; CHD is the most common cause of death with around one in six men (16%) and more than one in seven women (15%) dying from this disease (Mackay & Mensah, 2004).

Furthermore, in the UK, mortality statistics indicate that CHD claims 101,000 lives annually. CHD is the major cause of premature deaths. 20% of men and 11% of women (totalling 33,000 deaths) dying prematurely from CHD in 2005 (Allender et al., 2007). Although the CHD death rate in the UK, for men aged 35–74 years, fell by 42% between 1990 and 2000, greater reductions were recorded in Norway (54%) and Australia (48%). For women, in the UK, the death rate fell by 44%, whereas, in Australia and New Zealand, it fell by 51% and 48% respectively (Allender et al., 2007). The premature death rate in the UK from CHD for male manual workers is 58% higher than for non-manual workers; for female manual workers, the death rate is more than twice as high as that for non-manual workers (Allender et al., 2007). The UK mortality rates from CHD remain amongst the highest rates in Western Europe. Heart attacks occur at the rate of one every two minutes, and, in approximately 30% of the cases, death is the end result (Allender et al., 2007).

People of Asian/Pacific Islander nationality fare no better. The AHA (2004) published mortality statistics for the Asia/Pacific region that reveal 34.2% of males and 35.6% of females died from heart disease and stroke in 2001. In the United States, it has been reported that 1.2 million people were diagnosed with CHD in 2003, with 479,000 individuals, just fewer than 50%, dying as a result of their disease (Thom et al., 2008).

Morbidity statistics for CVD are acknowledged by health care agencies as being more difficult to collect and define, as opposed to mortality statistics. Data collected by the WHO MONICA project, although now over 10 years old, remain the most representative European-wide dataset of CVD morbidity (Tunstall-Pedoe, 2003). However, the Health Survey for England was undertaken in 2003 to assess the prevalence of CHD (defined as angina or a heart attack) morbidity in the general population (Allender et al., 2007). Data collected showed that in the male population, an estimated 7.4% or 1.5million individuals were affected, and, in the female population, 4.5% or 1.1 million were affected. These figures translate to a total CHD morbidity for the English population of 2.6 million people (Allender et al., 2007).

As has been demonstrated, from this review of the prevalence of the disease, CHD is the biggest global cause of morbidity and mortality and it has no cure. However, modification of individual risk factors contributing to CHD can reduce the risk of further events.

Risk factors for coronary heart disease

A number of factors impact on the risk of an individual developing CHD. Cardiac risk factors are features or behaviours that increase an individuals chances of developing CHD. The larger the number and/or severity of risk factors the higher the chances are for cardiovascular disease. Risk factors fall into two broad categories: modifiable and non-modifiable (Table 1). Modifiable risk factors are those created by unhealthy lifestyle choices. By choosing to actively adopt healthy lifestyle practices greatly reduces the risk in primary and secondary management of CHD.

Modifying risk factors is all about making healthy lifestyle choices. Modifiable risk factors are those that are within an individual's ability to self-manage in order to reduce the likelihood of developing a chronic disease or to reduce the risk of further acute disease events.

Table 1. Risk factors for CHD (NHFA, 2007).

Modifiable	**Non-modifiable**
High blood pressure High blood cholesterol Smoking Obesity Physical inactivity Diabetes Depression Social isolation	Gender Heredity (family history of CHD) Age

Pathophysiology and symptoms of coronary heart disease

Atherosclerotic plaque containing cholesterol, fat and other substances is deposited within the intima and inner media of the coronary arteries, (Mathur, 2002). This deposit leads to narrowing of the arteries and to a reduction of blood supply to the heart muscle, which can result in MI, also known as a heart attack, or to chest pain of cardiac origin, known as angina (Mathur, 2002). According to the NHFA (2007), frequently, many people are unaware of their CHD until they experience their first symptoms of angina, which can range from mild (such as indigestion-type discomfort) to severe (with central crushing chest pain, shortness of breath, nausea and vomiting), or they have an acute heart attack. Currently there is not one single, simple test for diagnosing CHD. However, a comprehensive examination for CHD may include a number of tests.

Diagnosis of coronary heart disease

More people are surviving with CHD today, for a number of reasons. There have been major advances in diagnostic procedures for acute and chronic presentation of suspected CHD, and there are now a number of tests available to assess individual risk for CHD or to obtain a diagnosis. Non-invasive diagnostic options include undertaking a physical assessment profile that may embrace: anthropometric measures of height, weight and waist; assessment of lifestyle behaviours (such as smoking habits, physical activity), or any family history of heart disease; blood pressure measurement and fasting blood tests to obtain a full lipid profile (Rice, 1999). Other non-invasive investigations described in the booklet *The Heart - Diagnostic Procedures* (Peters, 1993): are chest X-rays to elicit information on heart and lung shadows; a resting electrocardiogram (ECG) to record the heart's electrical activity; trans-thoracic echocardiography, which uses ultrasound waves to obtain images of the heart chambers and heart valves; and cardiac magnetic resonance imaging (MRI), which employs large magnets and radio-frequency waves to produce high quality, still and moving images of the heart (Cleveland Clinic Foundation Heart Centre, 2008).

Further investigations include trans-oesophageal echocardiography (TOE), where a small probe on the end of a long flexible tube is passed via the mouth into the stomach, in order to obtain images of the heart from a different angle to those obtained from a trans-thoracic echocardiogram (Queensland Health, 2004). Also an exercising ECG known as a "stress" test or exercising stress test (EST) is where the electrical activity of the heart is obtained during exercise (Peters, 1993). In addition there are sophisticated blood tests in the acute setting to assess cardiac enzyme levels, which are important marker of myocardial damage (Thom et al., 2008). However, the most common diagnostic procedure is an angiogram.

Coronary angiography

The most frequently used and valuable diagnostic procedure for CHD is coronary angiography (AHA, 1999). Coronary angiography or coronary angiogram is a more definitive diagnostic tool than other tests. Scanlon et al. (1999) have described this procedure as the radiographic visualization of coronary vessels following the injection of radio-opaque contrast media (AHA, 1999). Coronary angiography is performed in order to outline the coronary anatomy and to define the location and extent of any coronary artery obstruction (Scanlon et al., 1999). During the procedure, a long thin tube (catheter) is inserted via the groin or arm into an artery, and guided by

visual image, using X-rays, into the heart and the coronary arteries. When the catheter is correctly positioned, a radio-opaque dye is injected into the coronary arteries. The flow of dye is captured on X-ray, giving a two-dimensional outline of the filling, narrowing or blockages of the coronary arteries (Peters, 1993). Once a definitive diagnosis is made, appropriate treatment options can be implemented. Following diagnosis of CHD by coronary angiogram, patients fall into three treatment groups, coronary artery bypass grafting (CABG), medical management and percutaneous coronary intervention (PCI). PCI includes percutaneous transluminal coronary angioplasty (PTCA), with or without coronary stenting.

Interventional management of coronary heart disease

There are several revascularisation techniques in the acute and elective setting that are used to re-perfuse the myocardium. In the acute setting, thrombolytic therapy, utilising intravenous blood thinning drugs and primary angioplasty techniques to penetrate blood clots are often employed in an effort to prevent permanent myocardial damage, and both of these techniques can be considered as reasonable options (Brophy & Bogaty, 2004). Elective alternatives include PTCA, intracoronary rotational (rotablation) atherectomy, intracoronary directional atherectomy and CABG (Peters, 1994).

Percutaneous intervention for CHD involves an angioplasty procedure, with or without coronary stent implantation. PTCA is not strictly a surgical procedure, but it is only performed by specialised interventional cardiologists, while the patient is awake although lightly sedated. The procedure involves positioning a balloon-tipped cathter, inserted generally via the groin, into the blocked coronary artery. The balloon is inflated and deflated in order to compress the atherosclerotic plaque against the artery wall, making the lumen of the coronary artery wider. Intracoronary stents are expandable metal devices that come in various designs, lengths and diameters. They are implanted into the newly widened coronary artery by subsequent insertion of a stent deploying catheter. Once the catheter is in position, the stent is deployed by expanding the balloon. The balloon is then deflated and removed, leaving the stent inside the vessell to act as a piece of internal scaffolding, supporting the artery wall to remain patent or open, and allowing the vessel the opportunity to "remodel itself". The stent may be a bare-metal variety or one of the drug-eluting varieties. The choice of stent is determined by the interventional cardiologist performing the procedure. Drug-eluting stents are metal stents that have been coated with a special substance during the manufacturing process. With the drug-eluting variety, once inserted, the coating slowly letches from the stent. The purpose for choosing this type of stent is to slow down

the normal endotheliasiation process, because over endotheliasiation can cause occlusion, as is sometimes the case with their bare metal counterparts. In addition to PCI, life-style modification and pharmacological medical management are also prescribed (*Cardiac Interventional Procedures: Heart Disease,* 1994).

The more invasive CABG is, in general, an elective, rather than an acute revascularisation choice. While remaining a viable option, CABG has seen a reduction in case numbers due to the evolution of percutaneous interventions, such as, coronary angioplasty and stent implantation (Petersen, Peto & Rayner, 2004).

Although mentioned previously, it must be emphasised that there is no cure for coronary heart disease (NHFA, 2007). However, every person diagnosed with CHD should receive risk factor and lifestyle modification advice along with pharmacological intervention (NHFA, 2007). Short-term management includes: "normalisation" of post-operative physical and psychological experiences; wound care and pain management; provision of education material and support services; and recognition of the impact of personal, individual risk factors (NHFA, 2007). Long-term management focuses on risk factor reduction, secondary prevention of further disease, and the support mechanisms available to achieve these goals (NHFA & ACRA, 2004).

The NHFA, in association with the Cardiac Society of Australia and New Zealand (CSANZ), has developed, and regularly reviewed and updated, a best practice or treatment guide for people diagnosed with CHD. The guidelines were developed using a consensus approach, which involved an independent assessment of key Australian and international evidence-based clinical guidelines, scientific articles, and trial data.

The guidelines provide a general framework for appropriate practice, to be followed subject to the judgement of the individual patient's practitioner. All treatments should be individualised according to the patient's co-morbidities, drug tolerance, lifestyle/living circumstances and wishes (NHFA, 2007). The most recent guide - *A Summary Guide For Preventing Cardiovascular Events In People With Coronary Heart Disease,* is divided into five management areas containing seventeen risk-factor assessment or treatment options, and includes therapeutic targets and outcome goals (NHFA, 2007). An abbreviated version of this guide is provided in Appendix vii.

Whilst diet and lifestyle modification contribute significantly to risk reduction in the secondary prevention of CHD, initiation of therapeutic drugs to control blood pressure, reduce coagulopathy, and manage blood lipid levels are considered to be essential measures to reduce the risk of further coronary events. In combination with aspirin, beta blockers and angiotensin converting enzyme

(ACE) inhibitors, statins have kept pace with the interventional technology, enabling successful first-line medical management of CHD and as an ongoing treatment, following myocardial revascularisation (Ramsay, Whincup, Lawlor, Papacosta, Lennon, Thomas, et al., 2006).

There have been substantial pharmacological advances with clinically proven efficacy and worldwide recommendations for the introduction of statin therapy for cholesterol lowering. The evidence base for LLM, as a therapeutic intervention to reduce the risk of coronary events following diagnosis of CHD is unequivocal.

Summary

The purpose of this chapter was to draw attention to the cardiovascualar context of this study. It provided both an Australian and global overview of the impact of CVD with particular emphasis on CHD. CHD prevalence, contributing pathophysiological features and available diagnostic measures were described. In addition, CHD treatment guidelines and treatment options including revascularisation techniques and medical management leading to secondary prevention initiatives were summarised.

The following literature review will focus on LLM as a specific treatment to reduce the risk of further coronary events following CHD diagnosis.

CHAPTER 2

LITERATURE REVIEW

INTRODUCTION

The purpose of this study was to measure CHD patients' compliance with LLM and to analyse the reasons they gave for discontinuing this treatment. The decision to explore this study topic was originally influenced by the researcher's personal perception of the extent of non-compliance to LLM. This perception was formed from exposure to patient and peer anecdotes, observation of trends in the cardiac rehabilitation setting, and from research reports in nursing, health promotion and medical literature.

Coronary heart disease (CHD) accounts for almost 50,000 deaths in Australia each year. When patients are diagnosed and treated for CHD, guidelines embrace a number of treatment recommendations including the use of lipid lowering medication (LLM) to reduce blood lipid levels. Various medications can lower blood cholesterol levels. They may be prescribed individually or in combination with other drugs. However, there is a significant body of evidence indicating that patients' compliance with drugs in general, as well as with LLM specifically, is poor.

This chapter reviews the evidence base for LLM and identifies issues associated with their non-compliance. Initially, the mechanism of LLM is explained. A detailed review of the evidence base for their use is then presented. The degree to which healthcare providers initiate, monitor and titrate LLM, the methods that have been undertaken to measure compliance, the types of interventions that have been employed, and the subsequent outcomes of those interventions are also included in this review. From the patient perspective the risks associated with discontinuation of LLM are also explored.

LIPID-LOWERING MEDICATION

Mechanism of LLM

Following angiographically diagnosed CHD, one of the most important aspects of treatment and prevention of recurring CHD events is the management of blood cholesterol, also referred to as dislipidaemia or hypercholesterolaemia. Pharmacologically, this is achieved by initiating LLM.

The classes of drugs most commonly used for lipid lowering include statins and selective cholesterol absorption inhibitors (Davidson & Jacobson, 2001). Statins, also known as HMG CoA

reductase inhibitors, are a class of drugs that work in the liver to prevent the formation of cholesterol. They are most effective at lowering LDL cholesterol (sometimes referred to as 'bad' cholesterol) and raising high density lipoprotein (HDL) cholesterol (which may be referred to as 'good' cholesterol). Another class of drug known as selective cholesterol absorption inhibitors are a relatively new class of cholesterol lowering medications that work by preventing the absorption of cholesterol from the intestine. They are most effective at lowering LDL, but may also have modest effects on lowering triglycerides (TG) and raising HDL levels, according to the National Prescribing Service (Fletcher, 2005).

The efficacy of LLM in the management and treatment of CHD has been investigated intensively. Numerous international trials, described in the following section, have highlighted the benefits of implementing pharmacological lipid-lowering therapy in association with lifestyle and other risk factor modification in the treatment of CHD.

The evidence base for lipid lowering medications

Since 1994, no fewer than nineteen landmark clinical trials have been conducted, all aimed at assessing the benefits of pharmacological lipid-lowering medications (in particular the statin group of medications) in the prevention and management of CHD. These trials are listed chronologically in Table 2, and are discussed in detail in the following literature review. There is an abundance of evidence from these clinical trials, that supports a reduction in morbidity and mortality rates in people diagnosed with CHD, by adoption of risk-reducing behaviour modification in association with the use of pharmacological management therapies, including LLM.

Although there is no cure for CHD, irrespective of which treatment group patients are allocated to, every person with a CHD diagnosis should receive LLM. However, evidence suggests that compliance to LLM is poor, and that the reasons for patients ceasing these medications are unknown (Simons, Levis & Simons 1996)).

As pointed out in Chapter 1, since 1994, no fewer than nineteen landmark clinical trials have been conducted, all aimed at assessing the benefits of pharmacological lipid-lowering medications (in particular the statin group of medications) in the prevention and management of CHD These trials are listed chronologically in Table 2. The studies are discussed in the following section.

Several trials have been undertaken to assess the benefits of statin therapy in primary and secondary CHD prevention. Investigations have included groups of participants with mild, or average to low dislipidemia, as well as high risk groups with CHD plus diabetes or other CVD. In

addition to primary or secondary CHD prevention, outcomes in certain trials have specifically focused on TC reduction, or TC and LDL reduction, primarily LDL reduction, while others concentrated on risk reduction in CHD generally.

Table 2. Landmark statin clinical trials (Landmark statin trials, n.d.).

Year	Clinical Trial
1994	4S: Scandinavial Simvastatin Survival Study Group.
1995	WOSCOPS: West of Scotland Coronary Prevention Study.
1996	CARE: The Cholesterol and Recurrent Events Trial.
1998	LIPID: Long-term Intervention With Pravastatin in Ischaemic Disease. AFCAPS/TexCAPS: Atherosclerosis Prevention Study Air Force/Texas Coronary Atherosclerosis Prevention Study.
2001	MIRACL: Myocardial Ischaemia Reduction with Aggressive Cholesterol Lowering.
2002	HPS: Heart Protection Study. ALLHAT-LLT: Antihypertensive and Lipid-Lowering Treatment to prevent Heart Attack Trial. LIPS: Lescol Intervention Prevention Study. PROSPER: PROspective Study of Pravastatin in the Elderly at Risk.
2003	ALERT: Assessment of LEscol in Renal Transplantation. ASCOT-LLA: Anglo-Scandinavian Cardiac Outcomes Trial - Lipid Lowering Arm.
2004	A to Z: Aggrastat to Zocor. CARDS: Collaborative Atorvastatin Diabetes Study. PROVE IT - TIMI 22 Pravastatin or Atorvastatin Evaluation and Infection Therapy-Thrombolysis in Myocardial Infarction 22. REVERSAL: Reversal of Atherosclerosis with Aggressive Lipid Lowering.
2005	TNT: Treating to New Targets.
2006	SPARCL: Stroke Prevention by Aggressive Reduction in Cholesterol Levels: On-treatment Analysis. ASTEROID: A Study To Evaluate the Effect of Rosuvastatin on Intravascular Ultrasound-Derived Coronary Atheroma Burden.

Landmark statin clinical trials

Two primary prevention studies that have documented the value of statin drugs in primary care to lower CVD risk have been included in this review. *The West of Scotland Coronary Prevention Study* (WOSCOPS) of Shepherd et al. (1995) was a large, randomised, double-blind, placebo-controlled primary prevention trial involving men only. This study, involving 6,595 individuals with clinically established hypercholesterolemia, aged between 45 to 65 years, who were followed-up for an average of five years. Overall, its results determined that whilst there was no change in lipid levels in the placebo group, treatment with pravastatin reduced cholesterol levels by 20% and LDL cholesterol levels by 26%, in the treatment group. There were 248 defined coronary events in

the placebo group and 174 in the treatment group, demonstrating a reduction in the risk of a first MI by 31% and of death by 22%.

The second, primary prevention study was a randomised, double-blind, placebo-controlled primary prevention trial that involved 6605 male and female participants was the *The Air Force/Texas Coronary Atherosclerosis Prevention study* (AFCAPS/TexCaps) undertaken by Downs et al. (1997). The age range for males was 45 to 73 years and, for (postmenopausal) women, 55 to 73 years. This trial was designed and powered to test the hypothesis that LLM (lovastatin) in conjunction with an appropriate modified fat diet was more effective than diet alone in reducing acute major coronary events, such as unstable angina, fatal and non-fatal myocardial infarction, and sudden cardiac death (composite end points). Participants had no previous history, signs or symptoms of CVD and met the average lipid-profile criteria. They were followed-up for a mean 5.2 years. Furthermore, this cohort included women and the elderly making the outcomes applicable to a broader population than previous studies (Downs et al., 1997).

A female only investigation, being a subgroup LIPID Study, and undertaken by Hague, Forder, Simes, Hunt and Tonkin (2003), was designed to assess the secondary prevention effects of pravastatin in women. This study enrolled a cohort of 9,014 patients with a history of MI or unstable angina and plasma cholesterol levels of 4.0 to 7.0mmol/L at baseline. Participants were assigned by Hague et al. (2003) to the treatment group receiving 40mg pravastatin daily or to the placebo group. Of those enrolled 1,516 were women, with 756 being assigned to the treatment with LLM group. Participants were followed for six years and major cardiovascular disease events were measured. The earlier LIPID study had demonstrated a significant reduction in CVD events in all participants, and, although the subgroup analysis showed that relative treatments effects for females were not dissimilar to the effects for males, Hague et al. (2003) noted that it was not sufficiently large enough however, to demonstrate separate effects for females.

Apart from primary prevention benefits, the value of secondary prevention using statin therapy in patients with diagnosed CHD or who have suffered an acute CVD have been confirmed by a number of landmark studies. *The Scandinavian Simvastatin Survival Study* (4S) of Pedersen et al. (1994) was the first of the large clinical trials testing the then new class of drugs called statins. This study enrolled 4,444 patients with CHD and aged between 35 and 70 years. These patients had mild hypercholesterolemia with levels between 5.5 and 8.0mmol/l. The objective was to assess the effect of simvastatin on mortality and morbidity. Pedersen et al. assigned 2,223 patients to placebo and 2,221 to simvastatin treatment for a mean period of 5.4 years. The results demonstrated a 30% relative reduction in the risk of death with simvastatin treatment. The

absolute CHD mortality was reduced from 8.5% to 5.0%. Additionally, according to these researchers, there was no excess morbidity of non-cardiac deaths from causes such as cancer or suicide, a concern that had occasionally arisen about the use of statins (Pedersen et al., 1994).

Further, Sacks et al. (1996) in the double-blind *Cholesterol And Recurrent Events* (CARE) trial, demonstrated that, by reducing LDL cholesterol from average to low levels, there was a significant reduction in the number of recurrent coronary events. The primary end point of this trial was a fatal coronary event or a non-fatal myocardial infarction. This study, which enrolled 4,159 patients (3,583 males and 567 females) with only average cholesterol levels and a previous history of myocardial infarcts, was unlike previous trials that enrolled participants with high cholesterol levels. The CARE Trial demonstrated that, by reducing LDL cholesterol from average to low levels, there was a significant reduction in the number of recurrent coronary events. Although this trial showed no significant reduction in overall mortality rates, it demonstrated the efficacy of pravastatin compared to placebo in the secondary prevention of recurrent cardiac events in participants 60 years and over, in women, and in participants with a reduced ejection fraction (Sacks et al., 1996).

However, one of the largest studies completed was the *Long-term Intervention with Pravastatin in Ischaemic Disease* (LIPID) trial, which investigated lipid-modifying therapy (Tonkin et al., 1998). This study demonstrated the efficacy of pravastatin versus placebo as a secondary prevention initiative against mortality from CHD in over 9,000 patients who had a history of CHD and broad ranging cholesterol levels. This was a randomised, placebo-controlled trial that enrolled 9,014 participants (7,498 males and 1,516 females aged between 31 and 75 years) across 87 centres in Australia and New Zealand. Each participant had a history of myocardial infarction or a hospital discharge diagnosis of unstable angina within three to thirty-six months of recruitment and randomisation. The primary endpoint of the LIPID trial was death from CHD. The study results provided strong evidence that lowering cholesterol levels with pravastatin in patients with a broad range of initial cholesterol levels and a history of myocardial infarction or unstable angina reduced the risk of death from CHD, CVD, and all causes combined, and indicated that these benefits were not offset by adverse effects to pravastatin (Tonkin et al., 1998).

The previously discussed secondary prevention trials were followed by the *Heart Protection Study* (HPS) of Collins et al. (2002), which was the last of the large, placebo-controlled statin trials, enrolling 20,536 participants who were considered high-risk adults (aged 40-80 years) with coronary disease, other occlusive arterial disease, or diabetes, but with low to average total cholesterol and LDL cholesterol levels. Participants were randomly allocated by Collins et al. to

receive 40mg of simvastatin daily or matching placebo. Patients were followed for a five-year period at the end of which the authors demonstrated a reduction in the rates of myocardial infarction, stroke, and of revascularisation procedures by about one-quarter in the group allocated to 40mg of simvastatin daily. The addition of LLM to their existing treatments was demonstrated to produce further benefits for these patients and significantly, according to Collins et al. (2002), these benefits were irrespective of their initial cholesterol concentrations. Further, Brooks (2007) submitted that extended follow-up of HPS patients supports the prompt initiation and continuation of statin therapy in individuals who are assessed as being at increased vascular risk. Brooks (2007) reported on the results of the post-trial heart protection study (HPS) in which 7,519 survivors were followed up over four years. Data were collected annually from the participants by using a postal questionnaire, achieving an 80% response rate. While there were no additional benefits detected from statin use, this follow-up study provided sustained evidence for the safety and efficacy of long-term statin therapy. Brooks observed that the follow up also highlighted a significant risk reduction in revascularisation, therefore supporting the cost-effectiveness of timely initiation and ongoing treatment of at-risk individuals with statin therapy.

All of these trials addressed secondary prevention of CVD mortality and morbidity by means of statin therapy. The collective conclusion was that standard management of CVD risk in a patient with CAD or in someone who had suffered an acute cardiac event should incorporate the use of statin drugs as an integral part of their continuing care, irrespective of the cholesterol level of the individual patient (Nixon, 2006).

A more recent study targeting specific outcomes of statin intervention was the *Aggrastat to Zocor* (A to Z) trial of Morrow et al. (2006). These researchers found that early initiation of statin therapy was beneficial following acute coronary syndrome (ACS) events. The A to Z trial was a multinational, two-phase study of 3,813 patients presenting with either non-ST elevation or ST elevation acute coronary syndrome (ACS). Phase A was designed to compare efficacy of anticoagulant therapies. Phase Z was a double-blinded trial assessing whether early intensive statin treatment was more effective than the usual treatment of implementing dietary changes for several weeks and then commencing patients on a low-dose statin three to six months following an acute event. The researchers measured a biochemical inflammatory marker (high-sensitivity of C-reactive protein/hsCRP) that is associated with an adverse risk of cardiovascular events. Elevated levels of hsCRP are correlated with a higher risk of adverse outcomes in patients at risk of, or with, established coronary artery disease. Morrow et al. (2006) demonstrated that treatment with LLM lowers the levels of hsCRP in patients with atherosclerosis by 13% to 50% compared with placebo,

and that lowering the levels of this inflammatory marker is associated with more favourable clinical outcomes. The A-to-Z trials involved patients with acute coronary syndromes, unlike the TNT trials which involved patients with stable CVD (Cannon, Steinberg, Murphy, Mega & Braunwald, 2006).

The *Treating to New Targets* (TNT) trial, discussed in *Expert Column* by LaRosa (2005), one of the trial researchers, was an international, multicentre, double-blinded, randomised trial enrolling 10,000 males and females aged between 35 and 75 years and was geared to determine the safety and efficacy of atorvastatin in achieving target levels for LDL cholesterol. All the participants had clinically diagnosed CHD. Two groups were treated with atorvastatin, one group with 10mg daily, the other with 80mg; and participants were followed-up for a period of five years. The primary outcome measures for this study included fatal and non-fatal MI, resuscitated cardiac arrest and fatal or non-fatal stroke, with results at the end of the five-year period demonstrating a relative risk reduction in the primary outcome measures of 22% in the 80mg LLM group compared to the 10mg LLM group. The TNT trial was the first randomised trial to demonstrate the benefits of lowering LDL cholesterol below 2.6mmol/L (LaRosa, 2005). Despite the differing participant diagnosis in these two trials, A-Z and TNT, Cannon et al. (2006) concluded that initiation of high-dose LLM provides a significant benefit over standard-dose therapy for preventing predominately non-fatal CVD events.

