To develop and trial a new warfarin education program

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To develop and trial a new warfarin education program

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I, Judy Mullan, declare that this thesis, submitted in partial fulfillment of the requirements for the award of Doctor of Philosophy, in the Graduate School of Public Health, University of Wollongong, is wholly my own work, unless otherwise referenced or acknowledged. The document has not been submitted for qualifications at any other academic institution.

Judy R Mullan

21 June 2005
ABSTRACT

The principal purpose of this study was to identify, develop and trial a new warfarin education program to enhance warfarin knowledge, management and compliance in a wider patient population, inclusive of the ‘high risk’ group. This ‘high risk’ group included patients who were elderly, had low literacy skills and came from non-English speaking backgrounds.

Effective patient education is a central part of the practice of all health professionals because it helps to ensure safe and effective warfarin management. With recent increases in warfarin prescribing and warfarin-related adverse drug events the need for an effective patient warfarin education program is more apparent.

The study aims to improve currently available warfarin education programs delivered to warfarin prescribed patients in a home-based setting. The new program is conceptually based on five key elements: improved health professional/patient communication and partnerships; improved warfarin compliance; simple, easy-to-read warfarin information, improved continuity of care between hospital and community settings; and improved patient follow-up.

Unfortunately, during the course of the study, many similar strategies and interventions targeting these key elements were incorporated into the customary program, as well as the new program, which may have impacted on the final results of the study.

The study was conducted from February 2003 to February 2004, on consenting patients who were prescribed warfarin and admitted to Illawarra Health’s The Ambulatory Care Team (TACT). This prospective study included 50 intervention patients receiving the new warfarin education program, and 52 control patients receiving the customary warfarin education program offered to TACT patients. Many of these patient participants also came from the ‘high risk’ group, which included; the elderly, those with low literacy skills and those from non-English speaking backgrounds.

The evaluation phase of the study involved comparing and contrasting the effectiveness of the new warfarin education program against the customary
warfarin education program, in terms of the patients’ warfarin knowledge, management and compliance. The patients’ satisfaction with the information received and their therapeutic outcomes (therapeutic INR scores, healthcare visits and warfarin-related adverse drug events) were also compared and contrasted between the two programs.

The findings of this study suggest that the new warfarin information booklet (APPENDIX 12) was written in a better quality, easier-to-read format, than was the Boots warfarin information booklet (2003). Overall, the trend in the results suggested that the new warfarin education program more effectively educated patients, including the ‘high risk’ patients, about their warfarin therapy, as compared to the customary warfarin education program. The patients receiving the new warfarin education program were more knowledgeable about their warfarin, more confidently managed and complied with their warfarin therapy at home, and achieved better therapeutic outcomes, than did patients who received the customary warfarin education program. Interestingly, both the new and the customary warfarin education programs used in this study appeared to be more effective than other available warfarin education programs, achieving better warfarin knowledge scores and therapeutic outcomes, with fewer warfarin-related adverse drug events and healthcare visits.

The implications of this study are that by targeting the five key elements of an effective warfarin education program we can help to improve warfarin knowledge, management and compliance in many patients, including those from the ‘high risk’ group. Education based on the five key elements empowers patients to make educated decisions about their warfarin therapy; which in turn help to optimise their warfarin-related therapeutic outcomes and minimise warfarin-related adverse drug events.

One of the major benefits of this research, is that the five key elements of an effective patient education program, used in this new warfarin education program, can be generically applied to other patient medication education programs.
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CHAPTER 1
INTRODUCTION

1.1 INTRODUCTION

Medication-related errors are the major cause of adverse events within the healthcare system both in Australia and overseas, causing an estimated 10-20 percent of all medically related adverse events (Bates 1999; Dartnell, Anderson, Chohan, Galbraith, Lyon, Nestor and Moulds 1996; Leape, Kabcenell, Berwick and Roessner 1998). Australian research has shown that between 2 and 4 percent of all hospital admissions are due to adverse drug events, with an estimated cost of at least $350 million per annum (Australian Council for Safety and Quality in Health Care 2002; Roughead 1999; Runciman, Roughead, Semple and Adams 2003). A large proportion of these adverse events could be prevented by improving patient education and communication (Forster, Asmis, Clark and Saied 2004; Wilson, Runciman, Gibberd, Harrison, Newby and Hamilton 1995). The ‘Improving Medication Safety Workshop’ (Australian Council for Safety and Quality in Health Care 2001) recommended a national approach to reducing adverse drug events by targeting specific medications such as warfarin.

Inadequate patient education has been identified as a major cause of adverse drug events involving warfarin in hospital and community settings (Bhasale, Miller, Britt and Reid 1996). For ‘high risk’ groups which include the elderly, those with low literacy skills and people from non-English speaking backgrounds, the lack of literacy can be a major obstacle to effective healthcare, communication and education (Doak, Doak, Friedell and Meade 1998). Written patient medication information, including warfarin information, is often pitched at a level beyond the comprehension of patients with low literacy skills, who, without adequate education, face unnecessary health risks and possible hospitalisation (Baker, Parker, Williams and Clark 1998; Baker 1997; Estrada, Barnes, Martin-Hryniewicz, Collins and Byrd 1999; Estrada, Hryniewicz, Barnes-Higgs, Collins and Byrd 2000).
This thesis reports the development, implementation and evaluation of a new warfarin education program. The new program is founded on a conceptual framework targeting five key elements:

- health professional/patient communication and partnerships
- warfarin compliance
- simple, easy-to-read warfarin information
- the continuity of care between hospital and community settings
- patient follow-up.

The thesis contends that by incorporating strategies and interventions to target and improve these five key elements, there will be an improvement in the patients’ warfarin knowledge, management and compliance which will ultimately lead to optimal therapeutic outcomes and minimal adverse drug events. Special consideration in the development of the new program was given to the ‘high risk’ patient population, which include the elderly, those with low literacy skills and those from non-English speaking background.

The following two chapters discuss the literary sources used to support the need for a new warfarin education program, inclusive of simple, easy-to-read warfarin information. They also provide the evidence for the five key elements, which need to be targeted when producing an effective warfarin education program.

The fourth chapter describes the conceptual framework used to develop the new warfarin education program and the fifth chapter deals with the methodology used to target the key elements. Processes used to develop the new, simple and easy-to-read warfarin information booklet are described, as are interventions and strategies to improve health professional/patient communication and partnerships, warfarin compliance, continuity of care between hospital and community settings and patient follow-up. Chapter five also describes how evaluation questionnaires and outcome data were used to compare and contrast the new warfarin education program against the customary warfarin education program delivered to the patients admitted to Illawarra Health’s The Ambulatory Care Team (TACT).
The results of this research study and an analysis of the data collected for the 102 patient participants during the evaluation phase are summarised in Chapter 6. Information is provided about the improved readability, quality and suitability of the new warfarin booklet (APPENDIX 12), as compared to the Boots warfarin information booklet (2003) and other available written warfarin information. Data regarding the patients' warfarin knowledge, management and compliance was evaluated to compare the effectiveness of the new program against the customary warfarin education program delivered to The Ambulatory Care Team (TACT) patients. The data was also used to compare the patients’ satisfaction with the information they received and their therapeutic outcomes (i.e. therapeutic International Normalised Ratio (INR) scores and healthcare visits) over the three month follow-up period between the two groups.

The final chapter provides an overview of the study with discussions about the results, limitations, recommendations and implications for both current practice in warfarin education and future research. Detailed description is provided about the improved warfarin knowledge, management and compliance, as well as improved satisfaction and therapeutic outcomes for the patients receiving the new warfarin education program as compared to the customary warfarin education program. Acknowledgement is made about the fact that many similar strategies and interventions targeting the five key elements incorporated into the new warfarin education program were also incorporated into the customary warfarin education program. This certainly impacted on the final results making them less significantly different than initially expected. However based on the overall improvement in the warfarin education for all patients receiving the new warfarin education program, including the ‘high risk’ group, it is recommended that all home-based warfarin education programs adapt the new program as a best practice model for an effective warfarin education program. Based on the success of the results in this study, the final chapter concludes with a recommendation that to be effective all patient medication education programs need to target improving the following five key elements; health professional/patient communication and partnerships; medication compliance;
simple, easier-to-read medication information; continuity of care between hospital and community settings; and patient follow-up.

1.2 ABOUT THIS STUDY

The focus of this research is the development and evaluation of a new warfarin education program for a home-based ambulatory care service. The objective of the new program was to improve warfarin knowledge, management and compliance in a wider patient population, inclusive of the ‘high risk’ group.

The literature has identified inadequacies in current patient medication education practices, especially with regard to warfarin, in both hospital and community based settings. The researcher has witnessed first hand the impact of these inadequacies both professionally and personally. Professionally, through 20 years of experience as a hospital and community pharmacist, and personally, through her parents, who come from a non-English speaking background.

The patient populations who have the most problems with their medications and knowing how to manage them include the elderly, those with low literacy skills and those from non-English speaking backgrounds (Baker, Parker, Williams, Pitkin, Parikh, Coates and Imara 1996; Forster, Asmis et al. 2004; Nadar, Begum, Kaur, Sandhu and Lip 2003). Unfortunately, with limited time and resources during busy working schedules of health professionals who treat them, these patients are often poorly educated resulting in an increased incidence of poor therapeutic outcomes and adverse drug events (Australian Council for Safety and Quality in Health Care 2002). This research is important because it seeks to provide effective warfarin education to a patient population, inclusive of this ‘high risk’ group, which will help to reduce the large incidence of poor warfarin-related therapeutic outcomes and adverse drug events reported in the literature (Halstead, Roughead, Rigby, Clark and Gallus 1999).

This thesis contends that the improved warfarin knowledge and understanding acquired by patients from the new warfarin education program will empower them to make confident, informed decisions about their warfarin
management and compliance. The objective is to help optimise warfarin-related therapeutic outcomes and minimise warfarin-related adverse drug events (Australian Council for Safety and Quality in Health Care 2002).

1.3 OVERVIEW OF THE STUDY

The principal purpose of this study was to identify, develop and trial a new warfarin education program to enhance warfarin knowledge, management and compliance in a wider patient population. In order to achieve this several stages were included in the study:

- The first stage of the study involved the development of a new warfarin education program and a new warfarin information booklet, based on the best evidence with regard to effective patient medication education programs.
- The second stage of the study involved a 10-person ‘pilot test’ of the new warfarin education program to ensure that the new booklet, education session and evaluation questionnaires could be readily understood and answered by the pilot sample typical of the study population.
- The third stage of the study involved a comparative analysis of the new warfarin education program against the customary warfarin education program delivered to patients admitted to Illawarra Health’s, The Ambulatory Care Team (TACT). Comparing and contrasting the two programs, immediately and three months after the initial warfarin education session involved comparing the participating patients’ warfarin knowledge, management and compliance, as well as their satisfaction with the warfarin education programs. Outcome measures included: the proportion of therapeutic International Normalised Ratio (INR) scores; the number of general practitioner, emergency department and hospital visits; and the number of warfarin-related adverse drug events.
1.4 VALUE OF THIS RESEARCH

Warfarin is an oral anticoagulant which, until recently, has been mainly prescribed for deep venous thrombosis, pulmonary embolus, prosthetic heart valves, post hip surgery or to prevent the recurrence of myocardial infarction (Ansell, Buttaro, Thomas, Knowlton and The Anticoagulation Guidelines Task Force 1997; Gallus 1999). Recently, it has been found that warfarin dramatically reduces the risk of embolic stroke in patients with atrial fibrillation (AF) and that treatment benefits significantly outweigh the risks in these patients (Campbell, Roberts, Eaton, Coghlan and Gallus 2001; Tillman, Charland and Witt 2000). These new indications will increase the number of patients being prescribed warfarin (Cruickshank, Ragg and Eddey 2001; The Newcastle Anticoagulation Study Group 1998) and almost certainly increase the incidence of warfarin-related adverse events, based on current educational practices (Gurwitz, Field, Harrold, Rothschild, Debellis, Seger, Cadoret, Fish, Garber, Kelleher and Bates 2003; Halstead, Roughhead et al. 1999).

Historically, patient warfarin education has been inadequate (Connor 1998) and the amount of information given possibly even overwhelming (Ansell, Buttaro et al. 1997). A lack of patient education has been identified as a major cause of poor warfarin-related therapeutic outcomes and adverse drug events in both hospital and community settings (Bhasale, Miller et al. 1996; Halstead, Roughhead et al. 1999). It is timely therefore, to develop a more systematic approach to the delivery of warfarin education, which addresses the needs of a wider patient population, inclusive of elderly, low literacy and non-English speaking background patients. Such a program should aim to improve warfarin-related therapeutic outcomes and minimise adverse drug events by empowering patients to successfully comply with and manage their warfarin therapy at home, based on their improved warfarin knowledge and understanding.
1.5 THE SIGNIFICANCE OF THIS RESEARCH

Patient education is a central part of the practice of all health professionals and is a very important way in which to ensure safe and effective warfarin management. To date, warfarin education programs have been identified as primarily unstructured and inadequate (Bhasale, Miller et al 1996; Ansell Buttaro et al 1997; Connor 1998 and Halstead, Roughead et al 1999). This research assesses whether the way in which the warfarin education program is structured, the presentation of the written warfarin information and improved collaboration between patients, carers and relevant health professionals will have an impact on the effectiveness of the education program.

The new warfarin education program, which is delivered to patients in a home-based setting, is based on a conceptual framework incorporating the five key elements of an effective warfarin education program. The strategies and interventions introduced in the new program also address the needs of the 'high risk' patient population, in an attempt to ensure that they also benefit from the program and achieve optimal therapeutic outcomes with minimum adverse drug events.

One of the major benefits of this research is that the five key elements of an effective patient education program used in this new warfarin education program can also be generically applied to other patient medication education programs in both hospital and community settings.
CHAPTER 2
IDENTIFYING THE KEY ELEMENTS IN THE LITERATURE WHICH CONTRIBUTE TO ADVERSE DRUG EVENTS, INCLUDING WARFARIN-RELATED ADVERSE DRUG EVENTS

2.1 INTRODUCTION
In 1995, the use of medications in Australia was reported to be the most common health-related action taken by people suffering from illness or injury (ABS 1999). With that salient fact in mind, the purpose of this study was to promote improved warfarin medication education in a wider patient population, to help optimise therapeutic outcomes and minimise adverse drug events. The oral anticoagulant, warfarin, is the focus of this study because its inappropriate use is a large and unresolved problem (Halstead, Roughead et al. 1999). Warfarin also has the potential of becoming an even bigger problem with recent increases in prescribing for patients suffering from atrial fibrillation (Cruickshank, Ragg et al. 2001; Ezekowitz and Falk 2004).

This chapter commences with an introduction to patient education and its potential impact on therapeutic outcomes and adverse drug events. Further it reviews adverse drug events and their impact on healthcare costs by way of hospital admissions and general practitioner encounters. Medication-related adverse event terms are defined and the incidence of adverse drug events in Australia, are discussed. Key factors which contribute to adverse drug events are identified and include: poor health professional/patient communication and partnerships; poor medication compliance; inappropriate written medicine information; poor continuity of care between hospital and community settings; and poor patient follow-up (Australian Council for Safety and Quality in Health Care 2002; Roughead and Gilbert 2002). Consideration in this chapter is given to
implementing strategies and interventions to target each of these key elements, with a view to developing an effective warfarin education program.

The chapter concludes with an overview of the increasing problem of warfarin-related adverse drug events (Campbell, Roberts et al. 2001; Hirri and Green 2002), which may in part be due to the increase in warfarin prescribing (Elliott, Woodward and Oborne 2002; Gallus, Baker, Chong, Ockelford and Street 2000; Peterson, Jackson and Bereznicki 2002), as well as inadequacies in the currently available warfarin education programs (Connor 1998). This increasing incidence of warfarin-related adverse drug events and warfarin knowledge deficits in many patients (Cheah and Martens 2003; Nadar, Begum et al. 2003; Tang, Lai, Lee, Wong, Cheng and Chan 2003) highlight the need for a new, effective warfarin education program. Importantly, this new warfarin education program should be designed to address the needs of the ‘high risk’ patient population (the elderly, those with low literacy skills and those from non-English speaking backgrounds) who are more likely to experience poor warfarin-related outcomes (Estrada, Martin-Hryniewicz, Peek, Collins and Byrd 2004; Lambert and Wynne 2003; Nadar, Begum et al. 2003). When used in conjunction with the home healthcare delivery services (McGuire, Stowasser and Collins 1997), it is envisaged that this new education program will help to improve warfarin-related therapeutic outcomes and reduce the incidence of warfarin-related adverse drug events.

2.2 RATIONALE FOR THE SEARCH STRATEGY

Serious limitations in available warfarin education programs became increasingly apparent to the researcher through her 20 years’ experience as a hospital and community pharmacist, and through her elderly migrant parents. The researcher was also involved in developing and writing medication information leaflets over many years, and attempted, unsuccessfully, to persuade Boots Healthcare to rewrite its information booklet, ‘Warfarin: important instructions for patients’ (2002, 2003) in a simpler, more accessible format. The researcher then became interested in reviewing the home-based warfarin
education program delivered to Illawarra Health’s The Ambulatory Care Team (TACT) patients, including the development of a new simple, easy-to-read information booklet, leading to the study presented in this thesis.

The literature reviewed for this study focused on available patient medication information and in particular, warfarin information written in English. They also focused on ways in which to educate patients effectively about their medications, including improving their medication knowledge and understanding, management and compliance.

2.2.1 The search strategy

A number of sources were used to search the literature about factors possibly affecting patient medication education, medication compliance, therapeutic outcomes and adverse drug events. Pubmed (1966-present), CINAHL (1996-2004; 1966-present) and MEDLINE (1996-2004; 1966-present) were among the most commonly used databases. Proquest 5000 (Health and Medical), Expanded Academic Index (1980-Present), Australian Medical Index (AMI), Synergy (1999-present), Science Direct, Embase and the Cochrane Database of Systematic Reviews were also frequently accessed. The AUSTATS database was used to search Australian Bureau of Statistics (ABS) information, the Australian Institute of Health and Welfare (AIHW) website, the TGA website and the Web of Science database (1975-present) provided useful citation indices, which then could be further investigated. Finally, the First Search database and other Australian University sites were accessed to scan for any relevant theses, which may have been published about similar research studies. Only materials published in the English language or translated into English were accessed for the literature review.

The initial relevant search terms were quite broad and included: adverse drug events; medication compliance and/or concordance; community based patient compliance with drug therapy; medication self-management; patient education and teaching; medication information; continuity-of-care; patient follow-up; evaluation of education programs; hospital-in-the-home programs;
literacy/culture/non-English speaking backgrounds; and medication. The search was then narrowed down to: oral anticoagulants; warfarin (coumadin); warfarin-related adverse drug events; warfarin compliance; warfarin education programs; warfarin information; the evaluation of warfarin education programs; the effects of literacy, culture and non-English speaking backgrounds on warfarin knowledge and understanding. Warfarin, adverse drug events, medication compliance and patient warfarin education programs proved to be the most useful terms for the search strategy. Nevertheless, each of these terms introduced the researcher to many articles that were subsequently excluded as they dealt with hospital inpatient medication education programs, health behaviour change models and medication self-management programs rather than the patients’ anticoagulation management and education by a multidisciplinary team in their own home, which became an important criterion for inclusion.

During the three year study, Medline and Cinahl alerts via Autorun@ovid.com were also organised to scan for weekly updates on the following search terms; ‘warfarin’, ‘medication compliance’, ‘medication education’, ‘communication barriers’ and ‘ethnic and cultural barriers’. As was expected there was a great deal of duplication among these databases. Even though over 200 sources were used in the literature review, there were very few papers found which explored the key elements of an effective patient medication education program, and in particular a patient warfarin education program. There were many sources, which discussed the need to improve patient warfarin knowledge and understanding as a means to optimise therapeutic outcomes and minimise adverse drug events.

Inadequacies in acquiring sufficient information from the databases were countered by accessing a variety of sources including books on the subject, reports and government documents. These were obtained through library catalogues, interlibrary loans, pertinent web sites and searching the bibliographies and references listed in some of the accessed articles and sources.
2.3 THE IMPACT OF PATIENT EDUCATION ON THERAPEUTIC OUTCOMES AND ADVERSE DRUG EVENTS

Patient education improves health outcomes by promoting healthy behaviour and involving patients in their own health care decisions (JCAHO 1998). The process begins with the imparting of information, but it also includes interpretation and integration of information to bring about attitudinal or behavioural changes that benefit a person’s health status (Rankin and Duffy Stallings 2000). Verbal communication, patient involvement, the readability of written information and an evaluation of the learning outcomes have all been identified as important issues to consider when providing patient education (Webber 1990).

During recent times the notion of patient-centred care with patient education as the central focus has been incorporated worldwide in strategies to help achieve better therapeutic outcomes and reduce the incidence of adverse drug events. Strategies which encourage patients to become active participants in the decision making process about their care are the basis of the Joint Commission on the Accreditation of Healthcare Organization (JCAHO) Standards for Patient Education (JCAHO 1993) in the United States, the Medicines Partnership Task Force (The Royal Pharmaceutical Society of Great Britain 1997) in the United Kingdom, and the recent ‘Consumer Engagement in Health Care’ (Australian Government Department of Health and Ageing 2005) initiatives supported by the Australian Government. Even though these initiatives are becoming commonplace worldwide, there is very little evidence about their impact reported in the literature, which often gives a largely one-sided view. The common position is that if a medication and/or therapeutic regimen is not followed as prescribed, then the problem must somehow be with the patient. Neither the behaviour nor the attitude of the health professional, or the structure of the education program, are taken into consideration when evaluating the effectiveness of such initiatives. It is important therefore, to consider this point when reading through the evidence available in the literature.
There are very few data in the literature about the impact of patient education alone on the medication related therapeutic outcomes and incidence of adverse drug events. Typically patient education is discussed as one of several interventions including counselling, familial support, follow-up, compliance aids (Roter, Hall, Merisca, Nordstrom, Cretin and Svarstad 1998) used to promote medication compliance, thereby improving therapeutic outcomes and reducing adverse drug events.

A recent systematic review, found that interventions delivered by pharmacists (e.g. medication education and counselling, written information, medication review etc) directed toward hypertensive, hypercholesterolemic, chronic heart failure, or diabetic patients improved therapeutic outcomes and decreased the use and/or cost of health services, compared to patients not receiving the interventions (Beney, Bero and Bond 2004). Pharmacist provided videotapes, booklets, educational newsletters and follow-up have all been found to improve medication compliance, especially amongst elderly patients (Poston, Loh and Dunham 1998). There is also evidence in the literature that elderly patients who received home based pharmacy counselling, medication review and education services were more likely to be compliant with their medication than were patients who only received a home visit (Lowe, Raynor, Purvis, Farrin and Hudson 2000).

Esposito (1995) evaluated four educational programs to see which would be more effective in increasing medication compliance amongst elderly patients. He found that elderly patients were less likely to be compliant if they were provided with (i) a medication fact sheet and a discharge summary sheet, or (ii) a medication fact sheet with 30 minutes of verbal instruction on discharge from hospital, as compared to the patients who received (iii) a medication schedule written in large dark lettering, with a list of side effects and a dosage schedule, or (iv) a medication schedule and 30 minutes of verbal instruction. Even though the patient population was small in this study (n = 42) and hence the findings could not be reported statistically. It is noteworthy that the patients given a medication schedule, also known as a medication regimen, were more likely to be compliant.
with their medications and less likely to suffer from any adverse drug events. These results support the earlier work of Ascione and Shimp (1984) who also found that a reminder aid (e.g. written information, a medication reminder calendar, or a medication reminder package) with verbal reinforcement improved medication knowledge and compliance in 158 ambulatory cardiovascular patients. These studies and a preponderance of information available in the literature suggest that both written and verbal information given together, compared to being given alone, help to improve the patients and/or carers knowledge and satisfaction, resulting in better patient outcomes and fewer visits to health care providers (Forster, Smith, Young, Knapp, House and Wright 2004; Issacman, Purvis, Gyuro, Anderson and Smith 1992; Jenkins, Blank, Miller, Turner and Stanwick 1996).

In summary, patient education has been found to improve therapeutic outcomes and reduce the incidence of adverse drug events by promoting good medication compliance. During recent times, worldwide organizations have taken patient education one step further by encouraging patients to become active participants in the decision making process. According to the evidence in the literature successful patient medication interventions include: the provision of medication information (verbal and written), medication counselling, medication reviews and home based follow-up by all healthcare professionals and especially the pharmacist.

2.4 ADVERSE EVENTS

2.4.1 Background

Adverse events are a major concern to the healthcare system, causing significant personal burden and healthcare costs. Medication incidents are recognised as a leading cause of adverse events both in Australia and internationally (Forster, Murff, Peterson, Gandhi and Bates 2003; Kohn, Corrigan and Donaldson 1999; Leape, Brennan, Laird, Lawthers, Localio, Barnes, Herbert, Newhouse, Weiler and Hiatt 1991; Wilson, Runciman et al. 1995). Many of these
Adverse drug events are considered to be potentially preventable (Forster, Murff et al. 2003; Wilson, Runciman et al. 1995) through effectively educating patients about their medications and empowering them to make informed decisions about their medication management and compliance (Australian Council for Safety and Quality in Health Care 2002; Bhasale, Miller, Reid and Britt 1998; Mullen, Simons-Morton, Ramirez, Frankowski, Green and Mains 1997). Patient populations deemed to be at particularly ‘high risk’ of experiencing adverse drug events include: the elderly (Forster, Asmis et al. 2004; Gurwitz, Field et al. 2003); those with low literacy skills (Baker, Parker et al. 1996; Doak, Doak et al. 1985; Feifer 2003); and patients from non-English speaking backgrounds (Nadar, Begum et al. 2003; Shaw, Hemming, Hobson, Nieman and Naismith 1977). Elderly patients (aged 65 years and over) are more likely to experience adverse drug events because they generally take more medications (Australian Council for Safety and Quality in Health Care 2002) and often suffer from cognitive and/or physical limitations (Stewart and Caranasos 1989). Patients with low literacy skills are more susceptible to adverse drug events (Feifer 2003) because they know significantly less about their disease and how to manage their medications (Williams, Baker, Parker and Nurss 1998). These deficits in medication knowledge and understanding have also been found to exist among the non-English speaking background (NESB) patients (Nadar, Begum et al. 2003; Wilson, Racine, Tekieli and Williams 2003). An Australian study found that a considerable proportion (35 percent) of their 257 NESB patient participants had little or no understanding about their drug therapy (dose, frequency and drug function) (Shaw, Hemming et al. 1977), which almost certainly predisposed them to adverse drug events and poor compliance.

It is important, therefore, to examine what is known about adverse drug events and how their incidence can be reduced or even potentially prevented by way of improved patient medication education. It is also important to note that interventions and strategies which target improved patient medication education, should always consider the needs of the ‘high risk’ patient population.
2.4.2. Definitions

Due to the varying use of terms in the literature and throughout this chapter, specific definitions of medication related adverse events are listed below. The terms ‘adverse event’, ‘medication incident’, ‘adverse drug event’, ‘adverse drug reaction’ and ‘medication error’ are all used to describe medication related problems (Australian Council for Safety and Quality in Health Care 2002).