Recently, in a study to evaluate the effect of rosuvastatin on intravascular ultrasound-derived coronary atheroma burden (ASTEROID trial), Nissen et al. (2006) were able to demonstrate regression of coronary-atheroma volume by using intravascular ultrasound (IVUS), before and after initiation of statin therapy. This was a prospective, open-label, blinded end-points trial conducted in 53 facilities in the United States, Canada, Europe and Australia, and was designed to assess whether very intensive LLM therapy would result in coronary atherosclerotic regression. Nissen et al. (2006) recruited 507 participants for IVUS evaluation. After 24 months, 349 of them had a second evaluable IVUS study performed. Primary efficacy measures were: (1) a change in percent atheroma volume (PAV); and (2) a change in nominal atheroma volume in the 10mm sub-segment deemed to have the most severe disease at baseline. The efficacy measure (1) showed a regression in 63.6% of participants, and, for efficacy measure (2), 78.1% of patients demonstrated regression. This significant atherosclerotic regression, an explicit outcome in the design of this trial, was achieved, according to Nissan et al. (2006), by reducing LDL cholesterol levels to a mean of 1.6mmol/L and increasing HDL cholesterol by a significant 14.7%. Therefore, the use of statin drugs as an integral part of a comprehensive management strategy in primary and secondary

preventative CHD therapy to lower cardiovascular mortality and morbidity risk is clearly indicated (Nisson et al., 2006).

As has already been demonstrated, for almost a decade, researchers have been espousing the benefits of reversing existing CHD and preventing further episodes by initiating early statin therapy following an acute cardiac episode. However, there is a second and significant benefit in addition to the effects of reducing total LDL cholesterol levels. Jackson (2000), highlighting the efficacy of using statins in the treatment of ACS, discussed the additional benefits due to the mechanisms of atherosclerotic coronary plaque rupture (unstable plaque) and the plaque stabilising effects of lipid-lowering medications, particularly the statin group of medications. With increasing understanding and knowledge of the dynamic nature of atherosclerotic coronary lesions, Jackson (2000) asserted that there was now compelling evidence for the initiation of statin therapy very early in the post ACS patient.

In addition to very large trials, a considerable amount of other research has been undertaken into the benefits of lipid-lowering therapy for CHD. For example, in Australia, McElduff, Dobson, Jamrozik and Hobbs (2001) sought to determine the number of coronary events that could be prevented annually, if recommended treatment therapy targets were achieved. Their approach was to use published estimates of the benefits of risk-factor modification in addition to better medical care to predict the potential reduction in coronary events if "preventive and therapeutic strategies" were initiated for specific community groups (McElduff et al., 2001, p. 24). They selected three population groups, based on level of risk, and investigated the predicted outcomes of three interventions in each of those groups: a reduction of the mean level of cholesterol by 0.05mmol/L by pharmacological management with lipid lowering therapy, reducing cigarette smoking by 50%, and reducing the level of physical inactivity by 25%. The researchers estimated that, in achieving these three outcomes, the overall effect would result in a reduction each year of approximately 14,000 coronary events. However, according to McElduff et al., the most effective intervention achieving the highest reduction in coronary events was the lowering of mean cholesterol levels.

Further, Wang, Stafford, Ausiello and Chaisson (2001) have stated that hypercholesterolemia is a modifiable risk factor for coronary events, citing the results of statin therapy in lipid lowering from the landmark trials of Shepherd et al. (1995), Sacks et al. (1996) and Pedersen et al. (2000), which have been discussed above. These trials, as has been discussed, provided conclusive evidence of the benefits of lipid-lowering therapy in the treatment of CHD. The primary outcome of the research of Wang et al. was to measure the use of specific lipid-lowering therapy relevant to the publication of randomised clinical trials results and recommendations. Using a random sampling

approach and data on patients taking LLM from the *National Ambulatory Medical Care Survey* covering a number of years from 1980 to 1998, the researchers identified a cohort of 5,053 patient/physician visits. Interestingly, they concluded that the lipid-lowering-medications market and, in particular, the statin market had risen even before publication of the clinical trials that recommended their use. However, the authors indicated that the 30% relative risk reduction of the 4S study (Pedersen et al., 1994) cannot be discounted when considering any increases in statin prescribing habits around that time. Concurring with the clinical trial results, Wang et al. (2001) also highlighted the role of specific lipid-lowering medication, in particular statin therapy, in decreasing cardiovascular events, including mortality.

As previously stated, Scotland has one of the highest incidences of CHD in the World. Therefore, Wei et al. (2002) determined the effect, in this population, of adherence to statin treatment on all cause mortality after myocardial infarct. These authors undertook a six-year prospective cohort study that commenced in January 1985 and concluded in December 1995, to measure adherence to statin therapy. The cohort of 5,590 people (40.4% of whom were female) comprised patients with a hospital discharge diagnosis of their first MI between January 1990 and November 1995. At the conclusion of the study, 717 (12.8%) patients suffered a further MI, 1,299 (23.2%) died, and only 427 (7.7%) patients received LLM following discharge from hospital. Wei et al. (2002), as had Wang et al. (2001), also noted that the 4S trial results impacted dramatically on statin prescribing habits and that, between 1994 and 1995, the prescription of statins doubled. The researchers concluded that good compliance to taking LLM therapy was associated with a lower risk of recurrent MI

Similarly, Grundy (2006) reviewing the clinical implications of the *Incremental Decrease in Endpoints through Aggressive Lipid-lowering* (IDEAL) study concluded that the evidence for reducing LDL cholesterol was convincing and best practice for secondary prevention in CHD. However, Grundy commented that achieving target outcomes for LDL cholesterol required not just initiation of LLM prescription but also monitoring lipid levels and titrating therapy to achieve the recommended therapeutic goals.

Further, according to the results of a recent meta-analysis undertaken by Thavendiranathan, Bagai, Brookhart and Choudhry (2006), statins reduce the risk of major coronary and cerebrovascular events and reduce the need for revascularisation procedures. These researchers undertook the meta-analysis because of concerns related to some discrepancy in the existing data. Although there have been many trials involving tens of thousands of participants, interpretation of the data has been a problem. One of the limitations of their study reported by the authors was that some of the

trials they reviewed included secondary-prevention participants, and, as they were relying entirely on published data, they were unable to exclude this reportedly small group. Thavendiranathan et al. concluded that, although, in patients without CVD, primary prevention with statin therapy does not decrease the incidence of CHD or overall mortality, they found that statin therapy does decrease the incidence of major coronary and cerebrovascular events and revascularisation procedures.

Following the compelling evidence from clinical trials The National Lipid Association (NLA) in the United States implemented recommendations via its Statin Safety Taskforce. The recommendations cover both risk and benefits of statin therapy. In a review article giving an overview of the NLA recommendations, Jacobson and McKenney (2006), stated that statins are integral among CHD preventive therapies, significantly reducing the relative risk of coronary events and both coronary and all-cause mortality (vs. placebo) by approximately 23% to 37% in several landmark clinical trials by virtue of their ability to modify lipid levels as well as inflammatory, thrombotic, and other mechanisms of atherosclerosis.

Guidelines for the initiation and continuation of LLM have been developed and subsequently reviewed and updated regularly, both nationally and internationally. Treatment guidelines, as discussed in the following section, provide a systematic process whereby health-care practitioners have access to standards of adherence in prescribing care for the management of CHD.

Guidelines for the use of lipid lowering medication in coronary heart disease

Treatment guidelines provide recommendations for LLM initiation in primary prevention and as secondary treatment of CHD, and include pharmacological and behavioural management. The findings of the Z phase of the A to Z trial (Morrow et al., 2006) were quite revolutionary in influencing treatment-initiation guidelines for CHD globally. Prior to the results of this trial, lipid lowering was generally not initiated for a period of at least six weeks, giving the patient an opportunity to reduce total cholesterol levels by dietary management**.** Subsequent to these determinations of the clinical trials, LLM guideline recommendations have been reviewed and revised nationally and internationally by governments and other health care agencies. Two examples of contemporary guidelines where landmark clinical trials have been cited as having influenced guideline development are those of the American Heart Association/American College of Cardiology (AHA/ACC) (Smith et al., 2006) and the National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand (NHFA & CSANZ, 2007).

The evidence based results of the clinical trials provided the impetus for an update of the AHA/ACC 2001 recommendations. The AHA/ACC guidelines (Smith et al., 2001) recommended that, following twelve weeks of therapeutic lifestyle change, including dietary changes, LLM initiation could be considered. The revised AHA/ACC guidelines now recommend assessment of a fasting lipid profile in all cardiac patients and initiation of LLM to be commenced before hospital separation (Smith, et al., 2006).

Australian lipid-lowering guidelines were developed in 2001 (NHFA & CSANZ, 2001). They included treatment initiation for those patients considered to be at higher absolute risk of CHD and whose serum cholesterol was above target levels. The advice to practitioners at that time suggested monitoring diet fortnightly for six weeks, and then retesting serum lipid levels. If the results continue above therapeutic target levels, consideration should be given to commencing lipid-modifying therapy. However, in their most recent publication, which is aimed at preventing cardiovascular events in people with CHD, the NHFA & CSANZ (2007) have revised and updated their guidelines. The revised recommendations in the Heart Foundation document for the pharmacological management of CHD made four important statements: (1) that the therapeutic target goal in the treatment of dislipidemia for LDL-C should be <2.0 mmol/L; HDL-C >1.0 mmol/L and Triglycerides <1.5 mmol/L; (2) statin therapy is recommended for all patients with CHD unless contraindicated; (3) for hospitalised patients, therapy should be initiated during their admission; and (4) all patients should receive healthy eating advice. Changes to the previous guidelines were based on a review of literature, including the landmark statin clinical trials, already discussed.

Initiation, monitoring and titration of lipid-lowering medication

As evidenced by the discussion above and based on substantial anecdotal evidence and personal observation, there is poor management of hyperlipidaemia in the secondary prevention of CHD. This is the case, despite many clinical trials demonstrating that, in the management of dyslipidaemic patients with CHD, prescription of, and compliance to, pharmacological LLM results in a reduction of mortality and morbidity. However, a large number of clinical trials have also reported that a significant proportion of patients, who have been diagnosed with CHD, are achieving sub-optimal results in reaching and maintaining recommended therapeutic outcomes of pharmacological lipid lowering.

A group of researchers has suggested that failure to achieve therapeutic outcomes relates not just to the apparently low rates for long-term compliance with pharmacological lipid-lowering therapy by patients (Blackburn, Dobson, Blackburn, & Wilson, 2005). Similarly, Ellis et al. (2004) concluded that the failure to initiate, monitor and titrate by treating physicians, despite overwhelming evidence and publication of their benefits and treatment guidelines, has also contributed to the poor outcomes. Therefore, this too is significant when counting the economic cost of morbidity and mortality associated with LLM non-compliance.

Risks associated with discontinuation of lipid lowering therapy

There are a number of risks associated with discontinuation of lipid-lowering therapy or even poor or partial compliance. However, from a patient's perspective, failure to achieve target, secondary-prevention management goals, leads to an increased risk of mortality, and to an increased morbidity related to hospital readmission for medical assessment and management, along with an increased risk of new or repeat revascularisation procedures.

Citing serum cholesterol level as arguably the most important risk factor, Redfern, Ellis, Briffa and Freedman (2007) conducted a cross-sectional comparison study in a tertiary hospital in order to document the risk factor profile and risk factor knowledge of patients following an ACS and in patients who would not be attending an outpatient, standard, cardiac rehabilitation program. In all, 208 participants were recruited, and 144 were allocated to the group not attending cardiac rehabilitation (NCR), while 64 were allocated to attend, an outpatient, standard, cardiac rehabilitation group (SCR). This study was not designed to assess compliance to LLM. The main outcome measures of this study were to assess risk factor profile, and patient knowledge of risk factors. However, although knowledge does not necessarily equate to behaviour change, patient education is a major factor in post-CHD-diagnosis care. Redfern et al. (2007) found patients in the NCR group, in the main, had higher cholesterol levels, and were unaware of what their target cholesterol level should be when compared to the patients in the SCR group. The difference in total cholesterol level between the two groups was equal to a predicted increase in CHD risk of about 24% (Redfern et al., 2007). Overall, the researchers determined that risk factor knowledge, the number of risk factors and the risk factor level, were significantly worse in the NCR-patient group when compared to the SCR group. According to Redfern et al. this research highlighted a significant knowledge gap particularly when risk factor knowledge is known to correlate with increased adherence to behavioural lifestyle changes.

Medication compliance

The debate in relation to the use of the words adherence and compliance in relation to medication has been a topic of discussion in the research and health care literature for many years. In a background report on interventions for helping patients follow prescriptions for medications, Haynes, McDonald, Garg and Montague (2004) made the observation that the term *adherence* is not intended to apportion blame to the patient, prescriber or treatment. The indication, highlighted here, is that the term neither assigns nor denotes any level of inclusivity to patient, prescriber and the treatment. Further, some years earlier Campbell (1997) stated that adherence needs to be redefined from being a static concept to a dynamic process.

Compliance has been defined as "an acquiescing or yielding" or "base subservience" by the Macquarie Dictionary (Delbridge, 1982). The Macquarie Thesaurus (Bernard, 1984) lists, amongst the synonyms for compliance, the words deference, non-resistance, passiveness and submission. Of interest, is the fact that, no matter which term is applied to the failure to achieve target therapeutic outcomes in chronic disease management globally the label, compliance, by definition, completely excludes the patient from accepting a role as an equal and integral participant in his or her treatment regimen. However, for the purposes of this research, because it has been used most commonly in the literature reviewed, the term, compliance has been selected to represent continuation or cessation of prescribed LLM.

Non-compliance to medications is not unique to the CHD population. There is abundant evidence of non-compliance to pharmacological regimens, generally across a wide range of chronic disease processes, including HIV-AIDS, asthma, hypertension, chronic obstructive pulmonary disease, diabetes and chronic heart failure (e.g., DiMatteo, 1994; Campbell et al., 1998; Senterfitt, 1998; Sawyer & Fardy, 2003; Barber, Parsons, Clifford, Darracott & Horne, 2004; Putzer et al., 2004).

Neither is non-compliance more prevalent in a primary care setting, as opposed to secondary prevention or chronic disease management situations. For example, when discussing the management of AIDS, McAllister (2000, p. 22) concluded that "from the literature it is clear that non-adherence is ubiquitous." Patients who are treated with anti-HIV drugs require a complex regimen involving multiple medications and multiple daily doses. In the view of McAllister, these factors alone impact dramatically on long-term adherence and improved outcomes to treatment. Furthermore, non-compliance presents a similar challenge in the short-term management of acute

medical conditions and even for symptomatic relief, such as in the setting of viral or hormonal management, as it does in long-term management (Osterberg & Blaschke, 2005).

For example, the prevention of acute episodes of asthma and the management of asthma symptoms continues to be problematic. Morbidity rates for asthma in Australia are persistently high, primarily due to sub-optimal symptom recognition and treatment initiation. Moreover, according to Sawyer and Fardy (2003), target management goals are not being met in Australia for two reasons: under-prescription, because patients fail to see their general practitioner (GP) regularly; and under usage by patients of preventative medications, because of poor perception of the severity of the disease and a failure or inability to accurately assess any symptoms as they occur.

Another example is patients with Type II diabetes who either have, or are at risk of, other co-morbidities, including renal hypertension, macular degeneration and CHD (Putzer et al., 2004). Reducing the risk of CHD, which is the leading cause of death in patients with Type II diabetes, and managing lipid-lowering therapy, in particular LDL cholesterol, is recommended (Putzer et al., 2004). In their American study, Putzer et al randomly selected 239 patients from an Academic Family Practice and reviewed their charts to ascertain compliance with the American Diabetic Association's (ADA) treatment goals. They found that only 14.6% (30) of the cohort achieved these treatment goals. Thus Putzer et al. (2004) concluded that further study is needed to determine the reasons why patients fail to achieve lipid goals.

Non-compliance continues to be a universal and non-age related or disease related issue. For instance, in south-east England, a survey was conducted on an elderly cohort (75 years or over) who had just been commenced on new chronic-disease medication. The 258 participants had been diagnosed with one of the following chronic diseases: stroke, CHD, asthma, diabetes or rheumatoid arthritis. At ten days, thirteen participants had ceased their medications on medical advice, but 67 (30%) of the remaining 226 were non-compliant. At four weeks, 85 participants (38%) were non-compliant to at least one of their new medications (Barber et al., 2004). A significant proportion of patients, when commenced on medication became non-compliant in a relatively short period of time, and they intentionally choose to do so. Although Barber et al. (2004) offered no explanation of that observation, they stated their conclusions were that people starting chronic disease medications, require initial support to assist with compliance (Barber et al., 2004).

Compliance measurement and interventions

The impact of poor medication compliance on the health service industry is considerable. Increased readmission rates lead to an associated economic impact on national and state health budgets. When combined with societal impacts, in terms of preventable morbidity and mortality, the cost of non-compliance is substantial as has been discussed previously.

As has been indicated in the literature, patient compliance to medication measurement has been primarily achieved by methods driven by the needs of health care professionals, which have lacked a patient-centered focus. Mansur et al. (2001) have discussed a number of initiatives that have been employed over the years to measure compliance. These include retrospective or prospective patient-record audits, and audits of prescription presentation at a pharmacy for initial dispensing and subsequent repeat prescription within a given time frame. Pharmacological compliance and intervention measurements have also been undertaken employing patient self-reporting methods, electronic monitoring via use of patient record numbers, and follow-up systems utilising telephone-call or mailed reminders (Mansur et al., 2001). There is also some sound evidence in research undertaken by Simons et al. (1996) that supports improvement of long-term medication compliance involving the introduction of nurse-led clinics.

There are a number of ways to measure compliance to pharmacological therapy and these include: self-reporting questionnaires; pill counts and self-recorded diaries; and electronic devices to record when pill bottles are opened (Wang et al., 2001). In the case of LLM compliance, Wang et al. (2001, p. 232) have cited a lowered serum LDL as a "surrogate for adherence measurement". However, pathology testing of an individual's lipid profile is not without cost. As well, ordering the required tests the receipt and dissemination of the results fall within the province of the patient's medical practitioner. Access to such information may not be readily available to researchers.

Haynes et al. (2004) conducted a systematic review of interventions that had been implemented, all aimed at helping patients follow prescriptions for medications. The review was undertaken from a background of a 50% patient non-compliance rate to prescribed self-administered medications. A total of 6,568 citations relating to medication interventions were retrieved. Of these, 549 articles were examined in full, and 33 trials were identified as having tested 39 non-confounded interventions. Less than half of these interventions (19 out of 39) showed statistically significant improvement in medication compliance. Only seventeen reported statistically significant improvement in treatment goals. The report noted that most of the studies involved only small population groups. This review by Haynes et al. (2004) highlighted the fact that not one of the

studies, which they examined, sought the opinion of patients themselves in an effort to enhance compliance.

While the avenues of inquiry reported by Haynes et al. (2004) have led to a significant amount of information on non-compliance statistics, in reality they do not focus on strategies to achieve improved patient treatment and outcomes. Based on the evidence available in the literature, there has been little patient participation in identifying the rationale for non-compliance to pharmacological therapy. However, Jackson (2000), McDonald, Garg and Haynes (2002), and Smith (2000) have all recognised that a patient's perception of the importance of their therapy is significantly influenced by the way the therapy is initiated, and that poor compliance is associated with a lack of support, as well as a lack of information given to, and comprehended by, the patient. Therefore, the notion of examining compliance understanding, along with an exploration of the factors contributing to compliance enhancement, from a patient perspective, becomes compelling.

Fernandez, Davidson, Griffiths, Jeurgens and Salamonson, (2007) came to a similar conclusion following a cross-sectional study that sought to investigate medication compliance following PTCA. In their research, a cohort of 270 participants was followed up between twelve and 24 months after their revascularisation procedure by means of a mailed self-reporting questionnaire. Although the authors found that generally self-reported medication compliance was high, missed medication doses, cessation of medications due to feeling better or worse and poor knowledge of medication storage were an issue. Because this study used a similar study method to those previously described, what continues to remain unanswered is how the patient feels or what the patient preferences may be regarding their medication regimen. However, Fernandez et al. (2007) did acknowledge that, given medication compliance is imperative in the treatment and secondary prevention of CHD, much more investigation is required in order to clearly understand the multi-factorial issues that contribute to patient non-compliance. These factors, according to the researchers, include the scope of non-compliance and the characteristics of the patients who do not comply with long-term pharmacological treatment regimens.

Many things impact on medication compliance and the literature provides some evidence about why patients do not take their drugs. The reasons range from issues of ethnicity, education level, age, gender and socio-economic status to medication side effects and financial cost. McAllister (2000) has discussed a comprehensively referenced list of reasons for non-compliance and, although this author was addressing compliance to antiretroviral drug therapy, the list related to therapy non-compliance in general. It was claimed that non-compliance to treatment is not unique to one particular disease group. The reasons for non-compliance are summarised in Table 3.

Table 3. Identified reasons for non-compliance (after McAllister, 2000)

Variable	Detail
Demographics	Age & gender Literacy /education levels Medication & treatment access cost Culture/ethnicity
Beliefs & knowledge	Disease knowledge Understanding of treatment efficacy
Physical & disease state	Presence of symptoms Symptom severity
Social & psychological factors	Depression Social isolation Social support
Drug regimen	Complex medication regimen/polypharmacy Side effects
Prescriber & health care team	Commencement of medication Trust in health care team Support & reassurance provided Information given Follow-up on missed appointments
Clinical & service provision	Access to medical and pharmacy services Long waiting times & hours of service operation Difficulty obtaining appointments Distance and cost of access to services

Compliance issues related to lipid lowering medication specifically

A systematic review of randomised controlled trials to assess the effect of adherence-enhancing interventions for LLM specifically (Schedlbauer, Schroeder & Fahey 2007), found little evidence of successful and cost effective strategies that would improve LLM compliance. As already outlined, this finding is not dissimilar to those of other researchers into compliance to chronic disease treatment regimens generally.

The global incidence of CHD has been clearly stated and reiterated by health agencies and health researchers in a number of publications, an overview of which has been presented above. Following a diagnosis of CHD, it is recommended on the basis of unequivocal evidence that all patients in this diagnostic group should receive LLM as part of their treatment package. Nonetheless, there is also a substantial body of evidence that indicates that compliance rates with LLM are suboptimal. This leads to a failure to achieve therapeutic target levels for lipid lowering, resulting in a subsequent increase in CHD morbidity and mortality. In addition to mortality and

morbidity data, the economic impact of CHD must not be overlooked. Providing primary, secondary and tertiary investigations and treatment to the CHD population imposes a huge, annual, financial burden on health budgets. This is due in part to research-technology expenditure coupled with consumers' treatment expectations, and little consumer responsibility for primary prevention initiatives in developed countries around the world. The efficacy and cost effectiveness of LLM when target therapeutic outcomes are achieved cannot be disregarded as a primary and integral treatment method for CHD. Therefore, the reason or reasons why, despite compelling evidence and clear guidelines, LLM compliance is poor, requires thorough investigation.

Despite there being a large body of data from trials indicating that achieving optimal lipid levels is a significant factor in reducing secondary CHD morbidity and mortality rates, researchers have reported that a significant percentage of patients diagnosed with CHD are achieving sub-optimal results in reaching and maintaining the recommended therapeutic outcomes of pharmacological lipid lowering. For example, Simons et al. (1996) studied an Australian population and found that 60% of patients discontinued their lipid-lowering medication during the first year of treatment. Of interest, adverse events contributed to just 7% of the discontinuation rate. Their study also determined that, of the 60% of patients who discontinued taking their lipid-lowering medication within one year, 25% had in fact discontinued or were non-compliant with their LLM within one month and 50% within three months. Moreover, Simons et al. reported that this apparent discontinuation of a pharmaceutical intervention was related to other "so called" asymptomatic disease management strategies, such as those used in diabetes and hypertension management. Further, Nissen et al. (2004) and LaRosa et al. (2005) in support of the findings of clinical-trial findings, agree that lowering cholesterol levels, in particular total cholesterol (TC) and LDL cholesterol, in order to achieve the target lipid profiles identified in guidelines, is a determinate of successful lipid-lowering management. These authors similarly found less than optimal achievement of target therapeutic outcomes as a result of poor compliance to LLM.

The overall rate of patient compliance with the *American National Cholesterol Education Program* (NCEP) secondary prevention guidelines was found to have been 31% (Maviglia, Telch, Fiskio & Bates, 2001). This meant that 69% of the study group were either non-compliant or had not been commenced on lipid-lowering medications as a secondary prevention measure under the national guidelines.

Documented evidence abounds demonstrating that the percentage of survivors with a diagnosis of CHD far exceeds the numbers who die from CHD. Furthermore, there is also convincing evidence from a variety of clinical trials that supports a reduction in morbidity and mortality rates in people

diagnosed with CHD, by the adoption of risk-reducing-behaviour modification in association with the use of pharmacological management therapies. Pharmacological management therapy includes LLM (NHFA, 2007). Further, Wang et al. (2001) as previously discussed, made several observations in relation to LLM non-compliance. Of the 427 (7.7%) of participants who were prescribed LLM, they recorded 63.7% of that population with a greater than 80% compliance rate; women were more likely to comply and a lower socio-economic status was not related to non-compliance in their cohort.

A secondary analysis designed to examine the relationships between compliance with LLM and several domains of psychological and cognitive functioning was carried out by Stilley, Sereika, Muldoon, Ryan and Dunbar-Jacob (2004). At baseline in the initial study, participants completed personality, neuropsychological, anxiety and depression measures. These measures were repeated at four-weekly intervals for a period of 24 weeks, and medication compliance was tracked by using electronic-cap monitors. This study involved 158 adults with dislipidemia, and, although the study period of 24 weeks was relatively short, Stilley et al. (2004) demonstrated a statistically significant relationship between depression and non-compliance specifically to LLM. Moreover, Kaplan, Bhalodkar, Brown, White and Brown (2004) found that socio-cultural factors of non-compliance with LLM, such as being single and having children, being depressed, and not having health insurance, contributed to lower compliance levels.

In an attempt to measure the extent of cardiovascular morbidity associated with compliance/non-compliance to statin therapy, a retrospective study of 1,221 patients aged 30-70 years, over almost a seven year period, was conducted by Blackburn et al. (2005) Each patient received a new prescription for an LLM within one year of their first cardiovascular event. The primary end point included MI, unstable angina, PTCA, CABG and death. However, Blackburn et al. (2005) found patients in the compliant group were half as likely to experience a subsequent MI as the patients in the non-compliant group, and concluded that their analysis suggested a significant reduction in the incidence of myocardial infarction would be achieved by adherence to statin therapy. Therefore those patients in the non-compliant group clearly demonstrate that “Drugs don’t work in patients who don’t take them” (Koop, n.d.).

There are some people who are intentional non-compliers. According to Barber et al. (2004) and Sawyer and Fardy (2003), they comprise a relatively small collection of people who reject their diagnosis, treatment, or both, or simply cannot be troubled to take their medications. Patients who fall into this group, according to the researchers, require specific and intense intervention in an effort to initiate appropriate change behaviour. Intentional non-compliance may be linked to the

fact that many of the risk factors associated with CHD, such as hypercholesterolemia, hypertension and even diabetes, are asymptomatic. In an elective investigation for CHD, patients angiographically diagnosed with CAD, according to Jacobson (2004), may be unconvinced of the necessity to commit to lipid-lowering therapy and long-term lifestyle changes. Alternatively, if patients commence lipid-lowering therapy only to have a subsequent cardiac event, such as a MI, they are less likely to be convinced of the efficacy of their medications (Jacobsen, 2004).