- An *Adverse Event* (AE) is an incident in which harm resulted to a person receiving healthcare (Australian Council for Safety and Quality in Health Care 2001).
- *Medication incidents* are problems which occur in the prescription, dispensing and administration of medicines (Australian Council for Safety and Quality in Health Care 2002).
- An *Adverse Drug Event (ADE)* is a medication incident which leads to patient harm (Australian Council for Safety and Quality in Health Care 2002).
- An *Adverse Drug Reaction (ADR)* is a side effect caused by a medication on its own or in combination with other drugs (Australian Council for Safety and Quality in Health Care 2002).
- A *medication error* is a failure in the (drug) treatment process that leads to, or has the potential to, harm the patient (Ferner and Aronson 2000) and includes an act of omission or commission (Australian Council for Safety and Quality in Health Care 2001).
- *Preventability* of an adverse event is an error in management due to failure to follow accepted practice at an individual or system level (Wilson, Runciman et al. 1995)
- *Potentially preventable* includes the adverse events with a preventability scale of 50 percent or more (Wilson, Runciman et al. 1995)
2.4.3 Incidence of adverse drug events

Australian data indicate that adverse drug events make a significant contribution to unplanned hospital admissions. The Australian national hospital morbidity database shows that for a twelve month period from 1999 to 2000, 69,766 hospital separations were due to adverse drug events (Australian Council for Safety and Quality in Health Care 2002; Runciman, Roughead et al. 2003). Between 2 and 4 percent of all Australian hospital admissions have been identified to be medication related (Australian Council for Safety and Quality in Health Care 2002; Runciman, Roughead et al. 2003). This translates to 140,000 hospital admissions with an estimated cost in Australia of at least $350 million dollars per annum, in the public hospital system alone (Australian Council for Safety and Quality in Health Care 2002; Roughead 1999). The literature also confirms that the elderly are more likely to be admitted to hospital because of medication-related adverse drug events (Chan, Nicklason and Vial 2001; Hagan and Cooper 1999). Twenty percent of patients aged 65 years and over (Australian Council for Safety and Quality in Health Care 2002) and 30 percent of patients aged 75 years and over (Chan, Nicklason et al. 2001) are believed to experience unplanned medication-related hospital admissions.

Adverse drug events are not confined to hospital settings. They are also a major problem in community settings as reported in the BEACH survey (Bettering the Evaluation and Care of Health)(Runciman, Roughead et al. 2003). During 1999 - 2000, there were 4.1 adverse drug events recorded for every 1,000 general practice visits (Hargreaves 2001). The Australian incident-monitoring study which collected reports from 673 general practitioners from 1996 - 1998 found that adverse drug events, were responsible for 1,556 (60 percent) of the 2,582 adverse events reported (Steven, Malpass, Moller, Runciman and Helps 1999). Analysis of 805 incident reports from another Australian general practice study (October 1993 - June 1994) also found that adverse drug events (51 percent) were the most frequently reported adverse events, especially involving patients aged 65 years and over (Bhasale, Miller et al. 1998). It could be argued
that the data collected from these few general practice studies are not truly representative of the incidence of adverse drug events Australia wide. They do, however, provide a snapshot of the potential impact that adverse drug events can have on general practice encounters and healthcare costs in the community setting.

Although adverse drug events may be a common occurrence in both the hospital and community settings, they should not be considered to be unavoidable outcomes associated with medication use. Evidence in the literature suggests that a large proportion of these adverse drug events are potentially preventable (Gurwitz, Field et al. 2003; Rigby, Clark and Runciman 1999; Roughead, Gilbert, Primrose and Sansom 1998). A Canadian prospective cohort study of 400 patients discharged from hospital found that a majority of the 50 adverse drug events experienced by the 400 discharged patients could have been prevented with improved patient education, communication, continuity of care and patient follow-up (Forster, Murff et al. 2003). These claims are consistent with other reports which also found that potentially preventable adverse drug events could be reduced by improving patient medication education and communication (Dartnell, Anderson et al. 1996; Forster, Asmis et al. 2004; Forster, Clark, Menard, Dupuis and al 2004; Gandhi, Weingart, Borus, Seger, Peterson, Burdick, Seger, Shu, Federico, Leape and Bates 2003; Roberts and Stokes 1998). Similarly, an Australian study which reviewed the medical records of over 14,000 admissions to 28 hospitals during 1992, suggested that 43 percent of the reported adverse drug events could have been potentially prevented, identifying improved medication education and communication as potential areas for improvement (Wilson, Runciman et al. 1995). From a community perspective, an observational Australian study (October 1993 - June 1994) asserted that 322 (79 percent) of the 407 adverse drug events reported by 324 general practitioners could have been prevented by improving patient education, patient and health professional communication, as well as the continuity of care between hospital and community settings (Bhasale, Miller et al. 1998). Certainly each of these studies varied markedly in their estimate of how
many adverse drug events were potentially preventable. Importantly however, they all made the same claims that a significant proportion of the adverse drug events could be potentially prevented by improved patient education, patient/health professional communication and the continuity of care between hospital and community settings. Clearly these are factors consistently considered important in effective patient compliance to medication regimens.

In summary, it has been established that adverse drug events are leading causes of adverse events both in Australia and overseas. They contribute to an increase in healthcare costs by causing unplanned hospital admissions and general practitioner encounters. There are studies reported in the literature, which suggest that many of these adverse drug events could be potentially prevented by improving patient education, patient/health professional communication and the continuity of care between hospital and community settings.

### 2.4.4 Key elements which contribute to adverse drug events

#### 2.4.4.1 Introduction

Adverse drug events are a persistent and important problem of public health in terms of morbidity, mortality and cost (Peyriere, Cassan, Floutard, Riviere, Blayac, Hillaire-Buys, Quellec and Hansel 2003). Work in this area has only been underway in Australia for approximately 10 years, with an emphasis on medication safety and the reduction of adverse drug events in the past five years (Australian Council for Safety and Quality in Health Care 2001). Following the 1999 report by the National Expert Advisory Group on Safety and Quality in Australian Health Care, the Australian Council for Safety and Quality in Health Care was established in January 2000 to prioritise medication safety in Australia (Australian Council for Safety and Quality in Health Care 2002; Commonwealth Department of Health and Aged Care 2000). One of the major strategies identified by the council to minimise these potentially preventable adverse drug
events was to improve patient medication knowledge and understanding by effectively educating them about their medications (Australian Council for Safety and Quality in Health Care 2002).

Key elements identified in the literature as contributing to adverse drug events include: poor health professional/patient communication and partnerships; poor medication compliance; inappropriate written medication information; poor continuity of care between hospital and community settings; and poor patient follow-up (Australian Council for Safety and Quality in Health Care 2001). In order to help reduce the potentially preventable adverse drug events, it is therefore important to target each of these key elements, as well as addressing the needs of the ‘high risk’ patient population, in the development of patient education programs.

2.4.4.2 Poor health professional/patient communication and partnerships

Poor health professional/patient communication and partnerships have been identified by Bhasale, Miller et al (1998) and Elwyn, Edwards and Britten (2003) as important factors which contribute to adverse drug events and poor therapeutic outcomes. More recently Cox, Stevenson, Britten and Dunbar (2004) identified that these factors result in patients having poor knowledge and understanding of their medications, subsequently causing an inability to appropriately manage them at home.

DiMatteo (1997) claimed that poor communication could result in as many as half the number of all patients leaving their doctors’ offices not knowing what they have been told or how to follow their therapeutic regimens. Patients contributed to this poor communication through their unwillingness to ask questions and/or challenge the health professional’s authority, being overwhelmed with the information provided and misunderstanding medical jargon. Becker and Maiman (1980) also found that patients often feel that they are wasting the doctors’ valuable time and omit details which they deem unimportant or are too embarrassed to mention.
Ineffective patient/health professional partnerships are important as they can precipitate adverse drug events because patients may not know enough about their medications to manage them appropriately (Bhasale, Miller et al. 1998). Patients may feel unsupported in their attempts to become actively involved and to ask questions about their medications and therapeutic regimens (Cox, Stevenson et al. 2004; Elwyn, Edwards et al. 2003).

Patient populations most likely to experience poor therapeutic outcomes and adverse drug events because of poor health professional/patient communication and partnerships include the ‘high risk’ group. Elderly patients (aged 65 years and over) have been found to have problems communicating and forming partnerships with their health professionals (Stewart and Caranasos 1989). They typically take many medications and are overwhelmed with the information received (Col, Fanale and Kronholm 1990; Ryan 1999). Reports in the literature have identified that the proportion of people who use medications increases with age, from 42 percent of those aged less than 15 years, to 86 percent of those aged 65 years and over (ABS 1999).

Patients with low literacy skills, which may include the elderly, also experience poor health professional/patient communication and partnerships because their health professionals are often unaware of their communication problems which they seldom voluntarily admit and often try to conceal (Doak, Doak et al. 1985). Similarly, the language, social and cultural barriers for non-English speaking background (NESB) patients make it difficult for health professionals to assess how effectively they have communicated with these NESB patients (Davidhizar and Brownson 1999; Minas, Lambert, Kostov and Boranga 1996).

Strategies to improve health professional/patient communication and partnerships should also address the needs of each of these ‘high risk’ patient groups. Two major elements of effective communication between the health professional and the patient identified by DiMatteo (1997) are accurate transmission of information to and from the health professional and the patient,
as well as the health professionals’ emotional support and understanding of the patient as a unique individual.

Reports in the literature have identified that communication improved when health professionals offered patients encouragement, reinforcement of key points by using repetition, reassurance and feedback (Clark, Gong, Schork, Evans, Roloff, Hurwitz, Maiman and Mellins 1998; Estrada, Hryniewicz et al. 2000). A meta-analysis on the effectiveness of health education and health promotion undertaken by Kok, van den Borne and Mullen (1997) concluded that the effectiveness of health education is promoted by systematic planning and the use of learning principles in the intervention, including relevance, individualisation, feedback, rewards and facilitation. Providing environments which encourage patients to listen, feel confident enough to ask questions and participate in the decision making process have also been found to be important ways in which to improve communication and partnerships (Elwyn, Edwards et al. 2003; The Royal Pharmaceutical Society of Great Britain 1997). The incorporation of such strategies into patient education programs are believed to contribute to not only improved health professional/patient communication and partnerships (Cox, Stevenson et al. 2004), but also improved therapeutic outcomes (DiMatteo 1997; Elwyn, Edwards et al. 2003) and reduced incidence of adverse drug events (Ascione and Shimp 1984; Esposito 1995).

A number of principles for improved health professional/patient communication have been developed based on a large randomised control trial involving 472 asthma patients, their parents and 69 paediatricians (Clark, Gong et al. 1998). Positive outcomes from the trial were identified as successful therapeutic outcomes of patients, improved parents’ knowledge about how to manage their children’s asthma and a reduction in health care utilisation. The investigators recommended that the following communication principles be included in patient education programs.

- Attend to the patient (eye contact, sit closely with the patient slightly leaning forward)
- Elicit the patient’s underlying concerns about the condition
- Construct reassuring messages that alleviate fears
- Address any immediate concerns that the family expresses
- Engage the patient in interactive conversation through use of open-ended questions, simple language, and analogies to teach important concepts
- Tailor the treatment regimens by eliciting and addressing potential problems in the timing, dose or side effects of the drugs recommended
- Use appropriate non-verbal encouragement (pat on the shoulder, nodding) and verbal praise when the patient reports using correct disease management strategies
- Elicit the patient’s immediate objective related to controlling the disease and reach agreement with the family on a short term goal
- Review the long term plan for the patient’s treatment so the patient knows what to expect over time, knows the situation under which the physician will modify treatment, and knows the criteria for judging the success of the treatment plan
- Help the patient plan in advance for decision making about chronic condition (such as using diary information or guidelines for handling potential problems and exploring contingencies in managing the disease)

This is the only study that has approached the issue of health professional/patient communication in such a systematic manner. Other studies have identified some of these issues, for example DiMatteo (1997) identified that the accurate transmission of information, emotional support and understanding between the health professional and the patient were important in effective communication, but none have drawn the issues together in such a comprehensive fashion.

Extending the concept of communication, fostering and developing good health professional/patient partnerships are also considered to be important in medication education programs. Partnerships can empower patients to know and
understand more about their medication, enabling them to make better educated therapeutic decisions (Lorig, Sobel, Ritter, Laurent and Hobbs 2001; Mullen, Simons-Morton et al. 1997). In a study of 952 patients with chronic disease, by Lorig et al (1999), it was found that a structured self-management education program improved health status and reduced hospitalisation rates over a 6-month period. As compared with control group, the treatment group demonstrated significant improvement in five of the health status variables (self-rated health, disability, social/role activities limitation, energy/fatigue, and health distress; p< 0.02). The treatment group, as compared with the control group, also had fewer hospitalisations (p<0.05) and spent, on average, 0.8 fewer nights in the hospital (p = 0.01). The study concluded that these results were due to a number of factors including the patients improved knowledge and understanding about how to manage their medications and disease therapy at home, as well as their improved communications with their physicians.

The importance of good patient/health professional partnerships in helping to achieve optimal medication outcomes has only been recognised over the last 10 years with the promotion of the concept of patient concordance (Aslani and Du Pasquier 2002; The Royal Pharmaceutical Society of Great Britain 1997). Concordance describes the process whereby health professionals and patients exchange their views on treatment and come to an agreement about the need (or not) for a particular treatment (Elwyn, Edwards et al. 2003). In the United Kingdom the role of the Medicines Partnership Task Force (1997) is to support the national strategy through the promotion of concordance between the health professionals and their patients. In the absence of any evaluation data concerning the effectiveness of these collaborative strategies on the patients medication related therapeutic outcomes and adverse drug events it is only possible to speculate that such initiatives should produce positive effects.

Since poor communication and partnerships between health professionals and their patients are believed to contribute to poor therapeutic outcomes and adverse drug events (Elwyn, Edwards et al. 2003) it would seem reasonable to suggest that patient education programs should incorporate strategies which
target improved health professional/patient communication and partnerships. Offering encouragement, reinforcement, reassurance and feedback (Clark, Gong et al. 1998), as well as making patients feel confident to ask questions and be part of the decision making process (The Royal Pharmaceutical Society of Great Britain 1997) are amongst the factors reported in the literature to promote good health professional/patient communication and partnerships. These factors need to be considered in the development of patient medication education programs, especially for the ‘high risk’ group of patients.

2.4.4.3 Poor medication compliance

Medication compliance is a key indicator of the success of patient medication education programs. Current estimates of non compliance range from 20 to 70 percent for all medications (Barat, Andreasen and Damsgaard 2001; Stewart and Caranasos 1989) and 50 to 65 percent for long-term medications (Haynes, McKibbon and Kanani 1996), indicating there is much room for improvement through patient medication education. Further, patient populations most likely to encounter adverse drug events because of poor compliance, and hence are high priorities for improved education initiatives, include the elderly (Col, Fanale et al. 1990; Ryan 1999), those with low literacy skills (Feifer 2003) and patients from non-English speaking backgrounds (Davidhizar and Brownson 1999).

Medication compliance, synonymous with medication adherence and concordance, is defined as the extent to which patients follow the instructions they are given for prescribed treatments. There are several methods which can be used to measure compliance and these include pill counts, patients’ self-report, pharmacy dispensing records, electronic monitoring systems, as well as blood and urine assays. Some of the strengths and weaknesses of these different methods are summarised in the following
<table>
<thead>
<tr>
<th>Compliance Measurement</th>
<th>Strengths</th>
<th>Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pill count</td>
<td>- quick and easy</td>
<td>- cannot identify the number of days missed</td>
</tr>
<tr>
<td></td>
<td>- the number of tablets can be quickly inspected to see how many</td>
<td>- patients can manipulate tablet numbers</td>
</tr>
<tr>
<td></td>
<td>have been taken from the pack</td>
<td>- can be time consuming if conducted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>in a home setting</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- patients may resent having their pills counted</td>
</tr>
<tr>
<td>Self-reporting</td>
<td>- patients do their own reporting</td>
<td>- patient recall may be inaccurate</td>
</tr>
<tr>
<td></td>
<td>- quick and easy</td>
<td>- patients may be reluctant to admit</td>
</tr>
<tr>
<td></td>
<td>- subjective measurement</td>
<td>‘noncompliance’</td>
</tr>
<tr>
<td>Pharmacy dispensing records</td>
<td>- objective measure of compliance</td>
<td>- can be inaccurate if several pharmacies are involved</td>
</tr>
<tr>
<td></td>
<td>- quick and easy</td>
<td>- can prove to be timely and expensive if several pharmacies are involved</td>
</tr>
<tr>
<td></td>
<td>- can produce population based analyses</td>
<td>- can lead to errors if patients stockpile their medications</td>
</tr>
<tr>
<td>Electronic monitoring system</td>
<td>- provide a good record of the number of times a patient remembers to</td>
<td>- expensive and cumbersome when the electronic device does not fit the</td>
</tr>
<tr>
<td>(e.g. Medication event monitoring system MEMS)</td>
<td>take their medication</td>
<td>prescription medication bottle</td>
</tr>
<tr>
<td></td>
<td>- provide a good record of the interval between doses</td>
<td>- can causes problems if the device becomes faulty</td>
</tr>
<tr>
<td>Blood or urine assays</td>
<td>- effective and accurate for appropriate medications</td>
<td>- patients who are used to using reminder dosing units (e.g. blister</td>
</tr>
<tr>
<td></td>
<td></td>
<td>packs, dosette boxes etc) cannot use them with the electronic monitoring</td>
</tr>
<tr>
<td></td>
<td></td>
<td>device</td>
</tr>
</tbody>
</table>

According to this summary it would be true to say that each compliance measurement method is limited to some degree. These limitations have also been highlighted in different reports which have found that self-reporting can overestimate compliance (Haynes, McKibbon et al. 1996; Shalansky 2004), pill
counts can underestimate compliance (Grymonpre, Didur, Montgomery and Sitar 1998), electronic monitoring devices are useless if they become faulty or lost (Turner and Hecht 2001) and only complete pharmacy prescription data records can be used to correctly estimate medication compliance (Grymonpre, Didur et al. 1998).

There is no gold standard for measuring medication compliance, which is why different researchers have used different methods over time. Earlier studies typically used pill counts, whereas in recent times electronic monitoring devices such as the Medication Event Monitoring System (MEMS) have replaced pill counts as the reference standard (Farmer 1999). Reviewing the strengths and weaknesses of the different compliance measurements listed above it could be argued that no one single method is more reliable or superior to the other. Perhaps the best way to deal with these shortcomings is to use at least two or more of the most convenient and available compliance measurement methods, which can be used to achieve the study's goals. A good example of this, is a recent study which compared the compliance of HIV protease inhibitors for 108 HIV infected adults over an 8 week period (Liu, Golin, Miller, Hays, Beck, Sanandaji, Christian, Maldonado, Duran, Kaplan and Wenger 2001). The researchers used a medication event monitoring system (MEMS), a pill count, a self-report interview and a combination of all these results known as the composite adherence score (CAS) to measure medication compliance which was then compared to the HIV viral load in the blood. They found that the composite score showed the strongest predictive relationship with the HIV viral load, suggesting that a composite score of more than one compliance measurement method is a more reliable way in which to predict medication compliance. In light of this, it could be speculated that other studies which used two compliance measurements such as self-reports and pill counts (Esposito 1995), as well as pill count and electronic monitoring (Bansberg, Hecht, Charlebois, Chesney and Moss 2001; Girvin, McDermott and Johnston 1999) more accurately predicted medication compliance than did the studies which used only one medication compliance measurement such as; self-reporting (Katon, Rutter, Ludman, Von

The implications of the work to date are that at least two compliance measures should be used when and if appropriate. In the absence of information about the best way in which to measure warfarin compliance in a community setting it could be argued that the two most appropriate methods include blood assays known as the international normalised ratio blood tests, INR blood tests, and self-reporting. The INR blood tests alone are not ideal because the tests can be done at varying time intervals depending on how often they are ordered by the health professionals thereby possibly distorting the overall results. The pill counts would be difficult and time consuming to conduct in a community setting, the electronic monitoring devices would need to be attached to each of the different warfarin strengths which could also distort the results if certain strengths were not always required during the research study, and pharmacy dispensing records would not be ideal when and if participants were using multiple pharmacies. In summary therefore, even though using the INR blood test and self-reporting are not ideal, they are a step forward in the way warfarin compliance data can be collected and evaluated.

Researchers have found that many factors can contribute to poor medication compliance. These factors include poor knowledge and understanding (Fineman and DeFelice 1992; Fitten, Coleman, Siembieda, Yu and Ganzell 1995); cognitive and/or physical limitations such as failing eyesight and hearing complications (Stewart and Caranasos 1989), misinterpretation of instructions (Ruzicki, Bettesworth and Steele 1986); side effects (Ferguson, Ziedins, West, Richardson and Michocki 1996), visiting numerous medical practitioners, as well as having complex drug regimens which interfere with their daily living (Pendleton 1992).

Reports in the literature have identified that these factors especially contribute to poor medication compliance in the ‘high risk’ group (Ryan 1999; Schlenk, Dunbar-Jacob and Engberg 2004). In a study of elderly patients, aged
65 years and over, Col et al (1990) interviewed 315 patients admitted to hospital and found that of the 89 patients admitted because of adverse drug events, 36 (11.4 percent) were due to non compliance. The authors identified that having multiple medications, poor recall and seeing numerous physicians were amongst the many contributing factors for non compliance. Similarly, patients with low literacy skills may be non compliant because they cannot understand the information provided to them by their health professionals (Feifer 2003; Mayeaux Jr, Murphy, Arnold, Davis, Jackson and Sentell 1996; Roter, Rudd and Comings 1998). This may also be the case with non-English speaking background patients (Ziguras, Klimidis, Lambert and Jackson 2001; Ziguras, Lambert, McKenzie and Pennella 1998). Unfortunately, there is very limited evidence in the literature about factors, which contribute to poor compliance in the non-English speaking background patients. A major factor contributing to the poor representation of studies with these populations in the literature is the subjects’ lack of the English language, often used as ineligibility criterion for inclusion into studies. It may be fair to assume, however, that they would also experience poor compliance based on factors already discussed.

A recent systematic review of randomised trials of interventions to assist patients follow prescriptions for medications (Haynes, Montague, Oliver, McKibbon, Brouwers and Kanani 2001) identified that only 33 of the 1806 citations met the stringent criteria set by the reviewers. The criteria included that (i) both compliance and treatment effects were measured, (ii) there was at least 80% follow-up of each group studied; and (iii) for long-term treatments, the follow-up period was at least 6 months. The reviewers concluded that simplifying the medication regimen could improve compliance and treatment outcomes for both short and long term medications. However, to improve the compliance and therapeutic outcomes of long term medications the interventions needed to be more complex and include combinations of: more thorough patient education and counselling; reminders; close follow-up; reinforcement; supervised self-monitoring; family support and rewards for success. Surprisingly, given its simplicity, they specified that the single most important intervention was recalling
patients and making every effort to keep them in care. It is noteworthy that even though there is evidence to support the positive influence of both social and behavioural factors to improve compliance and therapeutic outcomes (Col, Fanale et al. 1990), these were not targeted by any of the randomised control trials evaluated in this review by Haynes et al (2001).

Similar results were also found in a meta-analysis (Roter, Hall et al. 1998) which summarised the results of 153 studies published between 1977 to 1994 evaluating the effectiveness of interventions to improve patient compliance with medical regimens. Inclusion criteria for the meta-analysis included: (i) an intervention to influence or improve compliance; (ii) a control group and an intervention group; (iii) compliance with a therapeutic recommendation; (iv) an association with compliance and at least one intervention variable; (v) sample size no less than 10 and (vi) a study published in English. This meta-analysis, similar to the systematic review by Haynes, McDonald, Garg and Montague (2002a), concluded that a mixed programmatic focus was much more effective at improving medication compliance and therapeutic outcomes than was a single programmatic focus. These mixed programmatic focus interventions included patient education, familial support, heath professional/patient communication and partnerships, as well as emotional support. Unfortunately, the effectiveness of such mixed interventions, in patients with low literacy skills and from non-English speaking backgrounds, have not been evaluated to date. It would be reasonable to assume however, that such mixed focus interventions would also help to promote medication compliance and therapeutic outcomes in these patient populations.

Other interventions shown to improve medication compliance include the use of compliance aids such as dosette boxes, reminders and blister packs (Roter, Hall et al. 1998; Wong and Norman 1987). A review of the 52 medication errors involving dosette boxes by Levings et al (1999) found that the problems were associated with incorrectly filling the dosette box and/or incorrect use of the dosette box. Even though this study concluded that more appropriate patient selection and more care with filling the dosette boxes would minimise these
adverse events, such compliance aids are not always the perfect solution to compliance problems. Not only are they expensive but they are also inappropriate for patients with significant cognitive impairment who cannot remember when and if they took their last dose of medications. This may subsequently result in patients either taking too many medications or not taking enough and therefore contributing to poor compliance and possible adverse drug events.

Stewart and Caranasos (1989) also have made recommendations to help improve medication compliance, especially in the elderly patients. Their recommendations include the following:

- Simple, clear instructions repeated periodically
- Written instructions
- Assessment of the cognitive function of the patient prior to the education, and tailoring the education to their ability
- Development of a routine for taking medications
- Construction of a chart when multiple medications were used.

There is little doubt that improved medication compliance will help to optimise therapeutic outcomes and minimise adverse drug events (Haynes, McDonald et al. 2002a). Reports in the literature suggest that to improve medication compliance a mixed programmatic intervention approach rather than a single-focus intervention approach would be more successful for both short and long term medications (Haynes, McDonald and Garg 2002b; Roter, Hall et al. 1998). Since it is not possible at this stage to identify which combination of factors would be most useful, patient medication education programs should target the factors known to contribute to improved medication compliance. These factors include patient education and counselling, reminders, close follow-up, reinforcement, family support and where appropriate the use of medication aids.
2.4.4.4 Inappropriate written medication information

It is difficult for patients to optimise their therapeutic outcomes and avoid adverse drug events if they receive insufficient and inappropriate medication information. This may result in errors in judgment, failure to recognise important signs and symptoms of side effects, and possibly completely misunderstanding therapeutic regimens and treatment plans (Bhasale, Miller et al. 1998).

Baker (1997) and Estrada, Hryniewicz et al. (2000) have found that much of the currently available written medication information cannot be read or understood by a large proportion of the population. This is because it is written between grade 9 and grade 14 levels, well beyond the comprehension of those educated at or below a grade six level (Rolland 2000). It has also been identified that written information often contains a lot of medical jargon and terminology which cannot be read or understood by many patients, especially those with low literacy skills (DiMatteo 1997; Murphy and Davis 1997). Written medication information available in Australia, known as consumer medicine information (CMI), has been found to include such complex terms (Baker 1997; Koo, Krass and Aslani 2001).

Since 1995 it has been mandatory that all prescription medicines in Australia be given to patients with the appropriate CMI, as outlined in the Therapeutic Goods Regulations (1990). These CMIs are available as package inserts, loose leaflets and in electronic format. The current legislation includes regulations about the content and presentation of CMIs but these regulations are not based on scientific evidence regarding how to communicate medicines information effectively to consumers. It has been reported that patients find CMIs difficult to read because of their font size, sheer volume of pages and their common inclusion of medical jargon (Koo, Krass et al. 2001).

In an attempt to improve medication-related therapeutic outcomes, the literature identifies the need to provide simple and easy-to-comprehend
medication information (Esposito 1995). This information should be appropriate for all patient populations, including the ‘high risk’ group. Poor literacy skills and written patient medication information will be discussed in much greater detail in the next chapter.

2.4.4.5 Poor continuity of care between hospital and community settings

Poor continuity of care between hospital and community settings has also been recognised as an important contributor to adverse drug events (Australian Council for Safety and Quality in Health Care 2002; Forster, Murff et al. 2003). Recently the Australian Pharmaceutical Advisory Council (APAC) introduced the ‘Guidelines on the continuum of care of quality use of medicines between hospital and community’ (Australian Pharmaceutical Advisory Council 1998) with the aim to improve communication between both settings. Even though there are no evaluation data available on the impact of adhering to these guidelines, based on the fact that they were initially introduced to address the communication problems between hospital and community settings it would be fair to suggest that their effects would be positive. In other words, adherence to these guidelines could help to optimise therapeutic outcomes and reduce adverse drug events by promoting the timely transfer of information, not only to the patient and/or their carer, but also to the patients’ health professionals working in the community setting (Thornton, Simon and Mathew 1999).

Unlike typical hospital inpatient healthcare delivery services, Illawarra Health’s The Ambulatory Care Team (TACT) is a multidisciplinary team, which provides home healthcare delivery services to Illawarra residents aged 16 years and over who would otherwise be hospitalised. TACT is similar to the proliferating number of ‘Hospital in the Home’ (HITH) services available in Australia since 1995 (Duke and Street 2003), which have provided home healthcare delivery for medical conditions requiring anticoagulation management and intravenous antibiotics. TACT differs to many other Australian HITH services in that it provides a pharmacist to deliver home-based medication education.
which is a new and emerging philosophy in patient medication education (Mullan 1999; Stowasser 1999; Stowasser, Collins and Stowasser 2002).

In the absence of good continuity of care between hospital and community-based settings (Balla and Jamieson 1994; Bolton, Mira, Kennedy and Moses-Lahra 1998), TACT is well placed to promote the continuity of care by incorporating the APAC guidelines (1998) into its everyday practice. There is an implication that adhering to these guidelines will help to optimise therapeutic outcomes and minimise adverse drug events.

2.4.4.6 Patient follow-up

Patient follow-up, including telephone follow-up, has been identified as an important strategy to help optimise therapeutic outcomes and minimise adverse drug events. Patient follow-up has the potential to improve health professional/patient communication and partnerships, medication compliance, medication information and the continuity of care because it directly impacts on each of these factors (Haynes, McDonald et al. 2002a).

Evidence to support the positive influence of telephone follow-up on health professional/patient communication and partnerships can be found in a study conducted by an American telephone anticoagulation service, which managed between 300 and 400 patients. Following a 12-month surveillance period, this service found that its patients, all of whom received telephone follow-up, were more proactive with their warfarin therapy and more likely to have therapeutic blood tests results, than were patients who did not receive the follow-up service (Waterman, Milligan, Banet, Gatchel and Gage 2001). Another study, which involved 30 African American men with type 2 diabetes, also found that telephone follow-up, accompanying a structured education program, contributed to favourable diabetes health outcomes and improved patient/health professional partnerships (Hendricks and Hendricks 2000). While these studies examine actions of patients with different health problems, it appears that the importance of patient follow-up is common to successfully managed community therapeutic programs.
A meta-analysis on the effectiveness of interventions to improve patient compliance and education concluded that telephone follow-up was an integral part of the essential mixed programmatic focus interventions (Roter, Hall et al. 1998). This meta-analysis included a study, which compared the effectiveness of improving medication compliance in 82 patients for a 10 to 14 day course of antibiotic therapy. The study found that the mean compliance for the telephone follow-up patients who also received written and oral counselling was significantly better than for the control patients who received neither telephone follow-up nor counselling. Those in the former group achieved 85.4 percent mean compliance while those in the latter just 76.6 percent mean compliance (Garnett, Davis, McKenney and Steiner 1981). Similarly, another study within the same meta-analysis, observing 60 Non Insulin Dependent Diabetes Mellitus (NIDDM) patients found that patients who received the follow-up intervention (by telephone calls and home visits) were more compliant with their diabetes management plan than were patients who received the standard educational program with no follow-up intervention (Estey, Tan and Mann 1990). Regardless of the fact that the medications were for both short and long-term use, the studies indicate that patient follow-up, including telephone follow-up, helped to improve medication compliance.

Regular follow-up in long-term self-management programs have been found to enhance outcomes for asthmatic children (Gebert, Hummelink, Konning, Staab, Schmidt, Szczepanski, Runde and Wahn 1998), as well as other chronic disease states (Lorig 1996). A recent Australian study found that home-based follow-up of patients discharged from hospital on warfarin therapy resulted in significant reductions in the number of haemorrhagic complications (Jackson, Peterson, Vial and Jupe 2004). An American study which evaluated the impact of a 12-month follow-up telephone call service provided by a pharmacist to 221 patients discharged from a general hospital found that fewer patients from the telephone call group returned to the emergency department within 30 days (10 percent phone call compared to 24 percent no phone call). This study found that not only did the follow-up telephone service reduce the incidence of adverse drug
events but it also increased patient satisfaction (Dudas, Bookwalter, Kerr and Pantilat 2001).

Based on the evidence in the literature it can be concluded that follow-up is an essential component for effective medication education. Patient follow-up, including telephone follow-up, can be used to specifically target and reinforce other factors such as; health professional/patient communication and partnerships, medication compliance and management, patient education and improved patient satisfaction, all of which help to optimise therapeutic outcomes and minimise adverse drug events.

2.4.4.7 Summary

In order to optimise therapeutic outcomes and minimise adverse drug events it is important to target key elements known to contribute to such events. These key elements have been found to include improving health professional/patient communication and partnerships, improving medication compliance, providing simple, easy-to-read written medication information, improving the continuity of care between hospital and community settings, and offering patient follow-up. Effective medication education should not only target these key elements, but should also address the needs of the ‘high risk’ patient population.

2.5 WARFARIN

2.5.1 Introduction

The focus of the discussion will now turn to the oral anticoagulant warfarin. Warfarin has been identified as a major medication causing adverse drug events, both in Australia and overseas (Australian Council for Safety and Quality in Health Care 2002; Forster, Murff et al. 2003; Hirri and Green 2002). To date, warfarin-related adverse drug events have been identified as a large and unresolved problem (Campbell, Roberts et al. 2001). This problem has the
potential to grow and escalate with continually emerging research findings demonstrating its benefits in patients with different disease states such as atrial fibrillation (Ezekowitz and Falk 2004; Gallus, Baker et al. 2000; Peterson, Jackson et al. 2002). Consistent with previous discussions of the 'high risk' patient population, those most likely to experience warfarin-related adverse drug events include the elderly, those with low literacy skills (Estrada, Martin-Hryniewicz et al. 2004; Lambert and Wynne 2003; Tang, Lai et al. 2003) and those from non-English speaking backgrounds (Nadar, Begum et al. 2003).

It could be argued that inadequate warfarin education programs (Connor 1998) and patient warfarin knowledge deficiencies (Cheah and Martens 2003; Lambert and Wynne 2003; Nadar, Begum et al. 2003; Tang, Lai et al. 2003) support the need for a new effective warfarin education program. This thesis promotes the development and implementation of a new warfarin education program, which acknowledges and averts the historical inadequacies, offering a considered approach to effective patient education. This improved patient education will in turn empower patients to make informed decisions about their warfarin therapy, helping to optimise their therapeutic outcomes and minimise adverse drug events (Ansell, Buttar et al. 1997; Kagansky, Knobler, Rimon, Ozer and Levy 2004).

2.5.2 Background

To understand why warfarin is being prescribed more frequently today, it is essential to know its function. Warfarin, which is derived from clover (Catania 1994), works by limiting the availability of vitamin K, a necessary component in the formation of coagulation factors II (prothrombin), VII, IX and X, and the anticoagulant proteins C and S. Warfarin prevents new clots from forming and existing clots from getting bigger (Catania 1994). The extent of the warfarin-induced blood coagulation defect, expressed as an International Normalised Ratio (INR), is the major determinant of treatment success or failure.
To achieve safe and effective warfarin treatment, patients need to be effectively educated about the most important considerations in managing their warfarin therapy. These considerations include: indications for therapy; how and when to take their warfarin; the importance of regular blood tests; target International Normalised Ratio (INR) levels; possible warfarin-related side effects and drug-to-drug interactions; and exercise, dietary and alcohol restrictions required to optimise therapy (Gallus 1999).

Until recently the use of warfarin has been limited to the treatment of venous thrombosis or pulmonary embolism, the prevention of systemic embolism caused by prosthetic heart valves and the recurrence of embolic stroke (Gallus 1999). Less frequently, warfarin has been used to prevent systemic embolism in refractory heart failure or when atrial fibrillation complicates cardiac valvular stenosis or incompetence. There has also been limited usage of warfarin to prevent venous thrombo-embolism after hip surgery, or to prevent a recurrence of myocardial infarction (Gallus, Baker et al. 2000).

More recently, it has been found that warfarin dramatically reduces the risk of embolic stroke in patients with atrial fibrillation (AF) and that treatment benefits significantly outweigh the risks (Ansell, Buttaro et al. 1997; Gallus, Baker et al. 2000). Despite these benefits in patients with atrial fibrillation, warfarin is underused, especially in elderly patients (DeBray, Couturier and Siguret 2003; Peterson, Jackson et al. 2002; Whittle, Wickenheiser and Venditti 1997), primarily because physicians perceive the risk of poor compliance and a lack of warfarin knowledge and understanding as being unacceptably high among these patient populations (Man-Son-Hing and Laupacis 2003). With an increased pressure to prescribe, however, and with the possibility of improving patient warfarin education, this situation may change in the near future.

2.5.3 Incidence of warfarin-related adverse drug events

The literature identifies that warfarin is responsible for a high incidence of adverse drug events (Australian Council for Safety and Quality in Health Care 2001; Forster, Murff et al. 2003; Runciman, Roughhead et al. 2003). With recent
increases in warfarin prescribing (Cruickshank, Ragg et al. 2001) and the likelihood that prescribing will further increase for patients diagnosed with atrial fibrillation (Gallus, Baker et al. 2000), warfarin-related adverse drug events will almost certainly grow in magnitude.

Australian data support the evidence that warfarin-related adverse events are a large and unresolved problem (AIHW 2003), causing an estimated cost of $100 million per annum for hospitalisation alone in 1992 (Rigby, Clark et al. 1999). From 1999 to 2000, warfarin was associated with 5,080 adverse drug events requiring admission to Australian hospitals, 7.3 percent of the total adverse drug events (AIHW 2002). Data from the Australian Institute of Health and Welfare (AIHW 2003), indicates that there has been a steady increase in the number of warfarin-related hospital admissions over the past few years. According to these data, hospital admissions with diagnosis code ICD-10-AM T455 (anticoagulant poisoning) increased from 434 in 1998/99, to 449 in 1999/00 and then to 471 in 2000/01, an increase of 8.5 percent over the three year period from 1998 to 2001. Similarly, hospital admissions for the external cause code ICD-10-AM Y442 (anticoagulants primarily affecting blood constituents), increased from 4,378 in 1998/99, to 5,080 in 1999/2000 and then to 5,228 in 2000/2001 (AIHW 2003), an increase of 19 percent over the three year period from 1998 to 2001. Unfortunately, there are no data available about the incidence of warfarin-related adverse drug events and the number of general practice encounters over the past few years. However, based on the hospital data and the evidence that patients can be successfully treated for warfarin induced bleeding in an outpatient setting (Brigden, Kay, Le, Graydon and Mcleod 1998), as well as the availability of guidelines to treat warfarin-related adverse events in both community and hospital settings (Gallus, Baker et al. 2000) it could be assumed that similar increases are being experienced in the community sector.

Data available from the Australian Therapeutic Goods Administration (TGA) Adverse Drug Reactions Advisory Committee (ADRAC 2005) also indicate that the reporting of suspected warfarin-related adverse drug events has increased progressively over the past few years, from 47 reports in 1992, to 103
reports in 1999 and then to 115 reports in 2004. Even though a significant portion of these reports relate to the loss of anticoagulant control either because of dose/compliance or interactions with other co-administered drugs and are not a true indication of the total number of warfarin-related adverse drug events their increase in number over the past few years supports the evidence that warfarin-related adverse drug events are on the rise in Australia.

It could be argued that this steady increase in warfarin-related adverse drug events could be attributed to the increase in warfarin prescribing (Arnsten, Gelfand and Singer 1997; Elliott, Woodward et al. 2002; Peterson, Jackson et al. 2002), rising from 1.673 million warfarin prescriptions in 1999 (Commonwealth Department of Health and Aged Care 2003) to 1.897 million warfarin prescriptions in 2002 (Commonwealth Department of Health and Aged Care 2004). However, many other factors have been found to contribute to adverse drug events. These factors include; poor health professional/patient communication and partnerships (Bhasale, Miller et al. 1996), poor warfarin compliance (Campbell, Roberts et al. 2001), poor and inappropriate written warfarin information (Estrada, Hryniewicz et al. 2000; Estrada, Martin-Hryniewicz et al. 2004), poor continuity of care between hospital and community settings (Bramley-Moore, Dwyer, Perlman and Sucic 1996) and poor patient follow-up (Pickette 2002). Importantly, warfarin-related adverse events are a major concern for the 'high risk' patient population which include the elderly and those with low literacy skills (Lambert and Wynne 2003; Tang, Lai et al. 2003), as well as the non-English speaking background patients (Nadar, Begum et al. 2003).

In summary, the incidence of warfarin-related adverse drug events is on the increase and will continue to rise with recent recommendations to prescribe warfarin for diseases such as atrial fibrillation (Elliott, Woodward et al. 2002; Peterson, Jackson et al. 2002). Strategies need to be put in place to improve patient warfarin education (Hirri and Green 2002; Kagansky, Knobler et al. 2004) by targeting the elements known to contribute to poor warfarin-related therapeutic outcomes and adverse drug events.
2.5.4 Inadequacies in currently available warfarin education programs

Effective patient education is paramount to the success of warfarin therapy (Kagansky, Knobler et al. 2004; Pubentz, Calcagno and Teeters 1998; Roche-Nagle, Chambers, Nanra, Bouchier-Hayes and Young 2003). Literature spanning 20 years suggests that most warfarin education programs are based on content, without demonstrating any structured framework, program design or outcome evaluation (Wyness 1989). It appears that over the years, warfarin education programs have evolved relying on the health professionals' intuition, convenience and habit as the use of warfarin has increased. The literature suggests that many of these education programs are inadequate (Connor 1998), presenting too much information and overwhelming patients (Ansell, Buttaro et al. 1997).

There is almost no reporting of current available warfarin education programs in the literature and as a consequence little evidence regarding effectiveness of such programs. A review by Wyness (1989) some 15 years ago provided evidence regarding 15 different warfarin education programs available at the time. The major emphasis for each of the programs was content rather than stating any education objectives or evaluation outcomes. The programs mainly used written information sheets and/or booklets as teaching aids, with two of the programs providing audiovisual videos. The points emphasized during the education programs were based on the individual choice of the educator rather than being based on any structural framework. The other important issue about these warfarin education programs was that none of them were evaluated which means that it is not possible to compare the effectiveness of the different programs.

The primary warfarin-related focus in the literature today is on the important warfarin information for health professionals (Deblinger 2000; Gibbar-Clements, Shirrell, Dooley and Smiley 2000; Hirsh, Dalen, Deykin, Poller and Bussey 1995). Evidence regarding the effectiveness of current warfarin education programs is almost nonexistent. Interestingly however, for anyone with access to a computer or the internet, there is a proliferation of information about
warfarin. This electronically available information primarily is not based on any systematic educational approach and is often devoid of scientific evidence. Examples of these include the Clever Clog – anticoagulation education software for use in the primary care setting, as well as the plethora of warfarin websites available on the internet, some of which are listed here; 
http://www.druginfornet.com/faq/faqcouma.htm; 
http://www.med.umich.edu/1libr/chheart/meds08.htm 
http://clinical.caregroup.org/altmed/interactions/drugs/warfarin.htm 
http://www.coumadin.com/consumer/INT_VitaminK1.asp 

Shortcomings in current warfarin education programs are borne out by reports of deficiencies in patients’ warfarin knowledge, which can predispose them to poor therapeutic control and adverse drug events (Lambert and Wynne 2003; Nadar, Begum et al. 2003; Wilson, Racine et al. 2003). Recent American (Cheah and Martens 2003) and English (Taylor, Ramsay, Tan, Gabbay and Cohen 1994) studies which evaluated patient warfarin knowledge, found that overall most patients exhibited warfarin knowledge deficits, even after they had received warfarin education. Cheah and Martens (2003) study of 50 hospital inpatients, found that although 68 percent were satisfied with the education they received, there was an overall warfarin knowledge deficit, with knowledge scores ranging from 6.3 percent to 87.5 percent, out of a possible 100 percent (Mean, 46.9; Standard Deviation 20.9). Taylor et al (1994) evaluated the warfarin knowledge scores for 70 outpatients using a different warfarin knowledge questionnaire. They also found that overall warfarin knowledge was poor, with only half the patients being able to identify adverse events associated with poor anticoagulant control, a safe level of alcohol consumption and possible drug-to-drug interactions with non-prescription drugs and warfarin therapy. Unfortunately, because these studies did not use the same warfarin education programs or the same questionnaire to analyse warfarin knowledge they cannot be directly
compared. They do suggest however, that currently used warfarin education programs are not effective in ensuring that the patients have adequate warfarin knowledge and understanding to safely manage their warfarin therapy at home.

Many studies have confirmed that the patients most likely to experience poor therapeutic outcomes and adverse drug events because of their warfarin knowledge deficits are the elderly (Tang, Lai et al. 2003), those with low literacy skills (Estrada, Martin-Hryniewicz et al. 2004) and patients from non-English speaking backgrounds (Nadar, Begum et al. 2003). Tang et al (2003) conducted a study in Hong Kong from January to March 1999 and found that overall warfarin knowledge was poor in the 122 patients evaluated, especially amongst the elderly and those with low literacy skills. Only 40 - 45 percent of the patients knew the strengths of their warfarin tablets, the reason for taking their warfarin and its effects on the body. The 60 patients who had read the written warfarin information had a better warfarin knowledge than those who did not, and illiteracy was noted as the main reason for not having read the written information. In this study not only were the elderly patients and those with low literacy skills found to have the poorest warfarin knowledge and understanding they were also found to have poorer anticoagulant control. Similarly, a study by Estrada et al (2004) found that of the 143 American patient participants over the age of 50, those with poor literacy skills had poorer than average warfarin knowledge and anticoagulant control. The study by Nadar et al (2003) on 180 non-English speaking background (NESB) patients attending a United Kingdom anticoagulation clinic, used different warfarin knowledge questionnaires to evaluate their warfarin knowledge data, but interestingly they also found that on average warfarin knowledge was poor with an average score of 5.5 (61.1 percent) out of a total score of 9 for the NESB and elderly patients. The results of these studies highlight that current warfarin education programs do not effectively educate patients, especially those at 'high risk,' about their warfarin therapy. This predisposes patients to poor therapeutic outcomes and warfarin-related adverse drug events. In addition, these studies also identify a limitation in the area of
warfarin education research, as there appears to be a lack in common validated instruments to determine the levels of warfarin knowledge and understanding.

There is also an absence of the descriptions and/or evaluations of Australian based warfarin education programs in the literature. It must be presumed therefore, that warfarin education in Australian hospital and community settings is based on an ad hoc set of messages decided upon by the health professionals. In the absence of consensus guidelines for warfarin education, the health professionals themselves decide what information about warfarin they should deliver to their patients. Concerns are mainly focused on the maintenance of an appropriate International Normalised Ratio (INR). It is only when these results are not within normal range that the health professionals question their patients in an attempt to discover what it is that they may be doing to cause their INR results to be outside therapeutic range.

As well as presenting the warfarin education on a seemingly ad hoc basis, other idiosyncrasies regarding warfarin education exist. Rather than use the warfarin consumer medicine information, CMI, many of the Australian health professionals delivering warfarin education either develop and use their own written patient warfarin information or alternatively use the Boots warfarin information booklets (2002; 2003). Unfortunately, much of this information is written at a level (Baker 1997; Estrada, Hryniewicz et al. 2000) beyond the comprehension of many patients and hence inappropriate as a written information resource.

Inadequacies in patient knowledge resulting from the currently available warfarin education programs highlight the need for a new more systematic approach to the delivery of warfarin education. Such a program should target the key elements believed to contribute to poor therapeutic outcomes and adverse drug events. During the development and implementation of this new program, special consideration should be directed to the development and/or use of validated instruments to determine if possible, the contribution of various components of the program to improved medication outcomes.
**2.5.5 The impact of improved warfarin education of warfarin-related therapeutic outcomes and adverse drug events**

A well-organised structured education program should enable patients to learn the necessary skills to achieve optimal therapeutic outcomes and minimise adverse drug events. Kagansky et al (2004) reported a combined retrospective and prospective cohort study on 323 patients, aged 80 years and older who were discharged from hospital on an oral anticoagulant. After following up these patients for approximately two to three years, the researchers found that the rate of major bleeds was highest amongst the patients who received poor quality warfarin education, which had been performed by the medical staff. The education programs consisted of an explanation about the purposes of the oral anticoagulant, the risk of complications and information about INR values. The poor quality of such education was found to be the most significant risk factor associated with bleeding complications in this elderly patient population. The results of this study like many others (Arnsten, Gelfand et al. 1997; Nadar, Begum et al. 2003; Roche-Nagle, Chambers et al. 2003) suggest that a good quality warfarin education program could help to reduce the incidence of bleeding complications associated with poor warfarin management.

Patients who have a poor understanding of the indications for warfarin use and its potential adverse effects are more likely to be non-compliant than are those who receive warfarin education (Arnsten, Gelfand et al. 1997). Barcellona et al (2002) found that the time spent within therapeutic range was improved for patients who knew why they were taking their oral anticoagulant, as compared to those who did not, significantly more so for the elderly patients aged 65 years and over (89 percent versus 76 percent, p = 0.04). This study also found that patients’ anticoagulation control could be improved by simply answering a warfarin knowledge questionnaire.

Evidence exists that poor compliance with anticoagulant treatment occurs in 10 – 26% of cases, especially among the elderly patients (Arnsten, Gelfand et al. 1997). An audit of hospital admissions over a 3 month period found that poor
anticoagulant compliance was the major contributing factor causing over-anticoagulation in 29 patients (Hirri and Green 2002). Similarly, Brigden et al (1998) also found that along with drug-to-drug interactions, poor compliance was a significant contributor to poor anticoagulation control in 65 patients admitted to hospital.

Comprehensive patient education about warfarin should also target improved patient education about drug-to-drug interactions with warfarin, which has been found to be responsible for many warfarin-related adverse drug events (Barcellona, Contu and Marongiu 2002; Brigden, Kay et al. 1998). Barcellona et al (2002) found that patients who knew more about potential food and warfarin interactions spent more time within therapeutic range than did those who did not. Similarly, Wilson et al (2003) identified that more than half of the 65 African American patients, aged 50 years and over in their study, could not read or understand the culturally inappropriate written information given to them, and were therefore more susceptible to warfarin related adverse drug events based on possible drug-food interactions.

Thus patients’ knowledge about warfarin is still generally poor, especially for patients in the ‘high risk’ group (Cheah and Martens 2003; Lambert and Wynne 2003; Nadar, Begum et al. 2003), highlighting the need for a more effective warfarin education program. This new program would need to target the many interventions found to help improve medication compliance (Haynes, McDonald et al. 2002a; Roter, Hall et al. 1998), as well as the many other factors believed to contribute to improved warfarin anticoagulation control. Such factors include encouraging patients to be involved in the decision making process (Dantas, Thompson, Manson, Tracy and Upshur 2004), promoting good health professional communication and partnerships (Barcellona, Contu, Sorano and Marongiu 2000), and providing easy-to-read culturally appropriate written warfarin information (Estrada, Hryniewicz et al. 2000; Wilson, Racine et al. 2003). Dantas et al 2004 conducted 21 face-to-face interviews with older patients and found that even though satisfaction was high amongst all patients, those who were more involved with the decision making process had a better warfarin...
knowledge and understanding than those who were not. Further evidence to support the need to promote health professional/patient communication and partnerships can be seen in the 96 percent response rate from the 264 patients attending two Italian anticoagulation clinics, indicating that doctor-patient relationships were very important to them (Barcellona, Contu et al. 2002). The importance of easy-to-read culturally appropriate written warfarin information will be further discussed in the next chapter.

2.5.6 Summary

Warfarin is one of the major medications causing adverse drug events, both in Australia and overseas (Australian Council for Safety and Quality in Health Care 2002; Forster, Murff et al. 2003). The incidence of warfarin-related adverse drug events is on the rise with recent recommendations for increased warfarin prescribing in atrial fibrillation (Cruickshank, Ragg et al. 2001). Inadequacies in the currently available warfarin education programs (Connor 1998) and patient warfarin knowledge deficiencies (Cheah and Martens 2003; Nadar, Begum et al. 2003; Tang, Lai et al. 2003), highlight the need for a new patient warfarin education program to help improve the patients' warfarin knowledge and understanding (Hirri and Green 2002). This new warfarin patient education program should target the key elements believed to contribute to poor warfarin-related therapeutic outcomes and warfarin-related adverse drug events, as well as the needs of the ‘high risk’ patient population.

2.6 CONCLUSION

This chapter has identified that many adverse drug events, including warfarin-related adverse drug events, which are potentially preventable, have a major impact on health, healthcare and healthcare costs, both in Australia and overseas. Improved patient medication education has been recognised as an important intervention, which can be used to help optimise therapeutic outcomes.
and reduce the potentially preventable adverse drug events. Recent and ongoing increases in warfarin prescribing are likely to lead to a further increase in the incidence of warfarin-related adverse drug events.

The literature has identified that current warfarin education programs are not as effective as they should be, because many patients, and especially ‘high risk’ patients, have deficits in their warfarin knowledge. This highlights the need for a new more systematic approach to the delivery of warfarin education targeting the key elements believed to contribute to poor therapeutic outcomes and adverse drug events, while addressing the needs of ‘high risk’ patients. The key elements which should be targeted include: improved health professional/patient communication and partnerships; warfarin compliance; simple, easy-to-read written warfarin information; continuity of care between hospital and community settings; and patient follow-up.