Advances in interventional technology have contributed to patients' perceptions of CHD as a chronic illness requiring life-long compliance to medications and risk-factor management. PTCA has been undertaken since 1997. By 1980, this procedure had found its way to Australia (Banta, 2004) and, today, globally, PTCA, plus or minus coronary artery stenting, is the most common intervention for patients with established CHD globally. Because patients undergoing this procedure are in hospital for less than 24 hours and are discharged with only a small puncture wound in their groin, the concept of having a chronic disease can be a challenging one for this population. Of note, Campbell and Torrance (2004) found that 43% of participants in their study believed that their CHD was cured. Therefore, the impact of CHD as a chronic disease, which subsequently requires life-time management, may be more significant for patients who are going home from hospital with a median sternotomy and wounds from vascular-graft harvesting of the legs, arms or both.

Summary

Chapter 1 demonstrated that CHD is a major chronic disease affecting many millions of people worldwide. In chapter 2 the literature was reviewed with specific reference to LLM as a preventative treatment to reduce the incidence of further coronary events following diagnosis of CHD.

Initially, the evidence base for LLM was presented. Landmark clinical trials over the last fifteen years, which investigated outcomes associated with LLM therapy, were reviewed. The overwhelming evidence from these trials supports the use of LLM as a 'gold standard' treatment for CHD. Current national and international guidelines reflect this.

From the perspective of healthcare providers, several areas were explored. The evidence in this area suggests that there may be a failure on the part of healthcare professionals to: initiate, monitor and titrate LLM; measure compliance; and intervention outcomes. This is despite the known risks of mortality and morbidity associated with poor/non-compliance with LLM. This, in turn, leads to

increased rates of hospital readmission for medical assessment and management, with an associated increased risk of new or repeat revascularisation procedures.

Medication compliance of drugs used to treat chronic disease, in general, was reviewed. The findings from the literature indicate that compliance rates are poor. There is some general information and evidence pertaining to poor medication compliance and there were no studies that directly investigated patients' reasoning and behaviour in relation to pharmacological medication compliance.

The review of available literature has failed to find any substantial information relating to patient perceptions of the impact of not taking LLM. However, with respect to LLM, there is no research evidence available to determine, from a patient perspective, what factors improved compliance behaviour or which factors affect non-compliance in taking LLM.

Because there was no obvious evidence of patients actively participating in research into discontinuation of pharmacological therapy generally, and LLM specifically, it is of concern that the rationale, which has been previously applied to theorising as to why patients cease medications, may be primarily assumptive on the part of researchers. Yacopetti (1999) assessed the validity and effectiveness of health promotion strategies devised for consumers of healthcare. He highlighted and summarised several areas for future study by healthcare professionals that embraced both patients and their healthcare team. He identified the need to explore what patients actually want in a health care setting, and what they feel would enhance their treatment participation. To date there has been no research that has explored consumers' expectations of health care in the context of LLM, and it is not known how long patients continue to take their LLM or the reasons they discontinue.

The literature reviewed in chapter 2 has not revealed any studies that have investigated the reasons why people stop taking their LLM. Therefore, the purpose of the study was to measure patients' compliance with LLM and to analyse their reasons for discontinuing the treatment. This study is significant as its aim was to reveal factors that contribute to noncompliance in order to positively impact on mortality rates associated with CHD.

CHAPTER 2

METHODOLOGY

INTRODUCTION

One of the aims of research in nursing is to develop theory intended for practice. Theory, when supported by research, provides the foundation for evidence-based nursing (EBN) or evidence-based practice (EBP) (Schneider, Elliott, LoBiondo-Wood & Haber, 2003). However, if there is little or no formal evidence available, it is difficult to determine best practice.

The literature review presented in chapter 2 has highlighted that there is a dearth of evidence available about LLM compliance, whereas reports in the literature about medication compliance in other chronic disease groups demonstrate that compliance is generally poor. The evidence base for the efficacy of LLM is very strong; mostly level 1evidence. As a consequence, national and international guidelines mandate their commencement for all inpatients diagnosed with CHD prior to hospital separation.

Research significance

The broad literature, if applied to LLM, would suggest that compliance is poor. However, there are no recent studies in this area, and it is not known from the patient's perspective why they cease to take their medications. If the reasons for non-compliance are known, nursing strategies could be developed aimed at improving compliance outcomes. This, in turn, would contribute to improved long-term secondary prevention outcomes for patients with CHD.

Research setting

This study was undertaken in one of Queensland's largest private hospitals, which offered a number of benefits. The hospital is a tertiary referral facility that is located in the capital city and provides a comprehensive range of investigative and interventional cardiac services for the population of Queensland and parts of northern New South Wales. With over 430 beds, the hospital provides a comprehensive range of clinical services across 35 areas of specialty, with over 900 accredited referring specialists. Importantly, the institution in question has tertiary level medical and surgical services within the specialty of cardiovascular disease diagnosis and management. These facilities are supported by a state of the art intensive care unit, cardiac catheter theatres, 24-hour emergency centre, radiology [magnetic resonance imaging (MRI),

computerised tomography (CT), positron emission tomography (PET) scanning and nuclear medicine], and pathology and pharmacy services.

The all inclusive cardiovascular care program includes two dedicated cardiac surgery suites, a dedicated eight-bed, cardiothoracic, post-operative intensive care unit, a twelve-bed dedicated coronary care unit, and a vascular centre, all supported by a comprehensive, multidisciplinary in-patient and out-patient cardiac rehabilitation program.

Because of the patient referral volume, visiting cardiologists that are accredited to practice in the hospital perform hundreds of investigative coronary angiography procedures annually. In fact, a minimum of 100 coronary angiography procedures annually per practitioner is required for hospital accreditation purposes. A significant percentage of patients who undergo coronary angiography investigation are diagnosed as having CHD. When CHD is identified in patients, they are advised by their cardiologist to consider one or more treatment options that include medical management, percutaneous interventions or open heart surgery. Therefore, the volume of potential research participants was advantageous to the present study.

Approximately 500 open heart surgeries are performed annually at the hospital, with the major caseload falling into the coronary artery bypass graft (CABG) category. Three cardiac catheter laboratories undertake thousands of procedures each year, with the biggest group being diagnostic coronary angiography. Pre- and post-procedure education sessions are provided daily for patients and their families covering a wide range of management issues. These include, but are not limited to, nutrition, risk factor management, care following open heart surgery or PCI as well as exercise.

Because the researcher is a full-time employee of this hospital, potential participants were readily accessible on an almost daily basis, as were their medical records, which included admission diagnosis, investigations, interventions and discharge medications. Pre-admission lists, cardiac catheter laboratory and open heart surgical lists were also available, allowing pre-planning for potential recruitment and/or follow-up on un-planned, weekend or after-hours admissions.

AIMS AND OBJECTIVES

The aims and objectives for this research study were developed from the following research question: What is the level of compliance of CHD patients with LLM and why do they cease taking them?

Aims

- Primary aim: to measure patients' compliance with LLM.
- Secondary aim: to analyse the reasons given for cessation by participants who discontinued LLM.

Objectives

The objectives of this research study were to:

- recruit a representative sample of the population of interest,
- follow-up this cohort for one year, on a monthly basis,
- establish the cohort's level of compliance with LLM,
- determine, from the patient's perspective, the factors that impact on decision making in regard to complying with LLM, and
- provide an opportunity for individual participants to respond in a manner that would aid the researcher to identify, interpret and report on what behaviours, beliefs and decision-making processes were related to, or responsible for, an individual continuing or discontinuing their LLM.

If discontinuation of LLM was established, the focus areas for research would concentrate on five key aspects:

- the rationale for cessation of LLM;
- knowledge and understanding of the link between the disease process, management of CHD, and LLM;
- alternative treatment options;
- information/education sources and knowledge gaps; and
- social support.

RESEARCH DESIGN

Philosophical assumptions

In order to determine the most suitable research approach it was first necessary to examine the relevant philosophical and methodological foundations of the research process with regard to the research question.

Ontology relates to how people understand the nature of reality; epistemology refers to a theory of knowledge and is about seeking knowledge, and it embraces enquiry into the relationship between the researcher and what/who is/are being researched, supplying the focus for a study; methodology, on the other hand, is the process of research by which knowledge is obtained, and provides the design for carrying out a study (Schneider et al., 2003; Polit & Beck, 2006; McIntyre, 2006). Ontology and epistemology are significant, in that they illustrate how research begins by outlining theoretical suppositions that are taken as given by the researcher, and methodology demonstrates how to generate new knowledge in a manner that is consistent with epistemology and ontology (McIntyre). Furthermore, methodology seeks the best means of identifying, gathering and interpreting the information collected; observation, measurement and interpretation depend on the understanding of the ontological and epistemological nature of the work at hand (McIntyre). In nursing research, ideas flow from ontology to epistemology, and then on to methodology, with an anticipated outcome of providing specific theories (Ruddock, as cited in McIntyre, 2006).

The integration and systematisation of research findings is achieved using a framework based on the characteristics or principles and assumptions of science. This is the prelude to the identification of a meaningful pattern or theory that is regarded as tentative and not necessarily the ultimate truth. Thus, this is the primary goal of science. Theory may be subject to revision or modification as and when new evidence is found. Positivist-rooted science systematises the knowledge-generation process objectively with the help of quantification, which is essential to enhance precision in the description of parameters and the discernment of the relationship among them. For the purpose of this research, in which the intention was to objectively measure a phenomenon (LLM cessation) a positivist-rooted methodology was deemed appropriate.

Positivist researchers use a line of inquiry that is independent of the phenomena being investigated. Johnson and Onwuegbuzie (2004) made the observation that purists of quantitative methodology communicate a positivist philosophy. That is, the belief that knowledge can only be acquired through direct observation and experimentation. Purists believe that, because the researcher

remains detached from the subject or object of the research, then this very separateness provides an environment for relatively independent results.

For the purpose of this study, it was clear that the positivist-based paradigm, which aligns most closely with quantitative research, was the most appropriate basis for this research. The intention of this research study was to objectively measure a specific outcome (LLM compliance) and to identify and quantify the reasons for ceasing LLM. Thus a quantitative design was required.

The next step in the research design process was to determine the most appropriate methodological approach.

Methodological approach

Quantitative research methodologies apply a systematic approach to inquiry; they strive for objectivity and generalisation. Conventionally, quantitative questions and methods investigate fixed or closed questions, which have been developed from theory, are directional, and describe relationships between variables.

For the purpose of this research, the theoretical supposition, based on the evidence in the literature, was that LLM compliance would be around 50% one year following hospital discharge of CHD patients. The primary aim of this research was to objectively measure LLM compliance. However, the factors that cause patients to cease LLM have not been reported in the literature. Thus, the secondary aim of this research was to describe the relationships between patients' reasons and their cessation of LLM.

Quantitative research is described as deductive. It can be used to measure and look for differences and to test theory. The major types of quantitative research are descriptive, quasi-experimental and experimental. Briefly, experimental and quasi-experimental studies are designed to examine cause and effect. An example of an experimental study is a randomised controlled trial (RCT), such as a drug trial. The three essential elements of experimental studies are manipulation, control and randomisation. Manipulation refers to the researcher doing something to at least some of the participants in the research, usually to the experimental group and not the control group. Control is applied to increase the probability of the findings being accurate by ensuring that the impact of extraneous variables (something unrelated or unconnected to the study, but capable of changing or varying the results) is reduced. Randomisation is a method of assigning participants randomly to

different groups in a way that applies equal probability of group allocation and reduces the risk of extraneous variables. Descriptive studies, on the other hand, examine variables in their natural setting without researcher intervention and do not test theory (Schneider et al., 2003).

Experimental designs are often referred to as being the most rigorous of all research designs, or to as being the 'gold standard' against which all other research designs are judged. However, for the purpose of this research, there was no intention to manipulate subjects, nor was there an intent to control extraneous variables. Thus an experimental design was inappropriate.

According to Schneider et al. (2003), quantitative research approaches have three main strengths. These strengths derive from the objectivity of the research design, the variety of sampling strategies available to the researcher, and the accessibility of data analysis systems. Quantitative methods use a problem statement as a means of identifying the population or sample group of interest. Data in a quantitative study are often based on random sampling methods. The manner of data collection in quantitative research should be both systematic and objective, meaning that all of the information is collected using the same tool with each participant in the study. An advantage of data collection using quantitative methods is that this process is often reasonably fast. The use of computer software for analysis reduces the time taken to determine outcomes. Statistical analysis can be undertaken using statistical software packages. The opportunity to provide study outcomes, in precise numerical values, means that the results are seen as having a number of positives.

Attributes of quantitative research findings are twofold: causality and generalisability (Knapp, 1998; Schneider et al., 2003). Causality is the principle that everything that happens must have a cause, and generalisability is the extent to which a study's findings are relevant to the broader population. If hypotheses are being tested, then statements relating to causality (cause and effect) can be made by the researcher. By using inferential statistical analyses, the researcher can then extrapolate results from the study sample to the general population. For the purpose of this research the intent was to establish the reasons (causality) why patients ceased taking LLM. Thus, a quantitative observational design was required. Further, the potential to generalise the findings to the population at large required a sufficiently large random sample.

Research design

Research design refers to the conceptual framework within which research is conducted. According to Shields and Tajalli (2006), conceptual frameworks can be described as an intermediate theory or a link, map or plan that enables all aspects of research to be connected.

When the research problem and purpose are linked to a framework, such as choice of methodology, whether to conduct surveys and interviews, analyse existing data, undertake direct observation, or conduct focus groups etc., the appropriate statistical analysis that needs to be applied then becomes obvious.

The primary aim of this study, to investigate compliance to pharmacological LLM, did not require experimentation in the form of providing an intervention to one group of participants and usual care to another group, the control group. Neither was there a condition requiring testing. Therefore, an experimental design was rejected because there was no condition to be tested and no variables to be manipulated. Further, the secondary aim of this study, to identify the LLM taking habits, or patterns of continuation or discontinuation, embraced the identification and exploration of the influences on compliance, from an individual perspective. Thus, a descriptive, observational design was selected in order to monitor LLM compliance. After thorough consideration of the potential research designs it was decided that a prospective cohort study was the most appropriate design because it would enable tracking of the study sample over a prolonged period.

Generally, a non-experimental (observational) prospective research design starts with a researcher's hypothesis (premise, supposition or assumption) of the presumed cause of a particular event, and then follows each participant over time to the presumed outcome (King, 2001). In the case of this research study, the group of people was defined as those patients who were angiographically diagnosed with CHD and discharged from hospital on pharmacological LLM. The hypothesis or presumed cause and presumed effect over time are followed in a non-lineal path. For the purposes of this study, if participants ceased LLM, "cause" would equate to the reasons or rationale they attributed to ceasing their therapy, and "effect" to the fact that they became non-compliant. Based on previous research with chronic disease samples, it was expected that approximately 50% of the sample would become non-compliant. This 'self-selecting' process would then enable comparison of difference between compliant and non-compliant participants.

Prospective cohort study

Prospective cohort studies have been instrumental in determining therapeutic guidelines. For example, in the course of undertaking a review of risk factor assessment and treatment guidelines for CHD, the prospective cohort studies of Hemingway and Marmot (1999), along with those of Kuper, Marmot and Hemingway (2005), were cited in Bunker et al. (2003). Data from these

prospective studies contributed significantly to the revision of target treatment guidelines for CHD in Australia (NHFA & CSANZ, 2007).

A cohort can be defined as a group of people who share a common attribute (Brockopp & Hastings-Tolma, 2003). (In this case, LLM prescription following diagnosis of CHD.) It is an epidemiological approach that explores from exposure to outcome; commonly a particular health outcome or disease state (Elliott & Thompson, 2008). In this case, the outcome under investigation was LLM cessation. Cohort studies are the best way to study incidence of an outcome such as attrition rates (Panacek, 2000). Prospective (longitudinal) design refers to the study group being observed over a period of time, with data collection at pre-determined intervals. One advantage of prospective cohort studies is that longitudinal observation of the individual through time and the collection of data at regular intervals both reduce participant recall error (King, 2001). Among the disadvantages of using a prospective cohort-study design is the time commitment required from both researcher and participant over the follow-up, data-collection period and the length of time that it can take to generate useful data. However, prospective cohort studies can also be expensive to conduct (King, 2001), and are sensitive to attrition.

SAMPLE

For the purpose of this study, a randomised sample of patients with CHD diagnosed by coronary angiogram was accessed. Participants meeting this criterion were deemed to be the most appropriate source of information because they were discharged from hospital having been continued on or commenced in hospital on pharmacological prescription of LLM.

Inclusion and exclusion criteria

The inclusion and exclusion criteria are described in Table 4, below.

Table 4. Inclusion and exclusion criteria.

Inclusion criteria	CHD confirmed on inpatient angiography; Commenced or continued on pharmacological lipid lowering therapy in hospital; >18 years of age; English speaking.
Intervention	PTCA/stent; CABG; CABG/valve;

	Medical management.
Exclusion criteria	Any form of dementia or pre-hospital separation, death, CVA, or other limiting mental or physical incapacity occurring before recruitment.
Discontinuation criteria	Death, CVA or any other limiting mental or physical incapacity occurring after recruitment.

Rationale for sample selection

Patients can be commenced on a treatment regimen for CHD in the absence of a coronary angiography confirmation of diagnosis. Their presenting risk factors, including hypertension, hypercholesterolemia and a strong family history in the absence of acute symptoms, may influence a medical decision to initiate pharmacotherapy. Therefore, the decision to include only participants who had been angiographically diagnosed with CHD was made for a number of reasons. The admission or provisional diagnosis assigned to patients can often differ markedly from their discharge diagnosis and/or intervention. The definitive diagnosis of CHD, in current practice, is obtained from coronary angiography. This investigation is always performed prior to percutaneous or surgical intervention, in order to determine the extent and location of the atherosclerotic disease and the most appropriate treatment option. The three most common and widely recognised treatment options for CHD are medical management (only), percutaneous intervention i.e. PTCA with or without stent insertion (with medical management), and surgical intervention i.e. CABG (with medical management).

Medical management of CHD involves lifestyle or behavioural modification and management combined with a medication regime. Lifestyle modification is aimed at reducing the risk of further events by understanding and making appropriate changes to any lifestyle issues that have contributed to the CHD. The most recent NHFA (2007) recommendation for lifestyle changes include smoking cessation, adoption of healthy eating patterns, reduction in alcohol consumption, exercise activity of at least 150 minutes per week, and maintaining a healthy weight range. Biomedical risk factors and medical-management recommendations include platelet-aggregation inhibition, beta blockade and ACE inhibitor therapy, in association with LLM.

According to the guidelines recommended by the NHFA (2007) and a number of international agencies and organisations, LLM should be part of the gold standard for treatment of CHD. Gold standard treatment guidelines for CHD are that LLM, ACE inhibitors, beta blockers and blood thinners (e.g., aspirin, plavix) should be prescribed. The guidelines recommend that these medications, including the LLM, should be commenced in hospital following a diagnosis of CHD.

Using these LLM guidelines as one of the elements in the inclusion criteria for this study facilitated identification of individuals of the population of interest.

Methods of sample selection

Random or probability sampling and convenience or non-probability sampling are the two most common sampling techniques used by researchers to conduct quantitative studies. Sample bias and generalisability of results are contentious outcomes of convenience or non-probability sampling. Yoon and Horne (2004) commented on sampling methods generally and survey research sampling in particular, drawing attention to the fact that research undertaken by survey is quite susceptible to sample bias. The ABS (2004) also supports the view that non-probability or convenience sampling almost certainly introduces bias, simply because it is non-random.

Randomisation

Employing the rationale attributed to quantitative design strengths to investigate participant compliance to lipid lowering therapy, and applying quantitative sampling methods to the cohort or representative group of the population of interest should ensure that the data obtained can be analysed in a manner that establishes generalisability of the findings to the population at large. For this study, generalisability of the findings from the sample population to the wider community was an intended outcome. Polit and Beck (2006) defined random sampling as a selection process in which each element in the population has an equal, independent chance of being selected. Indeed, Yoon and Horne (2004) encouraged researchers undertaking non-experimental research, such as a telephone survey, to use random sampling methods whenever they can, for these same reasons. Therefore, random sampling, which would enable generalisation, thus increasing credibility in the outcomes, was felt to be the best method for this study in order to achieve a representative sample of the population of interest.

Power analysis

Power analysis is a procedure used to delimit the sample size required in the study population, as well as to determine the power of a statistical test (Polit, Beck & Hungler, 2005).

The purpose of undertaking power analysis for this research study was to determine the number of participants that would be needed to achieve the stated objective, which was the comparison of

differences between compliance and non-compliance with LLM in the cohort. Power analysis can be conducted before, during or after the research has commenced. Here, power analysis was conducted beforehand.

For the purpose of this research study, based on previous research evidence from chronic disease groups, it was expected that approximately 50% of the cohort would become LLM non-compliant by the end of the twelve-month follow-up period. Rather than pre-selecting two groups (e.g. smokers and non smokers, or males and females) at the outset, these groups would be self-selecting during the follow-up period. Thus, at the end of twelve months, it was expected that there would be two similarly sized groups: those compliant with LLM, and those who were non-compliant.

Because there were no relevant data available, it was necessary to estimate a sample size based on whether the expected effect would be small, medium or large. This was achieved by applying a convention developed by Cohen (1987), embracing alpha (α) values that relate to the significance levels or the acknowledged and accepted error rate of the statistical analysis. Levels for α are usually set at 0.05 or 0.01. The α level is the probability of a type I error, which is the rejection of a correct null hypothesis occurring. For example, an α level of 0.05 indicates there is a 5% chance a true null hypothesis would be incorrectly rejected (Polit et al., 2005).

Three factors, α, sample size (η), and effect or gamma (γ) size, enable a fourth variable known as beta (*1* - β) or power, to be calculated. Beta (*1* - β) is the probability of a type II error occurring, which is the acceptance of a false null hypothesis. After considering the probability of type I and type II errors, a power level of 0.80 was selected for this study, as it was deemed to be preferable, with a 20% risk of committing a type II error. The decision to accept the probability of committing a type II error was made, despite the risk of a type II error being high, because the alternative would have required a much larger sample size, beyond the scope of this study.

Subsequently, an α value of 0.05, with a medium estimated effect size of 0.50 (because it was anticipated there would be two groups with approximately 50% of participants in each group), determined a sample size estimate of η = 63 x 2 (126). Thus, the aim of this research study was to recruit a cohort of 126 participants.

Other factors that impacted on sample size were the volume and manageability of data collection, the time requirement for telephone follow-up on a monthly basis, the university's requirements for a Masters of Nursing Research degree, and the fact that the student researcher was employed full-time in a senior nurse manager position. Thus, recruitment of the sample was necessarily limited to a three-month period.

Random sampling process

Participants were randomly selected by their Medical Record Number (MRN) and criteria set down by the National Health and Medical Research Institute Committee (NHMRC). Randomisation was achieved by using the last digit of each participant's MRN utilising a random numbers table. Patients who met the inclusion criteria were then selected to participate in the study. Once identified as individuals representative of the study population of interest, they were directly approached by the researcher and offered the opportunity to read and discuss detailed information related to the study, in order that they may consider being participants.

DATA COLLECTION

Data collection period

The literature review (chapter 2) revealed that a period of twelve months' follow-up of each participant would be required in order to capture the greatest percentage of non-compliant subjects. The evidence was very strong, indicating that within one year, between 50% and 80% of patients would no longer be compliant with their medication. In light of this, twelve months was the time frame chosen to undertake follow-up on the study cohort. The potential outcome of this study, as suggested in the literature review, would embrace high levels of non-compliance.

Data collection method

One component of the gold standard treatment for CHD is the initiation of, and long-term compliance to, LLM. In addition to anecdotal and observational information acknowledged by the present researcher, there is an abundance of literature relating to poor, long-term LLM compliance and the associated morbidity, mortality and economic costs of CHD, both nationally and internationally. Literature in general, relating to comprehension of this phenomenon, and outlined previously, has been process focused rather than patient focused. Gaining an understanding, from a patient perspective, of why people diagnosed with CHD cease taking their LLM had the potential to be fundamental in developing compliance directed patient education information. This may help to reduce the rate of non-compliance and hospital readmission, thereby reducing morbidity, mortality and the financial burden of CHD. This was a fundamental consideration when determining the approach to data collection.

This section describes the data collection approach used for this research. Two data collection methods were considered and examined as being potentially suitable avenues of inquiry: questionnaires and interviews, using either open or closed questions or a mixture of both. The interviews could be individual face-to-face, using open or closed questions or both. Alternatively, the same structure of open or closed ended questions, or a combination of both, could be administered as a telephone interview. In either case, data collection is dependent on the reliability of participants' self-reports. Direct questioning of an individual in relation to their experiences, perceptions, beliefs or thoughts is an approach that can elicit a large amount of information about a topic of interest (Polit, Beck & Hungler, 2005). Known as a self-report approach, researchers can apply a number of techniques that vary in structure in order to collect information.

The reasons for choosing a self-report data collection method were that:

- in the literature reviewed, the rationale for LLM cessation resulted from various researchers' assumptions and conclusions and was not drawn from a patient perspective; and
- the need to identify, report and interpret the behaviours, beliefs and observations of a specific group (Boynton and Greenhalgh, 2004).

Self-report

Although acknowledging that therapy non-compliance is multi-factorial, Yacopetti (1999) noted that, in all of the studies he reviewed, none had asked a patient what they felt enhanced their medication or treatment compliance. He strongly recommended that further research into compliance with treatment regimes should focus on patients' decision-making processes and the reasons underlying their decisions. The extensive literature review undertaken in this study demonstrated that, even after 1999, there continued to be a lack of information gathering from a patient perspective and there was no instrument in place designed to capture the requisite information. Thus, a more in-depth investigation tool needed to be developed by the researcher in the present study in order to assess the rationale behind LLM compliance from a patient perspective.

From a marketing perspective, populations, in general, are often asked to self-report on things such as accommodation standards, food preferences, and television-viewing habits the concept is not unfamiliar. Demonstrated strengths of self-reporting include the ability to produce precise

numerical estimates of participant responses when using a structured tool, which, in turn, enhances rigour and depth of knowledge about the subject of inquiry (McQuarrie, 2005).

Similarly, in the healthcare industry self-reporting methods are also employed. In a bid to examine the sensitivity of observational and self-reporting methods used in the assessment of disability and mobility of patients with osteoarthritis in either hip or knee, a group of researchers recruited 186 participants (Steultjens, Roorda, Dekker & Bijlsma, 2001). The researchers used one observational method and four self-reporting methods (four subscales of three questionnaires) for assessment, and the data were collected at recruitment and again twelve weeks later. The expected outcome was that the self-reporting outcomes would be mutually correlated, and that changes using the observational method would demonstrate no relationship to the self-reporting method. Ultimately, data analysis from this study was reported as finding no evidence for the differential responsiveness of the questionnaires and the observational method. In fact, unexpectedly, Steultjens et al. found the two methods were directly comparable. Further, they contended that the evidence of systematic convergence they demonstrated, highlighted the cost, convenience and accuracy of a self-reporting method.

An epidemiological study undertaken at the Johns Hopkins Bloomberg School of Public Health tested the validity of a self-reporting questionnaire by urine and blood analysis of participants taken at face-to-face interview (Satia-Abouta et al., 2003). The research aim was to collect accurate information on vitamin and mineral dietary supplementation. The study randomly recruited 220 people and a self-report was administered at baseline and again approximately three months later. This study found the questionnaire, when compared to urine and blood analysis results, was highly reproducible and valid for collecting information on supplemental usage in this group.

Interviews

For research purposes, individual face-to-face interviewing with open-ended questions, and unstructured or loosely structured interviews allows for rich amounts of data to be collected in relation to the interviewee and the focus of the research question. This method has high response rates and questions are less likely to be misconstrued, as the researcher can ascertain the level of understanding on the part of the participant. Unstructured, individual, face-to-face interviews are generally lengthy, time consuming and generate a vast amount of data, because the interviewer has an obligation to record everything that is said during the interview (Schneider et al., 2003).

However, a major challenge for interviewers, in an unstructured fact to face situation, is their inability to determine what is important, and to assess relevant versus irrelevant information, in relation to answering the research question, until such times as their findings can be evaluated.

As already indicated, the intent of this study was to follow each participant for a twelve-month period from the date of recruitment. Similarly, the one-year timeframe was chosen in response to the volume of evidence reviewed in the literature that stated that, within one year, between 50% and 80% of patients would be no longer compliant with their lipid-lowering medications. In addition, study participants, who were randomly allocated during their inpatient hospitalisation in a large tertiary hospital in Queensland, had the potential to be residing anywhere in this state or northern New South Wales. Practically, this made individual face-to-face interviews very difficult. When geographical location was taken into account in conjunction with data volume and problems with evaluation over a year-long-study period, individual face-to-face interviewing was discounted.

Questionnaire

A questionnaire, administered by telephone, was the selected data collection method for this research. Because collection of evidence from the patients' perspective was one of the objectives of this research, having rejected interviews, the use of a questionnaire was the most appropriate instrument of choice for data collection.

An enormous amount of research has been developed over 50 years or more directed to developing tools for analysing the type of data that self-reporting questionnaires produce. McQuarrie (2005) warned, however, that there are limitations to bear in mind when considering self-reporting as a data collection method. Structured questionnaires can tell you what has happened, but not why something happened. Neither can a questionnaire reveal what a researcher did not know he or she did not know. If researchers or designers of questionnaires are cognisant of what they do not know, then survey questions and answers will resolve that uncertainty. Indeed, a questionnaire is a precision tool, exact and accurate, and not a tool to be used for discovery, which is the process of finding out about something for the first time (McQuarrie, 2005). For this research, a questionnaire was appropriate because what was not known (LLM compliance and reasons for cessation) was known. The advantages of using a questionnaire are that specific questions are applied (which result in objective and quantifiable responses) and they usually are not time-consuming to administer.

Validity and reliability in questionnaire design

Validity in research terms means measuring what is needed to be measured. There are different types of validity (content, construct, criterion and face validity), and the type most appropriate for a researcher to use will be influenced by the objectives of the study at hand. Face and content validity are appropriate for consideration here. Face validity relates to the ability of a question to accurately measure the construct or concept of interest. Content validity assesses whether all the significant aspects of the construct are covered. The validity of questionnaire design and content can be established by using a panel of experts to review and advise on questionnaire design and content, as well as by undertaking a pilot study with a sample group of participants who would not be included in the final study population.

Further, assessing reading comprehension of the questionnaire and addressing the following questions enhances validity: does the questionnaire measure what it was intended to measure; is it representative of the content; is it appropriate for the population of interest; will it collect all the information required to answer the aims and objectives of this study; and finally does the tool actually look like a questionnaire?

Reliability in questionnaire design relates to the consistency and dependability or repeatability of the assessment tool. This is important when the assessment tool is designed to be reused over a period of time to measure change. Further, reliability can be defined as being internal or external. Internal reliability is a measure of consistency in data-collection methods, while external reliability relates to the accuracy of the measuring instrument to produce consistency in the results when they collected during different periods in time (Data Analysis Australia, 2007).

Reliability testing includes the test-retest method, which seeks to ascertain whether readministering the questionnaire under the same conditions would produce the same results. Reliability, also, can be established by pilot testing the questionnaire with a number of subjects who would not be included in the study sample (Radhakrishna, 2007).

Anderson, Bell, Adamson and Moynihan (2001) undertook a study involving eleven year old school children residing in an area with a high level of socio-economic disadvantage, with the aim of assessing their nutritional understanding before and after an intervention. These authors described their evaluation of the validity and reliability measures that they developed in the questionnaire and used in their knowledge assessment. Content validity of the questionnaire was assessed by an independent panel of health professional academics with nutritional qualifications.

Individual discussion with a convenience sample of eight to fourteen year old school children was undertaken to assess face validity. Reliability testing, as in the test-retest model, in association with pilot studies for reliability and validity testing of the draft questionnaire, were also undertaken. Anderson et al., despite reservations about the data accuracy or re-administration of their questionnaire to the same cohort, concluded that the questionnaire was a reliable instrument for measuring baseline and post-interventional, dietary knowledge from this group of school children.

Gulliford, Mahabir and Rocke (2004) evaluated the reliability and validity of the short-form, household food security scale in a different setting from the one in which it was originally developed. Food insecurity relates to the availability of nutritionally sound food groups, as well as the ability of an individual or family group to purchase nutritionally sound food groups (Gulliford et al., 2004). Food insecurity has the potential to affect not only what people eat, but also the health outcomes associated with nutritionally sound dietary habits when assessed as poor, average or satisfactory. Measuring food insecurity in epidemiological studies is attracting growing interest. In 1995 in the USA, following ten years of development, an eighteen-item, food-security questionnaire, including items applicable to adult and adult-children households was developed. Gulliford et al. (2004) decided to apply this USA-developed, food insecurity scale on a population in Trinidad and Tobago in the West Indies. Their study enrolled 631 eligible adults. Subsequently, food security data were obtained for 531 (84%) subjects from 286 households. The results generally supported the reliability and validity of the previously developed food-security scale when applied to this population. These results also supported, with the caution commonly associated with questionnaires, the use of this measure in future epidemiological studies to evaluate the distribution, determinants and associations of food insecurity in this and other populations (Gulliford et al., 2004).

In an attempt to elicit the information requirements of cancer patients undergoing radiation therapy in Western Australia, Halkett and Kristjanson (2007) designed a study that would test two new data collection tools for reliability and validity. One questionnaire was related to patients' radiation therapy concerns, with a second questionnaire developed to understand the information needs required during the patient's period of radiation therapy. Initially, 31 past breast-cancer patients completed and commented on the questionnaires, and, on a second occasion, 30 patients were employed to establish test-retest reliability. Responses to four questions from a six-member panel was undertaken to assess content validity of the items in each tool. The questions asked related to clarity of the questionnaire, the specificity of the questions to the topic of inquiry, and

repetitiveness or redundancy of questions asked. This study tested two new assessment tools for content validity, internal consistency and test-retest reliability. The results demonstrated that, although the small pilot study and the study population size had to be considered, overall, the scales performed well in all areas of criteria assessment (Halkett & Kristjanson, 2007).

Questionnaire administration

For the purpose of this research study it was important to select the most appropriate method of administering the questionnaire. Two methods were considered: postal questionnaire and telephone questionnaire.

Postal questionnaires

For this study, questions produced in written format had the potential to be administered as a questionnaire, posted to a participant for completion, and then returned to the researcher. There are advantages to using a structured self-reporting method such as this. Postal questionnaires are less expensive and less time consuming to administer, participants are able to maintain a degree of anonymity, and their opinions are not affected by researcher bias, as could happen during a telephone interview (Polit et al., 2005). These observations were a major consideration in this research study, because, as indicated, the participants were widely distributed geographically. However, there are a number of disadvantages to be considered for the researcher and the participant with using postal questionnaires (Schneider et al., 2003). Such questionnaires make it more difficult to control for variables, and literacy levels can impact on a participant's ability to read, comprehend and respond. Further, the researcher does not know if the questionnaire has actually been completed by the person recruited or somebody else, and the response rate to postal questionnaires is often poor. Low response rates can threaten the validity of studies by reducing the effective sample size and introducing bias.

In the DAMASK trial of Brealey, et al. (2007), the researchers needed to improve response rates from participants. This trial was multi-centred, pragmatic, and randomised to evaluate whether patients presenting to GPs with continuing knee problems should be referred for early access to magnetic resonance imaging or directly to an orthopaedic specialist. This group of researchers conducted an observational study in their primary care setting. Participants in the trial were required to complete a lengthy questionnaire several times after randomisation. When it became apparent at twelve months that their target number of responses was not going to be achieved,

thereby threatening the validity of the data being collected, the researchers decided to enhance their evidence-based strategy by initiating a financial incentive of £5.00 per person per questionnaire returned. The control group returned a response of 78.1% (82 of 105), compared with 88.0% (389 of 442) for the payment group. The researchers concluded that a direct payment of £5.00 significantly increased the completion of postal questionnaires for a negligible increase in cost.

In this research project, insufficient postal returns of questionnaires would have impacted on the validity of the data collection, so the above-cited approach was rejected, as funding for a participant payment was not an option for this student research project. Using a less expensive and time-consuming postal process could have enabled recruitment of a larger, randomly sampled group, which in turn would have enhanced the generalisability of the study outcomes. However, reportedly poor response rates to postal questionnaires significantly influenced the final decision not to choose postal questionnaires as the data collection method for this study.

Telephone questionnaire

Nurses undertaking research are most likely to use questionnaires or interviews as a means of collecting data, with both of these methods relying on a participant self-reporting process (McColl et al., 2001). The advantages and disadvantages of postal questionnaires have been outlined above. However, telephone interviews are seen as a means of maximising the advantages of using interviews while minimising their disadvantages (McColl et al., 2001). By eliminating travel and postage costs and reducing time, telephone interviews can be a low-cost and speedy method of data collection.

Most of the strengths of face-to-face individual interviewing methods also apply to telephone interviews (Polit et al., 2005; Schneider et al., 2003). The researcher has the opportunity to clarify a participant's comprehension of each question, and participants are less likely to hang up the telephone on a researcher than they are to discard a mailed questionnaire. A two-way conversation has the potential to improve the quality of the participant's responses.

Musselwhite, Cuff, McGregor and King (2007) have discussed the benefits and challenges of telephone interviewing as an effective method of data collection for clinical nursing research. They cited a number of potential challenges, such as maintenance and communication issues, including: keeping in contact with participants; ensuring comprehension by participants of the questions being posed; and avoiding compromise of the data collection by the researcher should participants provide irrelevant or unsolicited information. These authors concluded, however, that

telephone interviewing is a more efficient use of human and financial resources, and it provides an increased opportunity to foster positive relationships between researchers and participants.

Carr (1999), describing the findings from a semi-structured, telephone-interview survey on patients' experience of in-hospital pain, noted that the use of such an approach to data collection had generated a wealth of information not previously reported in this important area of research. Also, Worth and Tierney (1993) reviewed the strengths and weaknesses of telephone interviews and found that, even in elderly participants with co-morbidities such as impaired hearing, they were a successful means of data collection. Their findings were the result of literature reviews from first-hand accounts in more than 500 telephone interviews of elderly patients. The authors noted that although there were some challenges conducting interviews with participants who were hearing impaired or unwell, overall, they found telephone interviewing was both cost-effective and useful as a method of research data collection. Worth and Tierney further observed that a major contributing factor to the success of the telephone interviewing process was that each participant was personally interviewed and recruited prior to the first telephone contact.

A Queensland Health study investigating nursing recruitment and retention similarly chose telephone interviewing as their data collection option, because it was considered to be the most cost effective when compared with other interview options, in view of the wide range of geographic locations of informants to the study (Ministerial Taskforce, 1999). Cost effectiveness of telephone interviewing, was also a consideration for researchers involved in the *Australian Practice Nursing and Chronic Heart Failure* (APACHE) study (2003). In the methods section of their report, a number of reasons for choosing telephone interviews as a data collection method were discussed. The fact that participants could be contacted at a time suitable to them was seen as a positive to encourage participation. Like Worth and Tierney (1993), whom the researchers referenced, it was found that establishing a relationship with the participants before making the initial telephone call was advantageous.

After consideration of the advantages and disadvantages of self-reporting data generally and postal versus telephone questionnaires specifically, it was decided, for this research study, to use a questionnaire administered by the researcher to each participant over the telephone. Potentially, the participant responses to the research questions would provide realistic information from a patient perspective and give direction to future investigations.

Questionnaire design

There is an abundance of advice contained in the literature relating to questionnaire design and development. However, Polit et al. (2005) indicated that selecting or developing data collection instruments, which enable the researcher to translate the research phenomena of interest into measurable concepts, is one of the most challenging processes to be undertaken.

Data collection instruments enable and record monitoring and evaluation information and, if they are to fulfil these objectives effectively, they will require considerable time and effort to be given to preparation and design, to ensure reliability and validity (Bhattacharya, n.d.). Some of the steps that have been identified by Bhattacharya, for consideration in data collection instrument design, include reliability, validity, brevity and clarity in wording and structure. Piloting or pre-testing, revision and further testing on a number of occasions are also included in this author's recommendations.

According to Schneider et al. (2003), there are common considerations in the development of measurement tools. Although agreeing with Schneider et al. (2003), Bhattacharya (n.d.) commented that, while there can be no universal recommendations on the best way to design a questionnaire, there are some basic principles to be observed. Boynton et al. (2004) and Bhattacharya have suggested several key points to be considered, including: (1) keeping the research objective foremost in mind; in other words, a valid questionnaire should actually measure what it claims to be measuring; (2) keeping the instrument as short as possible, particularly when the questionnaire is administered in a telephone interview; (3) ensuring the questions are grammatically correct and clearly worded; and (4) standardising questions and their measures, so that each question is asked exactly the same way for each participant, and having their responses identically measured, increases the reliability of the instrument.

In a review of best practice applicable to surveys of health-service staff and patients McColl et al. (2001) have commented that the aim of quantitative surveys is to translate all of the information collected into statistical data in a manner that relates significantly to the study sample. These authors provided a plethora of recommendations for survey design, which they identified as principles of question wording, and which they attribute to Moser, Kalton and Oppenheim (Table 5).

Table 5. Principles of question wording (after Moser, Kalton, and Oppenheim, as cited in McColl et al., 2001).

• Use simple language

- Avoid acronyms, abbreviations, jargon and technical terms (this includes medical terms in questionnaires targeted at the general public, patients and consumers)
- Keep the question short (i.e., sentences of less than 20 words approximately)
- Avoid questions that are insufficiently specific
- Avoid ambiguity
- Avoid vague words and those with more than one meaning (e.g., dinner)
- Avoid double-barrelled questions (i.e., those with an "and" or an "or" in the wording).
- Avoid double negatives (e.g., a negative statement followed by a "disagree" response)
- Avoid proverbs and clichés when measuring attitudes
- Avoid leading questions (e.g., Do you agree that the NHS is under-funded?)
- Beware of loaded words and concepts
- Beware of presuming questions
- Be cautious in the use of hypothetical questions
- Do not overtax respondents' memories (e.g., by asking for detailed recall of trivial issues)

Open versus closed questions

An important decision for this research study was to use both open-ended and closed-ended questions. Using only open-ended questions was rejected, as this would have generated large amounts of data over the year-long period of collection. For example, in a study undertaken to assess patient dissatisfaction with medical services, researchers posted open-ended questionnaires to 2000 individuals in Lithuania (Bankauskaite & Saarelma, 2003). The volume of information from just one open-ended question (433 statements) in this survey was such that it required two stages of classification or thematic analysis to determine an outcome of their research inquiry. Bankauskaite and Saarelma stated that the original proposed administration of several questionnaires over a period of one year would have potentially generated a huge number of responses for analysis. For similar reasons, and due to time constraints, purely qualitative data collection in the form of open-ended questions was rejected for this research study.

Closed questions have the potential to discern when and what has happened, but open questions are better when used to understand why something has happened (McQuarrie, 2005). A simple method to identify the point of non-compliance to LLM was to ask a series of questions. The decision was made to develop a series of closed questions in order to determine the point at which participants became non-compliant with their LLM.

It was decided to use mostly closed questions with some open questions. This was because for most questions the possible answers could be predicted. However, for some questions this was not the case, especially for example, the reasons for LLM cessation. After all the data were collected, responses to the open questions were analysed, using simple thematic analysis, and categories were

generated. Once the responses had been categorised, they were assigned a numerical code for entry into a statistics database: Statistical Package for Social Scientists (SPSS).

The challenges associated with using open-ended questions, particularly at the end of a structured questionnaire, have also been reviewed by O'Cathain and Thomas (2004) who made a number of comments for researchers to consider. While these authors saw value in using open-ended questions in the pilot stages of questionnaire development, because of the insightfulness they may contribute to data quality and analysis, they also cited researcher dilemma as to whether or not open-ended responses should be analysed. However, they observed that clarity in regard to the role of open questions can be a valuable aid to the quality of the data and the data analysis. However, this means that the qualitative data generated by open questions do not have any meaning until they have been categorised and evaluated (Schneider et al., 2003).

Questionnaire development

This research study was designed to collect data using three sequentially applied questionnaires, each of which was to be administered via telephone by the researcher. The questionnaires included mostly closed questions, with some open-ended questions. The responses to the open-ended questions were subsequently categorised and quantified.

An initial, short questionnaire was developed to be administered one month after the recruitment date by telephone, and a subsequent questionnaire was administered, also by telephone, in the following months. At the point where cessation of LLM was established, a third, more detailed questionnaire, focusing on the individual's rationale for cessation, was to be administered.

As established in the literature above, reliability and validity are paramount requirements for questionnaire development. The next step in the process, for this study, was to develop a series of questionnaires that would serve as a reliable and valid data collection tool. The following section relates specifically to the data collection tool that was developed. In addition to providing further rationale for the selection of a questionnaire method of data collection, the ensuing discussion also provides the reasoning that underpinned the decision to use both open-ended and closed questions, although data analysis was approached from a quantitative perspective only. The rationale behind the development of three questionnaires is discussed and the reasons are given for adding an additional open-ended question to the final exit questionnaire, for approximately half of the participants.

McColl et al. (2001) made the observation that, in healthcare, questionnaires are often chosen as the means for primary data collection, with the aim being to collect valid and reliable information from the representative sample of interest. In order to reduce information error, it is imperative, according to these authors, that both the questionnaire design and the manner in which it is administered are thoroughly thought out.

Determining the questionnaire design for the data collection tool for this study was complex and demanding. It was a task that required a substantial amount of detailed and time-intense enquiry. The necessity to develop a completely new data collection instrument required not only design, but testing and retesting of the tool.

A key element in questionnaire development for this study was to design a questionnaire in two parts, so that patients' knowledge of the research purpose (which was to determine reasons for ceasing LLM), did not bias their compliance. Therefore, the questions were structured in a manner that would require responses in several fields of the participant's post-discharge journey.

From the literature review, it became apparent that asking questions of a population of interest was generally considered to be one of the best avenues for obtaining information. In this study, asking questions of a participant group that was discharged from hospital on LLM was the most appropriate avenue for investigation. Again, as has been ascertained, from exploration of the literature, no research instruments had been developed to enable investigation of compliance from a patient perspective. This lack of patient focused information gathering necessitated developing one or more data collection instruments that would be reliable and valid and address the research question. Defining the construct, or in other words, creating a systematic, orderly tool to measure compliance in the study cohort was a mandatory requirement.

A specifically designed questionnaire had the potential to collect data generated from participant feedback by using either closed or open-ended questions and responses or a mixture of both methods. Requirements of the questionnaire were to identify at what point participants became non-compliant, and, if they did so, to have the capacity to accurately measure why they were non-compliant.

Determining the questionnaire design for the data collection tool was both complex and demanding, and it was a task that required a substantial amount of detailed and time consuming enquiry. Development of a completely new data collection instrument for compliance/non-compliance to LLM required not only design of the tool, but also its testing and retesting.

Questionnaire pilot testing

Following an initial draft design, over several months, the three questionnaires developed for this research study were piloted, modified and retested a total of five times in order to establish their validity (does this questionnaire have the capacity to measure what is required to be measured?) and reliability (can this questionnaire be used over and over again with confidence?).

Each new draft of the *Initial* and *Subsequent* questionnaires was assessed for reliability and content validity by experienced cardiac health professionals from the disciplines of nursing and exercise science (n = 6) and by a group of six patients. Any changes recommended by the review groups were made to the questionnaire design and a new draft reflecting those changes was returned to the reviewers for further comment. The health professionals applied health promotion and adult learning concepts in their review process. This ensured that questions were written in simple English using words primarily containing no more than three, and preferably only two, syllables. Reviewers also sought to determine that the study objectives were not compromised by question structure. Compromise was considered from the quantitative response choices to some of the questions, as well as from the possibility of question structure alerting participants to the study's aim. Testing the drafts on the patient population assessed clarity of language, the potential for the research aim to be detected from the structure of the questions, and the approximate time required to administer the tool.

As for the previous two questionnaires, each new draft of the *LLM cessation* questionnaire was assessed for reliability and content validity by the same group of health professionals and patients. Again, any changes recommended by the review groups were made to the questionnaire design and a new draft reflecting those changes was returned to the reviewers for further comment. Developing such a comprehensive data collection tool took several months and eight drafts to develop the final version.

The same reliability and validity testing that was used in the initial and subsequent questionnaires, was applied using peer and patient review. Recommended changes were considered and undertaken as required following each review process, and a new draft reflecting the recommendations was returned to the review groups for their comment. Each new draft was reviewed by experienced cardiac health professionals from the disciplines of nursing and exercise science. Again, health promotion and adult learning concepts were applied in the review process, ensuring that questions were written in simple English, using words primarily containing no more than three, and preferably only two, syllables. Reviewers sought to determine not only that the study objectives were not compromised by the way in which questions were structured, but also,

because of the number of questions contained within each theme, that there was an appropriate and logical sequence to the questions.

Reviewers and the researcher also considered the format of questions in relation to the information that the research study was seeking. In other words, were the questions posed in a format that would provide insight into the complexities of patient compliance with LLM? Drafts were again tested on a small patient population to assess clarity and logical flow of the questions, as well as to estimate both the time it would take to administer the tool and whether the participants would feel that it was too onerous a task to answer them.

Some reviewers expressed concerns about the number of questions that could potentially be asked of participants, their willingness to respond, and the time it would take to administer such comprehensive questionnaires. In general, however, patient reviewers felt that, because the questions related to the individual personally, participants would not mind having to answer a large number of questions.

The final version of the *Initial* questionnaire contained six closed and one open-ended question. The *Subsequent* questionnaire contained six closed and two open-ended questions. The final version of the *LLM cessation* questionnaire contained five themes. Each theme contained a mixture of closed and open-ended questions that were designed to thoroughly explore the subject in question.

Questionnaire pre-amble

An introductory preamble was used prior to administering both the *Initial* and *Subsequent* questionnaires. This was in the form of a series of prompts that facilitated re-introduction of the researcher to the participant, a statement of the organisational affiliation of the researcher, and the purpose of the phone call. The participant was asked if they remembered consenting to be part of the study and if they were happy to continue in the study. If they no longer wished to participate then they were thanked for their time and excluded from the study group. If they agreed to continue, they were first asked to confirm that this was a convenient time for them to answer a few questions, were then read a brief outline of the study objectives, and were reminded that the telephone call was being recorded. Having the preamble as a routine part of both the initial and subsequent questionnaires enabled consistency and expediency in ensuring ongoing consent for taking part in the study, agreement to a recorded interview, and reassurance of privacy and confidentiality concerns about the information collected from each participant.

An unexpected, but additional benefit of the preamble in an era of unsolicited, offshore, telephone marketing bombardment of private households was that it allowed the researcher to quickly and succinctly identify herself and her purpose for telephoning, avoiding any unpleasant consequences for either party.

Both the initial and subsequent questionnaires could only be administered up until the time when a participant identified himself or herself as being no longer compliant with LLM.

Initial questionnaire: month one

An initial questionnaire (see Appendix III) was developed that was to be used once only; when participants were contacted for the first time. The purpose of this questionnaire was to re-establish contact with participants and ascertain their willingness to continue in the study. This questionnaire contained nine questions. The questions were designed to collect broad information about their health status. Only one questions focused on their medication compliance. This was intentional, so that participants were not alerted to the study's primary aim to determine LLM compliance. Had participants' been fully aware of this aim, they may have intentionally have modified their behaviour.

A closed question pertaining to the status of wounds at one month post-discharge was asked of all participants. This was because each recruit was discharged with either a puncture wound to the groin, following coronary angiogram with or without PTCA, or a median sternotomy wound following CABG surgery. Two closed questions were included to ascertain continuation of their exercise program and their perception of exercise activity levels. Two other closed questions related to the individual's perception of their heart health and whether they had seen their GP since they returned home. These were followed by an open-ended question related to the reasons for having seen or not seen their GP. A final closed question asked if any of their medications had changed since leaving hospital. If there was no change, the researcher would terminate the call with a reminder that further follow-up would occur in approximately one month. If there had been a change in medications the participant was asked which of the medications had changed. If the answer was LLM, then the LLM Cessation Questionnaire was to be initiated. If LLM was continued, the call would be terminated, with a reminder that they would be followed up again in approximately one month's time.

Subsequent monthly questionnaire: month two onwards

When pilot testing the questions from the initial questionnaire (see Appendix IV) in the context of a subsequent telephone call, it became apparent that the format of the questions would need some alteration. Wound status was no longer an issue, so that question was eliminated. For exercise as a secondary prevention initiative, attendance at, and completion of, a cardiac rehabilitation program was considered to be useful information for collection. An additional closed question, related to frequency, intensity, time and type of exercise, was added along with a closed, cardiac rehabilitation program completion question. An addition was also made to the medication question to ask participants to list the medications they were currently taking, with the responses to be recorded. Otherwise, all the remaining questions in the subsequent questionnaire remained the same as the initial questionnaire.

Lipid-lowering medication (LLM) cessation **questionnaire**

The LLM questionnaire was to be administered in the event that a participant reported non-compliance with LLM in response to the final question in either of the first two questionnaires. Its purpose was to gather information concerning the reasons participants gave for discontinuing their medication.

Based on observations outlined in the literature, the researcher's clinical experience, and information gained from discussions with expert colleagues, a conceptual framework, based on themes requiring investigation for the exit questionnaire (*LLM cessation* questionnaire), began to emerge. Side effects, cost, social support, age, ethnicity, education level, a preference for "natural" therapies and not having a thorough understanding of their disease development, progression and treatment options, are among the reasons that have been cited for non-compliance of patients to medication regimens generally and LLM specifically.

By means of constructing a flow chart and grouping these reasons into categories, five themes were identified to categorise the possible reasons for an individual's non-compliance with LLM. The themes required assessment of:

1. the rationale for cessation of LLM;
2. knowledge and understanding of the link between the disease process, management of CHD; and LLM;
3. alternative treatment options;
4. information/education sources and knowledge gaps; and

5. social support.

Thus, the final draft of the LLM cessation questionnaire (see Appendix VI) contained five themes. Each theme contained a mixture of closed and open-ended questions that were designed to thoroughly explore the subject in question. For example, Theme 1 contained 25 questions, twelve of which were open ended. Theme 2 consisted of 23 questions, nine of which were open-ended. Theme 3 asked three closed and three open-ended questions, while Theme 4 had a total of nine questions, six of which were open-ended. The final theme (Theme 5) had a total of eight questions, three of which were open-ended. In all, this questionnaire consisted of 71 questions of which 38 were closed and 33 were open-ended.