The next chapter focuses on the problems associated with patients having poor literacy skills and their inability to read and understand typically available written medication information, including warfarin information. The chapter recommends the use of a number of simple tests and instruments to assess and ensure that written patient medication information can be read and understood by a wider patient population, inclusive of those with low literacy skills. The chapter also recommends a number of simple instruments, which can be used to ensure that the patient medication education program is of a suitable, good quality standard, which will satisfy the patients’ needs.
3.1 INTRODUCTION

The previous chapter highlighted the need to target key elements which contribute to adverse drug events, in order to improve patient medication education, including patient warfarin education, and to help optimise therapeutic outcomes. Several interventions which focus on these key elements were discussed, with an emphasis on the need to accommodate the ‘high risk’ patient population. This chapter focuses on problems associated with low literacy skills and the readability of currently available written patient information, including warfarin information. It also highlights the importance of evaluation, which is often neglected in medication education programs.

Prior to developing and implementing any new patient medication education programs, however, it is important to consider the problems associated with patients having poor literacy skills. Unfortunately, poor literacy skills which can contribute to poor patient knowledge and understanding (Davis, Crouch, Wills, Miller and Abdehou 1990; Winslow 2001) can also aggravate the problems associated with poor medication compliance, poor therapeutic outcomes (Horner, Surratt and Juliusson 2000) and the increased incidence of adverse drug events (Feifer 2003). Research indicates that much of the currently available written patient medication information, used as an adjunct to verbal instruction, is written at levels beyond the comprehension of many patients, and especially those with low literacy skills (Koo, Krass and Aslani 2003; Mayeaux Jr, Murphy et al. 1996; Rutledge and Donaldson 1998). This chapter considers some of the readability tests, guidelines and evaluation instruments which can be used to ensure that
written patient medication information can be read and understood by a wider patient population, inclusive of those with low literacy skills.

Finally, the significance of evaluation cannot be overlooked and should be identified as an important intervention for an effective patient medication education program. Process, impact and outcome evaluation are invaluable ways in which to ascertain the suitability and quality of an education program. The patient’s satisfaction with the program is an important factor and assessing whether or not it achieves its goals and objectives are important ways in which to assess the success of the program.

3.2 LOW LITERACY SKILLS AND WRITTEN PATIENT MEDICATION INFORMATION

3.2.1 The problem of low literacy in healthcare

Low literacy is a pervasive and under-recognised problem in healthcare, both in Australia and overseas (Baker 1997; Mayeaux Jr, Murphy et al. 1996). Low literacy skills have been found to contribute to increased healthcare costs, adverse drug events, poor compliance (Feifer 2003) and an increase in hospital admissions (Baker, Parker et al. 1998; Winslow 2001). For many patients, a lack of literacy is a major obstacle to effective healthcare (Doak, Doak et al. 1998) because they lack sufficient knowledge to effectively manage their medications (Williams, Baker et al. 1998) and simply cannot read or understand the commonly used written information (Council on Scientific Affairs 1999; Davis, Michielutte, Askov, Williams and Weiss 1998; Roter, Rudd et al. 1998).

People with low literacy skills include not only the poorly educated but also the elderly (aged 65 years and over) and immigrants who speak English as a second language (Doak, Doak et al. 1996b). Based on data from the Australian Bureau of Statistics (ABS), a large proportion of the Australian population has low literacy skills. The 1996 Australian literacy survey identified that 20 percent of Australians aged 15 to 65 years, and 41 to 46 percent aged 65 to 74 years, have
very poor literacy skills (level 1) (Australian Bureau of Statistics 1996). Another investigation has also found that of the 20 percent of Australians who are from non-English speaking backgrounds (NESB), 2.5 percent speak little or no English (McLennan 1998). These patient populations cannot read or comprehend the typically available written medication information (Albright, Guzman, Acebo, Paiva, Faulkner and Swanson 1996; Baker 1997; Davis, Michielutte et al. 1998).

3.2.2 Written patient medication information

3.2.2.1 Background

Written educational materials are convenient, economical and very useful for providing medication information to patients and/or their carers (Bernier and Yasko 1991; Clark, AbuSabha, von Eye and Achterberg 1999). Research has identified that by adding simple and easy-to-read medication information to verbal instruction there is an increase in patient knowledge, compliance and satisfaction with therapeutic regimens (Baker, Roberts, Newcombe and Fox 1991; Roter, Hall et al. 1998). Evidence to support this is reported in a recent Cochrane collaborative review of 33 randomised clinical trials which concluded that combination strategies, including written medication information and counselling, improve compliance and clinical outcomes for both short-term (less than two weeks) and long-term treatments (Haynes, McDonald et al. 2002a).

Presently, the reading grade levels of written medication information, including warfarin information, available in Australia and overseas have been assessed to range from grade 9 to grade 14 (Baker 1997; Estrada, Hryniewicz et al. 2000; Weiss 1997). These are considerably higher than the average reading grade ability of many patients with low literacy skills, which is deemed to be below a grade 6 readability level (Davis, Crouch et al. 1990; Rolland 2000). Studies in America (Baker, Parker et al. 1998; Estrada, Martin-Hryniewicz et al. 2004; Gazmararian, Baker, Williams, Parker, Scott, Green, Fehrenbach, Ren and Koplan 1999) and in Australia (Baker 1997) confirm that these patients have difficulty reading currently available written medication information. The
readability of 30 consumer product information (CPI) leaflets, currently known as consumer medicine information (CMI), available in Australia (Baker 1997), using the Flesch Reading Ease (FRE) formula (Flesch 1948) (APPENDIX One) identified that only 40 percent or less of the patient population could read or understand these leaflets. Koo et al (2001) also identified that in an Australian study with 38 focus group participants over the age of 18, many of them were not only dissatisfied with the font size and volume, but they were also dissatisfied with the amount of medical jargon included in their CMI information.

Patients with low literacy skills are often too embarrassed to admit that they cannot read or understand commonly used written patient information (Mayeaux Jr, Murphy et al. 1996). They are more likely therefore to experience poorer therapeutic outcomes and adverse drug events than are patients from the general patient population (Baker, Parker et al. 1998; Consumers’ Health Forum of Australia 2000; Winslow 2001). Given that a sizeable proportion of the Australian population has low literacy skills (Australian Bureau of Statistics 1996), it has been recommended that written medication information should be available at or below the average reading ability of an Australian, estimated to be grade 8 (Buchbinder, Hall, Grant, Mylvaganam and Patrick 2001). Indeed others like Doak et al (1996) recommend that all written patient medication information should be available at or below a grade 6 reading level, which arguably would be more suitable for patients with low literacy skills. In some situations this may be possible, unfortunately however because of medication names and related terminology this may not always be possible.

Multiculturalism is identified as an important factor which affects the comprehension of written patient medication information (Voelker 1995; Westby 1995; Wilson, Racine et al. 2003). This is especially true in Australia where much of the information is almost exclusively written in English (Bajramovic and Tett 2000). Having the information translated into another language is not always an easy solution because many non-English speaking patients are illiterate in their native language, as well as in English. Ideally these patients need to be verbally educated about their medications in their own languages with the assistance of
an interpreter (Williamson, Stecchi, Allen and Coppens 1997). This would help to reduce the communication barrier and improve medication education, compliance and therapeutic outcomes for these non-English speaking background patient populations (Lambert and Minas 1998; Minas, Lambert et al. 1996).

In summary, a large proportion of the Australian population has low literacy skills and cannot read or understand the currently available written patient medication information, including warfarin information. The time has come to address this problem. All written patient medication information, including warfarin information, should be presented in a simple and easy-to-read format, written at or below a grade 8 to grade 6 reading level (Doak, Doak et al. 1996b). The inclusion of these factors into written medication information would help to ensure their readability and comprehension by a wider patient population, inclusive of those with low literacy skills (Butow, Brindle, McConnell, Boakes and Tattersall 1998).

3.2.2.2 Preparation of written patient medication information

A patient’s understanding and satisfaction with written information has also been found to be influenced by factors such as format, colour, text, print size and the use of illustrations (Clark, AbuSabha et al. 1999; Klug Redman 2001). It is important, therefore, to address these factors which help to engage the interest of most patient populations, including patients with low literacy skills (Koo, Krass et al. 2003).

There are a number of tools and guidelines available to assist with addressing factors such as format, colour, text, print size and illustrations. The United Kingdom Department of Health recently produced the ‘Toolkit for Producing Patient Information’ (2002) (APPENDIX 2) which is simple and easy to use. Alternatively, the ‘Guidelines for Writing Patient Information’ (Doak, Doak et al. 1996b) (APPENDIX 3) provide useful recommendations on how to ensure that these factors are addressed for patients with low literacy skills. The impact of both the ‘Toolkit for Producing Patient Information’ (2002) and the ‘Guidelines for
Writing Patient Information’ (1996) on the quality and suitability of health information have yet to be formally evaluated, however, they are functional, practical and easy to use.

When preparing written information for distribution to patients from non-English speaking backgrounds it is important to ensure that the information and illustrations are culturally sensitive. Seeking the advice of cultural group members and health professionals who are from these cultural groups during the planning and development stage helps to ensure that the information is in fact culturally-sensitive (Doak, Doak et al. 1996b). In most circumstances, when money and time permits, written patient information should be translated from English into the patients’ language, when and if required. This of course would only benefit the non-English speaking background patients who are literate in their native language (Williamson, Stecchi et al. 1997).

For the many health professionals who are involved in the preparation of written patient medication information, it is important to acknowledge that the patients’ understanding and satisfaction with the information can be influenced by factors such as format, colour, text, print size and illustrations (Clark, AbuSabha et al. 1999; Klug Redman 2001). Health professionals should therefore use simple tools and guidelines such as the ‘Toolkit for Producing Patient Information’ (The United Kingdom Department of Health 2002) and the ‘Guidelines for Writing Patient Information’ (Doak, Doak et al. 1996b) when preparing and developing written patient information.

3.2.2.3 Assessing the readability of written patient medication information

The goal of written patient medication information is to increase patient understanding and comprehension and to serve as resource material for the patient and/or their carer. It is the responsibility of health professionals to ensure that the available written medication information can be read and understood by the majority of patients, including those with low literacy skills. There are two methods which can be used to assess understanding and readability. The first method involves assessing the patient’s health literacy level to ensure that s/he
can understand the information. The second method involves assessing the readability level of the written patient medication information.

A number of tests are available to assess patients' health literacy levels. These include simple word recognition tests such as the Wide Range Achievement Test-Revised (WRAT-R) (Jastak and Wilkinson 1993), the Rapid Estimate of Adult Literacy in Medicine (REALM) (Murphy, Davis, Long, Jackson and Decker 1993) and the Slosson Oral Reading Test-Revised (SORT-R) (Slosson 1990). For research purposes, the Test of Functional Health Literacy in Adults (TOFHLA) (Nurrs, Parker, Williams and Baker 1995) is currently considered the most useful health literacy comprehension test because it has been found to have good content validity and it uses text from real healthcare settings (Davis, Michielutte et al. 1998). Overall, these tests tend to be time consuming to administer and busy health professionals might derive more benefit from assessing the readability of the written patient medication information, as opposed to assessing each patient's health literacy level.

Readability formulae are designed to make quick and easy assessments of readability and to estimate the reading grade level a patient requires to understand written information. Some of the well-known formulae include SMOG (McLauglin 1969) (APPENDIX 4), the Fry Readability Formula (FRY) (Fry 1968) (APPENDIX 5) and the Flesch Reading Ease (FRE) formula (Flesch 1948) (APPENDIX 1). Alternatively, there is the convenient and easy to use computerised Flesch-Kincaid program available on Microsoft Office Word 2000. Each of these readability formulae have a high correlation (Spadaro, Robinson and Smith 1980) which means that they can all be readily used and interchanged to assess the readability of written information. The major limitation for each of these formulae, as far as written patient information is concerned, is that they are not healthcare specific. Recently, an instrument called ‘The Readability Assessment Instrument’ (RAIN) (Singh 1994) was developed to estimate the readability and patient comprehension of written patient information. Unfortunately to date, the validity and the ease with which this instrument can be used is difficult to assess because its use has been limited to only one American
study analysing the readability of seven different patient ‘phenytoin’ information leaflets (Kirkpatrick and Mohler 1999).

In summary, there are two ways in which to assess whether or not written medication information can be read and understood by patients. The first way, which is considered more time consuming and less practical, is to assess the individual patient’s health literacy levels by using tests such as: Wide Range Achievement Test-Revised (WRAT-R) (Jastak and Wilkinson 1993); Rapid Estimate of Adult Literacy in Medicine (REALM)(Murphy, Davis et al. 1993); Slosson Oral Reading Test-Revised (SORT-R)(Slosson 1990); and the Test of Functional Health Literacy in Adults (TOFLA)(Nurrs, Parker et al. 1995). The second way is to assess the readability of the written medication information by using readability formulae such as SMOG (McLauglin 1969), the Fry Readability Formula (FRY) (Fry 1968), the Flesch Reading Ease (FRE) formula (Flesch 1948) and the computerised Flesch-Kincaid instrument on the Microsoft Office Word 2000 program, keeping in mind that they are not healthcare specific. In terms of convenience and efficiency, the latter is probably most suitable for busy health professionals to ensure that the information they are providing can be read and understood by the majority of their patients.

3.2.2.3.1 Assessing the readability of written warfarin information

Warfarin information available in Australia and internationally, has been assessed as being written at a level beyond the comprehension of patients with low literacy skills (Baker 1997; Estrada, Hryniewicz et al. 2000; Tang, Lai et al. 2003). An American study which used the Flesch-Kincaid Grade Level formula to determine the readability of 50 brochures commonly used in anticoagulation management units, found that all the brochures were written at levels beyond the comprehension of patients with low literacy skills, educated at or below a grade 6 level. This study found that the mean readability level of the brochures was grade 10.7 (95 percent; CI 10.1 to 11.2). No brochures had a readability level of grade 6 or below; 12 percent (n=6) had readability scores at grade 7 to 8 levels; 74 percent (n=37) had readability scores at grade 9 to 12 levels; and 14 percent
(n=7) were written at levels above grade 12 (Estrada, Hryniewicz et al. 2000). Another study conducted in Hong Kong found that poor literacy skills were the main reason for poor warfarin knowledge in 62 patients (50.8 percent) of the 122 patients studied. These patients were not able to read and understand the written warfarin information provided to them (Tang, Lai et al. 2003). Finally, the most recent American study conducted by Estrada et al (2004) found that 68 (47.6 percent) of the 143 patient participants over the age of 60 could not read health-related words written at or above grade 8 levels and were more likely to experience poor anticoagulant control over a three month period. Similar studies have not yet been conducted in Australia, nor have studies focused on patients’ use and/or satisfaction with their warfarin consumer medicine information (CMI) or the commonly used Boots warfarin information booklets (2002, 2003). In the absence of such data a computerised Microsoft Office Word 2000 Flesch-Kincaid test was carried out on the commonly used Boots warfarin information booklet (2002) which was found to be written at a grade 9.4 reading level and a grade 8.9 reading level for the more recent 2003 edition. Both booklets, therefore, which are commonly used by Australian health professionals, are written at grade levels well above the reading ability of patients with low literacy skills.

There appears to be an obvious lack of suitable written warfarin information, especially for patients with low literacy skills, both in Australia and overseas. This highlights the need to develop and produce a new warfarin information booklet written at or below a grade 8 level (Buchbinder, Hall et al. 2001), or preferably even below a grade 6 level (Estrada, Hryniewicz et al. 2000). Such a booklet should also adhere to recommended guidelines ensuring that it appeals to the patients’ understanding and satisfaction based on factors such as format, colour, text, print size and illustrations.

3.2.3 Summary

Written patient medication information is an efficient, relatively inexpensive adjunct to verbal instruction. Unfortunately, currently available written medication information, including warfarin information, is typically written at levels beyond
the comprehension of many patients, especially those with low literacy skills (Baker 1997; Estrada, Martin-Hryniewicz et al. 2004; Weiss 1997). Health professionals who have the responsibility of preparing and providing written patient medication information, including warfarin information, should acknowledge that a large proportion of the population has low literacy skills and should therefore ensure that the information is available at or below a grade 8 reading level (Buchbinder, Hall et al. 2001) or better still a grade 6 reading level (Estrada, Hryniewicz et al. 2000). There are many simple readability tests such as SMOG (McLauglin 1969), the Fry Readability Formula (FRY) (Fry 1968), the Flesch Reading Ease (FRE) formula (Flesch 1948) and the computerised Flesch-Kincaid instrument on the Microsoft Office Word 2000 program which can be used to ensure that information is written at an appropriate level.

3.3. EVALUATION OF PATIENT EDUCATION PROGRAMS

Evaluation is an essential component of an effective patient education program because it ensures that the program is suitable, effective and satisfies the patient’s needs. Evaluation can be classified in three different ways. The first is process evaluation, which measures the activities of the program, the quality of the program and assesses whom the program is reaching. The second is impact evaluation which measures the immediate effect of the program and the third is outcome evaluation which measures the long-term effects of the program (Hawe, Degeling and Hall 1990).

Process evaluation, which measures the activities of the program, assesses the quality of the program and the suitability of the program to reach target populations, can involve the use of readability, suitability, quality and patient satisfaction instruments. Examples of some readability tests which have already been discussed in this chapter, include the SMOG Formula (McLauglin 1969)(APPENDIX 4) and the Fry Readability Formula (Fry 1968)(APPENDIX 5). Several instruments are available to assess the suitability and the quality of the written patient information. One example of such an instrument is the ‘Suitability
Assessment of Materials instrument’ (SAM) (Doak, Doak et al. 1996b)(APPENDIX 6). SAM is a useful validated tool, which evaluates the content, literacy demands, graphics, layout and typography, as well as the learning stimulation, motivation and cultural appropriateness of the written information for patient populations, inclusive of the low literacy skilled populations. A second instrument is the ‘Bernier Instructional Design Scale’ (BIDS)(Bernier 1996)(APPENDIX 7) which is a useful instrument for identifying and measuring the presence (or absence) of instructional design and learning principles within the written information. A third quick and easy-to-use instrument is the ‘Checklist for print materials’(Bidford Maine Area Health Education Center 1996) (APPENDIX 8) which assesses the appropriateness of the written material for patients. All of these instruments can be used to evaluate the quality and the suitability of the written medication information, including warfarin information, for both the general and low literacy skilled patient populations. The results of these evaluations can also uncover deficiencies within the written medication information which may need to be addressed to improve its suitability and quality.

An important arbiter of the quality of medication information is the extent to which individuals perceive that the information has satisfied their needs (Horne, Hankins and Jenkins 2001). Assessing patients’ satisfaction with the amount of medication information provided is a prerequisite for developing partnerships in the quality use of medicines and the optimisation of therapeutic outcomes (Cox, Stevenson et al. 2004). It is important therefore to use tools such as the ‘Satisfaction with Information about Medicines Scale’ (SIMS)(Horne, Hankins et al. 2001)(APPENDIX 20) which assesses the patients’ satisfaction and/or dissatisfaction with the information they have received. Even though patient dissatisfaction can be a disappointment to the health professional, it gives them a chance to improve educational practices and hopefully remedy the situation.

Impact evaluation assesses whether or not the program has met its objectives by evaluating patient knowledge and understanding, and their adherence to recommended health behaviours such as medication management and compliance. Changes in patients’ medication knowledge and understanding,
as well as their medication management and compliance are measures of the impact of the medication education programs, including warfarin education programs. In the past, evaluation of warfarin education programs have been poor (Wyness 1990), with recent studies identifying that even though patients received warfarin education, they had deficits in their warfarin knowledge, often resulting in poor warfarin management and compliance (Cheah and Martens 2003; Lambert and Wynne 2003; Nadar, Begum et al. 2003; Tang, Lai et al. 2003). The results of these recent studies highlight the need to evaluate the impact of warfarin education programs on the patients’ warfarin knowledge and understanding.

Finally, outcome evaluation assesses whether or not the program has met its aims and objectives. Program outcome indicators need to translate into health status measurements, which can include blood test results and healthcare utilisation (for example; number of general practitioner, hospital and/or emergency department visits). These are important indicators of the long-term effectiveness of the education program and patients’ abilities to manage their own medications (Lorig and associates 1996). These outcome evaluations would be especially important for patients taking warfarin therapy, and in particular those suffering from atrial fibrillation, a recently promoted indication for lifelong warfarin therapy (Elliott, Woodward et al. 2002; Peterson, Jackson et al. 2002).

Evaluation is therefore an important component of an effective patient medication education program, including a warfarin education program, because it assesses the quality and suitability of the program, patients’ satisfaction with the program and the overall impact of the program in terms of patient knowledge and understanding, medication management and compliance. Finally, outcome evaluation measures the long-term effectiveness of the medication education program. Evaluation not only ensures that the program appeals to the patients and achieves its goals and objectives, but it also helps to identify possible inadequacies within the program which may need to be addressed to improve its quality and suitability.
3.4 CONCLUSION

Effective warfarin education is invaluable for patients to be able to manage their warfarin therapy and to make confident educated decisions about warfarin management which may affect their anticoagulant control and health status (Gibbar-Clements, Shirrell et al. 2000; Moore 1977). With recent increases in warfarin prescribing (Elliott, Woodward et al. 2002) deficits in patient warfarin knowledge (Cheah and Martens 2003; Nadar, Begum et al. 2003; Tang, Lai et al. 2003) and the rising incidence of warfarin-related adverse drug events (AIHW 2003), there is an obvious need to develop and implement a new and effective patient warfarin education program.

This chapter has discussed the difficulties faced by patients with low literacy skills in reading and understanding typically available written patient information, including warfarin information. These difficulties can negatively impact upon their therapeutic outcomes and in some cases lead to adverse drug events. Written patient warfarin information should therefore be available at no higher than a reading grade 8 level (Buchbinder, Hall et al. 2001), or preferably at or below a grade 6 level (Estrada, Hryniewicz et al. 2000). This would ensure that the warfarin information could be easily read and understood by a wider patient population, inclusive of those with low literacy skills.

Since factors such as format, colour, text, print size and the use of illustrations can impact upon a patient’s understanding and satisfaction with written patient information (Clark, AbuSabha et al. 1999; Klug Redman 2001), it is important to address each of these factors by adhering to simple guidelines when developing and producing written patient medication information. Examples of these guidelines include the ‘Toolkit for Producing Patient Information’ (The United Kingdom Department of Health 2002) and the ‘Guidelines for Writing Patient Information’ (Doak, Doak et al. 1996b). Adhering to these simple guidelines helps to ensure that the written information engages the interest of many patient populations, inclusive of those with low literacy skills (Koo, Krass et al. 2003).
This chapter has also discussed the importance of evaluation to ensure that medication education programs, including those for warfarin, are of good quality and are effective. Process, impact and outcome evaluation can be used to assess the suitability of the program to reach target populations, its effectiveness to improve patients' medication knowledge, management and compliance and its long-term effectiveness to achieve aims and objectives.

The next chapter will discuss in detail the conceptual framework used to develop and design a new patient warfarin education program. The advantage of using a conceptual framework is that it provides a blueprint to replicate successful key interventions and strategies and offers a systematic process to analyse success or failure of the program (Doak, Doak et al. 1996b). It is also noted in the literature that educational programs most likely to succeed are those developed and managed using structural frameworks (National Institutes of Health 2001). One of the most significant aspects of this research study is that even though there is a focus on developing an effective patient warfarin education program, the conceptual framework can be generically applied to any effective patient medication education program.
CHAPTER 4
CONCEPTUAL FRAMEWORK FOR AN EFFECTIVE PATIENT WARFARIN EDUCATION PROGRAM

4.1 INTRODUCTION

Historically, warfarin patient education programs have been inadequate (Connor 1998), overwhelming (Ansell, Buttaro et al. 1997) and not properly evaluated (Wyness 1989). Recent studies by Cheah et al (2003), Nadar et al (2003) and Lambert et al (2003) have all found that patients, and especially those from the ‘high risk’ group, have deficits in their warfarin knowledge after receiving warfarin education. These studies and others published within recent years (Barcellona, Contu et al. 2002; de Felipe Medina 2003; Roche-Nagle, Chambers et al. 2003) highlight the need for more effective warfarin education programs to reduce these warfarin knowledge deficits and to improve warfarin management and compliance in a wider patient population, inclusive of the ‘high risk’ group.

The new warfarin education program developed and trialed for this study was based on a conceptual framework which reflects ‘best evidence’ with regard to patient medication education programs. The new program targeted the five key elements identified in the literature which contribute to improved therapeutic outcomes and reduced incidence of adverse drug events. These five key elements were: improved health professional/patient communication and partnerships; warfarin compliance; simple, easy-to-read written warfarin information; continuity of care between hospital and community settings; and patient follow-up.

A full evaluation of the new program, which will be discussed in the next chapter, was also undertaken during the course of the study. During the evaluation phase the new program was compared to and contrasted to the customary warfarin education program delivered to The Ambulatory Care Team (TACT) patients prescribed warfarin.
This chapter outlines the conceptual underpinnings of these five key elements and describes how they link to form the basis of an effective warfarin education program. Importantly, using this conceptual framework to plan interventions and strategies which target improved patient education provides a blueprint to develop other much needed medication education programs.

4.2. Figure 1: Conceptual Framework For An Effective Warfarin Education Program

Health professional/patient communication & partnerships

Warfarin compliance

Simple, easy-to-read warfarin information.

Continuity of care between hospital and community settings

Patient follow-up

Effective Warfarin Education Program
4.3 INTERVENTIONS USED TO TARGET THE FIVE KEY ELEMENTS OF THE CONCEPTUAL FRAMEWORK IN THE NEW WARFARIN EDUCATION PROGRAM.

4.3.1 Health professional/patient communication and partnerships

Poor health professional/patient communication and partnerships have been identified as major contributors to poor therapeutic outcomes and adverse drug events (Bhasale, Miller et al. 1998; Cox, Stevenson et al. 2004; Elwyn, Edwards et al. 2003). Interventions which target this key element are recognised as important ways in which to improve patient knowledge and understanding and to empower patients to make confident, educated decisions about their medication management. The literature provides a range of strategies to help improve health professional/patient communication and partnerships.

Health professionals should focus on promoting their roles as good educators by developing good communication skills and collaborating more effectively with their patients (Aslani and Du Pasquier 2002; Rankin and Duffy Stallings 2000). Good communication and collaboration involves encouraging their patients to become part of the education process by asking questions, making comments and not being afraid to express their opinions (Dantas, Thompson et al. 2004). Health professionals need to ensure their manner is always encouraging, reinforcing, reassuring and approachable, especially when accepting feedback (Clark, Gong et al. 1998; Kok, van den Borne et al. 1997). They also need to seek the respect of their patients and in turn offer them respect for their beliefs, assumptions and attitudes (The Royal Pharmaceutical Society of Great Britain 1997). This study aimed to incorporate each of these strategies into the new warfarin education program in an attempt to maximise communication and collaborative interchange between the health professional (who is also the researcher/pharmacist) and the patient.

The establishment of effective partnerships is reliant on learning environments which encourage patients to listen, access information and to seek reassurance about their knowledge and understanding (Australian Council for
For the purposes of this study, therefore, the initial warfarin education sessions were delivered to patient participants in their own homes or at an alternate venue chosen by themselves.

Simple guidelines need to be adhered to by health professionals when establishing good communication and partnerships with the ‘high risk’ patient population. These simple guidelines, which were incorporated into the new warfarin education program, include: using simple language; speaking slowly; repeating and underlining key points; and not giving too many directives during the education session (Doak, Doak et al. 1996b; Mayeaux Jr, Murphy et al. 1996). It is also important to urge carers and/or family members to attend the education sessions (Doak, Doak et al. 1998) and ensure that interpreters are made available for non-English speaking background patients (Williamson, Stecchi et al. 1997).

In summary, interventions and strategies which promote good health professional/patient communication and partnerships are essential components of an effective warfarin education program because they help to optimise therapeutic outcomes and minimise adverse drug events (Cox, Stevenson et al. 2004; Elwyn, Edwards et al. 2003). These interventions and strategies need to target encouragement, reinforcement, reassurance and feedback (Clark, Gong et al. 1998; Kok, van den Borne et al. 1997) in an environment which encourages the patients, including those from the ‘high risk group’, to listen, access information and seek reassurance about their knowledge and understanding (Australian Council for Safety and Quality in Health Care 2002),

4.3.2 Warfarin compliance

Poor warfarin compliance is also a significant contributor to poor anticoagulation control (Arnsten, Gelfand et al. 1997) and warfarin-related adverse events (Brigden, Kay et al. 1998; Hirri and Green 2002). Knowing that the ‘high risk’ patient population, including the elderly and those with low literacy skills (Lambert and Wynne 2003; Tang, Lai et al. 2003), as well as the non-English speaking background patients (Nadar, Begum et al. 2003) are most likely
to experience poor warfarin-related therapeutic outcomes, it would be reasonable to assume that this is significantly contributed to by poor warfarin compliance. Targeting ways in which to improve warfarin compliance, especially in the ‘high risk’ group, is therefore a key element of an effective warfarin education program.

According to the literature, however, improved medication compliance can only be effectively achieved by including several interventions at the one time (Haynes, McDonald et al. 2002a; McDonald, Garg and Haynes 2002; Roter, Hall et al. 1998). These interventions include: educating the patients, carers and/or family members about the importance of regular medication compliance; explaining the implications of not complying with regular therapy; recommending compliance aids when and if required; offering encouragement, reinforcement, reassurance and follow-up; as well as undertaking medication reviews.

Good warfarin compliance can be encouraged by effectively educating the patient, their carer and/or family member about warfarin therapy (Barcellona, Contu et al. 2002). Several studies have highlighted the essential warfarin information, which needs to be understood. This includes: how warfarin works; the importance of taking warfarin appropriately and why regular monitoring is necessary; appropriate dosing schedules; possible side effects and drug-to-drug interactions; as well as possible necessary behaviour changes, for example; exercise, dietary and alcohol restrictions (Gibbar-Clements, Shirrell et al. 2000; Hirsh, Dalen et al. 1995). Carers and family members should always be urged to attend warfarin education sessions to promote information recall and encourage good patient warfarin compliance (Doak, Doak et al. 1996b).

Compliance aids such as blister packs, dosette boxes, medication alarms and medication cards help to improve medication compliance for all patient populations (Roter, Hall et al. 1998; Wong and Norman 1987), including the ‘high risk’ patients (Levings, Szep et al. 1999). They have been found to be especially useful for patients suffering from cognitive and/or physical limitations (poor eye sight, hearing impairment) (Barat, Andreasen et al. 2001; Wong and Norman 1987). For the purpose of this study, even though all patients were informed
about compliance aids, the 'high risk' patients were strongly encouraged to use compliance aids.

Offering the patients encouragement, reinforcement, reassurance and feedback promotes both good health professional/patient communication, partnerships and good medication compliance (Kok, van den Borne et al. 1997). These interventions in combination with patient follow-up, which will be discussed later in this chapter, were all used in the new warfarin education program to help promote warfarin compliance.

Patient medication reviews are an essential part of the practice of all pharmacists because they can reduce inappropriate prescribing and adverse drug events (Hanlon, Weinberger, Samsa, Schmader, Uttech, Lewis, Cowper, Landsman, Cohen and Feussner 1996). They also help to improve medication compliance in patients who suffer from any cognitive and/or physical limitations (Stewart and Caranasos 1989), as well as those taking multiple medications, including warfarin (Fulmer, Hollander-Feldman, Sook Kim, Carty, Beers, Molina and Putnam 1999). Medication reviews not only help to simplify the medication regimen for these patients but they also help to minimise possible drug-to-drug interactions with warfarin (Becker and Maiman 1980; Haynes, McDonald et al. 2002a). For the purposes of this study, the researcher/TACT pharmacist reviewed all the intervention patients’ medications, including their complementary medications, to ensure that they were taken appropriately in an easy-to-follow regimen. In the event of possible drug-to-drug interactions, the researcher/TACT pharmacist collaborated with the patients’ healthcare providers to ensure that the interacting drugs were ceased, changed or carefully monitored while taken in combination with the warfarin therapy.

In summary, targeting interventions to improve medication compliance and in this instance warfarin compliance is a key element of an effective education program. Several interventions were included in the new warfarin education program to help optimise warfarin compliance. These interventions included: educating the patients, carers and/or family members about their warfarin therapy; recommending compliance aids; offering encouragement,
reinforcement, reassurance and follow-up; as well as undertaking medication reviews. These interventions were especially important to help promote warfarin compliance in the ‘high risk’ patient population.

4.3.3 Simple, easy-to-read warfarin information

Evidence suggests that patients who receive insufficient and inappropriate medication information are more likely to experience poor therapeutic outcomes and adverse drug events (Bhasale, Miller et al. 1998). Therefore, it is important to provide simple and easy-to-read medication information (Esposito 1995; Houts, Witmer, Egeth, Loscalzo and Zabora 2001) which is appropriate, readily available and understood by all patients including those in the ‘high risk’ group (Doak, Doak et al. 1996b).

There are many tools, instruments and guidelines available, which can be used to ensure that warfarin information is written in a simple, easy-to-read format with culturally sensitive illustrations. Readability tools such as the SMOG test (McLauglin 1969)(APPENDIX 4), the Fry Readability Fry Readability Formula (Fry 1968) (APPENDIX 5) and the computerized Flesch-Kincaid Instrument available on the Microsoft Office Word 2000 program can be used to ensure that the information is written at a suitable level. While, the ‘Toolkit for producing patient information’ (The United Kingdom Department of Health 2002)(APPENDIX 2) and the ‘Guidelines for writing patient information’ (Doak, Doak et al. 1996b) (APPENDIX 3), can be used to ensure that the information is written in a simple, easy-to-read format with attention to colour, text, print size and graphics. Finally, the ‘Suitability Assessment of Materials” (SAM) instrument (Doak, Doak et al. 1996b) (APPENDIX 6), the ‘Bernier Instructional Design Scale’ (BIDS)(Bernier 1996)(APPENDIX 7) and the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) (APPENDIX 8) can all be used to ensure the quality and the suitability of the written information, especially for the ‘high risk’ patient population.

In the absence of available suitable written warfarin information (Estrada, Hryniewicz et al. 2000) the researcher/TACT pharmacist used all of the tools,
instruments and guidelines described above to develop the new warfarin information booklet (APPENDIX 12). They were all deemed to be important because of the evidence that patients’ use and satisfaction with written information is dependent upon its readability, presentation and quality (Clark, AbuSabha et al. 1999; Koo, Krass et al. 2003).

In summary, to improve warfarin-related therapeutic outcomes and minimise adverse drug events, patients must be given sufficient and appropriate written information. Good quality, simple, easy-to-read information, available in a suitable format with culturally sensitive illustrations is therefore necessary to effectively educate patients about their warfarin. Consequently, several tools, instruments and guidelines were used in the development of the new warfarin information booklet (APPENDIX 12) to ensure its readability, quality and suitability for a wider patient population, inclusive of the ‘high risk’ group.

4.3.4 Continuity of care between hospital and community settings

Poor continuity of care between hospital and community settings has been recognised as an important contributor to poor therapeutic outcomes and adverse drug events (Bhasale 1998; Forster, Murff et al. 2003). The need to focus on interventions which target the improvement of continuity of care with regard to medication and medication information, has only become a priority in Australia in the past few years. Many medication errors and adverse drug events have arisen due to inadequacies in the transfer of relevant medication and medication information between hospital and community settings (Clark, Graham and Williamson 1999; Dartnell, Anderson et al. 1996). Misadventures occur because patients, carers and community-based healthcare providers are often ill-informed about medication changes which took place while the patients were admitted to the healthcare services (Bhasale 1998).

The recently prepared Australian Pharmaceutical Advisory Council (APAC) ‘Guidelines on the continuum of care of quality use of medicines between hospital and community’ (Australian Pharmaceutical Advisory Council 1998) (APPENDIX 9) provide useful strategies to improve this continuum of care.
between hospital and community settings for medication management, including warfarin management. These APAC guidelines focus on the need to ensure that an accurate medication history and review is carried out for each patient, that patients are given medication and medication information in a timely manner and that their nominated healthcare providers are informed about the new medications and/or changes once patients have been discharged from the healthcare service.

Improved continuity of care between hospital and community settings are known to improve overall therapeutic outcomes and reduce adverse drug events (Australian Council for Safety and Quality in Health Care 2002), which is why the APAC ‘Guidelines on the continuum of care of quality use of medicines between hospital and community’ (1998) were incorporated into the new warfarin education program. All the patients’ medications were reviewed, warfarin medication, information and education was delivered to the patients, their carers and their general practitioners in a timely manner, upon admission and discharge from Illawarra Health’s The Ambulatory Care Team (TACT).

**4.3.5 Patient follow-up**

Patient follow-up has also been shown to improve therapeutic outcomes and reduce the incidence of adverse drug events (Dudas, Bookwalter et al. 2001). Patient follow-up can be achieved in several ways including: written communication; face-to-face interviews; group sessions; and telephone follow-up. All of these patient follow-up methods are useful and effective because they offer reassurance and reinforcement to the patients, encouraging them to be proactive with their treatment regimens (Hendricks and Hendricks 2000; Waterman, Milligan et al. 2001), while improving their satisfaction and reducing the number of medication-related problems (Dudas, Bookwalter et al. 2001).

Patient follow-up is therefore an essential component of an effective warfarin education program because not only does it have benefits of its own but it also positively impacts upon some of the other key elements which include: health professional/patient communication and partnerships; medication
compliance; and the continuity of care (Haynes, McDonald et al. 2002a). Based on limited time, resources and the fact that telephone follow-up appears to be equally as effective as the other follow-up methods in improving health professional/patient communication and partnerships (Hendricks and Hendricks 2000), medication compliance (Roter, Hall et al. 1998), patient education (Estey, Tan et al. 1990) and medication self-management (Dudas, Bookwalter et al. 2001), it was concluded that telephone follow-up is a suitable way in which to follow up patients and it was the method used in the study.

4.4 SUMMARY

In summary, having reviewed the literature, five key elements were identified which need to be targeted when developing an effective medication education program. These include: improved health professional/patient communication and partnerships; medication compliance; simple, easy-to-read medication information; the continuity of care between hospital and community settings; and patient follow-up. As well as targeting these key elements it is also necessary for effective programs to address the needs of the 'high risk' patient population, which include the elderly, those with low literacy skills, and those from non-English speaking backgrounds.

By introducing several interventions and strategies to target these five key elements, it was intended that the new warfarin education program would promote good health professional/patient communication and partnerships, encourage optimal warfarin compliance and provide simple, easy-to-read written warfarin information for the patients. Processes were also put in place for the new program to achieve improved continuity of care between hospital and community settings by adhering to the APAC guidelines (1998) and by providing patient telephone follow-up.

This chapter has discussed the conceptual underpinnings of the five key elements, which form the basis of an effective medication education program, and in this instance a new warfarin education program. Strategies and
interventions used to target these key elements in the new warfarin education program, developed for this study, were also identified and described.

The next chapter will outline the methodology used to incorporate this conceptual framework into the new warfarin education program, which will then be compared to and contrasted with the customary warfarin education program presented to patients prescribed warfarin, who are admitted to Illawarra Health’s The Ambulatory Care Team (TACT).
CHAPTER FIVE
METHODS

5.1. INTRODUCTION

The methods used in this study to develop, implement and evaluate the new warfarin education program are described in depth throughout this chapter. Initially, there is a description of the study design and how the five key elements reflecting ‘best evidence’ are incorporated into the new program. The actual program itself and the evaluation instruments used in the study are schematically described in section 5.4, which then goes on to discuss the results of the pilot study and the necessary ethical considerations. The chapter concludes with information about how eligible patient participants were recruited, which documentation they needed to complete and the questionnaires that were used for evaluation purposes. A tabled summary of the methodological process and a flowchart of the research study are also provided as an overview of the study process and design.

It is important to note that for the purposes of this study, when referral is made to the word ‘patient’ this also includes the primary ‘carer’ or ‘family member’ who was responsible for managing and administering warfarin medication, when patients did not do so themselves.

5.2 OVERVIEW OF THE STUDY

The purpose of the study was to develop and implement a new warfarin education program, to help improve warfarin knowledge, compliance and management in a wider patient population, inclusive of the ‘high risk’ patients. This ‘high risk’ group of patients included the elderly, those with low literacy skills and those from non-English speaking backgrounds. The study was conducted on patients who were admitted to Illawarra Health’s The Ambulatory Care Team
(TACT) and prescribed warfarin for either the first time, or after a period of no less than 15 years. Even though TACT operates from within Wollongong hospital, it is a community-based healthcare service, which visits, treats and educates patients in their own homes.

The study was a prospective study involving all patients newly prescribed warfarin and admitted to the Illawarra Health Ambulatory Care Team over a 12-month period from February 2003 to February 2004. A prospective study was considered reasonable because it looked forward in time and involved one group being exposed and the other group not being exposed to the new warfarin education program. Also, because outcome data such as warfarin knowledge and understanding, satisfaction with the education program, medication management and therapeutic data (e.g. warfarin levels) were to be collected after the exposure to the education program. After consultation with Dr Pam Davy, a statistician at the University of Wollongong, it was agreed that in order to detect a difference in warfarin knowledge and understanding between the two groups, at a power of 70% using the 5% level of significance, at least 100 participants - 50 control and 50 intervention - would be required for the study.

Power calculation is a statistical method used in the estimation of the sample size needed to increase the likelihood of demonstrating genuine differences within a study. A powerful study is very likely to find genuine differences if any exist, and a weak study could easily miss them (Hassard 1991). To ensure that a difference is in fact genuine and not merely a random occurrence, the level of significance or $\alpha$ level is usually set to 0.05 or less. Generally speaking a power of 80% is the preferred level for a study thereby providing a $\beta$ level of 0.2. It is more appropriate to relax the $\beta$ level rather than the $\alpha$ level in a study because $\beta$ errors (i.e. missing a genuinely better program or treatment and hence continuing with an established reasonable program or treatment), has less detrimental effects than $\alpha$ errors (i.e. switching from an established effective program or treatment to a new relatively, unknown program or treatment that is not actually any better)(Hassard 1991).
In this study, a $\beta$ level of 0.2 was assessed not to be practical because it required a large sample size which could not be managed within the duration and resources available for this PhD study. The $\beta$ level was relaxed and a power of 70% was used in the calculation of sample size. The participants’ warfarin knowledge was considered the most important variable because it was expected to impact on the other variables being investigated (i.e. self-management, medication-taking-measures, satisfaction with information, and health care related outcome measures). The calculation was therefore based on this variable, using a power of 70% and a 5% level of significance.

The main implication of the power calculation is that it would only be expected to identify a statistically significant difference in the warfarin knowledge variable for both groups within the time and resource constraints of this study. A sample size of 100 with equal allocation to each arm was deemed adequate to identify an improvement of one point for the mean warfarin knowledge questionnaire scores attributable to the new warfarin education program intervention. This calculation was based on a standard deviation of 4.5, a power of 70%, a 5% significance level and a one sided test.

For the purposes of this study the group of patients receiving the new warfarin education program are referred to as the intervention patients and the group of patients receiving the customary warfarin education program are referred to as the control patients. The new warfarin education program, was conceptually based on the five key elements of an effective patient medication education program, also included a newly developed warfarin information booklet (APPENDIX 12). This new booklet was derived from a review of the literature and written in a simple, easy-to-read format, whereas the customary warfarin education program involved the TACT pharmacist reading through the Boots warfarin information booklet (2003) with the patient in their own home.

Evaluation was incorporated into the study at three levels: process, impact and outcome evaluation. This enabled the researcher/TACT pharmacist to analyse and assess the suitability, quality and effectiveness of the new program as compared to the customary program, in terms of the patients’ warfarin
knowledge, compliance and management. The patients’ satisfaction with the program and their long-term outcomes (therapeutic INR scores, as well as general practitioner, hospital and emergency department visits) were also compared and contrasted between the two programs. Unfortunately, customary practice did not remain static during the study period due to the continuously evolving professional practice of the TACT service. This is acknowledged as a limiting factor of the research study and will be discussed in the final chapters of this thesis.

The overall purpose of the study was to develop and implement a new warfarin education program to help improve warfarin knowledge, compliance and management in a wider patient population, inclusive of ‘high risk’ patients. The conceptual framework of this new program, which incorporated five key elements of an effective patient medication education program, can be readily used as a blueprint for any other medication education program, in both community and hospital settings.

5.3 THE PROCESS FOR THE DESIGN AND DEVELOPMENT OF THE NEW WARFARIN EDUCATION PROGRAM AND THE NEW WARFARIN INFORMATION BOOKLET

5.3.1 Introduction

The design of the research study involved several important components. Firstly, the new warfarin education program incorporated interventions and strategies to target the five key elements of an effective patient medication education program which included: improved health professional/patient communication and partnerships; warfarin compliance; simple, easy-to-read warfarin information; the continuity of care between hospital and community settings; and patient follow-up.

Secondly, evaluation was incorporated to compare and contrast the new warfarin education program against the customary warfarin education program delivered to TACT patients prescribed warfarin. Important components of the
evaluation process included assessing the readability, suitability and quality of the new written warfarin information booklet (APPENDIX 12) against the Boots warfarin information booklet (2003). In addition, analysis of the patients’ warfarin self-management, compliance, knowledge and understanding, as well as their satisfaction with the warfarin education program, provided important data to compare and contrast the two education programs.

Finally, reviewing the patients’ International Normalised Ratio (INR) blood test results, the number of healthcare visits and side effects experienced, helped to assess and compare the long-term effectiveness of both education programs. These results provided data to compare the warfarin-related therapeutic outcomes and adverse drug events for both programs over the three-month period.
The following diagram provides an overview of the methods used to design, develop and evaluate the new warfarin education program, including the new warfarin information booklet (APPENDIX 12).

**Figure 2: Overview of the methods used to design, develop and evaluate the new warfarin education program, including the new warfarin information booklet (APPENDIX 12).**

**KEY ELEMENTS**

- Health professional/patient communication and partnerships
- Warfarin compliance
- Simple, easy-to-read warfarin information
- Continuity of care between hospital and community settings
- Patient follow-up

**EVALUATION OUTCOMES**

- Warfarin knowledge
- Warfarin management
- Warfarin compliance
- Good quality, suitable warfarin information written at an appropriate reading grade level
- Patient satisfaction with warfarin information
- Outcome measures (i.e. therapeutic INR score, reduced GP and hospital visits; reduced warfarin-related adverse drug events)

The chapter will now discuss how the five key elements and evaluation components were incorporated into the new warfarin education program design.
5.3.2 Health professional/patient communication and partnerships

Several measures were incorporated into the new warfarin education program design to promote good health professional/patient communication and partnerships. The measures introduced by the health professional included: offering the patient encouragement, reinforcement, reassurance and feedback; delivering the initial education session in a home environment; urging carers and/or family members to attend the education session; providing interpreters for non-English speaking background patients; and always using simple and easy-to-understand language.

Encouragement was given to patients by asking lots of questions, inviting them to make comments (Kok, van den Borne et al. 1997), and respecting their opinions (The Royal Pharmaceutical Society of Great Britain 1997). Examples of the questions asked to offer encouragement can be found in the ‘Transcript of the new warfarin education session’ (APPENDIX 11). During the education sessions, the patients were also urged to become active participants in their own healthcare by recording their own INR results, warfarin doses and appointment times in the new warfarin information booklet (APPENDIX 12).

Reinforcement was provided by using the new written warfarin information booklet (APPENDIX 12), underlining the main points and referring to the illustrations as visual aids (Doak, Doak and Lorig 1996a). The ‘Warfarin Counselling Checklist ’ (APPENDIX 13) was used to ensure that all the main points had been discussed and reinforced. Typical questions asked to reinforce patients’ understanding of the warfarin information included:

- “Why do you believe that the warfarin has been prescribed for you?”
- “Which brand of warfarin has been prescribed for you?”
- “What dose should you take today?”

Reassurance throughout the program was promoted by ensuring that the patients were comfortable and confident enough to seek reassurance by addressing them in a positive, caring and motivating manner (The Royal Pharmaceutical Society of Great Britain 1997). Even when the patients had completely misunderstood or misinterpreted instructions, they were politely
corrected and positively reassured about their ability to safely and successfully manage their own warfarin therapy at home.

Informal feedback was received before, during and after the initial warfarin education sessions, as well as during the follow-up phone calls and on completion of the evaluation questionnaires after three months of warfarin therapy. Positive and negative comments, as well as opinions, were perceived to be of benefit because they could be used to improve the patient warfarin education program. The patients’ beliefs, opinions, assumptions and attitudes were always treated with utmost respect (The Royal Pharmaceutical Society of Great Britain 1997). A typical example included patients perceiving that they were endangering their lives by taking warfarin, known to them as rat poison. In these instances, it was acknowledged that even though warfarin was rat poison it did have many therapeutic advantages, which were then explained to the patients.

The initial education sessions took place in the patients’ homes or in an alternative place specified by the patients, where it was ensured that they were relaxed and comfortable. Environments conducive to learning were sought by recommending that all radios, televisions, computers and stereos were turned off. Carers and family members were also positively encouraged to attend the education sessions and to ask questions and make comments.

For patients from non-English speaking backgrounds, Illawarra Health interpreters were made available during the education sessions to translate the information into their native language. In an attempt to improve communication with these patients it was always necessary to make direct eye contact with them, rather than directing all the conversation toward the interpreters (Williamson, Stecchi et al. 1997).

The information was presented slowly, using simple and easy-to-understand language, especially when educating the ‘high risk’ patient population (Mayeaux Jr, Murphy et al. 1996). Main points were emphasized using the ‘Warfarin Counselling Checklist ’ (APPENDIX 13) and the ‘New
Warfarin Information Booklet’ (APPENDIX 12) as guides to ensure that important points were covered.

In summary, developing good health professional/patient communication and partnerships was a key element targeted by several interventions in the new warfarin education program. These interventions included promoting encouragement, reinforcement, reassurance and patient feedback, supporting a collaborative approach by valuing the patients’ opinions and comments and inviting them to be active participants in their own healthcare. Education sessions were conducted in the comfort of the patients’ home and often in the presence of carers and/or family members who were also urged to attend. Non-English speaking background patients were provided with an interpreter, and the language used during the education session was always simple and easy-to-understand, which was especially beneficial for the ‘high risk’ patient population.

5.3.3 Warfarin compliance

Good warfarin compliance was another key element targeted in the new warfarin education program (Haynes, McDonald et al. 2002a). Interventions, such as improving the patients’ understanding of their warfarin therapy in treating their disease, encouraging family support and compliance aids, as well as minimising the complexity of their medication regimens, were considered priorities in the new warfarin education program. These interventions were particularly important for the ‘high risk’ patient population.

Patients were educated about how warfarin works to treat their disease, how to take it appropriately and how to monitor their warfarin therapy, as per the ‘New warfarin Education Program Objectives’ (APPENDIX 14). Examples of patients successfully treated with warfarin were given, as per the ‘Transcript of the new warfarin education session’ (APPENDIX 11), to try to encourage optimal warfarin compliance. Some examples of the questions patients were asked to ensure that they had a good understanding about why they had to comply with their warfarin therapy, included:

➢ “Do you understand why you have been given warfarin tablets?”
“When is the best time to take your warfarin tablets?”

Family members and carers were contacted by telephone prior to the education session and strongly urged to attend the session. Not only did they provide the necessary support and encouragement to help optimise warfarin compliance, especially among the ‘high risk’ patients, but they also helped patients with information recall (Doak, Doak et al. 1996b).

Compliance aids such as blister packs, dosette boxes, medication alarms and medication cards identified to improve medication compliance (Levings, Szep et al. 1999; Wong and Norman 1987), were recommended to all patients. They were especially recommended to the elderly living alone and to those suspected to be suffering from cognitive and/or physical limitations (for example poor eye sight, hearing impairment). Medication alert bracelets were also recommended to these patients.

Minimising the complexity of the patients’ medication regimen was another intervention used in the new program to help improve warfarin compliance. Medication reviews were carried out to develop a simple, easy-to-follow dosage regimen for the patients. They were asked to physically show the researcher/TACT pharmacist all their prescribed, non-prescribed and complementary medicines, which they took in addition to their warfarin therapy. The medication review ascertained the importance of all the patients’ medications and helped to identify any potential drug-to-drug interactions, especially between warfarin and complementary medicine, which were acted upon in collaboration with the patients’ healthcare providers. Typical examples of medication review recommendations included:

- suggesting that other medications, when and if possible, be taken in the morning and warfarin be taken alone in the evening.
- advising patients to stop taking prophylactic Aspirin.
- recommending that interacting complementary medications be discontinued until after the warfarin therapy was complete.
In summary, improving warfarin compliance was one of the key elements targeted in the new warfarin education program. Improving the patients’ warfarin knowledge and understanding, encouraging family support and the use of compliance aids, as well as conducting medication reviews were all used as interventions in the new program to help improve warfarin compliance. Several of these interventions, which included familial support and compliance aids, were especially recommended for the ‘high risk’ patients.

5.3.4 Simple, easy-to-read written warfarin information

Several interventions incorporated in the new program aimed to improve patient comprehension, especially among patients with low literacy skills. These interventions included designing the booklet in a simple and easy-to-read format with culturally sensitive illustrations and adhering to recommended guidelines ensuring its good quality and suitability. As already mentioned in this chapter, it was important to ensure that the language used during the education sessions was simple and easy-to-understand, particularly when educating the patients with low literacy skills (Mayeaux Jr, Murphy et al. 1996).

The new booklet (APPENDIX 12) was written in a simple and easy-to-read format so that it could be read and understood by a wider warfarin prescribed population, inclusive of those with low literacy skills. Several available tools, guidelines and principles were used to ensure that the booklet was written in a format to help improve knowledge, understanding and information recall (Houts, Witmer et al. 2001). The manual SMOG test (McLauglin 1969) (APPENDIX 4), the Fry Readability Formula (Fry 1968) (APPENDIX 5) and the computerized Flesch-Kincaid instrument available on the Microsoft Office Word 2000 program were used to ensure that the booklet was written below a grade 8 reading level.

The ‘Toolkit for producing patient information’ (The United Kingdom Department of Health 2002) (APPENDIX 2) and the ‘Guidelines for writing patient information’ (Doak, Doak et al. 1996a) (APPENDIX 3) were used to ensure that the information was presented in a simple, easy-to-read format with attention to colour, text and print size. Consequently, the booklet was written in a
large 12 font print size, with bulleted points and ample white spaces to avoid looking too cluttered. These modifications were especially useful for elderly patients who have problems seeing and reading currently available written patient information (Rutledge and Donaldson 1998).