Data collection process

Data collected during a participant, inpatient admission included the demographics listed on the patient identification label, a researcher copy of the consent form, and photocopies of the participant's discharge medication.

Soon after commencement of data collection by telephone using the initial questionnaire, it became apparent that the patient record data entered by admissions staff on the identification label was not always accurate. It then became an imperative, during the recruitment phase, to confirm that the recorded data, such as home and alternative phone numbers, were correct, to ensure that participants could be followed-up.

As indicated above, at each follow-up telephone call, the researcher introduced herself and then asked the series of questions set out in the preamble to each questionnaire. Preliminary questions that were asked enquired into the convenience of the participant answering questions at that particular time, whether the participant remembered having spoken to the researcher during their hospital admission, if they were happy to continue in the study and if they remembered that the conversation was being recorded. These prompts, contained in the initial and subsequent questionnaires, were included, so that the researcher could use the same format to introduce herself, remind the participant about the research project and the tape recording of telephone calls, assess convenience of the telephone call, and provide an opportunity for the participant to confirm his/her willingness to continue in the study. The initial questionnaires took between five and ten minutes to administer over the telephone.

Telephone calls were made from a private, closed-door room, ensuring that there was no extraneous noise that would either distract the researcher or participant or interfere with the

recording of the call. Calls were recorded using a digital voice recorder, and no participant voiced any concern about this process. However, initially, the use of a recording device created some challenges for the researcher in that recording the telephone conversation used up a large amount of the capacity of the recording device. Ultimately, a process of recording one conversation, listening to that recording, transferring the detail to the questionnaire, and then deleting the recording proved to be the most efficient and effective way of capturing data (also see below).

The original research intention was to telephone each participant on a monthly basis. In reality, this proved to be quite challenging, as the number of phone calls required in order to actually reach a participant far exceeded the researcher's original expectation. This issue will be dealt with in more detail in the research limitations section of this thesis.

When telephone contact was made with participants, each question on the questionnaire was read in its entirety and the participant's responses were recorded. Questions, if necessary, were repeated, but the researcher was careful to avoid interjecting with any comments or explanations that could sway a participant's response. During telephone follow-up calls, the aim was to keep the participant on track, so that the survey was completed as quickly as possible. Responses to closed questions were documented immediately into the questionnaire, whereas responses to open questions were recorded and then documented later, after listening to the voice recording.

DATA ANALYSIS

As noted above, all data were categorised numerically. They were then entered into a statistics software program (SPSS, version 17) for analysis.

In social research, there are two branches of statistics: descriptive statistics and inferential statistics.

Descriptive statistics

Descriptive statistics or descriptive analyses, which are the basis of most qualitative data analyses, organise, identify and provide simple summary descriptions of what the data are showing. Descriptive statistics are concerned with the description and presentation of the basic features of the data that are collected in a study, and to simplify and present large amounts of data in an easy

to manage format. Several techniques can be utilised to present, summarise or format what the data demonstrate, including graphs, tables and summary statistics. The most commonly used are measures of central tendency or spread.

Central tendency measures the middle or centre of a collection of data, and the three most common measures that are used to estimate central tendency are the mean, the median and the mode. The mean, also known as the average, is the most common measure of central tendency. The median relates to the middle number occurring in a data set that has been arranged in ascending or descending order, and the mode relates to the most frequently occurring value in the data set.

Inferential statistics

In contrast, inferential statistics are concerned with reaching conclusions or making inferences that extend beyond the collected study data to more general conditions or populations. Inferential statistical procedures enable information collected from reasonably small studies to be extrapolated to the broader community, and to investigate or test questions, models and hypotheses by means of parametric and non-parametric tests.

Parametric tests require level 1 (high-level) data and a normal distribution of data spread. These tests use distribution scales such as bell curves to make assumptions about the distributions of sample values and parameters, or utilise tests of difference, such as the t-test.

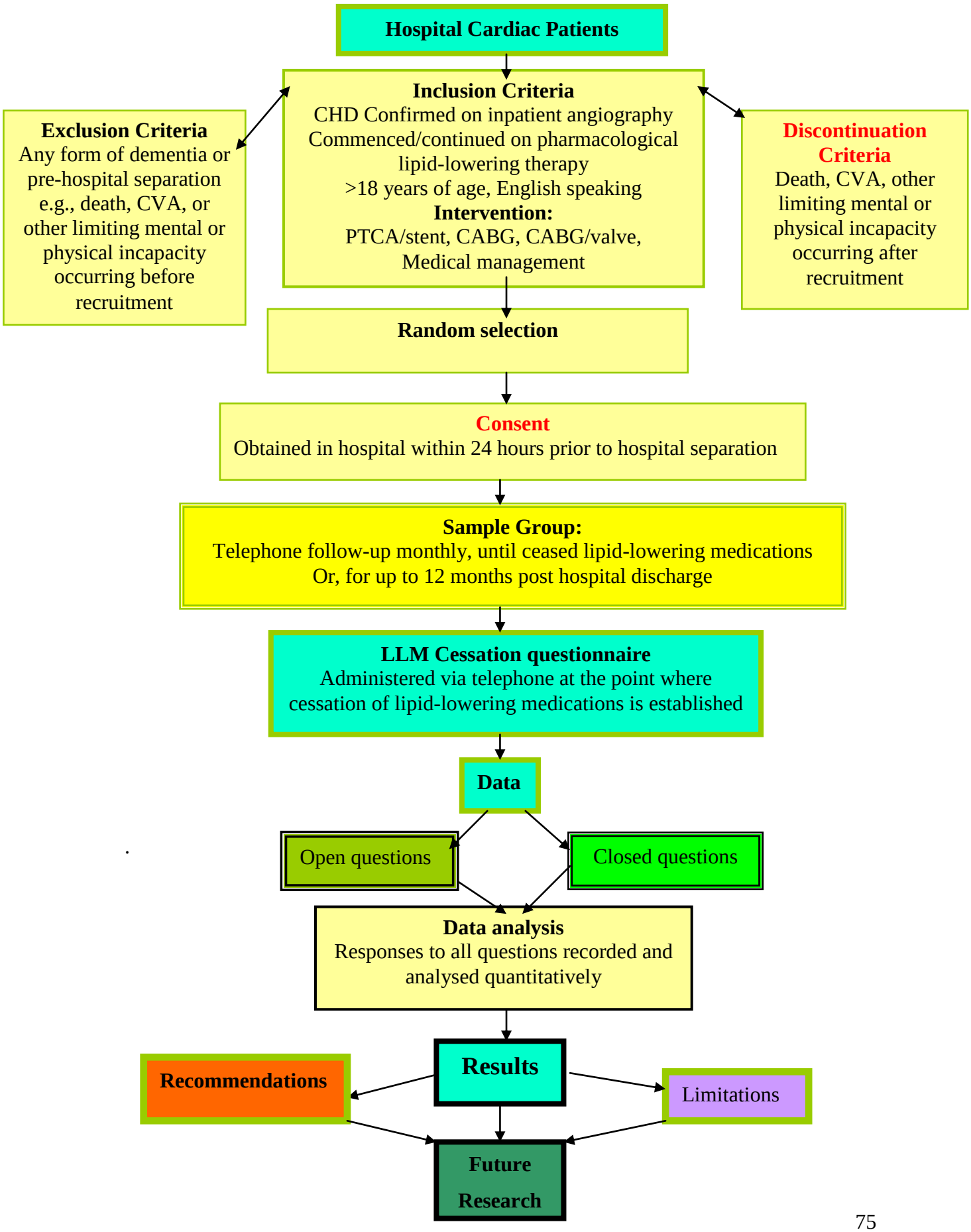
On the other hand, non-parametric tests can be used with all three levels of data, these being: interval/ratio data that relate to measurable or scale-type data such as weight and temperature; ordinal data that relate to information such as age grouping, for instance 0-10 years, 11-20 years, and so forth; and category data, such as gender (male/female). Non-parametric tests of difference include the Mann-Whitney U test.

In this study, the objective was to compare the differences between participants who were compliant with LLM and those who were non-compliant. Estimates of non-compliance were based on research into CHD and other chronic disease management fields. All the research undertaken for this study predicted a high level of non-compliance to pharmacological disease management in general, and an average of 50% non-compliance at one year following LLM prescription. Descriptive statistics were used to describe characteristics of the sample. It was then intended to analyse differences between the compliant and (expected) non-compliant groups using non-parametric tests of difference, and to explore differences within the whole sample. Non-parametric tests were to be used because the data that was collected was at the categorical level.

Conceptual framework of research process

The flowchart (Figure 1) demonstrates the conceptual framework and provides a summary of the research process used in this study. It outlines the process from participant recruitment during hospital admission, taking into account the delimited inclusion, exclusion and discontinuation criteria, the randomisation process, and collection of consent from participants; it highlights the process of participant follow-up, from the first month after hospital separation, and the administration of each questionnaires for a twelve-month period or until establishment of LLM cessation. The final section of the flow chart embraces the data-analysis and results-dissemination processes.

Figure 1. Research methodology flowchart.



ETHICAL CONSIDERATIONS

Informed Consent

Written consent to participate in this study was obtained from each individual in hospital within 24 hours prior to hospital separation. Recruitment and consent involved an initial meeting between the researcher and the patient, during which a verbal outline of the research project was discussed. A patient information letter was then left with the potential participant, an appointment was made for a follow-up meeting, and an opportunity was provided for questions or further discussion. The patient-information letter contained detailed information outlining the scope and duration of the study, the time requirements for participation, and what procedures would be implemented to meet the participant's expectations in relation to his/her privacy. Confidentiality issues, storage and dissemination of data were provided in the patient-information document and discussed with all potential participants during their inpatient admission.

At a follow-up meeting prior to discharge, there was further opportunity for discussion and clarification of any questions and concerns the patient may have had. The patient was then asked if he/she was prepared to participate in the study. If patients responded in the affirmative, they were then asked to read and sign two consent forms, one being their copy, and the second, the researcher's copy. If they declined, they were thanked for taking the time to consider participation and wished good health in the future.

Anonymity and confidentiality of participants

Although the participants, by necessity, are known to the researcher their identities have not and will not be disclosed to anyone thereby assuring the anonymity of the individuals. Participant responses will only be be reported as aggregated data, thus maintaining confidentiality.

However, it has been discussed by Holloway & Wheeler, (1995) that patients may feel an inequality between themselves and nurses because they see nurses as being in control. Therefore, in order to avoid participants feeling manipulated in any way by the nurse researcher's position in her employed role, when the subjects were recruited for this research they were not known to the research student in any professional capacity.

Security of data

Paper-based records are kept in a locked cabinet in the offices of The Wesley Research Institute. Only the researcher has access to these records. Information stored on the researchers computer is password protected, with the password known only to the researcher. Further, the security applied to these data accords with the requirements of the NHMRC (2007). Consent forms are stored separately from other data, and all data are archived for a minimum of five years and a maximum of seven years.

Disposal of data

At the conclusion of the study, any remaining recordings of telephone interview data will be destroyed; all written information and documentation will be shredded; and all personally identifying information stored digitally will be erased from all the electronic storage modalities, such as computer hard drives, floppy discs, CDs, DVDs and USBs.

CHAPTER 3

RESULTS

Introduction

Before reporting the results of this study, it is important to first clarify that the results were unexpected. Inconsistent with the findings in the literature, in this study, none of the sample became non-compliant with LLM. Thus, the final questionnaire was not administered. However, the responses to the initial and subsequent questionnaires were analysed, and it is these that are reported primarily in this chapter.

Initially, in this chapter, an analysis of the cohort characteristics is presented. This is followed by a brief description of LLM compliance, and the reasons provided by a sub-set of the sample for their continued compliance. The chapter concludes with an analysis of within sample differences between exercise levels and heart health rating.

Descriptive statistics have been used to describe the basic features of the data gathered from this study. Together with graphic and tabular presentation, they form the basis for presentation of the results. Data analysis was undertaken using SPSS software. Categorical (nominal) data were gathered from the initial and subsequent questionnaires. Responses to open-ended questions were categorised and clustered thematically. Each theme cluster was given a numerical value, which enabled quantitative analysis.

Numerical data were descriptively analysed using frequency distributions, percentages and proportions, being then exported from SPSS into Microsoft Excel for graphical presentation and interpretation, employing bar charts, line graphs and histograms. Differences in the sample were explored using non-parametric tests of difference, since all variables were at the category level.

Follow-up phone calls

Due to the time limitations of the study, the student researcher was only able to make one attempt each month to contact each subject. Thus, the number of successful phone calls made each month was variable; with an average connection success rate per month of 29.7 calls per month. A total of 356 successful calls were made over the 12 month period. In the final follow-up month, all subjects were phoned repeatedly until a response was obtained. This resulted in a 100% connection success rate in month 12.

Sample

In all, 120 randomly selected and consented subjects, representative of the population of interest, were recruited and followed up by telephone every month for twelve months following hospital discharge. One participant declined to continue in the study at the initial follow-up telephone call, giving the simple reason that they had no further interest in participating. This reduced the sample size to 119.

At the conclusion of the study, a further sixteen people had been lost to follow-up, leaving the total sample size at 103, of whom 77% (η = 79) were male and 23% (η = 24) were female. The mean age of the sample was 65.3 years (SD 9.6) and ranged from 40 to 85 years. The mean age of women (67.2 years; SD 10.75) was slightly greater than men (64.7 years; SD 9.22).

For the purpose of sub-set analysis, the sample was clustered according to five age groups (See Table 6) of whom the majority was in the age range 61-70 years. The subjects belonged to one of three intervention groups: medical management (η = 11, 10.7%); PCI (n= 41, 39.8%); and CABG (η = 50, 48.5%).

Table 6. Gender by age group and intervention group of participants

	Age group					Intervention group		
	40-50	51-60	61-70	71-80	81-90	Medical	PCI	CABG
Male	5 (4.8%)	23 (22.3%)	31 (30.1%)	16 (15.5%)	4 (3.9%)	9 (8.7%)	29 (28.2%)	40 (38.8%)
Female	2 (1.9%)	4 (3.9%)	9 (8.7%)	7 (6.8%)	2 (1.9%)	2 (1.9%)	12 (11.7%)	10 (9.7%)
Total	7 (6.8%)	27 (26.2%)	40 (38.8%)	23 (22.3%)	6 (5.8%)	11 (10.7%)	41 (39.8%)	50 (48.5%)

As can be seen in Table 6, there was a greater number of females in the PCI group, whereas there was a greater number of men in the CABG group. More males aged from 51 to 80 years underwent CABG while the female CABG group was generally older, from 61 to 80 years of age. 51 to 70year olds comprised the largest number in the PCI intervention group for both males and females (also see Table 6). Women who were in the medical management group were older than their male counterparts; the majority of women fell into the 71 to 90 age group, whereas medically managed males ranged in age from 51 to 90 years, with the largest group aged between 61 and 70 years. A similar distribution was found in the PCI intervention group, with females falling into the 50 to 80 age group, and males, into the 40 to 80 age group. For participants who underwent CABG, the age range was the same for both males and females (40 to 90 years). However, proportionately, males

underwent CABG ten years earlier than females. The predominant age group for this intervention for males was 50 to 80 years, whereas for females, it was 60 to 70 years.

Cardiac rehabilitation

Just over half of the subjects completed their cardiac rehabilitation program (54%, η = 56). When gender was investigated, it was found that this figure was consistent in that 54% (η = 43) of males completed the program as did 54% of females (η = 13) (see Figure 2). Chi-Square Tests did not demonstrate a statistical significance between gender and completion of an OCR program.

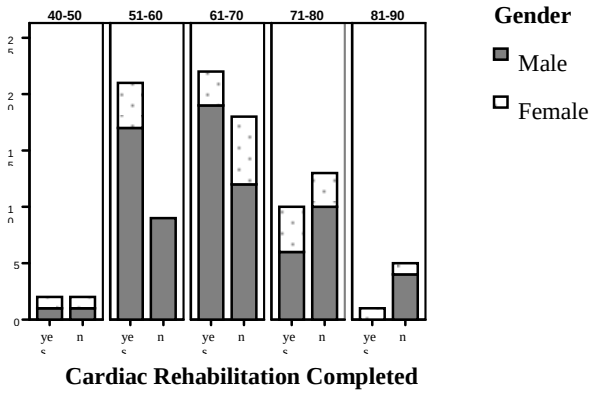


Figure 2. Cardiac rehabilitation completed by age group and gender

All participants were given information, including contact details, about their nearest cardiac rehabilitation program prior to hospital separation. Participants in the 40 to 50 age group reported equal cardiac rehabilitation completion and non-completion by gender, and the majority of completers and non-completers were in the 51 to 80 age group. Fewer people over 81years of age completed a cardiac rehabilitation program.

General practitioner visits

Overall, 97% of patients saw their general practitioner (GP) at least once in the twelve-month, follow-up period. Participants were not categorised into intervention groups in relation to their GP visits or the reasons for those visits. One participant admitted to not having a GP. Figure 3 demonstrates that there was variability in the number of successful contacts; the majority of those contacted, however, had seen their GP within the previous month. Figure 4 shows the main reasons

for GP attendance. The primary reason was for routine prescription refills or regular blood testing. A small number of patients reported ongoing cardiac related problems, and other medical conditions as their reasons for attending. Other reasons for GP attendance included surgical wound care, some non-cardiac related issues, clearance to return to work.

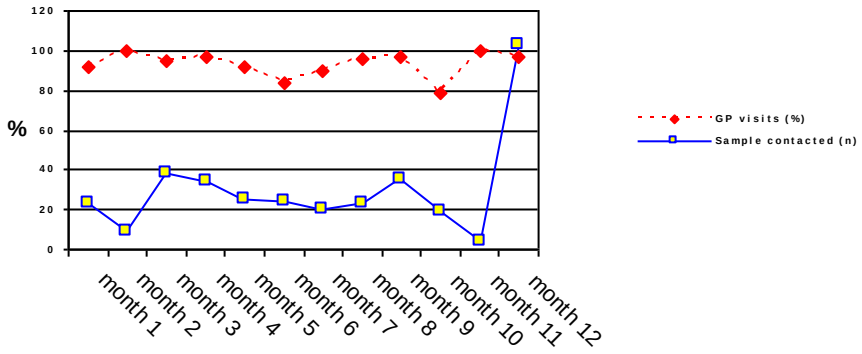


Figure 3. GP visits

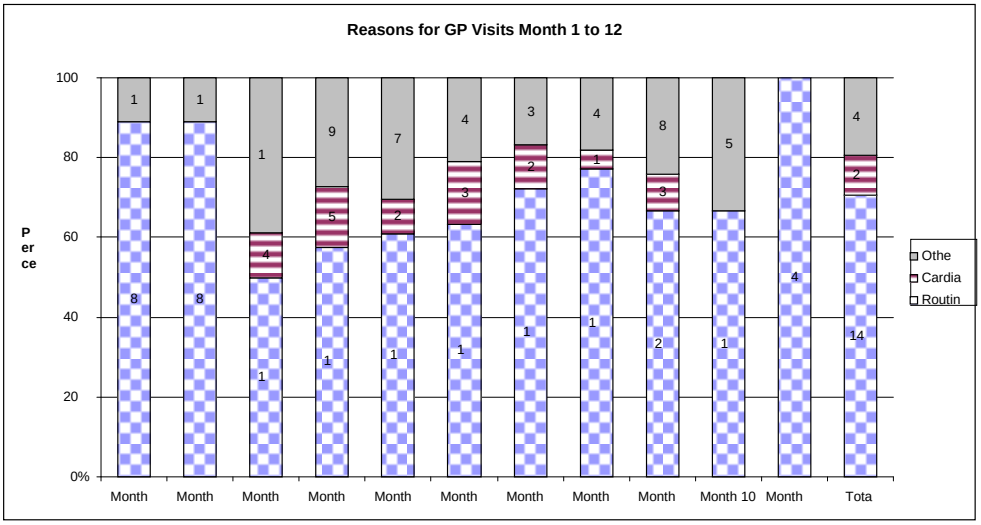


Figure 4. Reasons for GP visits

Lipid lowering medication compliance

All 103 participants were compliant with their LLM at month twelve. Halfway through the data collection process, due to the unexpectedly high compliance rate it was predictable that all subjects might be LLM

compliant at month 12. Therefore, at the approximate halfway point in data collection, an additional question was added to the one-year exit interview, to examine the reasons for continued LLM compliance.

55 participants provided a primary reason for continuing with their LLM. Of these, the majority (η = 30; 55%) gave their reason for continuation as perceived "health benefit". Other reasons given were: previous cessation of LLM had resulted in a subsequent cardiac event (5%); recognition of medication efficacy (7%); specialist advice plus the health benefit (7%); specialist advice (24%); and health benefits. One person was unsure.

Heart health and exercise

Participants were asked to rate their own perception of their heart health following hospital separation throughout the study follow-up period. The choices of response were: (1) became worse; (2) remained the same; and (3) improved. Not all participants were able to be contacted on a monthly basis which meant that a progressive assessment of heart health along the continuum was not possible. However, in general, the majority of participants reported that their heart health had worsened every month (see Figure 5).

In the first month of follow-up 87% (η = 20) of participants contacted reported that their heart health was worse and 13% (η = 3) believed it had improved. At the third month, 76% (η = 28) of the cohort reported worse heart health and 24% (η = 9) believed there was no change in their heart health. In month nine 56% (η = 13) of participants contacted perceived their heart health as worse, 39% (η = 9) felt there was no change, with 4% (η = 1) felt their heart health was improved. However, at month twelve 63% (η = 65) responded that their heart health was worse, with 37% (η = 38) reporting no change. Also Figure 5 shows that in month twelve, no participants reported a self-perceived improvement in their heart health.

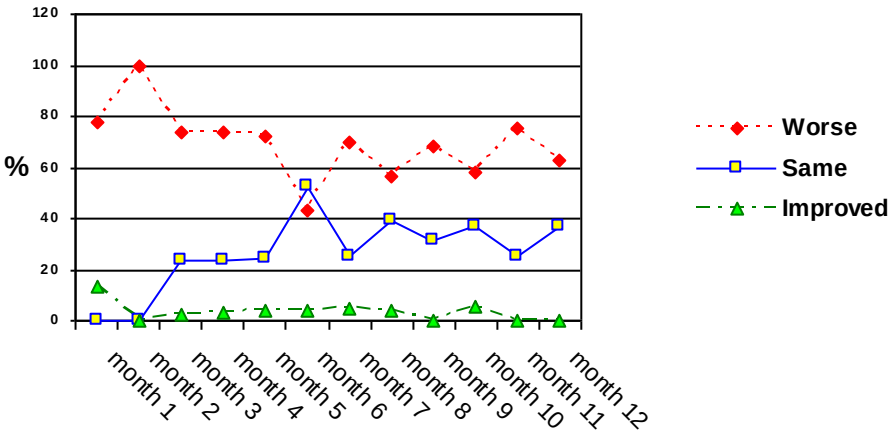


Figure 5. Self-rating of heart health

Frequency of exercise assessment was reported by participants as a choice of one response from a series of questions, asking if they exercised: (1) not at all; (2) once a week; (3) three times a week; (4) most days of the week; or (5) every day of the week. As noted above, it is difficult to make clear interpretations of exercise patterns when comparing percentages of a minority sub-set of the cohort. However, in month 12, when the entire cohort was contacted, 66.3% of participants were exercising at least once per week (see Figure 6).

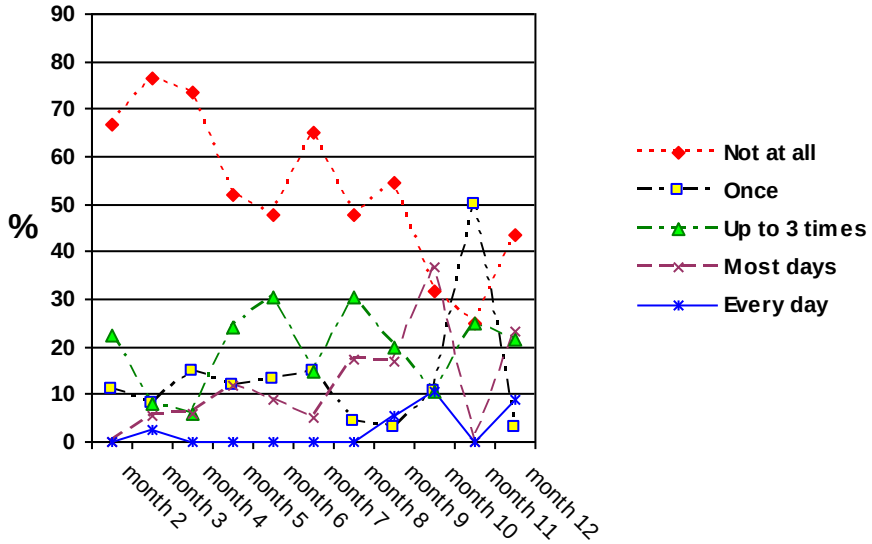


Figure 6. Frequency of exercise

Further analysis of heart-health perception by intervention group and exercise frequency was undertaken for month 12. Statistical analyses were not undertaken to compare differences between intervention groups due to the small numbers of participants receiving medical management. However, as can be seen in Table 7, the majority of participants who received either PCI or CABG intervention reported that their heart health was worse. However, although the sub-set is small (η = 11) the minority of patients who were medically managed reported worse heart health.

For the purpose of analysis, exercise frequency in month 12 was recoded into three groups: no exercise, exercising 1-3 times per week, or exercising 4-7 days per week. Although there were no statistically significant differences, Table 7 demonstrates that of those participants who reported no change in their perception of the health of their heart, the majority were not exercising at all by month twelve, with the greatest number not exercising at all being in the PCI group. Within the group of participants who reported that their perception of the health of their heart was worse, an even greater number were no longer exercising at all. At month 12, 44% (η = 45) of participants were no longer doing any exercise, 21% (η = 22) reported exercising three times a week, 23% (η = 24) were exercising most days of the week, and 9% (η = 9) were undertaking daily exercise (Table 7).

Table 7. Heart health at month 12

	Intervention group			Weekly exercise frequency		
Heart health	Medical	PCI	CABG	None	1-3 times	4-7 times
Worse	4 (36.4%)	25 (60.9%)	35 (70.0%)	25 (55.6%)	15 (60.0%)	25 (75.7%)
Same	7 (64.0%)	16 (39.0%)	15 (30.0%)	20 (44.4%)	10 (40.0%)	8 (24.2%)
Total	11 (10.7%)	41 (39.8%)	50 (48.5%)	45 (43.7%)	25 (24.3%)	33 (32.0%)

Further analysis was undertaken to compare levels of exercise in month 12 with perceived heart health. Exercise level at month 12 was categorised into three groups: exercise level increased, remained the same, or reduced. 40% (η = 42) of participants' exercise levels had reduced. Of these, 37 (88%) perceived their heart health to be worse. Of those whose level of exercise was unchanged (η =42), 22 (52.4%) perceived their heart health to be

worse. However, of those participants who increased their exercise level (η = 19) only 31.6% perceived their heart health to be worse. These findings were statistically significant ($p < 0.001$, $X^2 = 21.452$. df = 2).

There was no significant difference in frequency of exercise between genders, or by intervention group. However, there was a significant difference in exercise frequency between age groups, with around 50% of those in the two younger age groups (40-60 years; 61-70 years) reporting exercise frequency of at least once per week ($p = 0.022$, $X^2 = 11.44$, df = 4).