Visual images and illustrations were included in the new booklet because research has shown that memory has many more access points for visuals than for words and letters (Doak, Doak et al. 1996b). The illustrations were used to highlight important concepts (Rutledge and Donaldson 1998) and to help encourage desired behaviour (Davidhizar and Brownson 1999), such as using an electric razor or a soft bristle toothbrush. Twenty Illawarra Health interpreters from different cultural backgrounds were also asked to comment on whether or not the visual images and illustrations were culturally appropriate.

The quality and the suitability of the new warfarin booklet was assessed by the researcher/TACT pharmacist and two of her colleagues, using the validated ‘Suitability Assessment of Materials’ (SAM) instrument (Doak, Doak et al. 1985)(APPENDIX 6), the ‘Bernier Instructional Design Scale’(BIDS)(APPENDIX 7), and the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996)(APPENDIX 8). The SAM instrument was especially useful in assessing and evaluating the suitability of the booklet for patients with limited literacy skills (Doak, Doak et al. 1985), while the BIDS instrument identified the presence (or absence) of instructional design/learning principles, and the Checklist provided an assessment for the appropriateness of the written material for patients.

On completion of the first draft of the new warfarin information booklet (APPENDIX 12), comments were sought from two literacy and educational experts from the University of Wollongong (Professor Brian Ferry and Professor Brian Cambourne). They were asked to give their expert opinions about the suitability and the quality of the booklet for the general population, inclusive of those with low literacy skills and from non-English speaking backgrounds. Comments and opinions were also sought from ten pharmacists working in community and hospital settings, as well as allied health colleagues from ‘The
Ambulatory Care Team’ (TACT). All of these comments, including those made by the Illawarra Health interpreters, were collated and, where appropriate, changes were made to the new warfarin information booklet prior to the research study. These changes are comprehensively detailed in the pilot study section of this chapter.

In summary, the new warfarin information booklet was written in a simple, easy-to-read format to ensure that a wider warfarin prescribed population, including those with low literacy skills, could read and understand the booklet. Several validated tests, guidelines and instruments were used to design and develop the new booklet and to evaluate its quality and suitability. The language used during the education sessions was simple and easy-to-understand, once again targeting a wider patient population, inclusive of those with low literacy skills.

5.3.5 The continuity of care between hospital and community settings

Improved continuity of care between hospital and community settings was also specifically targeted in the new warfarin education program. The ‘Guidelines on the continuum of care of quality use of medicines between hospital and community’ (Australian Pharmaceutical Advisory Council 1998) (APPENDIX 9), known as the APAC guidelines, were used. These guidelines were incorporated in the new warfarin education program from the beginning. The customary warfarin education program did not include these guidelines at the beginning of the study. However, it is important to note that since TACT is a new service undergoing continuous development, some of the interventions recommended by the APAC guidelines were incorporated into the customary TACT program during the study period, following directions from area health service management. Typical examples include: faxing the patients’ general practitioner with the details of their admission and subsequent discharge from the TACT service; encouraging the patients to record their INR results, warfarin doses and appointment times in their booklets; and giving patients information sheets about
potential warfarin interactions with other drugs, including complementary medicines (APPENDIX 27).

Each of the seven APAC principles will now be discussed with a brief explanation of the interventions used to target these principles in the new warfarin education program. Many of these interventions such as; medication reviews, family support and interpreter services, have already been discussed elsewhere in this chapter because they also target some of the other key elements.

Principle 1: It is the responsibility of the admitting institution to ensure the development and coordination of a medication discharge plan for each patient. The person responsible for coordinating the development, implementation, and monitoring of the medication discharge plan, including medication supply and medication information, should be identified as soon as practicable after admission.

New consenting patients requiring warfarin therapy had the details of their admission to TACT and proposed warfarin management faxed to their general practitioners. These patients were then placed in either the control or intervention groups by the TACT pharmacists and educated within four days of their admission to TACT. Non-consenting patients were not part of the study, but still received the customary warfarin education program.

Principle 2: Hospital staff should obtain an accurate medication history, including prescription and over-the-counter medicines and other therapies such as herbal products, at the time of admission.

After admission to TACT and during the initial education session the researcher/TACT pharmacist carried out a thorough medication review of all the patients’ medications including prescription, over-the-counter medicines and complementary medicines.
Principle 3: Hospital staff should evaluate the current medication at the time of admission, in consultation with the patient’s general practitioner, with a view to:

- identifying the appropriateness and effectiveness of current medication, and rationalising current medications if appropriate
- paying particular attention to any problems associated with current drug therapy, including any possible relationship with the current medical condition, and
- documenting allergies and any previous adverse drug reactions

The purpose of the medication review was to identify the appropriateness of all the patient’s medications, to review the times that they were taken and to minimise potential drug-to-drug interactions, side effects and/or adverse drug events such as allergies. When changes to prescribed medications were necessary, the researcher/TACT pharmacist collaborated with the patient’s medical practitioners and other members of TACT staff, prior to recommending the changes. For simple recommendations such as the timing of the warfarin doses, the type of analgesic and/or self-prescribed complementary medicines used, the researcher/TACT pharmacist spoke directly to the patient and/or carers without involving any of the other healthcare practitioners.

Principle 4: During the hospital stay, treatment plans relating to the probable medication management during the stay and, where applicable, at discharge, should be developed in consultation with the patient and/or carer. Hospital staff should negotiate with the patient issues relating to treatment and the development of a discharge plan, and these discussions should be documented in the patient’s notes. This plan should form part of the overall care plan or critical pathway.

- The use of interpreters may be required to ensure good communication with people from non-English speaking backgrounds.
To enable the discharge process to be successful, there needs to be effective communication and coordination between all relevant parties in the hospital environment.
-Where appropriate, community health providers, especially the patient’s general practitioner, should be consulted.
-Carers should also be consulted where appropriate.

During the initial warfarin education session the researcher/TACT pharmacist informed the patients about their warfarin management plan using the new warfarin education program.

Non-English speaking patients were provided with accredited Illawarra Health interpreters to translate all the relevant information to them in their native language.

All patients were informed that after their discharge from TACT, they would be expected to promptly visit their general practitioners who would then be responsible for monitoring their warfarin therapy. All patients, including those from the ‘high risk’ patient population, were encouraged to visit only one general practitioner and one local community pharmacist, in an attempt to minimise poor therapeutic outcomes and adverse drug events (Pendleton 1992), and to improve the continuity of care.

On discharge from TACT the patient’s general practitioner was faxed with the details about his/her discharge, warfarin dose and INR results. When it was appropriate, other healthcare providers who cared for the patient in the community setting were also informed about their discharge from the service (for example palliative care nurse).

Principle 5: Prior to discharge, pre-discharge medication review and dispensing of adequate medication should take place in a planned and timely fashion. Adequate medication means sufficient medication to carry the patient through to the next arranged review (by their general practitioner, outpatient clinic, or some other arrangement), or to complete the course of treatment.
If patients are discharged with inadequate supplies of medication, this can compromise quality of care for the patient. Supply of the medication from the hospital facility must be adequate to ensure continuity of medication is not interrupted by the inability to obtain further ongoing supplies if required, within a reasonable timeframe.

On admission to TACT, patients were supplied with sufficient 1mg, 2mg and 5mg warfarin tablets to maintain their warfarin therapy appropriately. Upon discharge from TACT, only five days’ supply of the warfarin tablets were dispensed to patients to encourage them to promptly visit their general practitioners. In the event of a public holiday or the possibility that general practitioner appointments could not be arranged within the five-day period, either the patient continued to be monitored by TACT or more warfarin tablets were provided.

**Principle 6:** At the time of discharge, each patient should be provided with a discharge folio containing relevant information such as Consumer Medicine Information, a medication record, patient/carer plan, and information on the availability and future supply of medication.

After the initial warfarin education session patients were given the new warfarin information booklet (APPENDIX 12) to keep as a resource and they were instructed during the session on how to record their own INR results, warfarin doses and appointment times in the back of the booklet. They were told that their warfarin supplies and warfarin monitoring after their discharge from TACT would be the responsibility of their general practitioners.

**Principle 7:** No patient should be discharged from hospital until the details of the admission, medication changes (including additions/deletions) and arrangements for follow-up have been communicated to the healthcare provider(s) nominated by the patient as being responsible for his or her ongoing care.
As already discussed, once the patient had been discharged from the TACT service, his/her general practitioners were sent a fax outlining their warfarin management, warfarin dose and INR results upon discharge. Other health practitioners caring for the patient were also notified of their discharge, when and if it was appropriate to do so.

Improving the continuity of care between hospital and community settings was a key element incorporated into the new warfarin education program. Several interventions were included in the new program to accommodate each of the seven APAC guidelines, which aimed to improve this continuum of care. These interventions included: the timely transfer of both warfarin medication and information to the patients, their carers and their healthcare practitioners; conducting medication reviews; and effectively educating the patients about their warfarin management. Some of these interventions, which were deemed to have a positive impact and complied with the APAC guidelines, were also incorporated into the customary warfarin education program during the course of the research study. The possible impact of this on the study design and outcomes will be discussed in the later chapters of this thesis.

5.3.6 Patient follow-up

Patient follow-up is the last of the key elements of an effective patient warfarin education program targeted in the new warfarin education program. Patient follow-up was incorporated as follow-up telephone calls, which took place both one week and three months after the initial warfarin education session.

The follow-up telephone calls one week after the initial education session encouraged patient feedback. Patients were asked whether or not they had any problems or concerns with the warfarin therapy and/or information. These calls were also used to reinforce and reassure the main points of warfarin information to the patient, as per the ‘Warfarin Counselling Checklist’ (APPENDIX 13).

The main objectives of the follow-up phone calls three months after the initial warfarin education session were to reassure and reinforce warfarin information to the patients and to collect evaluation data. The evaluation data
pertained to questionnaires about their warfarin management; compliance; knowledge and understanding; as well as their satisfaction with the warfarin information provided, and possible warfarin-related therapeutic outcomes (Refer to Appendices 17-21). The ‘Warfarin Knowledge’ questionnaire (APPENDIX 19) was a particularly useful follow-up educational tool, because if patients answered questions incorrectly, their answers were documented and they were then given the correct answer. In other words, this questionnaire helped to reinforce correct warfarin information to the patients.

In summary, the follow-up telephone calls allowed the patients to have their warfarin knowledge and understanding reinforced. They also encouraged the patients to provide feedback and to discuss any queries or concerns they may have experienced. During the study period, the three-month follow-up telephone calls were also used to complete patient questionnaires, which were used for evaluation purposes.

5.3.7 Evaluation

Evaluation was incorporated into the new warfarin education program, at the three levels of: process, impact, and outcome. These different evaluation modalities were used to assess and analyse the readability, quality and suitability of the new booklet (APPENDIX 12) used in the new program, and to evaluate patient’s warfarin management, compliance, knowledge and understanding, satisfaction with the warfarin information provided and their health outcomes. Analysis and assessment of the evaluation information was used to compare the new warfarin education program to the customary warfarin education program delivered to TACT patients.

Process evaluation was used to compare the readability, quality and the suitability of the new warfarin education program to the customary program. Instruments used to assess the readability and the suitability of the written warfarin information in both programs have already been described in this chapter. These instruments included the following readability formulae: the
SMOG test (McLauglin 1969) (APPENDIX 4); the Fry Readability Formula ((Fry 1968) (APPENDIX 5); and the computerized Flesch-Kincaid instrument available on the Microsoft Office Word 2000 program. Quality and suitability instruments used during the process evaluation phase included: the ‘Suitability Assessment of Materials’ (SAM) (Doak, Doak et al. 1985)(APPENDIX 6); the ‘Bernier Instructional Design Scale’(BIDS)(Bernier 1996) (APPENDIX 7);and the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996)(APPENDIX 8). Process evaluation was also used to contrast the patients’ satisfaction with both programs by using the validated ‘Satisfaction with Information about Medicines Scale’ (SIMS) (Horne, Hankins et al. 2001) (APPENDIX 20), immediately and three months after the initial warfarin education session.

Impact evaluation assessed whether or not the program had met its objectives by evaluating patient knowledge and understanding, as well as adherence to recommended health behaviour changes, such as warfarin management and compliance. In the absence of a validated warfarin knowledge questionnaire, a series of questions were drafted for the ‘Warfarin Knowledge’ questionnaire (APPENDIX 19) based on several different warfarin studies conducted over the past three decades by Scalley et al (1979), Witte et al (1980) and Wyness (1989), as well as the ‘Warfarin Education Program Objectives’ (APPENDIX 14) and the contents of the new warfarin information booklet (APPENDIX 12). In addition to the ‘Warfarin Knowledge’ questionnaire (APPENDIX 19), patients were asked to complete the ‘Self-Management’ questionnaire (APPENDIX 17) adapted from Lorig et al ‘Self-Efficacy Questionnaire’ (1996 page 41-44) and the ‘Medication-Taking-Measures’ (MTM) questionnaire (Morisky, Green and Levine 1986)(APPENDIX 18), immediately and three months after the initial education session. These latter questionnaires were used to assess and compare their warfarin-related management and compliance behaviours.

Outcome evaluation assessed whether or not the program had worked toward achieving its goals within a three-month period, and to compare the new
warfarin education program to the customary warfarin education program. The ‘Outcome Measures of the Warfarin Education Program’ questionnaire (APPENDIX 21) was adapted from Lorig et al (1996 pages 53-55) ‘Health Outcome Measures for Health Care Utilization’ and was completed over the telephone, three months after the initial warfarin education session. Information collected from this questionnaire included the number of healthcare provider visits (general practitioner, hospital and/or emergency department), the number of warfarin-related adverse drug events experienced and the patient’s INR blood test results. When patients had neglected to record their own INR results, the researcher/TACT pharmacist obtained their results from the relevant pathology services.

Process evaluation data were used to assess and compare the readability, quality and the suitability of the written warfarin information used in both education programs. Impact evaluation data were used to contrast the patient’s satisfaction with each of the education programs, as well as their impact on patients’ warfarin knowledge and understanding, and his/her adherence to recommended warfarin management and compliance behaviours. Finally, outcome evaluation data were used to compare the effects that both programs had on the patients’ health outcomes, which included warfarin blood test results and healthcare utilisation (for example; the number of general practitioner visits and/or hospital visits).

5.3.8 Summary

In summary, the new warfarin program was based on introducing interventions and strategies to target the five key elements of an effective patient medication education program. These five key elements were: health professional/patient communication and partnerships, warfarin compliance, simple, easy-to-read written warfarin information, the continuity of care between hospital and community settings and patient follow-up. As well as targeting each of these key elements the new warfarin education program also addressed the
needs of the 'high risk' patient population, to ensure that they too would be effectively educated about their warfarin therapy.

Evaluation was incorporated into the research study to compare the readability, quality and suitability of the new warfarin information booklet (APPENDIX 12) to the Boots warfarin information booklet (2003) used in the customary warfarin education program. Data collected from the ‘Self-Management,’ ‘Medication-Taking Measures’ and ‘Warfarin Knowledge’ questionnaires (Appendices 17-19), as well as the ‘Satisfaction with Information about Medicines Scale’ (SIMS) and ‘Outcome Measures of the Warfarin Education Program’ questionnaires (Appendices 20-21) were all used to compare and contrast the overall effectiveness of the new warfarin education program, with the customary warfarin education program delivered to TACT patients.

5.4 THE NEW WARFARIN EDUCATION PROGRAM

The new warfarin education program and the new warfarin information booklet (APPENDIX 12) were founded on the ‘Warfarin education program objectives’ (APPENDIX 14). These objectives were identified in the literature as ‘best evidence’ for educating patients about their warfarin therapy (Haines 1998; Witte, Gurwich et al. 1980; Wyness 1989) and provided well-defined and measurable instructional aims for the education program. Not only were the contents of the new warfarin information booklet founded on these objectives, but they were also based on information derived from the Boots Healthcare ‘Warfarin important instructions for patients’ (2000) and Beata Bajorek’s ‘Warfarin medication information booklet for patients and their carers’ developed for use in her Ph.D. study; ‘Stroke prevention in elderly patients with atrial fibrillation’ (Bajorek 2002).

The new warfarin education program consisted of an initial home-based one-to-one verbal warfarin education session, during which the new warfarin information booklet (APPENDIX 12) was used as a written and visual aid. At the
end of the session the patients were given the booklet as a written information resource and were asked to complete the first set of evaluation questionnaires (Appendices 17-20). Follow-up phone calls for the new program were made both one week and three months after the initial warfarin education session to offer encouragement, reassurance, reinforcement and to promote feedback. The three-month follow-up evaluation questionnaires (Appendices 17-21) were also completed over the telephone.

A typical transcript of the initial warfarin education session used in the new warfarin education program can be found in APPENDIX 11 and a complete schematic representation of the new warfarin education program will now follow.

The new warfarin education program was based on a conceptual framework, which incorporated interventions and strategies targeting the five key elements of an effective patient medication education program. These interventions and strategies were not chronologically added to the program and often targeted more than one of the key elements. The following symbols will therefore be used to represent the key elements targeted by the different interventions and strategies in the new warfarin education program.

- Patient/health professional communication and partnerships
- Warfarin compliance
- Simple, easy-to-read written warfarin information
- Continuity of care between hospital and community settings
- Patient follow-up

Prior to arriving at the patient’s home

- An appointment for the initial education session was made over the telephone and the appropriate information, checklists and questionnaires, as per APPENDIX 10, were packed (🔗).
- The patient’s general practitioner was faxed about their patient’s
admission to TACT and their proposed warfarin therapy ( ).

- Carers and family members were encouraged to attend the education session ( , ).

- For non-English speaking background patients, Illawarra Health interpreters were booked for the education sessions ( , ).

On arrival at the patient’s home

- The researcher/TACT pharmacist identified herself and reminded the patients about the follow-up phone calls, one week and three months after the initial education session ( ).

- The researcher/pharmacist ensured that the environment was conducive to learning, (for example TVs, radios etc were asked to be turned off) and it was ensured that the patients were relaxed and comfortable ( ).

- The researcher/TACT pharmacist completed the patients’ ‘Demographic Data Sheet’ (APPENDIX 16) and the ‘Warfarin Pretest Questionnaire’ (APPENDIX 15). The pretest questionnaire ascertained the patient’s previous experience(s), if any, with warfarin and whether or not they had any preconceptions, feelings or fears concerning their warfarin therapy. Each of these issues was dealt with in a positive, reinforcing and reassuring manner ( ).

- The researcher/TACT pharmacist enquired about the patient’s past and present illnesses, as well as their current treatment, to ensure that they would not impact upon their warfarin therapy (for example patients with cancer receiving cytotoxic therapy would have had problems stabilizing their INR results and warfarin therapy) ( ).
During the Initial Warfarin Education Session (refer to APPENDIX 11 for a typical transcript of the education session)

- Encouragement, reassurance, reinforcement and positive feedback were always used by the researcher/TACT pharmacist in an attempt to promote collaboration and active patient participation (�, ♥).

- The researcher/TACT pharmacist remained friendly, approachable and supportive throughout the education session. Speaking in a clear, positive, interested and enthusiastic manner, trying to help motivate the patients to learn and comprehend the information given to them (�).

- The researcher/TACT pharmacist always used simple, easy-to-understand language, the ‘New Warfarin Information Booklet’ (APPENDIX 12) and the ‘Warfarin Counselling Checklist’ (APPENDIX 13) to ensure that all the main points had been carefully explained to the patients and/or their carers (�, ❼, ♥).

- The new warfarin information booklet (APPENDIX 12) was written in a simple, easy-to-read format using validated tests, guidelines and instructions to ensure that it could be read by a wider patient population, inclusive of those with low literacy skills (❼).

- The new warfarin information booklet (APPENDIX 12) was used as a written and visual aide for the verbal education session. The researcher/TACT pharmacist underlined main points within the booklet, referring to the illustrations as visual aids to reinforce the information (�, ❓).

- Information provided during the education program was based on the ‘The New Warfarin Education Program Objectives’ (APPENDIX 14) and focused on improving the patients’ knowledge and understanding about how warfarin works, how to take it safely, what...
the INR blood test results mean, possible side effects and the effects other medications, diet, alcohol and lifestyles can have on warfarin therapy (♥).

- Patients were given limited supplies of 5mg, 2mg and 1mg warfarin tablets during their admission to TACT. They were asked to show the researcher/TACT pharmacist which combinations of warfarin tablets they would use to provide a dose equivalent to 9mg, 8mg, 4mg and 3mg of warfarin. This exercise helped to educate and reinforce patients about how to calculate their appropriate warfarin dose (♥, ❦).

- The researcher/TACT pharmacist performed a medication review on all the patient’s medications, including their complementary medicines, to ensure that there were no drug-to-drug interactions with their warfarin therapy. Recommendations were subsequently given about suitable times to take their medications and when necessary to cease or change medications which interacted with their warfarin after collaborating with their healthcare providers (♥, ❦).

- Patients taking complementary medicines were reminded about the ‘Patient information on potential drug-to-drug warfarin interactions’ leaflet (APPENDIX 27) and asked, if necessary, to cease the interacting complementary medications or to discuss them with their healthcare providers (❧).

- Patients were shown how to keep a record of their INR results, warfarin doses and appointment times on pages 18-21 of the new warfarin information booklet (APPENDIX 12). They were encouraged to continuously record this information as a valuable resource for themselves and all their healthcare providers (❣, ❧, ❦).
• All patients and especially elderly patients living alone, who suffered from any cognitive and/or physical limitations, were strongly encouraged to use compliance aids (for example dosette boxes, blister packs, alarms, calendars) (♥).

• Patients were continuously asked questions throughout the education session to verify their comprehension of the warfarin information (for example Why do you think that you been started on warfarin tablets? What is your target INR?) (❖, ♥).

• Patients were informed that their general practitioners would be responsible for their warfarin monitoring and further warfarin prescriptions after their discharge from TACT (❖).

• Patients were encouraged to use the new warfarin information booklet (APPENDIX 12) as a simple, easy-to-read written information resource (□).

• Patients were advised about other reliable warfarin information resources such as; the TACT office, their healthcare providers, the National Prescribing Service (NPS) (they were given a fridge magnet with the NPS telephone number) and the internet sites available in the back of the new warfarin information booklet (APPENDIX 12) (❖, ❖).

• Patient feedback, which included their comments and opinions, was encouraged not only during the follow-up phone calls but also throughout the education program (❖).

• At the conclusion of the initial warfarin education session, patients were encouraged to ask questions and were reassured that if they complied with the recommendations, as per the education session, they would be able to effectively manage their warfarin therapy at home (❖, ♥).

• When patients were discharged from TACT, their general
practitioners were faxed the details of their discharge, warfarin dose and INR values during their admission to TACT ( ).

**Telephone Follow-up Calls (one week and three months after the initial warfarin education session)**

- Patients received follow-up phone calls, one week and three months after the initial warfarin education session. During these phone calls warfarin information was reinforced according to the 'Warfarin Counselling Checklist' (APPENDIX 13) ( , , ).
- The patients were also encouraged to discuss any queries or concerns, and to express their comments and opinions about the warfarin education program ( , , ).

**Evaluation**

The following is a summary of the evaluation instruments, tools and questionnaires used in the new warfarin education program.

- The readability, quality and the suitability of the new warfarin information booklet was assessed using the following
  - SMOG test (McLauaglin 1969) (APPENDIX 4)
  - The Fry Readability Formula (Fry 1968) (APPENDIX 5)
  - The computerized Flesch-Kincaid instrument available on the Microsoft Office Word 2000 program
  - The ‘Suitability Assessment of Materials’ (SAM) (Doak, Doak et al. 1985) (APPENDIX 6)
  - The ‘Bernier Instructional Design Scale’ (BIDS) (Bernier 1996) (APPENDIX 7)
  - The ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) (APPENDIX 8)
• The patients were asked to complete the following questionnaires, immediately and three months after the initial warfarin education session.
  ➢ ‘Self-Management’ questionnaire (APPENDIX 17)
  ➢ ‘Medication-Taking- Measures’ questionnaire (APPENDIX 18)
  ➢ ‘Warfarin Knowledge’ questionnaire (APPENDIX 19)
  ➢ ‘Satisfaction with Information about Medicines Scale’ (SIMS) (APPENDIX 20)

• Three months after the initial education session patients were also asked to complete the ‘Outcome Measures of the Warfarin Education Program’ questionnaire (APPENDIX 21).

5.5 ETHICAL CONSIDERATIONS

Prior to the commencement of the pilot study and the research study, ethics approval had to be sought from the following:

• The University of Wollongong Ethics Committee
• The Management of the Illawarra Health Service
• The TACT medical director
• The Illawarra Health interpreter service
• Patients participating in the research study

An ethics approval request to conduct the research study was submitted by the researcher/TACT pharmacist to the University of Wollongong Ethics Committee in November 2002. Illawarra Health’s upper management officials, The Ambulatory Care Team’s (TACT) medical director and the Illawarra health interpreter service were all informed about the research study and also asked for their written consent. Once permission and written consent were received from
each of these committees and/or persons, the researcher/TACT pharmacist continued with the pilot study and then the research study.

During the course of the research study there were several ethical issues, which needed to be considered and addressed. TACT staff members were informed about the research study in an education session presented by the researcher/TACT pharmacist, where they also received the ‘Research information sheet for Illawarra Health staff’ (APPENDIX 23). During this education session, they were informed that a patient’s refusal to participate in the study would in no way detrimentally affect their TACT healthcare service. They were given the ‘Suggested dialogue for patient recruitment and obtaining consent’ (APPENDIX 24) as a guide to help them approach and recruit patient participants for the study. TACT staff members were also told that they were under no obligation to approach and recruit patients for the study and that their decision to do so was purely on a voluntary basis.

The researcher/TACT pharmacist was a TACT employee prior to the study, which meant that she had ready access to the patient’s medical notes and hospital data. The patient participants were informed about the study and the researcher/TACT pharmacist’s access to this information in the ‘Patient participant information sheet’ (APPENDIX 25). The patients consented to participate in the study and granted their permission for the researcher/TACT pharmacist to access their medical information by signing the ‘Patient participant consent form’ (APPENDIX 26).

Written confirmation about patient confidentiality and the de-identification of patient details was made available to all participants through the ‘Patient participant consent form’ (APPENDIX 26). The patients were also verbally informed about these confidentiality issues during the recruitment phase of the study. The ‘Patient participant information sheet’ (APPENDIX 25), the ‘Patient participant consent form’ (APPENDIX 26) and the TACT staff, reassured patients that their refusal to participate and/or to withdraw from the study at any time would in no way impact detrimentally on their TACT healthcare service.
As already mentioned in this chapter, when interventions incorporated into the new warfarin education program were perceived to be best practice and complied with the APAC guidelines, they were also at times incorporated into the customary warfarin education program, during the course of the study. These changes were based on recommendations from area health service management and were out of the control of the researcher. The implications of these changes on the study results will be discussed in a later chapter.