Comparisons between OCR completers and non-attendees/non-completers

Further analysis was undertaken to compare differences between the groups who completed an OCR and those who did not (see Table 8).

Differences in self reported exercise level at month 12 were examined. The majority of participants (n = 56; 54.4%) reported completing an OCR whereas the remainder either did not attend or did not complete. Of those who had completed an OCR, around half (46%) reported that their exercise levels had improved compared to 34% of the non-completers/attendees.

At month 12, participants were asked for a simple yes/no response to: "Are you still exercising?" The responses to this question were compared with their perceptions of heart health and whether they had completed an OCR or not. Table 8 demonstrates that of those participants who had completed an OCR, the majority (η = 39; 70%) stated they were still exercising, implying that 30% were not. However, when questioned specifically about their exercise level, a greater percentage indicated that they were not exercising at all (38%; n = 21). In the non-completers/attendees group, just over half report that they were exercising at month 12 (n = 25; 53%), implying that 47 % were not. Similarly to the OCR completers, when questioned about their exercise level, 51% (η = 24) reported they were not exercising at all.

Although no participants rated their heart health as improved at month 12, only 29% (η = 16) of the OCR completers believed that their heart health was worse compared to 47% (n = 24) of the non-completers/attendees.

Table 8. OCR completers and non-completers/attendees

		OCR completers (n = 56)	OCR non-attendees and non-completers (n = 47)
Exercising at month 12		39 (70%)	25 (53%)
Exercise level	None	21 (38%)	24 (51%)
	1-3 times per week	16 (29%)	9 (19%)
	Most days	12 (21%)	12 (26%)
	Every day	7 (13%)	2 (4%)
Heart health	Same	40 (71%)	25 (53%)
	Worse	16 (29%)	24 (47%)

An analysis of cardiac rehabilitation completion by intervention only, showed a significant difference in the completion rate for participants undergoing CABG ($p = 0.009$, $df = 2$, $X^2 = 9.431$). Cardiac rehabilitation by age group was analysed initially in ten year age groups, commencing with 40 to 50 year olds and finishing with the 81 to 90 year old groups and was non significant. Subsequent recoding of these groups into 40 to 60 year olds, 61 to 70 year olds and 71 to 90 year olds also was non significant and gender revealed fewer participants in the medically managed group attended and completed a cardiac rehabilitation program. In contrast, 70% of participants who had undergone CABG did complete OCR ($\eta = 36$). Of the 41 participants who underwent PCI, there was almost equal representation in the groups who did and did not attend/complete a cardiac rehabilitation program with those who did (Figure 7).

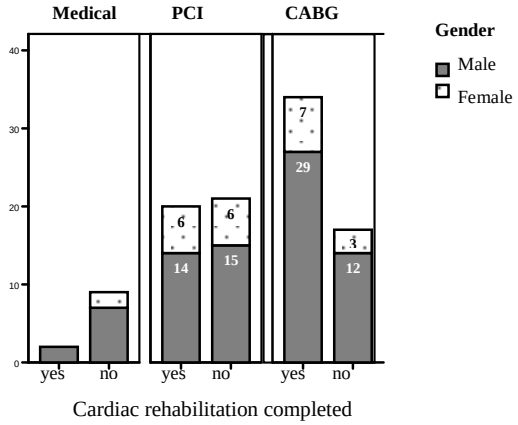
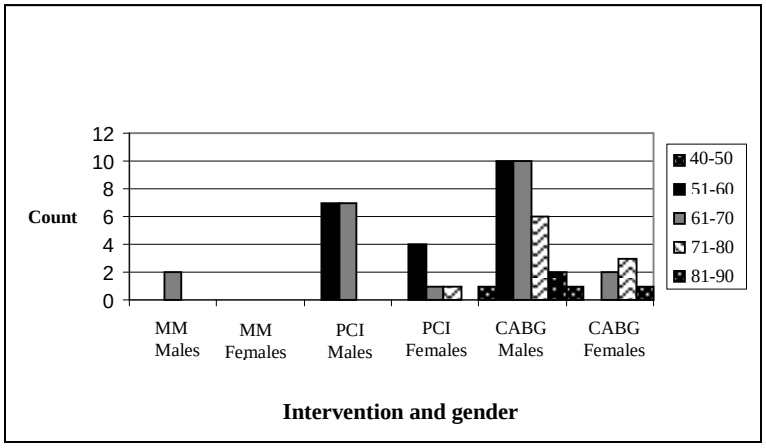


Figure 7. Cardiac rehabilitation completed by intervention and gender

Further analysis of cardiac rehabilitation completion was undertaken by intervention, age group and gender. The largest number of participants from both genders who completed a cardiac rehabilitation program was in the 51 to 60 age group, with the majority of males falling between 51 and 70 years, and the majority of females, between 61 and 80 years. Of the total PCI group (η = 41), only 18 or 44% completed a cardiac rehabilitation program, compared to the CABG group (η = 51) where 33 or almost 65% completed a program (Figure 8).

Figure 8. Cardiac rehabilitation completed by intervention, age group and gender



CHAPTER 4

DISCUSSION

Introduction

As indicated in the preceding sections of this thesis, data were collected using telephone questionnaires, to measure patients' self-reported compliance to LLM and to analyse the reasons given by those who discontinued this medication. The origin of this research work arose from a perception, developed from fifteen years of experience working in cardiac rehabilitation, that the level of compliance with LLM was unknown. This view was formed from exposure to patient and peer anecdotes and from research reports in nursing, health promotion and medical literature, published over the past decade (and cited in the literature review section), that indicated high levels of discontinuation of LLM within twelve months of commencement. Significantly, however, the results presented in this chapter run contrary to these reports and observations, and were an unexpected but positive outcome. The reasons for this are explored in the following chapter. Further, this unexpected result, in its own right, has led to the formulation of a number of recommendations for future research, which are also outlined in the concluding chapter.

Sample

The participants who completed this study were randomised to ensure generalisation of the cohort to the wider population, however it must be emphasised that the study sample were all private patients, in a private hospital with private health insurance. It should be noted that the identification of CHD, was confirmed by coronary angiography. However, diagnosis did not include disease distribution, severity, or percentage quantification primarily because this information is not routinely contained in the patient record. Insufficient detail recorded in the patient record also meant that the allocation of a participant to medical management could not be delineated to determine if the treatment of choice was made based on mild stenotic disease or significant stenosis not suitable for a revascularisation procedure. It should also be noted that participants were not identified as to whether this was an initial or subsequent cardiac admission/event/intervention.

Those participants who completed the study belonged to one of three intervention groups prior to hospital separation. The groups were medical management; PCI with or without coronary stenting, and CABG. Gender distribution by intervention was similar across all groups. The average age of participants fell into the 61 to 70 year group. The age range by gender, of participants who underwent CABG, was 40 to 90 years. The predominant age group for CABG in males was between 50 and 80 years, while, for females, it was between 60 and 70 years. These findings were

consistent with other studies in demonstrating that males, proportionately, underwent CABG ten years earlier than did females.

97% of the cohort had seen their general practitioner at least once in the twelve month follow-up period. In the main, the link with their GP has afforded routine checks of blood tests, blood pressure and the provision of repeat medications. The quality of the relationship between GP and the patient, and the regularity of GP contact may be factors that influence patients' compliance with drug therapy. However, in this study, of the 55 patients who provided reasons for their continued LLM compliance, these were not mentioned. A larger, more detailed study, perhaps utilising qualitative methodology could be undertaken to examine this further.

Lipid lowering medication compliance

At month twelve, all participants, contrary to the findings in the comprehensive literature review undertaken for this research, reported that they were continuing to take their LLM. This was an unprecedented, unexpected and significant result. The possible reasons for this result are considered in some detail in this section.

The compliance findings in this study may be attributable solely to national and international changes to the LLM implementation guidelines, which have occurred since 2003. To reflect on previous discussion of guideline changes since 2003, national and international guidelines have moved from a previously recommended framework of initially implementing lifestyle and dietary changes and reviewing the need for LLM six to ten weeks post hospital discharge. According to the latest guidelines recommended by the NHFA (2007) LLM should be part of the gold standard for treatment of CHD. Gold standard treatment guidelines for CHD are that LLM, ACE inhibitors, beta blockers and blood thinners should be prescribed. The new model recommends LLM initiation immediately following a diagnosis of CHD in association with lifestyle and dietary changes. The most significant change has been the recommendation for LLM in hospitalised patients, to be commenced during the in-patient setting. Uptake of the revised guidelines by cardiology specialists in the in-hospital setting, particularly in the case of this study, where participants were recruited in a private hospital and discharged on LLM, appears to be a contributing factor in the finding of 100% continued compliance to LLM at month twelve.

As well, government legislation is also beginning to impact on treatment of CHD during the inpatient stay. At a state level, a body having recent and significant impact on the public and private sector in terms of quality and safety of health care initiatives in Queensland is the Health

Quality and Complaints Commission (HQCC, 2006). This is an independent body dedicated to improving the quality and safety of health services in Queensland. Briefly, the HQCC was established under the Health Quality and Complaints Commission Act 2006, which commenced on 1 July 2006. The commission was established by the Queensland Government in response to a major recommendation contained in the Queensland Health Systems Review (known as the Forster Report) in late 2005. The purpose of this commission is to provide for oversight and review of and improvement in the quality of health services and also the independent review and management of health complaints. To this end, hospitals are required to review patient medical records across specified diagnosis related groups, in order to assess compliance to defined treatment and management guidelines. For example AMI patients are assessed in a number of areas including previous AMI admission, implementation of recommended medication regimen, or documentation of the reason for non-initiation, a written discharge plan, and eligibility and referral to a cardiac rehabilitation program. Similar changes have also been recommended internationally by a number of organisations including the AHA and the WHO.

The type of intervention ascribed to each participant was not a predictor of compliance in this study, given the 100% self reported compliance rate. However, a number of questions should be considered given the results in this study because the economic impact of CHD cannot be overlooked. Providing primary, secondary and tertiary investigations and treatment to the CHD population imposes a huge, annual, financial burden on health budgets. This is due in part to research-technology expenditure coupled with consumers' treatment expectations, and little consumer responsibility for primary prevention initiatives in developed countries around the world. They are; what are the effects of discharge on LLM as opposed post discharge commencement of LLM?

In a similar vein, is LLM initiation by a cardiac specialist seen as more significant and therefore worthy of long term compliance by patients? Also, does an acute event inpatient setting have greater impact to long term compliance? Further research is required in these areas.

One important fact, not taken into account in this study, that is worthy of further investigation, is that self-reported compliance to LLM did not include any assessment of a participant's regularity to LLM compliance or the frequency of missed LLM therapy. The efficacy and cost effectiveness of LLM when target therapeutic outcomes are achieved cannot be disregarded as a primary and integral treatment method for CHD. However, achievement of therapeutic target lipid levels, as a surrogate measure of compliance, was not ascertained from the participants as this was beyond the scope of the study.

A point mentioned previously was that the socio-economic data of the subjects was not available to the research student. However, the issue of medication compliance in relation to socio-economic status has been reported widely in the literature (Pharmacy Guild of Australia, 2008). In broad terms the better and individual's socio-economic status the better are the medication compliance rates.

Another factor, in this study, that may have contributed to LLM compliance and is worthy of consideration is health insurance cover. In Australia patients can access both public and private hospital care (see Medicare Australia, n.d., for the ensuing detail). Medicare is the name given to the Australian Government public health care funding system. This system provides eligible people with access to free treatment as public patients in a public hospital. Medicare also provides free or subsidised treatment for Australian citizens on a private basis by doctors (both general practitioners and specialists). Eligibility for Medicare also gives access to the Pharmaceutical Benefits Scheme (PBS) which covers most prescription pharmaceuticals provided by pharmacies. Medicare agreements, are funded from individual income deductions, provide "free" (as in, no cost at the point of service delivery) accommodation and treatment as a public patient in a public hospital. Medicare does not however, cover treatment as a private patient in any kind of hospital. People who choose to be treated as a private patient, either in a private or public hospital, are responsible for all of their health costs.

For people who are not eligible for Medicare, the private health care sector provides very high quality services (Private Health, n.d.). Private health insurers and Medicare work in tandem to provide Australia's current health care system. Among the benefits of this are shorter waiting times for elective surgery and less demand for public hospital beds. Because all of the participants in this study had private health insurance, it is possible that they may have placed a higher personal value on healthcare that had been "paid for", as opposed to "free" public healthcare.

The provision of information relating to all aspects of CHD secondary prevention measures, including pharmacological management, is a cornerstone of long-term risk modification management. Although this data lacks specific detail, of the 55 participants who were asked their primary reason for continuing to take their LLM, 55% ($\eta = 30$) gave responses that were thematically categorised as health benefits. Only 7% ($\eta = 4$) of the respondents reported that their primary motivation for continuing their LLM was because they understood how the medications worked. The common medication theme for all the participants was *hospital discharge on LLM*. Therefore, in light of the reported responses given for LLM compliance, consideration should be given whether or not in-hospital initiation of LLM is more significant in affecting the way in which

patients view the importance of their medications, as opposed understanding the action and efficacy of LLM. Of interest is the fact that there were no reported adverse reactions to LLM in the cohort despite anecdotal evidence to the contrary confirmed in the literature. This of major significance given the results, although Australian researchers Simons et al. (1996) found that adverse events contributed to only 7% discontinuation rate for LLM in their 12 month prospective study.

Cardiac rehabilitation

An unusually high number, 54.4% (n = 56) of participants reported attending and completing an OCR. There was no significant difference between the age groups of attendees and non-attendees/completers. Similarly there was no significant gender difference between either group. In keeping with previous Australian research findings, the majority of the group who completed an OCR program fell into the 51 to 60 age group. Generally, men were aged between 51 and 70 years, and women, ten years older, in the 61 to 80 age group, with those aged 91 or older, for both genders being less likely to attend or complete a program (Sundararajan, Bunker, Begg, Marshall and McBurney, 2004).

An important component of cardiac rehabilitation in both the inpatient and outpatient setting is patient and where possible, family education. A number of topics are routinely addressed. Included in both phases of cardiac rehabilitation is education related to prescribed medication e.g., the action of the drug (i.e. to lower cholesterol levels, to thin the blood etc.), the dose and timing of administration, storage of the drug and possible side effects. However, considering the responses from the second half of the cohort it is worth further investigation as to whether knowledge and understanding of drug efficacy essential is essential to compliance.

Of those who completed an OCR, 46% reported that their exercise levels had improved compared to 34% of the group who had not attended/completed an OCR. In the group who self reported no change in their exercise levels from hospital discharge to month twelve, 38% belonged to the OCR completed group and 45% to the OCR non-attendance/completed group. A further 16% of OCR completers believed that their exercise levels had become worse, compared to 21% in the non OCR attendees/completed group.

The significance of sub-optimal exercise compliance demonstrated in this study cannot be ignored from the perspective of long-term secondary prevention of CHD, particularly when compared with the high level of OCR completion. At month twelve, in response to the question on self perception

of heart health, not one participant reported improvement following hospital separation. Further, when perception of heart health was compared to reported exercise frequency at month twelve, it emerged that the majority of participants, who reported no change in their perception of heart health, were no longer engaging in any exercise outside of those activities required in their daily living and/or employment situation. Additionally, the largest group of participants that reported no perceived change in heart health, and that were no longer undertaking any exercise activity were the PCI intervention group. Significantly, the PCI group had the least number attending an OCR program. This suggests that patients, who are discharged from hospital twelve to 24 hours following PCI, with the only physical evidence of their intervention being a puncture wound to the groin, may have less awareness of their non-curable, chronic disease diagnosis. When compared with patients who undergo CABG, and who are subsequently discharged from hospital after five to seven days with a still-healing, median sternotomy, evidence of several drain wounds, in addition to the pain, discomfort and emotional consequences involved with such major surgery, the PCI group may be considered to emerge relatively unscathed.

Overall, with the decline in exercise, reported above, combined with little or no perceived improvement in heart health, the reasons why so few people include a routine exercise activity into their life-style adaptation are worthy of further investigation. In particular, it might be concluded, based on the results of this study, that there is a correlation between perception of heart health and exercise frequency, given that not one participant in the total study group reported an improved perception of heart health at month twelve.

Another result that emerged from this study related to outpatient cardiac rehabilitation (OCR) attendance and completion. Attendance and completion of an OCR program, following a cardiac event, in particular following diagnosis of CHD, is a recommended progression in the continuum of care for this patient group (NHFA & ACRA, 2004) and usual practice in the organisation from which the cohort was recruited. Systematic literature reviews of randomised controlled trials assessing the benefits of cardiac rehabilitation have shown that patients attending rehabilitation after myocardial infarction have a 25% decrease in all-cause mortality (Sundararajan et al., 2004). All participants recruited for this study were given information, including contact details, about their nearest OCR program prior to hospital separation. At follow-up, just over half of the subjects reported having commenced and completed such a program (54%, $\eta = 56$), with an equal gender distribution of 54% ($\eta = 43$) of males and 54% ($n = 13$) of females. When compared with previous research related to cardiac rehabilitation attendance, the self-reported OCR completion rate was appreciably higher (54%) in the present study. In a sample of 12,821 patients in Victoria, in 1998,

with a hospital-discharge diagnosis of AMI, or an intervention of CABG or PTCA, Sundararajan et al. (2004) demonstrated that only 24% attended OCR. Further, in Queensland, Scott, Lindsay and Harden (2003) reported that, during 2001, of 59% of patients eligible to be referred to an OCR program, only 29% were subsequently referred. The substantial OCR completion rate identified in the current study represents a significant improvement on past research findings. This progress, in Queensland, appears to have resulted from the combined approach of front line cardiac rehabilitation healthcare professionals, the Queensland Cardiac Rehabilitation Association, and Queensland Health, to improve communication links related to OCR referral. The process facilitating this advancement has been developed over a number of years. This is an important finding because the flow-on benefit of attending and completing an OCR program is that there has been a decrease of 27% in total mortality and a 31% reduction in cardiac mortality for patients with CHD (Jolliffe et al., 2000).

In the present study, cardiac rehabilitation completion in relation to intervention group was analysed. For the PCI group ($\eta = 41$), only 44% ($\eta = 18$) completed a program, compared with the CABG group ($\eta = 51$), where almost 65% ($\eta = 33$) continued to completion. This too, is consistent with the findings of previous research (Sundararajan et al., 2004).

The outcomes related to OCR are extremely interesting. Given this cohort had a greater than expected referral rate to OCR and were more likely to complete the OCR program (compared to previous trends), it would suggest the cohort appears to be to some degree "health" conscious and are likely to have some knowledge of aspects which improve CVD health. Again these findings would suggest that generally attending and completing and OCR impacts positively in maintaining long term secondary prevention behaviours (in this case, exercise) when compared with the responses of individuals who do not complete an OCR.

In the group who self reported no change in their exercise levels from hospital discharge to month twelve, 38% belonged to the OCR attendance group and 45% to the OCR non-attendance group. A further 16% of OCR attendees believed that their exercise levels had become worse, compared to 21% in the non OCR attendees group. Of the questions asked of participants with regard to exercise, the question regarding their level of exercise revealed that a number of participants could not or did not distinguish a difference between being physically active and participating in a continuous aerobic activity. These data were then compared to the self reported actual days of exercise and also by OCR attendance and completion at month 12. 29% ($\eta = 16$) of the OCR group continued to exercise up to three times a week, 21% ($\eta = 12$) on most days of the week and 12.5%

(η = 7) every day. This would indicate that by attending an OCR individuals are more likely to experience positive long term exercise levels and benefits.

OCR attendance and completion was further compared to the participants self reported perception of heart health and their levels of exercise at month 12. Again, the results demonstrated a better response generally for those participants who attended an OCR, where only 29% (η = 16) of the OCR completers believed that their heart health was worse compared to 47% (n = 24) of the non-completers/attendees. This finding also would give further support to the efficacy of attending an OCR in terms of long term compliance related to exercise habits leading to more positive outcomes and benefits. Had there been less reported compliance to LLM it may have proved useful to include a psychosocial well being tool, as a pre and post measure to perhaps assist with an explanation for patient behaviours including perception of heart health and exercise habits over the 12 month period.

Overall, with the decline in exercise, reported above, combined with little or no perceived improvement in heart health, the reasons why so few people include a routine exercise activity into their life-style adaptation are worthy of further investigation. In particular, it might be concluded, based on the results of this study, that there is a correlation between perception of heart health and exercise frequency, given that not one participant in the total study group reported an improved perception of heart health at month twelve.

Study strengths and limitations

Although this study demonstrated a totally unexpected 100% LLM compliance rate the understanding of non-compliance to an LLM medication regimen remains unknown. In addition to LLM compliance, there are a number of other positive outcomes, outlined below, that have been derived from undertaking this study. Further, with the benefit of hindsight, the study has identified that the approach to it could have been conducted differently, and this has led to a number of recommendations for future research.

The questionnaires used in the study were completely original in concept because of the inability on the part of the researchers to locate any model suitable for use or as a basis for adaptation. Considerable time and effort was given to develop each of the questionnaires. The test-review-revise-retest method, although tedious, made the telephone follow-up professional, consistent and

efficient. The initial and subsequent questionnaires were short, succinct tools that elicited the required information in a timely and economical manner. The wording in the questionnaires was well constructed and, as a result, did not divulge, in any form, the primary nature of the research, although it did enable the necessary information to be obtained, again, for emphasis, without revealing the main purpose of the research. The final questionnaire that was designed to be administered once LLM cessation was established was never used. However, the five themes, each with multiple open and closed-ended questions could be revised and implemented in another study as a final questionnaire to more fully explore patients' compliance rationale, rather than non-compliance.

Participants appeared to enjoy or appreciate being part of a research project. The reasons for this, however, were not captured by the scope of the study, with conjecture suggesting that, in the main, the interest shown in them, as individuals, by the researcher, while they were participating, gave them the opportunity to share their story or journey, and, perhaps, to potentially make a meaningful contribution for future travellers with CHD.

When such a significant finding occurs it is important to consider whether or not the patients' knowledge of the research was a contributing factor. Unexpected positive findings can sometimes be explained by a "Hawthorne effect". This effect has been reported to be a potential influence during research, when participants are aware that their behaviour is being researched. As a consequence of this awareness they modify their behaviour (usually in a positive manner) so that they are perceived in a good light by the researcher. However, in this study, the participants were unaware that LLM compliance was the focus of interest and that was because of careful wording in, and requisite pre-testing of, the research questionnaires, the participants were unaware that their medication adherence was being monitored. They were given the opportunity, via questionnaire design, to truthfully, and without guilt, report non-compliance. This uniform result should be generalisable to the population at large, although, the cohort was sourced from a private hospital, follow-up studies should also embrace patients from the public hospital system. Therefore it cannot be concluded that the Hawthorne effect was a factor. Nevertheless, it cannot be discounted that the fact that participants were followed up and contacted in an 'official' capacity by a researcher may have had some influence on the health behaviours of some people.

The very nature of self reporting is also a limitation given that participants may feel an obligation to answer questions in a way they perceive the researcher would prefer, rather than giving a totally honest response.

Although the present study was randomised, and therefore considered generalisable to the population at large, because the cohort was recruited from a private hospital, there may be a benefit in undertaking the same study recruiting another group of participants from a public hospital.

Although the response level to telephone interviews was reflective of the findings from the literature, use of this follow-up method proved relatively inexpensive. It also provided sufficient access to the participants, resulting in capture of meaningful data for analysis. However, the number of telephone calls required, in order to make contact with participants, was both time consuming and frustrating, with fewer than half of the total number of calls achieving contact. Also, there were hidden costs, not mentioned in the literature, associated with telephone interviewing, embracing the increasing numbers of people who either provide a mobile phone number as their primary contact number or have call diversion to an answering/messaging facility associated with their land line or mobile phone number. Mobile phone calls cost more than land line calls, especially when originating from a land line, and significantly more so when the person who is being contacted is overseas and has their mobile phone on "global roaming"; this occurred on two occasions during the study. Answering/messaging systems, such as VoiceMail and MessageBank, incur additional costs, because, when a call is automatically answered, a cost is incurred, and often, these costs, in the current study, were compounded by repeated attempts to successfully achieve direct contact.

Demographic data entered onto identification labels in patients' hospital records were found, in this study, to occasionally contain incorrect information. This problem was experienced in the first month of the recruitment phase. Subsequent confirmation of the accuracy of such information was made with each participant at the time of obtaining consent, thereby eliminating the potential to recruit a person who would be otherwise lost to follow-up.

Further, people moved from their residential address and/or changed telephone numbers without advising the researcher. Electronic methods of tracing participants, such as *White Pages* online, were found to be not dynamic enough for the time frame of the study. And, this also led to "dead-end" calls with their attendant costs and time consumption.

Some participants like to chat and may even look to the follow-up phone calls as a surrogate doctor visit. As such, the researcher was unable to answer many questions that were asked by respondents. As a clinician, while tempting to offer advice, it was necessary, in a research role, to just ask questions and record responses.

For some participants, there appeared to be a “sense of loss” when told that this would be the last phone call they would be receiving. Comments such as “I’ll miss your phone calls”, or “I’ve looked forward to hearing from you” were not uncommon.

The inability to achieve the original aim of the study, which was to explore the factors, from a patient perspective, that influenced non-compliance to LLM could be construed as being disappointing and a study limitation, although it is viewed here as being otherwise given the unparalleled 100% compliance.

CHAPTER 5

CONCLUSIONS AND RECOMMENDATIONS

The original purpose of the study was not achieved. However the 100% compliance at 12 months, to LLM finding is a significant one, particularly from a health-benefit perspective.
The study drew a number of conclusions from the results. The type of intervention ascribed to each participant was not a predictor of compliance in this study, given the 100% self reported compliance rate. Neither was knowledge and understanding of medication action appear to be an influencing factor in self-reported LLM compliance. In fact, the most common theme provided by participants for compliance was the perceived health benefits of being on the medication. It is also interesting to note that there were no self-reported adverse reactions to LLM in the cohort.

Other outcomes of the research were the reported improvement in OCR program attendance and completion, with those participants who completed an OCR reporting better outcomes overall. The PCI group was the largest group who reported worsening of heart health, also the largest group no longer exercising and contained the least number of participants who completed an OCR.
This study was designed to have an inclusive, rather than a prescriptive, approach to research, with the desire to enhance patient empowerment and autonomy. Some of the possible benefits to participants included the knowledge that their opinions as consumers was valued, and that those opinions would be considered by the researcher when analysing the data to determine what are the issues that impact on people in the management of CHD.

Recommendations

This study is the first to demonstrate 100% self reported compliance to LLM at the completion of a twelve month follow up period. However, as this study did not achieve its primary aim (assessment of the factors that influence compliance to LLM), the final questionnaire, which was designed to be administered once LLM cessation was established, was never used. Additional research is required in order to explore patients' comprehension of their individual disease pathology, recommended treatment, and the pharmacological action and benefits of prescribed medications, as well as, from healthcare practitioners' perspective, ascertaining a greater understanding of their medication-taking habits and any psychosocial factors that impact on any of these issues.