5.6 THE PILOT STUDY

Prior to the research study being conducted, a pilot study was completed to trial the new warfarin education program. Ten pilot group participants were educated using the new program as a ‘one off’ education session, including being given the new warfarin information booklet (APPENDIX 12). The 10 pilot group participants had similar demographic variables such as age, social status and educational backgrounds to the eligible TACT patient participants, ensuring that their answers to the evaluation questionnaires, their comments and opinions would benefit the eligible patient participants (Doak, Doak et al. 1996b). The 10 pilot group participants had never been prescribed warfarin but they volunteered to take part in the trial warfarin education session.

At the end of their single education session, each of the pilot participants was asked to complete the same four evaluation questionnaires which were to be used in the research study. These questionnaires included the ‘Self-Management’, ‘Medication-Taking-Measures’ and the ‘Warfarin Knowledge’ questionnaires (Appendices17-19), as well as the ‘Satisfaction with Information about Medicines Scale’ (SIMS) questionnaire (APPENDIX 20). As an added measure, they were also asked to complete the DISCERN questionnaire (Charnock, Shepperd, Needham and Gann 1998) (APPENDIX 22) which would help to identify their perception about the reliability and the quality of the new warfarin information booklet. At the completion of their individual education sessions, they were asked for their opinions and/or comments about the warfarin
education session, the booklet and the questionnaires. The results of the pilot group study will now be briefly discussed.

There were five male and five female pilot group participants, ranging in age from 38 to 70 years. Their educational status varied from a grade 4 level to a tertiary level, with four of the participants coming from non-English speaking backgrounds. All of the participants were able to readily answer each of the questionnaires, except for the ‘Warfarin Knowledge’ questionnaire (APPENDIX 19). A few of the participants found some of the knowledge questions to be ambiguous and confusing, which is why these questions were revised after the pilot study. The changes made to the ‘Warfarin Knowledge’ questionnaire prior to it being used in the research study as per APPENDIX 19, included:

- **Question 1:** “What is your medicine called (generic and brand name)?”
  - Revised Q1: “Which brand of warfarin is prescribed for you?”
- **Question 9:** “What are the appropriate levels for an INR blood test?”
  - Revised Q 9 “What is your target INR blood test range?”
- **Question 17:** “Do you need to make any modifications to your daily activities while you are taking warfarin?”
  - Revised Q 17 ”Name TWO activities or things you need to be careful doing while taking warfarin.”

The warfarin education session was not changed after the pilot study because over 80 percent of the pilot group participants were satisfied with the information given to them, according to the results of the ‘Satisfaction with Information About Medicines Scale’ (SIMS) (APPENDIX 20) and their positive comments. Overall, the new warfarin information booklet remained largely unchanged after the pilot study, because the results of the DISCERN
questionnaire (APPENDIX 22) indicated that 90 percent of the pilot group participants perceived the booklet to be of a ‘high’ to ‘very high’ quality with minimal short comings. The minor changes made to the booklet, based on the pilot participants’ comments and opinions, included: having a bright front cover on the booklet; showing people living a normal life while taking warfarin; a contents page for easy access to page numbers; and making the MedicAlert bracelets an ‘optional’ alternative for the patient.

At the conclusion of the pilot study and once the minor changes had been made, the researcher/TACT pharmacist then collated the comments and opinions about the draft version of the new warfarin information booklet from the literacy experts at the University of Wollongong, her work colleagues and the Illawarra Health interpreters. Once again, a few minor changes were made to the booklet, prior to it being printed in its final version as per APPENDIX 12. These minor changes included:

Page 2: ‘This booklet will help you lead a normal life whilst on this therapy. This booklet will help you understand….’ was replaced with ‘The purpose of this book is to help you understand;’

Page 8: ‘Have the INR test done every time your doctor orders one’ was replaced with ‘Follow your doctor’s orders for INR testing’

Page 10: ‘To help let people know, you can order a MedicAlert bracelet from your pharmacist’ was replaced with ‘You can also wear a MedicAlert bracelet (which you can buy from your pharmacist) to let people know that you take warfarin’

Page 15 ‘Additional things to remember’ was replaced with ‘Other factors to consider’

Other changes throughout the booklet also involved replacing the term “healthcarers” with “healthcare providers”, clearly labelling illustrations and deleting those which were deemed unnecessary, as well as altering some of the formatting in the booklet.
On the completion of these changes to the new warfarin information booklet and the questionnaires, based on the results of the pilot study as well as the comments and opinions of the literacy experts, work colleagues and interpreters, the booklets were printed and the research study commenced in January 2003. The methodological process of this research study will now be discussed.

5.7 THE RESEARCH STUDY

5.7.1 Background

Illawarra Health’s The Ambulatory Care Team (TACT) is a multidisciplinary team consisting of medical practitioners, pharmacists, physiotherapists and registered nurses. TACT provides a home-based outpatient management service for conditions that would otherwise be managed in hospital including; intravenous antibiotics, subcutaneous enoxaparin injections and warfarin management, pre- and post-operative care, as well as wound management. Patients who are treated with the oral anticoagulant warfarin and educated in their own homes are focused upon for the purpose of this research study. It is also important to note that both the educators involved in this study were pharmacists employed by the TACT team for at least four years.

5.7.2 Eligible participants, informed consent and confidentiality

Once permission to conduct the research study was received from the University of Wollongong Ethics Committee, the Illawarra Health management, the TACT medical director and the Illawarra Health interpreter service, the researcher/TACT pharmacist conducted an education session to inform the other TACT staff members about the study. During this education session, the TACT staff members were given the ‘Research information sheet for Illawarra Health staff’ (APPENDIX 23) and the step-by-step guide on how to go about recruiting
patients on a voluntary basis, as per the ‘Suggested dialogue for patient recruitment and obtaining consent’ (APPENDIX 24).

All patients accepted for admission to The Ambulatory Care Team (TACT) during the study period who were over 18 years of age, resided in the Illawarra Health area and were newly prescribed warfarin, or those who were recommencing warfarin therapy after at least 15 years, were considered eligible for the research study. For the purposes of this study patient participants aged 65 years and over were referred to as elderly, and those educated at or below a grade 6 level were referred to as having low literacy skills, as deemed by Davis et al (1990) and Rolland (2000). Patients from non-English speaking backgrounds were also considered eligible for the research study because Illawarra Health interpreters were made available to translate all the relevant information to them. On admission to TACT eligible patients were verbally informed about the study as detailed below and asked to consent to becoming patient participants by signing the ‘Patient participant consent form’ (APPENDIX 26).

Informed consent is an ethical obligation fundamental to research. Obtaining informed consent and maintaining confidentiality are critical to the way we deliver healthcare and remain a crucial part of our medico legal responsibility to the patient and to society (Betancourt and Jacobs 2000). Thus, eligible patient participants were informed about the study by having the ‘Patient participant information sheet’ (APPENDIX 25) read out to them by either a TACT pharmacist or another TACT staff member during one of their initial home visits. Subsequently, after reading through the ‘Patient participant consent form’ (APPENDIX 26), consenting patients were asked to sign the consent form and reminded about their right to withdraw from the study at any time.

All data collected during the course of the research study were processed in a way that protected the patients’ confidentiality and anonymity, with only the data containing fully completed evaluation questionnaires (Appendices 15-21), immediately and after three months, being used for analysis. Patient participant
details and consent forms were securely stored separately from the other data and coding was used during data collection. Patient participants were given sufficient time, prior to and following education and evaluation sessions, to raise any questions or concerns they may have had in relation to the research study and/or the data collection process.

5.7.3 Research participants and the study

For the purposes of this research, over 100 consenting patient participants were recruited for the study, with the intention to allocate 50 patient participants to the control group and 50 patient participants to the intervention group. Patient recruitment continued until there were at least 50 control patients and 50 intervention patients who had completed all questionnaires, inclusive of the three month follow-up questionnaires. To ensure consistency, the control group patients were educated by a TACT pharmacist using the customary warfarin education program and the Boots warfarin information booklet (2003). The intervention group patients, on the other hand, were educated by the TACT researcher/pharmacist, using the new warfarin education program and the new warfarin information booklet (APPENDIX 12). Typical transcripts for both the customary and the new warfarin education sessions can be found in APPENDIX 28 and APPENDIX 11, respectively.

The patient participants in the study were allocated into the control or the intervention group depending on what day of the week they were admitted to TACT and which TACT pharmacist, the researcher - referred to as the researcher/TACT pharmacist - using the new warfarin education program or the non-researcher pharmacist – referred to as the TACT pharmacist - using the customary warfarin education program was available at work. It was an allocation by convenience because the non-researcher TACT pharmacist worked with TACT on a Monday and the researcher/TACT pharmacist worked with TACT on a Thursday and it was common practice that all new warfarin prescribed patients admitted to TACT received warfarin education within four days. As a result, the
patient participants who consented between Friday and Sunday were allocated into the control group, for the TACT pharmacist to educate with the customary warfarin education program. The patient participants who consented between Monday and Thursday, on the other hand, were allocated to the intervention group, for the researcher/TACT pharmacist to educate with the new warfarin education program. The allocation of patients to the control or intervention groups could be problematic if there were different referral patterns over different days of the week. From experience with TACT referral patterns this was not expected to occur, however referral and other patient data were collected for each patient and compared as part of the data analysis to confirm that this method of patient allocation resulted in comparable patient samples for both groups.

Non-English speaking background patients were also recruited by inviting an Illawarra Health interpreter to translate all the relevant information to the patients. The researcher/TACT pharmacist was especially interested in the non-English speaking background patients because they are often excluded from similar studies based on their language barriers, and yet they are in the ‘high risk’ group, which we know little about.

Demographic variables such as age, nationality, sex, educational level and morbidities were recorded on the ‘Patient Demographic Data’ (APPENDIX 16). Demographic data were collected by the pharmacists from the patients, their inpatient notes and/or the Illawarra Health DRACIS database. These demographic data were used in the analysis to investigate their possible effects on the patients’ warfarin knowledge and understanding, self-management and compliance, as well as to compare their effects on the two different warfarin education programs.

Evaluation questionnaires were completed in the patients’ homes, immediately after the initial warfarin education sessions, and then over the telephone during the three-month follow-up. The purpose of the evaluation questionnaires was to assess and analyse the effectiveness of the new warfarin
education program, and to compare and contrast it with the customary warfarin education program, given to TACT patients receiving warfarin therapy.

Data collected from the ‘Self-Management’ (APPENDIX 17) and ‘Medication-Taking-Measures’ (APPENDIX 18) questionnaires from both intervention and control patients helped to compare the impact of the two programs on the patients’ perception about warfarin self-management and compliance. Comparing the results of the data collected from the ‘Warfarin Knowledge’ questionnaires (APPENDIX 19) assisted with analysing which program - the new or the customary - was superior in terms of improving warfarin knowledge and understanding. Reviewing the ‘Satisfaction with Information about Medicines Scale’ (SIMS)(APPENDIX 20) established whether or not the patients were more or less satisfied with either of the two education programs. Finally, data collected from the ‘Outcome Measures of the Warfarin Education Program’ questionnaire (APPENDIX 21) was used to compare the therapeutic outcomes of both education programs over the three-month period. The outcomes reviewed included; therapeutic INR blood test results, visits to general practitioners, hospitals and emergency departments, as well as possible warfarin-related adverse drug events.

5.7.4 Data processing and analysis

All information gathered from patient participants for the purposes of this study, including personal details and questionnaires, was de-identified and secured in a locked cabinet at the University of Wollongong. No personal details were provided to other patient participants nor were they identified in any of the journal articles, conference presentations and thesis publications resulting from this research study. Clinical data collected from patient participants were kept by Illawarra Health’s medical records department and stored according to its standard record keeping practices. No information was left on the network computer that could be accessed by anyone other than the researcher/TACT
pharmacist herself. On completion of the research study and after the required
time all identifying details will be appropriately destroyed.

On completion of the research study, a period of approximately 12
months, all the information was collected and collated by the researcher/TACT
pharmacist. The information collected from the questionnaires was quantitatively
coded and entered into a JMP database created for the study by the
researcher/TACT pharmacist in the JMP statistical computer program (Sall
2000). The ‘Self-Management,’ ‘Medication-Taking- Measures’ and the
‘Satisfaction with Information about Medicines Scale’ (SIMS) questionnaires
(APPENDIX 17, 18 and 20) are all scale form questions which are readily
entered quantitatively into the database. On the other hand, the ‘Warfarin
Knowledge’ questionnaire (APPENDIX 19), which consisted of open-ended
questions, was coded ‘post facto’ by the researcher/TACT pharmacist following
the pilot phase, and also entered quantitatively into the database. The ‘Outcome
Measures of the Warfarin Education Program’ questionnaire’ (APPENDIX 21)
had a combination of numerical values, pre-coded answers and open-ended
questions. The numerical values and pre-coded answers were quantitatively
added to the database, whereas the answers to the open-ended questions were
typed into the database for thematic analysis. Similarly, any comments that were
made by the patients and/or their carers during the three-month follow-up period
were also typed into the database for thematic analysis.

On completion of data entry, the quantitative data were analysed by the
researcher/TACT pharmacist with the assistance of a qualified statistician at the
University of Wollongong. Several statistical tests were used to compare the new
warfarin education program against the customary warfarin education program.
These tests included: t-tests to determine whether or not mean scores for the
different questionnaires were significantly different for the two programs; paired t-
test to compare immediate scores and follow-up scores within the same groups
of patients; ANOVA tests to compare the mean scores for both groups taking into
account several variables at once; correlation coefficients to analyse the
relationships between the mean scores for each of the questionnaires and the
number of healthcare visits, as well as the percentage of International Normalised Ratio (INR) blood test results within therapeutic range; and chi-squared tests to evaluate whether or not there were any relationships between two variables such as category (i.e. intervention or control) and education level. The results of these tests and analyses will be discussed at length in the following chapter.

5.7.5 Summary of the methodological process of the research study

The following is a summary of the methodological processes of the study. Table 1 gives an overview of the differences between the new warfarin education program given to the intervention group patients and the customary warfarin education program given to the control group patients.

Table 1: Summary of the methodological processes of the research study

<table>
<thead>
<tr>
<th>METHODOLOGY PROCESS</th>
<th>50 INTERVENTION PATIENTS</th>
<th>50 CONTROL PATIENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>TACT staff member will invite eligible patients to participate in the research study as per APPENDIX 24. If they agree to participate they will be given the ‘Patient participant information sheet’ (APPENDIX 25) and asked to sign the ‘Patient participant consent form’ (APPENDIX 26). The consent form will then be filed in a secured cabinet in the TACT office.</td>
<td>✔</td>
<td>✔</td>
</tr>
<tr>
<td>Note: For non-English speaking background patients an Illawarra Health interpreter will be present to translate the information to the patient.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>METHODOLOGY PROCESS</td>
<td>50 INTERVENTION PATIENTS</td>
<td>50 CONTROL PATIENTS</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>--------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Consenting patient participants will be allocated to the intervention or control groups and then telephoned by the TACT pharmacists to make a suitable appointment time for the initial education session to take place. They will also be reminded about the evaluation questionnaires and the follow-up telephone calls.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Carers and/or family members will be strongly encouraged to attend the initial warfarin education session.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Initial warfarin education sessions will be delivered in the patient's home or an alternative place specified by the patient.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>A collaborative approach to the education session will be highly promoted, using encouragement, reassurance, reinforcement and positive feedback.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Intervention patients will be asked many questions and will be encouraged to make comments and given their opinions throughout the education program.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>An Illawarra Health interpreter will be in attendance for all non-English speaking background patients.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Researcher/TACT pharmacist will ensure that the environment is conducive to learning i.e. turn off any televisions, radios etc, and ensure that the patient is comfortable and relaxed.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>All patient participants will have their ‘Demographic Data’ (APPENDIX 16) recorded by the TACT pharmacist.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Patient participants will be pre-tested for their understanding about warfarin (APPENDIX 15).</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>METHODOLOGY PROCESS</td>
<td>50 INTERVENTION PATIENTS</td>
<td>50 CONTROL PATIENTS</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Researcher/TACT pharmacist will educate the intervention patient participants with the new warfarin education program using the ‘Transcript of the new warfarin education session’ (APPENDIX 11), the ‘New warfarin information booklet’ (APPENDIX 12), the ‘Warfarin Counselling Checklist’ (APPENDIX 13) and the ‘New Warfarin Education Objectives’ (APPENDIX 14) to ensure that all main points have been taught and reinforced.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Researcher/TACT pharmacist will speak in simple, easy-to-understand language, underlining key points in the new warfarin information booklet (APPENDIX 12), which will also be used as a visual aid.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>TACT pharmacist will educate the control patient participants with the customary warfarin education program as per the ‘Transcript for the customary warfarin education program’ (APPENDIX 28) using the Boots warfarin information booklet (2003).</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Intervention patients will be encouraged to disclose the use of all other medicines including complementary medicines in order to check for drug-to-drug interactions, by way of a complete medication review.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Control patients will be asked to disclose other prescribed medication</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>‘Patient information on potential drug-to-drug warfarin interactions’ (APPENDIX 27) will be issued to all patient participants.</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Intervention patients will be encouraged to record their INR blood test results, warfarin doses and appointment times in the back of their new warfarin booklets.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>METHODOLOGY PROCESS</td>
<td>50 INTERVENTION PATIENTS</td>
<td>50 CONTROL PATIENTS</td>
</tr>
<tr>
<td>-----------------------------------------------------------------------------------</td>
<td>--------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Compliance aids will be highly recommended for ‘high risk’ patients living alone or believed to be suffering from any physical and/or cognitive limitations.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Intervention patients will be asked to show the researcher/TACT pharmacist how to make up warfarin doses equivalent to 9mg, 8mg, 4mg and 3 mg.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>The National Prescribing Service ‘Medicines Line’ 1300 888 763 (given as a fridge magnet) and other suitable websites available in the new warfarin information booklet will be recommended to intervention patients as suitable resources for more warfarin information.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>TACT office number 42 225 328 will be made available for any patient queries and concerns.</td>
<td>✓ ✓</td>
<td>✓ ✓</td>
</tr>
<tr>
<td>Intervention patients will be given telephone reinforcement, reassurance and follow-up, one week after the initial warfarin education session.</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>All patient participants will be given evaluation questionnaires (Appendices 17-20) to complete, immediately and three months after the initial warfarin education session. The immediate questionnaires will be completed in the patient’s home, and the three-month follow-up questionnaires will be completed over the telephone.</td>
<td>✓ ✓</td>
<td>✓ ✓</td>
</tr>
<tr>
<td>All patient participants will complete the ‘Outcome Measures of the Warfarin Education Program’ questionnaire (APPENDIX 21) over the telephone three months after the initial education sessions.</td>
<td>✓ ✓</td>
<td>✓ ✓</td>
</tr>
</tbody>
</table>
A simplified version of this table is presented on the following page, as a flowchart of the research study

**Figure 3: FLOWCHART FOR THE RESEARCH STUDY**

100 Consenting patient participants

50 Control patients

Pretest Questionnaire (APPENDIX 15)

Customary warfarin education program

Evaluation Questionnaires (APPENDICES 17-20) (immediately and three-month follow-up)
- ‘Self-Management’
- ‘Medication-Taking-Measures’
- ‘Warfarin Knowledge’
- SIMS

Three months after initial warfarin education session
- ‘Outcome Measures of the Warfarin Education Program’ questionnaire (APPENDIX 21)

50 Intervention patients

Pretest Questionnaire (APPENDIX 15)

New warfarin education program

Evaluation Questionnaires (APPENDICES 17-20) (immediately and three-month follow-up)
- ‘Self-Management’
- ‘Medication-Taking-Measures’
- ‘Warfarin Knowledge’
- SIMS

Three months after initial warfarin education session
- ‘Outcome Measures of the Warfarin Education Program’ questionnaire (APPENDIX 21)
5. 8 SUMMARY

This chapter has provided an overview of the process for the design, implementation and the development of the new warfarin education program including the new warfarin information booklet (APPENDIX 12). The new warfarin education program has been discussed at length detailing which of the interventions and strategies have been used to target the five key elements of an effective medication education program. Evaluation has also been incorporated as a major component of the research study. Data collected from the evaluation questionnaires, as well as the tools, instruments and guidelines used to assess the new booklet (APPENDIX 12) and the Boots warfarin information booklet (2003) will be used to compare and contrast the process, impact and the outcomes of the new and customary warfarin education programs.

Ethical considerations were reported on, as were the changes made to the new program and the booklet based on the results of the pilot study and the comments made by the literacy experts from the University of Wollongong, the researcher/pharmacist’s colleagues, the Illawarra Health interpreters and the pilot group participants. Finally, the methodological process of the research study itself was discussed and summarised as a table and a flowchart.

The time has now come to analyse the data and discuss the findings of the different evaluation modalities used in this research study. These analyses and evaluations will be described in detail throughout the next chapter of this thesis.
CHAPTER 6
RESULTS

6.1 INTRODUCTION

The analysis of the findings is presented in this chapter. Initially, there is a discussion about the results of the tests used to assess the readability of the new warfarin information booklet compared with the typically used Boots warfarin information booklet (2003). The readability tests used included the SMOG test (McLauglin 1969), the Fry test (Fry 1968) (See Appendices 4-5), and the computerised Flesch-Kincaid instrument available on the Windows 2000 Word program. The chapter then discusses the results of the ‘Suitability Assessment of Materials’ (SAM) (Doak, Doak et al. 1985) instrument, the ‘Bernier Instructional Design Scale’ (BIDS) (Bernier 1996) (See APPENDIX 6-7) and the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996), used to compare the quality and the suitability of the new booklet to the Boots warfarin information booklet (2003).

Throughout the rest of the chapter, discussion focuses on comparing and contrasting data collected from evaluation questionnaires and the outcome measures of the new warfarin education program against the same evaluation questionnaires collected for the customary warfarin education program. Data were collected using the ‘Self-Management’ questionnaire (APPENDIX 17); the ‘Medication-Taking Measures’ questionnaire (APPENDIX 18); the ‘Warfarin Knowledge’ questionnaire (APPENDIX 19) and the ‘Satisfaction with Information about Medicines Scale’ (APPENDIX 20). These questionnaires were completed immediately and then three months after the initial warfarin education sessions. Analysis of the ‘Patient Demographic Data’ (APPENDIX 16) and the ‘Outcome Measures of the Warfarin Education Program’ questionnaire’ (APPENDIX 21) were also used to compare the new warfarin education program to the customary warfarin education program.

Readability scores for the new warfarin information booklet (APPENDIX 12) and the Boots warfarin information booklet (2003) were derived from the SMOG test (McLauqlin 1969), the Fry test (1968) and the Microsoft Word 2000 computerised Flesch-Kincaid test. These test results are presented below.

The SMOG test (McLauqlin 1969) was performed twice on 30 sentences from the new booklet. The first test was performed on 10 consecutive sentences taken from pages 3, 8 and 14 - 15 of the new booklet, and the second test was conducted on the contents page, as well as pages 7 - 8 and 15 of the booklet. These pages were chosen because they provided 10 consecutive sentences for testing from the beginning, middle and end of the booklet as per the test instructions. In both instances, the SMOG test results indicated that the new booklet was written at a grade 8 reading level. In comparison, the two SMOG tests carried out on the Boots warfarin information booklet (2003) analysing 10 consecutive sentences from pages 2, 10 and 17; as well as pages 3 - 4, 10 and 18 of the booklet, indicated that it was written at a grade 10 - 11 reading level.

The Fry Readability Formula (1968) otherwise known as the Fry test, was performed on three 100 word passages from the text, omitting the headings. Specific pages from each booklet were chosen and tested. According to the Fry test (1968), carried out on 100 words from pages 3, 8 and 10, the new warfarin information booklet was written at a grade 6 reading level. The following is a summary of these Fry test results:

Page 3 (100 words) 8.3 sentences; 149 syllables
Page 8 (100 words) 7.7 sentences; 125 syllables
Page 10 (100 words) 13 sentences; 151 syllables.

In contrast, the results of the Fry test (1968) conducted on pages 2, 8 and 14 of the Boots warfarin information booklet (2003) found that it was written at a grade 14 reading level. The following is a summary of these Fry test results:

Page 2 (100 words) 6.5 sentences; 155 syllables
The Fry test results indicate that, on average, the readability scores for the new warfarin information booklet (APPENDIX 12) were 8 grades lower than the Boots warfarin information booklet (2003). Also, the new booklet had, on average, a larger number of sentences per page and a smaller number of multi-syllable words, implying that it was easier to read than the Boots booklet.

The last readability test used to compare the two booklets was the Microsoft Word 2000 computerised Flesch-Kincaid test. This test also calculated reading ease level, which was based on the average number of syllables per word and the average number of words per sentence. Scores for the reading ease level range from 0 (zero) to 100 and the higher the score, the greater the number of people who can readily understand the written information (Flesch 1974). This final test found the new warfarin information booklet had been written at a grade 6.7 reading level, with a 62 percent reading ease level. The results for the Boots warfarin information booklet (2003) on the other hand, indicated that it had been written at a grade 8.9 reading level with a 58.5 percent reading ease level. Once again, these results found that the reading grade level of the new warfarin information booklet was lower than the Boots warfarin information booklet. This test also found that the new warfarin information booklet had a slightly higher reading ease level than the Boots warfarin booklet, suggesting that it could be read and understood by a greater proportion of the population.

The scores for each of the different readability tests indicated that the new warfarin information booklet (APPENDIX 12) was written between a grade 6 - 8 level and that the Boots warfarin information booklet (2003) was written between a grade 8.9 –14 level. Thus, the new booklet was written at a reading level at least 2 - 3 grades lower than the Boots booklet (2003) used in the customary warfarin education program. The researcher/TACT pharmacist chose the actual sentences and words used in the readability tests but the potential for bias was small, as the choices of sentences were limited within each of the booklets.

In order to compare the quality and the suitability of the new warfarin information booklet to the Boots warfarin information booklet, the researcher/TACT pharmacist and two of her colleagues completed the following tests on both booklets; the ‘Suitability Assessment Materials’ (SAM) (Doak, Doak et al. 1985), the ‘Bernier Instructional Design Scale’ (BIDS) (Bernier 1996) and the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) (Appendices 6 - 8). The results for each of these tests, which are especially useful for assessing the quality and the suitability of the written information for patients with low literacy skills, will now be presented.

The ‘Suitability Assessment Materials’ (SAM) (Doak, Doak et al. 1985)(APPENDIX 6) is an instrument used to obtain a numerical rating for suitability factors other than readability. SAM addresses suitability in terms of content, literacy, demand, graphics, layout, learning stimulation/motivation, and the culture of the intended audience. The SAM ratings were analysed as percentage ratings according to the following criteria: superior material = 70 -100 percent; adequate material = 40 - 69 percent; and not suitable material = 0 - 39 percent.

The SAM scores for the new warfarin information booklet completed by the researcher/TACT pharmacist and two of her colleagues were 92 percent, 95.2 percent and 83 percent. Each of the raters indicated that the new booklet was well within the superior rating (70 -100 percent) for the SAM instrument. None of the raters gave the new booklet a ‘not suitable’ rating (0 – 39 percent) for any of the factors in the SAM instrument. In contrast however, two of the raters assigned SAM scores of 55 percent and 44.7 percent within the adequate rating range (40 – 69 percent) and one rater assigned 33.3 percent within the not suitable rating range (0 – 39 percent) for the Boots warfarin information booklet (2003). Thus, according to the SAM scores, the new warfarin information booklet was superior to the Boots warfarin information booklet (2003) in terms of quality.
and suitability. It could therefore be suggested that the new booklet was more suitable than the Boots booklet especially for patients with low literacy skills.