Even though the final questionnaire was never used, the five themes (rationale for cessation of LLMs; knowledge and understanding of the link between the disease process, management of CHD, and LLM; alternative treatment options; information/education sources and knowledge gaps; assessment of social support), each with multiple open and closed-ended questions, could be revised and implemented in another study as a final questionnaire to more fully explore and

understand patients' compliance rationale, as opposed to non-compliance. There remains a paucity of information and understanding of the factors that influence patient compliance with LLM. Further research related to investigation of LLM compliance specifically, as well as chronic disease therapy compliance generally should be encouraged. Health professionals require a comprehensive understanding, from the patient's perspective of the factors than influence LLM compliance as well as non-compliance in order to initiate and maintain pharmacological medication regimens that achieve and maintain long-term therapeutic target levels.

One aspect of interest in the results was that the common medication theme for all the participants. That was *hospital discharge on LLM*. Further consideration should be given as to whether or not in-hospital initiation of LLM is more significant in affecting the way in which patients view the importance of their medications, than education relating to the action and efficacy of LLM.

Investigation of doctor prescribing habits would be one way of eliciting information regarding contemporaneous medical practice in treatment of the CHD population. Inquiry should relate not only to determining increases in the prescription of pharmacological LLM, but also the approach, manner or method by which this treatment is initiated by medical practitioners.

Also, considering the responses to the rationale associated with their medication compliance from the second half of the cohort it would be worth further investigation in order to ascertain whether knowledge and understanding of drug efficacy is essential to compliance?

As mentioned previously the socio-economic data of the subjects was not available to the research student. The issue of medication compliance in relation to socio-economic status may benefit from replication of this study in a public hospital as that may provide more insight in this area in particular from a "fee" versus "free" perspective of the study population.

Finally, telephone follow-up could be undertaken less frequently, for example at three, six and twelve month or at just six and twelve month intervals without effecting outcomes.

APPENDIX I

INFORMATION LETTER TO PARTICIPANTS

TITLE OF PROJECT:
Coronary artery angiography: patient follow-up study

NAMES OF SUPERVISORS:
Professor Paul Fulbrook, Ms Majella Hales,

NAME OF STUDENT RESEARCHER:
Ms Sandra McKellar

NAME OF PROJECT IN WHICH ENROLLED:
Master of Nursing by Research

My study aims to find out what factors may influence treatment and recovery after discharge from hospital, following a diagnosis of Heart Disease.

I will be collecting information via recorded telephone questionnaires. I will arrange with you a mutually convenient time for this telephone call to take place in order to reduce any inconvenience to you, the participant. I do not anticipate that the questions I will be asking will place you at any risk or cause you discomfort.

The study will involve me telephoning you at monthly intervals and asking you a series of questions related to your recovery. The phone call, which will be recorded, will take no more than 10 minutes of your time with the exception of one only questionnaire that may take up to 30 minutes to complete over the telephone.

Because you were admitted to hospital with heart problems and have had a coronary angiogram, you are my best source of information. Collecting your answers to some questions on this subject will provide realistic and practical information that may lead to better management in the future.

Some of the potential benefits of taking part in this research project include: knowing that your opinion as a patient is valued and will be considered when seeking to determine what it is that may make a difference to people during treatment for and recovery from heart disease. The study design focuses totally on you, the patient. It is anticipated that the information obtained from people such as yourself in this study has the potential to involve health care professionals in reviewing and changing the education, support and decision making processes that are currently required for patient education in the treatment and recovery phase after a diagnosis of heart disease, based on a patient's view.

You are free to refuse to take part in this study and if you do choose to take part you have the right to withdraw from the study at any time. If you choose to withdraw from the study this will not affect your future healthcare at The Wesley Hospital.

All your information will be identifiable only by myself, as the researcher. You will be known as a number only, to myself, the primary researcher. All the information related to this study will be kept in confidence and stored in a locked file by myself, the researcher in the offices of the Wesley Research Institute (WRI). Only the details of non-identifying information e.g., summary details, will be reported in publications or other communications to colleagues.

Any questions about this project should be directed to the Principal Supervisor and the student researcher

1) Professor Paul Fulbrook, PhD., MSc., PGDE., BScHons., DPSN,

2) Ms Sandra McKellar,

on telephone number (07) 3623 7420

in the School of Nursing.

Full campus address: Australian Catholic University

Brisbane Campus, PO Box 456, Virginia Q'ld 4014

At the end of each telephone interview I will provide time to answer any questions you may have about the procedures involved in this study. All the audiotapes of recorded telephone conversations related to this study will be destroyed at the conclusion of the study.

At your request, we can provide feedback on the results of this study.

This study has been approved by the Human Research Ethics Committees at the Australian Catholic University and Uniting Healthcare.

In the event that you have any complaint or concern about the way you have been treated during the study, or if you have any query that the Supervisor and Student Researcher has not been able to satisfy, you may write to the Chair of the Human Research Ethics Committee at the address below.

Chair, HREC

C/- Research Services,

Australian Catholic University

Brisbane Campus

PO Box 456

Virginia Q 4014

Tel: (07) 3623 7294

Fax: (07) 3623 7328

Any complaint or concern will be treated in confidence and fully investigated. Participants will be informed of the outcome.

If you agree to take part in this project, you should sign both copies of the Consent Form, retain one copy for your records and return the other copy to the Student Researcher.

APPENDIX II

CONSENT FORM

TITLE OF PROJECT:

Coronary artery angiography: patient follow-up study.

NAMES OF SUPERVISORS:

Professor Paul Fulbrook, Miss Majella Hales

NAME OF STUDENT RESEARCHER:

Ms Sandra McKellar

I……*(the participant)* have read (or, *where appropriate*, have had read to me) and understand the information provided in the Letter to Participants. Any questions I have asked have been answered to my satisfaction. I agree to take part in a monthly recorded telephone interview for up to 12 months, realising that I can withdraw at any time. I agree that research data collected for the study may be published or may be provided to other researchers in a form that does not identify me in any way.

I would like to receive a copy of the research findings summary, by post.

Please tick the appropriate box Yes☙ No☐

NAME OF PARTICIPANT……

(block letters)

SIGNATURE:…… DATE……

SIGNATURE OF PRINCIPAL SUPERVISOR:……..

DATE:……

SIGNATURE OF STUDENT RESEARCHER:……...

DATE:……

APPENDIX III

Initial Monthly Telephone Questionnaire

Patient ID Date / /

Introductory preamble

Hello…… My name is Sandy McKellar, and I am a researcher from The Wesley Hospital in Brisbane.

Do you remember speaking with me and agreeing to participate in my research project just before you went home from hospital?

Y N

If Yes.

Are you happy to continue in the study?

Y N (If No, then participant is excluded)

If they don't remember consenting before leaving hospital

Just to remind you my study is looking at what factors may influence a persons treatment and recovery after discharge from hospital, following a diagnosis of Heart Disease.

Because you were admitted to hospital with heart problems what you can tell me will be valuable. You are my most appropriate source of information. Collecting your answers to some questions on this subject will provide realistic and practical information that will lead to investigations for better management in the future.

The study will involve me telephoning you at monthly intervals and asking you a series of questions related to your recovery. The phone call will be recorded, and will take approximately 10 minutes of your time and will be scheduled for a mutually convenient time. Your Privacy & Confidentiality will be protected at all stages of this study.

Are you happy to continue in the study?

Y N (If No, then participant is excluded)

As we discussed when you were in hospital, I just have a few quick questions I would like you to answer please.

1. Is your groin wound healed? (for PCI and medically managed patients)
   Chest incision/scar/wound healed? (for surgical patients)

   Y N

2. Are you exercising each day?

   Y N

3. Since you were discharged from hospital, has your level of exercise activity
   (a) Improved
   (b) Remained the same
   (c) Become worse

4. Since you were discharged from hospital how would you rate the health of your heart?
   (d) Improved
   (e) Remained the same
   (f) Become worse

5. Have you seen your GP since returning home?

   Y N

If Yes or No

6. Is there a reason why you have seen/not seen your GP?

……
……

7. Have any of your tablets changed since you left The Wesley Hospital?

Y N

If No-------- thank you, I will phone you again in one month

If Yes-------- what medications have changed?

If **NOT** LLM ‘s ----------thank you, I will phone you again in one month

APPENDIX IV

Subsequent Monthly Telephone Questionnaire

Patient ID **Date / /**

Introductory preamble

Hello…… My name is Sandy McKellar, and I am the researcher from The Wesley Hospital in Brisbane. Do you remember me telephoning you last month?

Y N

If Yes.

Are you happy to continue in this study?

Y N (If No, then participant is excluded)

If they don't remember the details and consenting before leaving hospital……

"Just to remind you my study is looking at what factors may influence a persons treatment and recovery after discharge from hospital, following a diagnosis of Heart Disease.

Because you were admitted to hospital with a heart problem, what you can tell me will be valuable. Collecting your answers to some questions on this subject will provide realistic and practical information that will lead to investigations for better management in the future.

The study will involve me telephoning you at monthly intervals and asking you a series of questions related to your recovery. Our phone call, which will be recorded, will take approximately 10 minutes of your time, but depending on some of your answers it could take up to ½ an hour.

Your Privacy & the confidentiality of the information you provide will be protected at every stage of this study."

Have you completed your cardiac rehab program?

Y N

1. Are you exercising? And how often are you exercising?

Y N

Qualitative Response:

2. Since you were discharged from hospital, has your level of exercise activity
   - (g) Improved
   - (h) Remained the same
   - (i) Become worse

3. Since you were discharged from hospital how would you rate the health of your heart?
   - (j) Improved
   - (k) Remained the same
   - (l) Become worse

4. Have you seen your GP since returning home?

   Y N

   (If Yes or No)

5. Is there a reason why you have seen/not seen your GP?

   Qualitative Response:

6. Have any of your tablets changed since you left The Wesley Hospital?

Y N

If Yes -------- thank you, I will phone you again in one month

If No -------- How have your tablets changed?

If **NOT** LLM's------- thank you, I will phone you again in one month.

APPENDIX V

Subsequent Monthly Telephone Questionnaire
Administered to the second half of participants

Patient ID **Date / /**

Introductory preamble

Hello…… My name is Sandy McKellar, and I am the researcher from The Wesley Hospital in Brisbane. Do you remember me telephoning you last month?

Y N

If Yes.

Are you happy to continue in this study?

Y N (If No, then participant is excluded)

If they don't remember the details and consenting before leaving hospital……

"Just to remind you my study is looking at what factors may influence a persons treatment and recovery after discharge from hospital, following a diagnosis of Heart Disease.

Because you were admitted to hospital with a heart problem, what you can tell me will be valuable. Collecting your answers to some questions on this subject will provide realistic and practical information that will lead to investigations for better management in the future.

The study will involve me telephoning you at monthly intervals and asking you a series of questions related to your recovery. Our phone call, which will be recorded, will take approximately 10 minutes of your time, but depending on some of your answers it could take up to ½ an hour.

Your Privacy & the confidentiality of the information you provide will be protected at every stage of this study."

Have you completed your cardiac rehab program?

Y N

6. Are you exercising? And how often are you exercising?

Y N

Qualitative Response:

7. Since you were discharged from hospital, has your level of exercise activity
   (m) Improved
   (n) Remained the same
   (o) Become worse

8. Since you were discharged from hospital how would you rate the health of your heart?
   (p) Improved
   (q) Remained the same
   (r) Become worse

9. Have you seen your GP since returning home?

   Y N

   (If Yes or No)

10. Is there a reason why you have seen/not seen your GP?

Qualitative Response:

6. Have any of your tablets changed since you left The Wesley Hospital?

Y N

If No In your own words, what is the primary reason you have stayed on your LLMs?

Qualitative Response:

APPENDIX VI

Pharmacological Lipid Lowering Cessation

Patient ID

Date / /

The Transcript for a Recorded Participant Telephone Survey

(To proceed from that point of monthly telephone follow-up questions with participants, when cessation of LLM's is ascertained)

Theme 1.

Assessing Rationale for Cessation of Pharmacological Lipid Lowering Therapy

1(a). **(Use participants name)**, Earlier in this telephone conversation you said that you have stopped taking your (LLM's – drug specified). Is that correct?	LLM Y N
1.(b). (If yes) Can you tell me the main reason why you stopped taking the (LLM's – drug specified)? **1.(c)** Were there any other factors or reasons that caused you to stop taking the (LLM's – drug specified)?	Main Reason Other Factors
Preamble **1.(d)** **(Use participants name)**, I am very interested in what you have just said, and would like to talk to you a little more about those things you have just named such as (list reasons here) that led you to stop taking the (LLM's – drug specified). **1.(e)** You have said that **"SIDE EFFECTS"** was the main reason or one of the reasons you stopped taking (LLM's – drug specified). Do you think that the (LLM's – drug specified) affected you physically in any way?	Side Effects Y N
1.(f) (If yes) **Would you tell me in what way they affected you physically?**	
1.(g) Do you think that the (LLM's – drug specified) affected you emotionally in any way?	Y N
1.(h) (If yes) I would like you to tell me some more about how you were affected emotionally?	
1.(i) Do you think the (LLM's – drug specified) affected your ability to function mentally in any way?	Y N
1.(j) (If yes) Would you describe how you were effected mentally?	

1.(k) You said that **"COST"** of the (LLM's – drug specified), was the main reason or one of the reasons you stopped taking (LLM's – drug specified). Is that correct?	LLM Y N
1.(l) You said that **"MEDIA REPORTS"** about (LLM's – drug specified) was the main reason or one of the reasons you stopped taking (LLM's – drug specified)?	Y N
1.(m) I would like you to tell me about the things you heard or read in the media – just in your own words.	
1.(n) I would also like to know if you can tell me what media sources you remember hearing this information from e.g. TV etc.	
1.(o) Have you discussed your medication with anyone else?	Y N
1.(p) (If Yes) Who have you discussed them with?	
1.(q) (If yes) What did you talk about?	
1.(r) "BECAUSE YOU'D FINISHED THE PRESCRIPTIONS/REPEATS YOU WERE GIVEN HOSPITAL – BY YOUR CARDIOLOGIST, DOCTOR, SURGEON ETC" You identified.as the main reason or one of the reasons you stopped taking (LLM's – drug specified).	Y N
1.(s) Please tell me why you thought that?	
1.(t) You said that "BECAUSE YOUR CHOLESTEROL HAD NEVER BEEN HIC PROBLEM" was the main reason or one of the reasons you stopped taking (LI drug specified).	Y N
1.(u) Please tell me or explain a little more about what you mean by "never been high or not a problem?	
1.(v) Do you know what your cholesterol level was or is?	Y N
1.(w) (If Yes) What is your cholesterol level?	
1.(x) (Yes or No) How regularly do you get it checked?	

1.(y) (Yes or No) Who arranges those tests?	

Theme 2

Assessing Knowledge & Understanding of the Link between the Disease Process, Management of CHD & LLM's

2.(a) **(<u>Use participants name)</u>** In hospital you had an angiogram. That is the procedure where they put a special catheter or tube into blood vessels in your groin area and up into your heart, then they injected some special dye and took pictures of the blood vessels around your heart and the chambers of your heart. Were you told about the results of your angiogram?	Y N
2.(b) (If yes) **Were your results discussed in a way you could understand?**	Y N
2.(c) (If yes) Are you able to tell me who discussed your results with you? Eg. Nurse, physio, surgeon, cardiologist, other	
2.(d) Did you feel you had the opportunity to ask questions?	Y N
2.(e) Were you shown either a drawing of a heart on which the doctor drew an outline of the results of your angiogram for you or a photograph of your heart taken during your angiogram?	Y N
2.(f) (If No) Do you think that would have been helpful/unhelpful?	Y N
2. (g) Why do you say that?	
2.(h) (If No) How do you think that would have been helpful/unhelpful?	
2.(i) (If yes) Was it useful for you to see the drawing or photo?	Y N
2.(j) Did that diagram/photo help you to better understand what the results of your angiogram were?	Y N
2.(k) Do you remember being told exactly what the angiogram revealed was wrong with your heart?	Y N
2.(l) (If No) You have said that you "weren't told" or "don't remember being told" the results of your angiogram. Is that correct?	Y N
2.(m) (If Yes) In your own words would you please tell me what was, or is wrong with your heart?	
2.(n) (If the respondent had an intracoronary intervention) When you were in TWH as well as the angiogram, you had a	

procedure called an Angioplasty and a stent put into your heart. correct?	Y N
2.(o) In your own words, why do you think you had a PTCA/Stent?	
2.(p) When you were in TWH as well as the angiogram, you had an operation called coronary artery bypass graft surgery. Is that correct?	Y N
2.(q) In your own words, why do you think you had Surgery(CABG's)?	
2.(r) When you were discharged from TWH you were given a number of tablets to take and they included your (LLM's – drug specified). Is that correct?	Y N
2.(s) Can you tell me, in your own words, why you went home on (LLM's – drug specified).	
2.(t) Good, now can you also tell me what the (LLM's – drug specified) does and how it works?	
2.(u) **(Use participant's name)** (It is approximately "x" months since you were in TWH). I would like to know how you feel about your heart health at this point in time (now). In order to make it a little easier for you, I would like you to think about a scale or ruler numbered from 1 to 10 A score of 10 tells me that you feel your heart problems are now cured or fixed. A score of 1 tells me that you feel your heart problems are worse or not fixed at all. A score of 5 to 6 would indicate that your heart problems are about the same as when you were in hospital. To what extent do you think you heart is cured or fixed?	1 2 3 4 5 6 7 8 9 10
2.(w) Good. Now in your own words why do you think you heart is cured or fixed/not cured or fixed?	

Theme 3

Assessment of Alternative Treatment Options

3.(a) (Use participant's name). Apart from the CABG/PTCA/medications do you know any other ways to take better care of your heart? Please just answer yes or no.	Y N
3.(b) Please can you tell me some of those ways or things you can do to have a healthier heart?	
3.(c) (Use participant's name) Do you take any tablets or medications for your heart, other than those prescribed by a docto	Y N
3.(d) (If yes) Would you tell me what they are and what they are for?	
3.(e) (If Yes) Where or how did you find out about these other drugs?	
3.(f) (If yes) Do your doctors know that you take these medications?	Y N

Theme 4

Assessment of Information/Education Sources and Knowledge Gaps

4.(a) Were you given information about all of your medications before you left TWH?	Y N
4.(b) (If Yes) Do you feel you were given **enough** information about all the medications you were to take, before you left TWH?	Y N
4.(c) (If No) What information do you think you would have found helpful?	
4.(d) (If yes) Who gave you the information about your medications?	
4.(e) How was the information given to you?	
4.(f) Which of the following phrases describes you best? A person who never asks questions about their medications? A person who sometimes asks questions about their medications? A person who generally asks questions about their medications? A person who always asks questions about their medications?	 Never Sometimes Generally Always
4.(g) Generally where or who do you go to, to find out the answers to these questions about your medications or other health questions?	
4.(h) Who would you consult to get repeat prescriptions?	
4.(i) Who would you consult in the first instance to discuss any changes to your medications?	

Theme 5

Assessment of Social Support

5.(a) Now we know you take medications every day. Do you pu out ready to take yourself?	Y N
5.(b) (If no) Who gets them ready for you?	
5.(c) (If yes) Describe how you go about taking your medications?	
5.(d) Do you get your prescriptions refilled yourself?	Y N
5.(e) (If No) Who usually gets them filled for you?	
5.(f) When would you usually get the scripts filled?	Before they run out? After they run out?
5.(g) Do you ever forget to take your medications?	Y N
(If yes) How often do you forget?	Never? Sometimes? Frequently?

(Insert Participants Name), That brings me to the end of my questions. I would like to thank you very much for your participation, and to ask if there is there anything more you would like to add?

Or do you have any questions you may like to ask?

Prompt: Referral to GP when and where assessed as necessary.

APPENDIX VII

Lifestyle/behavioural risk factors and management (NHFA, 2007).

Smoking	Goal: Complete cessation and avoidance of secondhand smoke.
Nutrition	Goal: Establishment/maintenance of healthy eating patterns, with saturated and trans fatty acid intake ≤ 8% of total energy intake.
Alcohol	Goal: Low risk alcohol consumption in those who drink.
Physical activity	Goal: Progress, over time, to at least 30 minutes of moderate intensity physical activity on most, if not all, days of the week (150 mins per week minimum).
Healthy weight	Goal: Waist measurement ≤ 94 cm (males) or ≤ 80 cm (females); BMI = 18.5–24.9 kg/m^2.*

Biomedical risk factors and medical management (NHFA, 2007).

Lipids	Goal: LDL-C <2.0 mmol/L; HDL-C >1.0 mmol/L; Triglycerides <1.5 mmol/L.
Blood pressure	Goal: Dependent on age and presence of diabetes, proteinuria, renal insufficiency. •Adults ≥65 (unless there is diabetes and/or renal insufficiency and/or proteinuria ≥0.25 g/day): <140/90 mm Hg. •Adults <65; and all adults with diabetes and/or renal insufficiency and or proteinuria 0.25–1 g/day: <130/85 mm Hg. •Adults with proteinuria >1 g/day (with or without diabetes):

	<125/75 mm Hg. •Generally ACE Inhibitors are recommended as first-line antihypertensives in patients with cardiovascular disease.
Diabetes	Goal: Identify undiagnosed type 2 diabetes; maintain optimal BSL in those with diabetes (HbA1c ≤ 7%). Screen all patients with CHD for diabetes.

Pharmacological management (NHFA, 2007).

Antiplatelet agents	Use aspirin 75–150 mg/day for all patients unless contraindicated. Additional role for clopidogrel in patients with recurrent cardiac isc events; stent implantation.
ACE Inhibitors Angiotensin II Rec Antagonists Beta-blockers	For all patients post-MI, unless contraindicated, and continued indefinitely, especially in high risk patients.
Statins	For all patients with CHD unless contraindicated. In hospitalised patients, therapy should be commenced during that admission.
Anticoagulants	Use warfarin in patients at high risk of thromboembolism post MI.

Non-pharmacological management (NHFA, 2007).

Ongoing prevention Cardiac rehab Programs	After the acute event, all patients should be actively referred to a comprehensive ongoing prevention/cardiac rehabilitation serv
Chest pain action plan	All patients to have a written action plan to follow in event of ch including advice on use of anti-anginal medication and emergen (dial 000 for ambulance) if symptoms are severe, get worse or la minutes.

Psychosocial factors and assessment (NHFA, 2007).

Psychological management	Assess all patients for comorbid depression. Initiate psychological and medical management if appropriate.
Social support	Assess all patients for level of social support and provide follow-up for those considered at risk through referral to cardiac rehabilitation services and/or to a social worker or psychologist. Consider role of patient support groups.

APPENDIX VIII

UnitingHealthCare

PO Box 499
TOOWONG 4066

Phone: 3232 7500
Facsimile: 3232 7109
Email: lorrainer@wesley.com.au

ABN: 87 842 457 440

1 July 2005

Please quote our reference: **2005/16**

Ms Sandra McKellar
Clinical Manager
HeartWise
The Wesley Hospital Cardiac Rehabilitation Services

Dear Ms McKellar

RESEARCH PROPOSAL: *What factors influence the choices that patients make about taking pharmacological lipid-lowering medications*: A Prospective, Cohort Study

I am pleased to advise that the Uniting HealthCare Human Research Ethics Committee reviewed the above research proposal at its meeting on 30 June 2005 and granted full approval for the study.

It is a strict condition of approval that any departure from the protocol detailed in the proposal submitted for approval be reported immediately to the Committee. If there is any change to the status of the project, this should be reported.

Approval for the project is given subject to your agreement to the Uniting HealthCare Human Research Ethics Committee requirements for the monitoring of research, which have been based on the Australian Health Ethics Committee guidelines. Please note the requirement to submit a report annually or at the completion of the project, as appropriate.

Yours sincerely,

Douglas Killer MBBS FRACP
Executive Officer
Uniting HealthCare Human Research Ethics Committee

The Wesley Hospital Multidisciplinary Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's Statement on Human Experimentation and Supplementary Notes

✚ *The Wesley Hospital* ✚ *St Andrew's War Memorial Hospital*
✚ *The Sunshine Coast Private Hospital* ✚ *St Stephen's Hospital Maryborough*
✚ *The Wesley Hospital Townsville*

APPENDIX IX

Human Research Ethics Committee

Committee Approval Form

Principal Investigator/Supervisor: Professor Paul Fulbrook Brisbane Campus

Co-Investigators: Ms Majella Hayes Brisbane Campus

Student Researcher: Ms Sandra McKellar Brisbane Campus

Ethics approval has been granted for the following project:
What factors influence choices that patients make about taking pharmacological lipid lowering medications: a prospective, cohort study.

for the period: 1 October 2005 to 31 October 2006

Human Research Ethics Committee (HREC) Register Number: Q200506 8

The following standard conditions as stipulated in the *National Statement on Ethical Conduct in Research Involving Humans* (1999) apply:

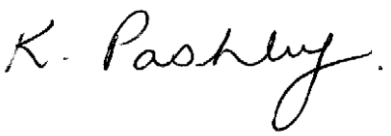
(i) that Principal Investigators / Supervisors provide, on the form supplied by the Human Research Ethics Committee, annual reports on matters such as:
- security of records
- compliance with approved consent procedures and documentation
- compliance with special conditions, and

(ii) that researchers report to the HREC immediately any matter that might affect the ethical acceptability of the protocol, such as:
- proposed changes to the protocol
- unforeseen circumstances or events
- adverse effects on participants

The HREC will conduct an audit each year of all projects deemed to be of more than minimum risk. There will also be random audits of a sample of projects considered to be of minimum risk on all campuses each year.

Within one month of the conclusion of the project, researchers are required to complete a *Final Report Form* and submit it to the local Research Services Officer.

If the project continues for more than one year, researchers are required to complete an *Annual Progress Report Form* and submit it to the local Research Services Officer within one month of the anniversary date of the ethics approval.



Signed: .... Date: 8 September 2005
(Research Services Officer, McAuley Campus)

REFERENCES

ABS. (2004). Education services - Statistics - A powerful edge - Sampling methods - Non-random sampling. Australian Bureau of Statistics. Retrieved June 3, 2008, from: http://www.abs.gov.au/websitedbs/D3310116.NSF/a91a469056624a32ca256eb000026ca7/a9a3a3d8155170954a2567ac002161a6!OpenDocument

AHA. (2004) Asian/Pacific Islanders and cardiovascular diseases - statistics. American Heart Association. Retrieved May 20, 2007, from: http://www.americanheart.org/downloadable/heart/1075706941602FS03AS04.pdf

AIHW (2006). Chronic diseases and associated risk factors in Australia 2006. Australian Institute of Health and Welfare, AIWH Catalogue No. PHE 81. Available from: http://www.aihw.gov.au/publications/phe/cdarfa06/cdarfa06.pdf

Allender, S., Peto, V., Scarborough, P., Boxer, A., & Rayner, M. (2007). Coronary heart disease statistics 2007 edition. Retrieved April 24, 2008, from: http://www.ws3.heartstats.web.baigent.net/uploads/documents%5C48160_text_05_06_07.pdf

Anderson, A.S., Bell, A., Adamson, A., & Moynihan, P. (2001). A questionnaire assessment of nutrition knowledge - validity and reliability issues. Public Health Nutrition, 5(3), 497–503.

Bankauskaite, V., & Saarelma, O. (2003). Why are people dissatisfied with medical care services in Lithuania? A qualitative study using responses to open-ended questions. International Journal for Quality in Health Care, 15, 23-29.

Barber, N., Parsons, J., Clifford, S., Darracott, R., & Horne, R. (2004). Patients' problems with new medication for chronic conditions. Quality and Safety in Health Care, (13), 172-175.

Bernard, J.R.L. (Ed.). (1984). The Macquarie Thesaurus. South Australia: Griffin Press Limited.

Bhattacharya, R. (n.d.). Designing a questionnaire for medical research and audit. Retrieved March 19, 2008 from The Royal College of Surgeons of Edinburgh Surgical Knowledge and Skills Website: www.edu.rcsed.ac.uk/lectures/lt25.htm

Blackburn, D.F., Dobson, R.T., Blackburn, J.L., & Wilson, T.W. (2005). Cardiovascular morbidity associated with nonadherence to statin therapy. Pharmacotherapy, 25(8), 1035-1043.

Boynton, P. M., & Greenhalgh, T. (2004). Selecting, designing and developing your questionnaire. British Medical Journal, 328, 1312-1315.

Brealey, S.D., Atwell, C., Bryan, S., Coulton, S., Cox, H., Cross, B. et al. (2007). Improving response rates using a monetary incentive for patient completion of questionnaires: An observational study. BMC Medical Research Methodology, 7, 12. Retrieved October 15, 2007, from: http://www.biomedcentral.com/1471-2288/7/12 (doi: 10.1186/1471-2288-7-12).

Brooks, L. (2007). Heart protection study follow-up confirms consistent benefit and long-term safety of statin treatment. Retrieved December 6, 2007, from: http://www.medscape.com/viewarticle/556067_print

Brockopp, D.Y., & Hastings-Tolma, M.T. (2003). *Fundamentals of Nursing Research*, 3rd Edition. Boston: Jones and Bartlett Publishers.

Brophy, J.M., & Bogaty, P. (2004). Primary angioplasty and thrombolysis are both reasonable options in acute myocardial infarction. Annals of Internal Medicine, 141, 292-297.

Bunker, S.J, Colquhoun, D.M., Esler, M.D., Hickie, I.B., Hunt, D., & Jelinek, V. M., et al. (2003). "Stress" and coronary heart disease: psychosocial risk factors. Medical Journal of Australia, 178, 272–276.

Campbell, D.A. (1997). Psychosocial issues in adherence, Asthma Adherence Workshop Report, National Asthma Campaign. Paper presented at the Asthma Adherence Conference - A guide for health professionals, pp. 30-31. Melbourne (No other conference/report details available from National Asthma Council Australia Website: http://www.nationalasthma.org.au/HTML/management/adherence/adh009.asp).

Campbell, M., & Torrance, C. (2004). Coronary angioplasty: Impact on risk factors and patients' understanding of the severity of their condition. Australian Journal of Advanced Nursing, 22(4), 26-31.

Campbell, N.C., Ritchie, L.D., Thain, J., Deans, H.G., Rawles, J.M., & Squair, J.L. (1998). Secondary prevention in coronary heart disease: a randomised trial of nurse led clinics in primary care. Heart, 80(5), 447-452.

Cleveland Clinic Foundation Heart Centre. (2008). New innovations - Cardiac Imaging: Integrated, applications-driven use of cardiac CT and MRI. Cleveland Clinic Heart and Vascular Institute. Retrieved June 6, 2008, from: http://www.clevelandclinic.org/heartcenter/pub/history/future/mri.asp?firstCat=56&secondCat=57&thirdCat=529

Cohen, J. (1987). *Staistical Power Analysis for the Behavioural Sciences.* Hillsdale, New Jersey: Lawrence Erlbaum Associates.

Collins, R., Armitage, J., Parish, S., Sleight, P., Peto, R., & Youngman, L. (2002). MRC/BHF heart protection study of cholesterol lowering with simvastatin in 20,536 high-risk individuals: A randomised placeo-controlled trial. The Lancet, 360(9326), 7-22.

Data Analysis Australia. (2007). What are you really measuring? Reliability and validity in questionnaire design. Retrieved April 6, 2008, from: http://www.daa.com.au/analytical-ideas/questionnaire-validity/

Davidson, M.H., & Jacobson, T.A. (2001). How statins work: The development of cardiovascular disease and its treatment with 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors. Retrieved May 14, 2008, from Medscape Cardiology Clinical Updates: http://www.geocities.com/Heartland/Ridge/4839/statins.html

Delbridge, A. P. (Ed.). (1982). The Macquarie Dictionary. Sydney, Australia: Macquarie Library Pty Ltd.

DiMatteo, M.R. (1994). Enhancing patient adherence to medical recommendations. Journal of the American Medical Association, 271(1), 79-83.

Downs, J.R., Beere, P.A., Whitney, E., Clearfoeld, M., Weis, S., Rochen, J., et al. (1997). Design and rationale of the Air Force/Texas coronary atherosclerosis prevention study (AFCAPS/TexCAPS). American Journal of Cardiology, 80, 287-293.

Elliott and Thompson (2008). Common quantitative methods. In Schneider, Z., Whitehead, D., Elliott, D., Lobiondo-Wood, G., & Haber, J. (2008). *Nursing & Midwifery Research: Methods and Appraisal for Evidence-based Practice*, 3rd Edition. Sydney: Mosby Elsevier, pp.156-174.

Ellis, J.J., Erickson, S.R., Stevenson, J.G., Bernstein, S.J., Stiles, R.A., & Fendrick, A.M. (2004). Suboptimal statin adherence and discontinuation in primary and secondary prevention populations: Should we target patients with the most to gain? Journal of Internal General Medicine, 19(6), 638-645.

Fernandez, R., Davidson, P., Griffiths, R., Jeurgens, C., & Salamonson, Y. (2007). What do we know about the long term medication adherence in patients following percutaneous coronary intervention? Australian Journal of Advanced Nursing, 25(2), 53-61.

Fletcher, P. (Ed.). (2005). Targeting ischaemic heart disese: Improving health outcomes with multiple medications. NPS News, 41. Retrieved May 18, 2007, from National Prescribing Service Limited Website: http://www.nps.org.au/site.php?content=/html/news.php&news=/resources/NPS_News/news41

Graham, I., Atar, D., Borch-Johnsen, K., Boysen, G., Burell, G., Cifkova, R., et al. (2007). European guidelines on cardiovascular disease prevention in clinical practice: Executive summary. European Heart Journal, 28(19), 2375-2414.

Grundy, S. (2006). The clinical implications of IDEAL: In the context of recent intensive statin therapy trials. Retrieved October 1, 2006, from Medscape & eMedicine Website: http://www.medscape.com/viewarticle/520891_print

Gulliford, M.C., Mahabir, D., & Rocke, B. (2004). Reliability and validity of a short form household food security scale in a Caribbean community. BioMed Central Public Health, 4, 22. Retrieved April 26, 2008 from: http://www.biomedcentral.com/1471-2458/4/22 (doi: 10.1186/1471-2458-4-22).

Hague, W., Forder, P., Simes, J., Hunt, D., & Tonkin, A. (2003). Effect of pravastatin on cardiovascular events and mortality in 1516 women with coronary heart disease: Results from the long-term intervention with pravastatin in ischemic disease (LIPID) study. American Heart Journal, 145(4), 643-651.

Halkett, G.K.B., & Kristjanson, L.J. (2007). Validity and reliability testing of two instruments to measure breast cancer patients' concerns and information needs relating to radiation therapy. Radiation Oncology, 2, 43. Retrieved from: http://www.ro-journal.com/content/2/1/43 (doi: 10.1186/1748-717X-2-43).

Haynes, R.B., McDonald, H.B., & Garg, A.X. (2002). Helping patients follow prescribed treatment: Clinical applications. Journal of the American Medical Association, 288, 2880-2883.

Haynes, R.B., McDonald, H.B., Garg, A.X., & Montague, P. (2004). Interventions for helping patients to follow prescriptions for medications. The Cochrane Database of Systematic Reviews, 2: CD000011. Retrieved July 5, 2007, from: http://gateway2.ovid.com/ovidweb.cgi

Hemingway, H., & Marmot, M. (1999). Psychosocial factors in the aetiology and prognosis of coronary heart disease: Systematic review of prospective cohort studies. British Medical Journal, 318(7196), 1460–1467.

Holloway, I., & Wheeler, S. (1995). Ethical issues in qualitative nursing research. Nursing Ethics, 2(3), 223-232 (doi: 10.1177/096973309500200305).

HQCC. (2006). A guide for health providers. The Health Quality and Complaints Commission, Queensland. Retrieved July 8, 2008, from: http://www.hqcc.qld.gov.au/_uploads/241111Fact_Sheet_-_A_guide_for_Health_Providers_-_170907.pdf

Jackson, G. (2000). The role of statins in acute coronary syndromes: Managing the unmet need. International Journal of Clinical Practice, 54(7), 445-449.

Jacobson, T. A. (2004). The forgotten cardiac risk factor: Noncompliance with lipid-lowering therapy. Medscape Cardiology, 8(2). Retrieved October 10, 2007, from: http://www.medscape.com.viewarticle/496144_print

Jacobson, T.A., & McKenney, J.M. (2006). Overview: Recommendations of the statin safety task force and benefit: Risk considerations with stain therapy. Medscape Cardiology, 10(2). Retrieved May 26, 2008, from: http://www.medscape.com.viewarticle/548530

Johnson, B.R., & Onwuegbuzie, A.J. (2004). Mixed methods research: A research paradigm whose time has come. Educational Researcher, 33(7), 14-26.

Jolliffe, J.A., Rees, K., Taylor, R.S., Thompson, D., Oldridge, N., & Ebrahim, S. (2000). Exercise-based rehabilitation for coronary heart disease. Cochrane Database of Systematic Reviews 2000, Issue 4. Article No. CD001800 (doi: 10.1002/14651858.CD001800). Retrieved June 18, 2008, from: http://mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD001800/frame.html

Kaplan, R.C., Bhalodkar, N.C., Brown, E.J., White, J., & Brown, D.L. (2004). Race, ethnicity, and sociocultural characteristics predict noncompliance with lipid-lowering medications. Preventive Medicine, 39(6), 1249-1255.

King, M. P. (2001). Cross-sectional and longitudinal research designs issues - In the studies of human development. Retrieved March 18, 2008, from The Graduate Research in Nursing Website: http://www.graduateresearch.com/King.htm#Prospective%20vs.%20Retrospective%20Research

Knapp, T.R. (1998). Quantitative nursing research. London: Sage Publications.

Kuper, H., Marmot, M., & Hemingway, H. (2005). Systematic review of prospective cohort studies of psychosocial factors in the etiology and prognosis of coronary heart disease. Seminars in Vascular Medicine, 2(3), 267-314.

Landmark statin trials. (n.d.). Retrieved September 30, 2007, from the Medscape Resource Centre Website: http://www.medscape.com/resource/statins/rc-statins4

LaRosa, J. (2005). Clinical implications of the TNT trial. Retrieved May 21, 2008, from: http://www.medscape.com/viewarticle/506717_print

LaRosa, J.C., Grundy, S.M., Waters, D.D., Shear, C., Barter, P., Fruchart, J-C., et al. (2005). Lipid lowering with atorvastatin in patients with stable coronary disease. New England Journal of Medicine, 352, 1425-1435.

Mackay, J. & Mensah, G. (Eds.). (2004). Global burden of coronary heart disease. Chapter 13 in: The atlas of heart disease and stroke, p.46. Geneva, Switzerland: World Health Organisation. Available from: http://www.who.int/cardiovascular_diseases/resources/atlas/en/

Mansur, A.P., Mattar, A.P.L., Tsubo, C.E., Simao, D.T., Yoshi, F.R., & Daci, K. (2001). Prescription and adherence to statins of patients with coronary artery disease and hypercholesterolemia. Arquivos Brasileiros de Cardiologia, 76, 115-118.

Mathur, S. (2002). Epidemic of coronary heart disease and its treatment in Australia. Cardiovascular Disease Series, No. 20. AIHW Cat. No. CVD 21. Retrieved May 14, 2008, from Australian Institute of Health and Welfare Website: http://www.aihw.gov.au/publications/cvd/echdta/echdta.pdf

Maviglia, S.M., Telch, J.M., Fiskio, J., & Bates, D.W. (2001). Using an electronic medical record to identify opportunities to improve compliance with cholesterol guidelines. Journal of General Internal Medicine, 16, 531-537.

McAllister, J. (2000). Antiretroviral drug therapy for HIV-infection: Developing an adherence framework. Retrieved May 22, 2008, from: http://www.clininfo.health.nsw.gov.au/hospolic.stvincents/2000/drug_therapy.html

McColl, E., Jacoby, A., Thomas, L., Soutter, J., Bamford, C., Steen, N., et al. (2001). Design and use of questionnaires: A review of best practice applicable to surveys of health service staff and patients. Health Technology Assessment, 5(31). Retrieved April 4, 2008, from: http://www.ncchta.org/pdfexecs/summ531.pdf

McDonald, H.B., Garg, A.X., & Haynes, R.B. (2002). Interventions to enhance patient adherence to medication prescriptions. Journal of the American Medical Association, 228(22), 2868-2879.

McElduff, P., Dobson, A.J., Jamrozik, K., & Hobbs, M.S.T. (2001). Opportunities for control of coronary heart disease in Australia. Australian and New Zealand Journal of Public Health, 25(1), 24-30.

McIntyre, P. (2006). Creative practice as research: 'Testing out' the systems model of creativity through practitioner based enquiry. Retrieved April 4, 2008, from: http://www.speculation2005.qut.edu.au/papers/McintyreP.pdf

McQuarrie, E.F. (2005). The market research toolbox: A concise guide for beginners (2nd ed.). London: Sage Publications.

Medicare Australia. (n.d.). Medicare Australia information retrieved July 6, 2008, from: http://www.medicareaustralia.gov.au/ (also see: http://www.tourhosts.com.au/archive/ipba2006/pdf/medicare.pdf)

Ministerial Taskforce. (1999). Nursing recruitment and retention. Retrieved April 16, 2008, from Queensland Health Website: http://www.health.qld.gov.au/nursing/docs/3484_3.pdf

Morrow, D.A., de Lemos, J.A., Sabatine, M.S., Wiviott, S.D., Blazing, M.A., Shui, A., et al. (2006). Clinical relevance of C-reactive protein during follow-up of patients with acute coronary syndromes in the aggrastat-to-zocor trial. Circulation, 114, 281-288.

Musselwhite, K., Cuff, L., McGregor, L., & King, K. (2007). The telephone interview is an effective method of data collection in clinical nursing research: A discussion paper. International Journal of Nursing Studies, 44(6), 1064-1070.

NHFA. (2007). Heart disease risk factors. Retrieved April 28, 2008, from: http://www.heartfoundation.org.au/Heart_Information/Risk_Factors.htm

NHFA & ACRA. (2004). Recommended Framework for Cardiac Rehabilitation '04. National Heart Foundation of Australia and Australian Cardiac Rehabilitation Association. Available from: http://www.heartfoundation.org.au/document/NHF/cr_04_rec_final.pdf

NHFA & CSANZ. (2001). Lipid management guidelines - 2001. National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand. Medical Journal of Australia, 175 (Supplement), S57-S85. Retrieved January 28, 2008, from: http://www.heartfoundation.org.au/document/NHF/guideline_lipid_mgt_2001.pdf

NHFA & CSANZ. (2005). Position statement on lipid management - 2005. The National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand. Retrieved January 28, 2008, from: http://www.heartfoundation.org.au/document/NHF/Lipids_HLCPosStatementFINAL_2005.pdf

NHFA & CSANZ. (2007). Reducing the Risk in Heart Disease 2007 - A summary guide for preventing cardiovascular events in people with coronary heart disease. National Heart Foundation of Australia and the Cardiac Society of Australia and New Zealand. Retrieved, January 28, 2008, from: http://www.heartfoundation.org.au/document/NHF/reducingrisk_heartdisease_summary_2007.pdf

Nissen, S.E., Murat, T.E., Schoenhagen, P., Brown, B.G., Ganz, P., Vogel, R.A., et al. (2004). Effect of intensive compared with moderate lipid-lowering therapy on progression of coronary atherosclerosis: A randomized controlled trial. Journal of the American Medical Association, 291(9), 1071-1080.

Nissen, S.E., Nicholls, S.J., Sipahi, I., Libby, P., Raichlen, J.S., Ballantyne, C.M., et al. (2006). Effect of very high-intensity statin therapy on regression of coronary atherosclerosis, the ASTEROID trial. Journal of the American Medical Association, 295(13), 1556-1565.

Nixon, J.V., (2006). Who should receive a statin drug to lower cardiovascular risk? Does the drug and the dose of the drug matter? Journal of Vascular Health and Risk Management, 2(4) 441–446.

O'Cathain, A., & Thomas, K.J. (2004). "Any other comments?" Open questions on questionnaires - a bane or a bonus to research? Medical Research Methodology, 4(1), 25 (doi: 10.1186/1471-2288-4-25).

Osterberg, L., & Blaschke, T. (2005). Adherence to medication. The New England Journal of Medicine, 353, 487-497.

Pedersen, T.R., Wilhelmsen, L., Faergeman, P., Strandberg, T.E., Thorgeirsson, G., Troedsson, L., et al. (2000). Follow-up study of patients randomized in the Scandinavian simvastatin survival study (4S) of cholesterol lowering. American Journal of Cardiology, 86, 257–262.

Panacek, E.A., (2000). Designing and performing cohort studies. Retrieved July 11, 2008 from: http://www.saem.org/download/panacek2.pdf Edward A.,

Peters, T. (1993). The Heart - Diagnostic procedures. New Jersey, USA: Peters & Co.

Peters, T. (1994). Cardiac interventional procedures - Heart disease. New Jersey, USA: Peters & Co.

Petersen, S., Peto, V., & Rayner, M. (2004). Coronary heart disease statistics 2004. Retrieved January 28, 2008, from: http://www.heartstats.org/uploads/documents%5C2004pdf.pdf

Pink, B. (2008). Cardiovascular disease. In 2008 Year Book Australia. Australian Bureau of Statistics, 90, pp. 346-347. ABS Catalogue No. 1301.0. Retrieved April 28, 2008, from: http://www.ausstats.abs.gov.au/ausstats/subscriber.nsf/0/8D6ED0E197FE38A6CA2573E7000EC2AD/$File/13010_2008.pdf

Polit, D.F., & Beck, C.T. (2006). Essentials of nursing research: Methods, appraisal, and utilization (6th ed.). Philadelphia: Lippincott Williams & Wilkins.

Polit, D.F., Beck, C.T., & Hungler, B.P. (2005). Essentials of Nursing Research: Methods, Appraisal, and Utilization (5th ed.). New York: Lippincott Williams & Wilkins.

Private Health. (n.d.). privatehealth.com.au: Australian health system. Retrieved July 6, 2008, from: http://www.privatehealth.com.au/ahs.htm

Putzer, G., Roetzheim, R., Ramirez, A.M., Sneed, K., Brownlee, H.J., & Campbell, R.J. (2004). Compliance with recommendations for lipid management among patients with Type 2 diabetes in an Academic Family Practice. Journal of the American Board of Family Practice, 17(2), 101-107.

Queensland Health. (2004). Transoesophageal echocardiogram (TOE) - Procedural consent form and consent information. Retrieved June 13, 2008, from: http://www.health.qld.gov.au/informedconsent/ConsentForms/cardiac/cardiac_23.pdf

Radhakrishna, R.B. (2007). Tips for developing and testing questionnaires/instruments. Journal of Extension, 45(1). Article No. 1TOT2. Retrieved April 27, 2008, from: http://www.joe.org/joe/2007february/tt2p.shtml

Ramsay, S.E., Whincup, P.H., Lawlor, D.A., Papacosta, O., Lennon, L.T., Thomas, M.C., Ebrahim, E., & Morris, R.W. (2006). Secondary prevention of coronary heart disease in older patients after the national service framework: Population based study. British Medical Journal, 332, 144-145.

Redfern, J., Ellis, E.R., Briffa, T., & Freedman, S.B. (2007). High risk-factor level and low risk-factor knowledge in patients not accessing cardiac rehabilitation after acute coronary syndrome. The Medical Journal of Australia, 186(1), 21-25.

Rice, M. (Ed.). (1999). A Practitioner's Guide to Cardiac Rehabilitation. Australian Cardiac Rehabilitation Association (no other publishing details given).

Sacks, F.M., Pfeffer, M.A., Moye, L.A., Rouleau, T.L., Rutherford, J.D., Cole, T.G., et al. (1996). The effects of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels (CARE). New England Journal of Medicine, 335(14), 1001-1009.

Satia-Abouta, J., Patterson, R.E., King, I.B., Stratton, K.L., Shattuck, A.L., Kristal, A.R., et al. (2003). Reliability and validity of self-report of vitamin and mineral supplement use in the vitamins and lifestyle study. American Journal of Epidemiology, 157(10), 944-954.

Sawyer, S.M., & Fardy, H.J. (2003). Bridging the gap between doctors' and patients' expectations of asthma management. Journal of Asthma, 40(2), 131-138.

Scandinavian Simvastatin Study Group. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S).

Lancet. 1994;344:1383-1389.

Scanlon, P.J., Faxon, D.P., Audet, A-M., Carabello,B., Dehmer, G.J., Eagle, K.A., et al. (1999). ACC/AHA guidelines for coronary angiography: Executive summary and recommendations. Circulation, 99, 2345-2357. Retrieved May 4, 2008, from: http://www.circ.ahajournals.org/cgi/content/full/99/17/2345

Schneider, A., Elliott, D., LoBiondo-Wood, G., & Haber, J. (2003). Nursing research: Methods, critical appraisal and utilisation. Sydney: Mosby.

Scott, I.A, Lindsay, K.A., & Harden, H.E. 2003. Utilisation of outpatient cardiac rehabilitation in Queensland. Medical Journal of Australia, 179(7), 341-345.

Senterfitt, W. (1998). The challenge of medication adherence. Retrieved January 28, 2008, from: http://www.beingalivela.org/news0698/0698_chall.html

Shepherd, J., Cobbe, S.M., Ford, I., Isles, C.G., Lorimer, A.R., Macfarlane, P.W., et al. (1995). The west of Scotland coronary prevention study (WOSCOPS). New England Journal of Medicine, 333, 1301-1307.

Shields, P.M., & Tajalli, H. (2006). Intermediate theory: The missing link to successful student scholarship. Retrieved April 16, 2008, from: http://ecommons.txstate.edu/cgi/viewcontent.cgi?article=1036&context=polsfacp

Simons, L.A., Levis, G., & Simons, J. (1996). Apparent discontinuation rates in patients prescribed lipid-lowering drugs. Medical Journal of Australia, 164, 208-211.

Smith, S.C. (2000). Clinical treatment of dyslipidaemia: Practice patterns and missed opportunities. American Journal of Cardiology, 86 (Supplement), 62L-65L.

Smith, S.C., Blair, S.N., Bonow, R.O., Brass, L.M., Cerqueira, M.D., Dracup, K., et al. (2001). AHA/ACC guidelines for preventing heart attack and death in patients with atherosclerotic cardiovascular disease: 2001 update. Circulation, 104, 1577-1579.

Smith, S.C., Allen, J., Blair, S.N., Bonow, R.O., Brass, L.M., Fonarow, et al. (2006). AHA/ACC guidelines for secondary prevention for patients with coronary and other atherosclerotic vascular disease: 2006 update. Journal of the American College of Cardiology, 47, 2130-2139.

Steultjens, M.P.M., Roorda, L.D., Dekker, J., & Bijlsma, J.W.J. (2001). Responsiveness of observational and self-report methods for assessing disability in mobility in patients with osteoarthritis. Arthritis Care and Research, 45(1), 56-61.

Stilley, C.S., Sereika, S., Muldoon, M.F., Ryan, CM., & Dunbar-Jacob, J. (2004). Psychological and cognitive function: Predictors of adherence with cholesterol lowering treatment. Annals of Behavioural Medicine, 2, 117-124.

Sundararajan, V., Bunker, S.J., Begg, S., Marshall, R., & McBurney, H. (2004). Attendance rates and outcomes of cardiac rehabilitation in Victoria, 1998. Medical Journal of Australia, 180, 268–271. Retrieved on June 14, 2007, from: http://www.mja.com.au/public/issues/180_06_150304/sun10417_fm.pdf

Thavendiranathan, P., Bagai, A., Brookhart, M.A., & Choudhry, N.K. (2006). Primary prevention of cardiovascular diseases with statin therapy: A meta-analysis of randomised controlled trials. Archives of Internal Medicine, 166, 2307-2313.

Thom, T., Haase, N., Rosamond, W., Howard, V., Rumsfeld, J., Manolio, T., et al. (2008). Heart disease and stroke statistics - 2006 update: A report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Circulation, 113, 85-151.

Tonkin, A., Aylward, P., Colquhoun, D., Glasziou, P., Harris, P., Hunt, D., et al. (1998). Prevention of cardiovascular events and death with pravastatin in patients with coronary heart disease and a broad range of initial cholesterol levels: The long-term intervention with pravastatin in ischaemic disease (LIPID) study group. Retrieved May 20, 2008, from: http://content.nejm.org/cgi/content/full/339/19/1349

Tunstall-Pedoe, H. (Ed.) (2003). The WHO MONICA Project. MONICA Monograph and Multimedia Sourcebook, World Health Organization. Retrieved January 28, 2007, from: http://whqlibdoc.who.int/publications/2003/9241562234.pdf

Vita-Finzi, L. (2008). Preventing chronic disease, a vital investment. Retrieved January 12, 2008, from World Health Organization Website: http://www.who.int/chp/chronic_disease_report/en/

Vos, T., & Begg, S. (2007). The burden of cardiovascular disease in Australia for the year 2003. Retrieved November 29, 2007, from the National Heart Foundation of Australia Website: http://www.heartfoundation.org.au/document/NHF/Burden_of_CVD_2003_Web_07Aug.pdf

Wang, T.J., Stafford, R.S., Ausiello, J.C., & Chaisson, C.E. (2001). Randomized clinical trials and recent patterns in the use of statins. American Heart Journal, 141(6), 957-963.

Wei, L., Wang, J., Thompson, P., Wong, S., Struthers, A.D., & MacDonald, T.M. (2002). Adherence to statin treatment and readmission of patients after myocardial infarction: A six year follow up study. Heart, 88, 229-233.

Weinrauch, L. A. (2007). MedlinePlus medical encyclopaedia. Retrieved March 20, 2008, from: http://www.nlm.nih.gov/medlineplus/ency/article/007115.htm

Worth, A., & Tierney, A.J. (1993). Conducting research interviews with elderly people by telephone. Journal of Advanced Nursing, 18(7), 1077-1084.

Yacopetti, N. (1999). Re-thinking the approach to health care delivery reviewing patient compliance. Retrieved May 22, 2008, from: http://www.ciap.health.nsw.gov.au/hospolic/stvincents/stvin99/Nic.htm

Yoon, S.L., & Horne, C.H. (2004). Accruing the sample in survey research. Southern Online Journal of Nursing Research, 5, Issue 2. Retrieved June 3, 2008, from: http://www.snrs.org/publications/SOJNR_articles/iss02vol05.pdf

Yusuf, S., Reddy, S., Ôunpuu, S., & Anand, S. (2001). Global burden of cardiovascular diseases. Part I: General considerations, the epidemiologic transition, risk factors, and impact of urbanization. Circulation, 104, 2746–2753.