The ‘Bernier Instructional Design Scale’ (BIDS)(1996) (APPENDIX 7) is an instrument used to identify the presence (or absence) of instructional design and learning principles contained in printed educational materials (Bernier 1996). The rating scale for the BIDS instrument is based on the following numerical scores given to each of the 35 items in the instrument: 0 = not met; 1 = partially met; 2 = met; and, NA= Not Applicable.

Based on the same results for all three raters, analysis of the BIDS instrument on the new booklet, using the criteria discussed above, found that 26 items met the instructional design and learning principles and that no items were found not to meet the instructional design and learning principles. For the Boots warfarin information booklet (2003) on the other hand, all three raters found that only 8 items met the instructional design and learning principles and that the following four items did not meet the instructional design and learning principles (BIDS score= 0);

- Q.4 Drawings/illustrations are recognisable to the target group with or without explanatory text.
- Q.5 Drawings/illustrations are labelled clearly.
- Q.6 Drawings/illustrations represent racial and ethnic groups appropriate to the target audience.

Therefore, according to the three raters and the results of the BIDS instrument, the new warfarin information booklet met the instructional design and learning principles much more so than did the Boots warfarin information booklet (2003). Unlike the new booklet, the Boots booklet (2003) was found not to meet the instructional design and learning principles for drawings, illustrations and their cultural sensitivity. All in all, therefore, the new booklet appeared to suit the needs of the wider patient population, much more so than did the Boots booklet (2003), because of its adherence to instructional design and learning principles.
The third and last instrument used by the three raters to compare the quality and the suitability of the two booklets was the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) (APPENDIX 8). This 17-item checklist provided a quick and easy way in which to assess the appropriateness of the written material for patients. Points in the checklist which were not ticked and identified as missing by all three raters, were recorded as potential deficiencies in the suitability of the written information within the booklets.

According to the results of the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) (APPENDIX 8) there were no potential deficiencies in the suitability of the new warfarin information booklet because each of the 17 items in the checklist was ticked by at least two of the raters. The Boots warfarin information booklet (2003), however, was found to have potential deficiencies in 7 of the 17-item checklist because they were not ticked by any of the three raters. These items included:

- 1. The cover is attractive. It indicates the core content and intended audience.
- 5. A summary that stresses what to do is included.
- 8. Text is vivid and interesting. Tone is friendly.
- 13. Illustrations are simple - preferably line drawings.
- 14. Illustrations serve to amplify text.
- 17. Interaction is invited via questions, responses, suggested action, etc.

In other words, the Boots booklet was found not to have an attractive cover, it did not include summaries and interesting text, the pages appeared cluttered and there was a lack of illustrations and invitations for patients to interact. Once again the new warfarin information booklet was found to have fewer potential deficiencies in appropriateness and suitability than the Boots warfarin information booklet (2003).

In summary, the results of the ‘Suitability Assessment Materials’ (SAM) (Doak, Doak et al. 1985), the ‘Bernier Instructional Design Scale’ (BIDS) (Bernier
1996) and the ‘Checklist for print materials’ (Bidford Maine Area Health
Education Center 1996) independently performed by the researcher/TACT
pharmacist and two of her colleagues, indicated that the new warfarin information
booklet was considered to be superior in terms of quality and suitability, as
compared to the Boots warfarin information booklet (2003). The new booklet was
also found to comply with instructional design, learning principles and have fewer
potential deficiencies in terms of appropriateness and suitability than the Boots
booklet. These results imply that the new booklet in terms of quality and
suitability, as compared to the Boots booklet, would better suit the needs of a
wider patient population, inclusive of those with low literacy skills.

6.4 COMPARING AND CONTRASTING THE NEW WARFARIN EDUCATION
PROGRAM WITH THE CUSTOMARY WARFARIN EDUCATION PROGRAM.

6.4.1 Patient participants and demographic variables

6.4.1.1 Introduction

Data collection was conducted from February 2003 to February 2004. All
consenting patients who were admitted to The Ambulatory Care Team (TACT)
and commenced warfarin therapy for the first time, or recommenced warfarin
after a period of at least 15 years, were included. Of the 114 patients who
consented to participate, five patients could not be contacted for the three month
follow-up evaluations, five patients had their warfarin therapy discontinued by
their general practitioners, one died from cancer-related illness and one withdrew
from the study. Consequently, complete data were collected from 102 patient
participants, 55 females and 47 males. Fifty intervention patients had received
the new warfarin education program and 52 control patients had received the
customary warfarin education program delivered to Illawarra Health’s The
Ambulatory Care Team (TACT) warfarin prescribed patients.
This next section of the chapter compares and contrasts the intervention and control patient participants’ demographic variables including: gender, age, educational level, ethnicity, source of referral and referral diagnosis. The last demographic variable reported in this section is the percentage of patient participants who had a carer and/or a family member present during the initial warfarin education session.

6.4.1.2 Gender

The results in table 2 indicate that there was a reasonable balance of males and females in the research sample population (N=102). Forty-six percent (47) of the patient participants were male and 54 percent (55) were females. The intervention group had a smaller percentage of male participants, 38 percent (19), than did the control group, 54 percent (28). Consequently, the female participants in the intervention group outnumbered those in the control group, 62 percent (31) as compared to 46 percent (24). A Pearson’s correlation chi-square test, p-value equal to 0.1085, indicates that there were no significant differences in the gender between the intervention and control group participants.

Table 2: Gender of patient participants.

<table>
<thead>
<tr>
<th>Patient Participant</th>
<th>Male</th>
<th>Female</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention (n=50)</td>
<td>38% (19)</td>
<td>62% (31)</td>
</tr>
<tr>
<td>Control (n=52)</td>
<td>54% (28)</td>
<td>46% (24)</td>
</tr>
<tr>
<td>Total number of participants (N=102)</td>
<td>46% (47)</td>
<td>54% (55)</td>
</tr>
</tbody>
</table>

6.4.1.3 Age

Table 3 shows that the ages of the patient participants were similar for both groups, with patients aged between 65-74 years being the most common age group. Interestingly, 62.8 percent (64) of all participating patients were aged 65 years and over, which means that they were elderly and in the ‘high risk’ group. This elderly population can be further subdivided into 68 percent (34) of the intervention patients and 57.7 percent (30) of the control patients. A Pearson’s correlation chi-square test, p-value equal to 0.3715, indicates that
there were no significant differences in the ages between the intervention and control group participants.

**Table 3: Age of patient participants.**

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Percentage of intervention population (n=50)</th>
<th>Percentage of control population (n=52)</th>
<th>Percentage of total patient population (N=102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;85</td>
<td>2.0% (1)</td>
<td>5.77% (3)</td>
<td>3.92% (4)</td>
</tr>
<tr>
<td>75-84</td>
<td>22% (11)</td>
<td>25.0% (13)</td>
<td>23.53% (24)</td>
</tr>
<tr>
<td>65-74</td>
<td>44% (22)</td>
<td>26.9% (14)</td>
<td>35.29% (36)</td>
</tr>
<tr>
<td>55-64</td>
<td>18% (9)</td>
<td>17.3% (9)</td>
<td>17.64% (18)</td>
</tr>
<tr>
<td>45-54</td>
<td>10% (5)</td>
<td>11.53% (6)</td>
<td>10.78% (11)</td>
</tr>
<tr>
<td>&lt;44</td>
<td>4% (2)</td>
<td>13.47% (7)</td>
<td>8.82% (9)</td>
</tr>
</tbody>
</table>

**6.4.1.4 Education level**

As shown in table 4, the intervention group patients had been educated from between grade 1 and tertiary levels, and the control group patients had been educated between grade 4 and tertiary level. These results suggest that the intervention group patients experienced a wider range of educational levels than did the control group patients.

Table 4 also shows that 36 percent (18) of the intervention group patients and 30.8 percent (16) of the control group patients were educated at or above a grade 10 level. Thirty-two percent (16) of the intervention group patients and 50 percent (32) of the control group patients were educated between grades 7 and 9. Finally, and most importantly, 32 percent (16) of the intervention group patients and 19.23 percent (10) of the control group patients were educated at or below a grade 6 level, which, according to the literature means they are classified as patients with low literacy skills (Doak, Doak et al. 1996b). These results indicate, therefore, that similar percentages of patients in both groups were educated at or above a grade 10 level. Whereas more control group
patients were educated between grade 7-9 levels, and considerably more intervention group patients were educated at or below a grade 6 level. In other words, the intervention group had a larger proportion of 'high risk' patients with low literacy skills than did the control group.

Table 4: Educational levels of patient participants.

<table>
<thead>
<tr>
<th>Educational Level</th>
<th>Percentage of intervention patient participants (n=50)</th>
<th>Percentage of control patient participants (n=52)</th>
<th>Percentage of total patient participants (N=102)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>2.00% (1)</td>
<td>0.00% (0)</td>
<td>0.98% (1)</td>
</tr>
<tr>
<td>Grade 2</td>
<td>6.00% (3)</td>
<td>0.00% (0)</td>
<td>2.94% (3)</td>
</tr>
<tr>
<td>Grade 3</td>
<td>4.00% (2)</td>
<td>0.00% (0)</td>
<td>1.96% (2)</td>
</tr>
<tr>
<td>Grade 4</td>
<td>8.00% (4)</td>
<td>1.92% (1)</td>
<td>4.90% (5)</td>
</tr>
<tr>
<td>Grade 5</td>
<td>4.00% (2)</td>
<td>1.92% (1)</td>
<td>2.94% (3)</td>
</tr>
<tr>
<td>Grade 6</td>
<td>8.00% (4)</td>
<td>15.38% (8)</td>
<td>11.76% (12)</td>
</tr>
<tr>
<td>Grade 7</td>
<td>8.00% (4)</td>
<td>3.85% (2)</td>
<td>5.88% (6)</td>
</tr>
<tr>
<td>Grade 8</td>
<td>12.0% (6)</td>
<td>23.08% (12)</td>
<td>17.65% (18)</td>
</tr>
<tr>
<td>Grade 9</td>
<td>12.0% (6)</td>
<td>23.08% (12)</td>
<td>17.65% (18)</td>
</tr>
<tr>
<td>Grade 10</td>
<td>20.0% (10)</td>
<td>15.38% (8)</td>
<td>17.65% (18)</td>
</tr>
<tr>
<td>Tertiary</td>
<td>16% (8)</td>
<td>15.38% (8)</td>
<td>15.69% (16)</td>
</tr>
</tbody>
</table>

According to the data in table 4, the median grade educational level for the intervention group was grade 8, and grade 9 for the control group. The mean grade level for the intervention group was grade 7.94, and grade 8.83 for the control group, assuming that patients educated at a tertiary level were educated to an equivalent of a grade 13 level. The mode level of education for the intervention group was grade 10, and grade 8 and 9 for the control group. It is important to note, that 20 percent (10) of the intervention group patients, as opposed to 46.16 percent (24) of the control group patients, achieved the modal level of education. Even though the mode level of education was higher in the intervention group than that for the control group, a much smaller percentage of intervention group patients achieved the mode level of education than did the control group patients.

A chi-squared test was used to analyse whether or not there was a relationship between the two groups (i.e. intervention and control) and the
patients’ level of education. The results of this chi-squared test found no significant difference (p-value 0.2992), suggesting that there was no difference in the patients’ level of education between the two groups. While these results were found to be insignificant, a larger proportion of the intervention group patients, as compared to the control group patients, were educated at or below a grade 6 level (32 percent compared to 19.2 percent, respectively).

6.4.1.5 Ethnicity

Table 5 indicates that 14.7 percent (15) of the patient participants were from non-English speaking backgrounds (NESB). Both the intervention (18 percent (9) and control (11.5 percent (6) groups had similar small numbers of NESB patients. The nationalities represented by these NESB patients (n=15) were: Greek, 20 percent (3); Croatian, 13.3 percent (2); Italian, 13.3 percent (2); Turkish, 13.3 percent (2); German, 6.7 percent (1); Lebanese, 6.7 percent (1); Macedonian, 6.7 percent (1); Maltese, 6.7 percent (1); Serbian, 6.7 percent (1) and Spanish, 6.7 percent (1). No single nationality significantly outnumbered another within the two groups.

Interestingly, seven of the nine NESB intervention group patients were educated at or below a grade 4 level, whereas only one of the six NESB control group patients was educated at or below grade 4 level. Overall, therefore, even though both groups had similar numbers of NESB patients, the NESB intervention group patients were less educated than the NESB control group patients.

<table>
<thead>
<tr>
<th>Patient Participants</th>
<th>Non-English Speaking Background (NESB)</th>
<th>English Speaking Background</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention (n=50)</td>
<td>18% (9)</td>
<td>82% (41)</td>
</tr>
<tr>
<td>Control (n=52)</td>
<td>11.5% (6)</td>
<td>88.5% (46)</td>
</tr>
<tr>
<td>Total number of participants (N=102)</td>
<td>14.7% (15)</td>
<td>85.3% (87)</td>
</tr>
</tbody>
</table>
6.4.1.6 Source of referral

The results in table 6 show that the sources of referral for the patient participants in both groups were similar. The hospital ward referrals to The Ambulatory Care Team (TACT) for both groups significantly outnumbered the emergency department and general practitioner referrals.

Table 6: Referral sources of patient participants.

<table>
<thead>
<tr>
<th>Patient Participants</th>
<th>Referral Source</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Emergency Department</td>
</tr>
<tr>
<td>Intervention (n=50)</td>
<td>26% (13)</td>
</tr>
<tr>
<td>Control (n=52)</td>
<td>19.2% (10)</td>
</tr>
<tr>
<td>Total number (N=102)</td>
<td>22.6% (23)</td>
</tr>
</tbody>
</table>

6.4.1.7 Referral diagnosis

The results in table 7 indicate that the most common referral diagnosis for both the intervention and control group patients was deep venous thrombosis, followed by atrial fibrillation. The table also shows that similar percentages of patients in both groups were diagnosed with deep venous thrombosis, atrial fibrillation and pulmonary embolus.

Table 7: Referral diagnoses of patient participants.

<table>
<thead>
<tr>
<th>Patient Participants</th>
<th>Deep Venous Thrombosis (DVT)</th>
<th>Atrial Fibrillation (AF)</th>
<th>Pulmonary Embolus (PE)</th>
<th>Other (Transient Ischaemic Attacks, Cerebrovascular Accident, Cardiac Valve, Leg Stent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention (n=50)</td>
<td>46% (23)</td>
<td>24% (12)</td>
<td>16% (8)</td>
<td>14% (7)</td>
</tr>
<tr>
<td>Control (n=52)</td>
<td>36.5% (19)</td>
<td>32.7% (17)</td>
<td>9.6% (5)</td>
<td>21.2% (11)</td>
</tr>
<tr>
<td>Total number (N=102)</td>
<td>41.2% (42)</td>
<td>28.4% (29)</td>
<td>12.8% (13)</td>
<td>17.65% (18)</td>
</tr>
</tbody>
</table>
6.4.1.8 Carers and/or family members

Over half the participating patient population had a carer and/or family member present during the initial warfarin education session (60 percent intervention and 52 percent control). Interestingly, only five of the nine NESB intervention group patients, as compared to five of the six NESB control group patients, had a carer present during the education sessions.

6.4.1.9 Summary

In summary, the results of the demographic data indicate that overall the intervention and control group patients had similar demographic variables. There was an even distribution of males and females in the participating patient population, with a large proportion of the patients classified as 'high risk' because they were aged 65 years and over (62.8 percent), educated at or below grade 6 levels (25.5 percent) and/or came from non-English speaking backgrounds (14.7 percent). The patients in both groups were referred to The Ambulatory Care Team (TACT) mainly from the hospital ward, with a variety of diagnoses, the most common of which was deep venous thrombosis. Interestingly, over half of the participating patient population had a carer and/or family member present during the initial warfarin education session.

6.4.2 ‘Self-Management’ questionnaire (APPENDIX 17) results

The ‘Self-Management’ questionnaire (APPENDIX 17) adapted from Lorig et al ‘Self-Efficacy Questionnaire’ (1996 page 41-44), was used to evaluate the patient participants’ perception about their ability to manage their warfarin therapy at home, and to compare the scores between the intervention and control groups. The scores for this questionnaire, which were completed immediately and three months after the initial warfarin education session, were combined to give a score out of 20. A score between 16 and 20 suggested that the patient was highly confident, a score between 8 and 15 suggested that the patient was moderately confident, and a score below 8 suggested that the patient was not confident about managing their own warfarin therapy at home.
To assess whether or not there was a difference in the ‘Self-Management’ questionnaire scores between the intervention and control groups, a mean score for the ‘Self-Management’ questionnaire was calculated and then t-tests were performed on these mean scores. As shown in table 8, the mean ‘Self-Management’ questionnaire scores were higher for the intervention group patients than the control group patients, immediately and after three months. Results of the t-tests for the immediate scores (p-value 0.1727), and for the three-month follow-up scores (p-value 0.207), indicate that they did not differ significantly. In other words, both groups perceived that they were highly confident about managing their warfarin therapy at home, immediately and three months after the commencement of their warfarin therapy.

Table 8: t-test results comparing intervention and control group patients’ mean ‘Self-Management’ questionnaire scores immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Self-Management questionnaire</th>
<th>Intervention patients’ mean SM score (n=50)</th>
<th>Control patients mean SM score (n=52)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate</td>
<td>19.08</td>
<td>18.44</td>
<td>0.1727</td>
</tr>
<tr>
<td>Three-month follow-up</td>
<td>19.90</td>
<td>19.73</td>
<td>0.2007</td>
</tr>
</tbody>
</table>

(In the table ‘immediate’ = questionnaire completed immediately after the initial warfarin education session; ‘three-month follow up’ = questionnaire completed three months later; SM = Self-Management)

The results in table 8 also indicate that the mean ‘Self-Management’ questionnaire scores for both groups improved over the three-month period. Paired t-tests were used to analyse whether or not the mean three-month follow-up ‘Self-Management’ questionnaire scores differed to the immediate mean scores for each of the groups. Table 9 shows that the mean ‘Self-Management’ questionnaire scores were significantly different for both groups three months after the initial warfarin education session, with a p-value equal to 0.0009*** for the intervention group patients and a p-value equal to 0.0024** for the control group patients. Although, the mean scores were not significantly different between the two groups, they both significantly increased after three months of warfarin therapy. The
intervention group patients’ scores increased by approximately 0.82 and the control group patients’ scores increased by 1.288. Both groups therefore, perceived that their warfarin management at home had improved over the three-month period.

Table 9: Paired t-test results comparing intervention and control group patients’ ‘Self-Management’ mean scores immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Difference between mean SM scores (SM₁-SM₂)</th>
<th>Lower CL Mean</th>
<th>Mean</th>
<th>Upper CL Mean</th>
<th>Degrees of Freedom (df)</th>
<th>t value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention group (SM₁-SM₂)</td>
<td>-1.285</td>
<td>0.82</td>
<td>-0.355</td>
<td>49</td>
<td>-3.54</td>
<td>0.0009***</td>
</tr>
<tr>
<td>Control group (SM₁-SM₂)</td>
<td>-2.097</td>
<td>1.29</td>
<td>-0.479</td>
<td>51</td>
<td>-3.20</td>
<td>0.0024**</td>
</tr>
</tbody>
</table>

(In the table: SM₁ = immediate ‘Self-Management’ questionnaire score; SM₂ = three-month follow-up ‘Self-Management’ questionnaire score; CL = 95% confidence interval of the difference)

Upon completion of their ‘Self-Management’ questionnaire (APPENDIX 17), all participating patients were asked to make comments about whether or not they were worried about taking warfarin tablets. Similar comments were made by patients in both groups expressing their concerns. These concerns related to having to adjust their lifestyle behaviours (diet, alcohol intake and sporting activities), recognising serious side effects, having to take the warfarin regularly and undergoing regular blood tests. Examples of some of these immediate comments included:

- **Intervention 4** “...worried about side effects and blood tests…”
- **Intervention 97** “ I’m worried because it is a heavy duty drug…”
- **Control 5** “Worried about restrictions…”
- **Control 113**: “A little worried about adjusting habits…”

Other examples of comments made three months after the commencement of warfarin therapy included:

- **Intervention 97** “Don’t like taking warfarin…”
- **Control 5** “Don’t want restrictive lifestyle…”
Importantly, some of the initial concerns relating to lifestyle behaviours appear to have been maintained over the three-month period.

In summary, even though the intervention group patients achieved higher mean scores for their ‘Self-Management’ questionnaire, immediately and after three months, t-tests found that these mean scores were not significantly different. Paired t-test results, however, found that the mean scores for the ‘Self-Management’ questionnaires for both groups improved significantly over the three month period. This indicates that the patients in both groups perceived that their warfarin management at home improved over time. Interestingly, the comments expressed by patients in both groups reflected their concerns about having to adjust their lifestyle behaviours while on warfarin medication, and these concerns persisted over the three-month period.

6.4.3 ‘Medication-Taking Measures’ questionnaire (APPENDIX 18) results

The ‘Medication-Taking-Measures’ (MTM) questionnaire (APPENDIX 18) is a validated scale designed to test medication compliance. A score of 4 is considered high compliance, 3 moderate compliance, and 2 or less is low compliance.

A summary of the ‘Medication-Taking-Measures’ (MTM) scores for the questionnaires, completed immediately and three months after the initial warfarin education session, is presented in table 10. The results in this table suggest that even though similar trends in the MTM questionnaire scores were found for both groups, the actual percentages and numbers of patients with low, moderate and high compliance scores differ between the two groups. A higher proportion of the intervention group patients, rather than the control group patients, achieved high compliance scores for the immediate (62 percent versus 53.85 percent) and the three month follow-up (80 percent versus 71.15 percent) MTM questionnaires. These results imply that the new warfarin education program encouraged patients to be more confident about their warfarin compliance, than did the customary warfarin education program.
Table 10: ‘Medication-Taking-Measures’ questionnaire scores for intervention and control group patients immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>MTM Score</th>
<th>Intervention Patients (n=50) (immediate)</th>
<th>Control Patients (n=52) (immediate)</th>
<th>Intervention Patients (n=50) (3-month follow-up)</th>
<th>Control Patients (n=52) (3-month follow-up)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low Compliance (MTM Score ≤ 2)</td>
<td>30% (15)</td>
<td>23.08% (12)</td>
<td>8% (4)</td>
<td>11.54% (6)</td>
</tr>
<tr>
<td>Moderate Compliance (MTM Score=3)</td>
<td>8% (4)</td>
<td>23.08% (12)</td>
<td>12% (6)</td>
<td>17.31% (9)</td>
</tr>
<tr>
<td>High Compliance (MTM Score=4)</td>
<td>62% (31)</td>
<td>53.85% (28)</td>
<td>80% (40)</td>
<td>71.15% (37)</td>
</tr>
</tbody>
</table>

(In the table: MTM Score = ‘Medication-Taking-Measures’ questionnaire score; immediate = immediate scores after the initial warfarin education session; and 3-month follow-up = scores achieved three months after the initial warfarin education session)

To ascertain whether or not there was a significant difference in the mean MTM questionnaire scores for both groups, t-tests were performed. Table 11 shows the results of these t-tests. P-values equal to 0.7389 and 0.2592 respectively, for the immediate and the three-month follow-up scores, suggest that the mean scores were not significantly different. Although the compliance scores for both groups appeared to differ in table 10, the results in table 11 suggest that they were not significantly different. This means that the new warfarin education program appeared to be equally as effective as the customary warfarin education in encouraging patients to be confident about their warfarin compliance.
Table 11: t-test results comparing intervention and control group patients’ mean ‘Medication-Taking-Measures’ questionnaires scores immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Patient participants</th>
<th>Mean MTM score intervention patients (n=50)</th>
<th>Mean MTM score control patients (n=52)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immediate</td>
<td>2.92</td>
<td>3.0192</td>
<td>0.7389</td>
</tr>
<tr>
<td>Three-month follow-up</td>
<td>3.7</td>
<td>3.5192</td>
<td>0.2592</td>
</tr>
</tbody>
</table>

(In the table: Immediate = questionnaire completed immediately after the initial warfarin education session; Three-month follow-up = questionnaire completed three months after initial warfarin education session; MTM = ‘Medication-Taking-Measures’ questionnaire)

The results in table 11 also indicate that the MTM questionnaire scores increased for both groups after three months of warfarin therapy. To assess whether or not this increase over the three-month period was statistically significant, a paired t-test was performed comparing the mean scores for each group. The results of the paired t-tests are summarised in table 12 and indicate that there was a significant difference between the immediate and three-month follow-up mean MTM questionnaire scores for both groups. The p-value for the intervention group patients was 0.0017** and the p-value for the control group patients was 0.0243*. On average, the three-month follow-up mean MTM questionnaire scores increased by 0.78 for the intervention group patients and 0.5 for the control group patients. Therefore, the paired t-tests for both groups suggest that there was a significant improvement in the MTM questionnaire scores over the three-month period. This means that the patients in both groups became significantly more confident about their warfarin compliance over time.

Table 12: Paired t-test results comparing intervention and control group patients’ ‘Medication-Taking-Measures’ mean scores immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Difference between mean MTM scores (MTM₁-MTM₂)</th>
<th>Lower CL Mean</th>
<th>Mean</th>
<th>Upper CL Mean</th>
<th>Degrees of Freedom (df)</th>
<th>t value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention group (MTM₁-MTM₂)</td>
<td>-1.251</td>
<td>-0.78</td>
<td>-0.309</td>
<td>49</td>
<td>-3.33</td>
<td>0.0017**</td>
</tr>
<tr>
<td>Control group (MTM₁-MTM₂)</td>
<td>-0.932</td>
<td>-0.50</td>
<td>-0.068</td>
<td>51</td>
<td>-2.32</td>
<td>0.0243*</td>
</tr>
</tbody>
</table>

(In the table: MTM₁ = immediate ‘Medication-Taking-Measures’ questionnaire score; MTM₂ = three-month follow-up ‘Medication-Taking-Measures’ questionnaire score; CL = 95% confidence interval of the difference)
Comments made by the patients in both groups on the completion of their ‘Medication-Taking-Measures’ questionnaire (APPENDIX 18) were also comparable. Initially, the comments reflected their carelessness toward medication compliance, especially when they had never taken regular medication before. Some of these initial comments included:

- **Intervention 19** “I’m a little careless and forgetful…”
- **Intervention 28** “Have never had to take regular medicines before…”
- **Control 9** “Never really taken medication before…”
- **Control 54** “Always do what the doctor tells me to…”

The comments made three months later were mainly about forgetting to take their warfarin tablets on a few occasions. Eighteen percent (9) of the intervention group patients and 32.7 percent (17) of the control group patients commented on how many times they had forgotten to take their warfarin during the three-month period. These comments may be an indication that both groups of patients understood the importance of good warfarin compliance and may have been more diligent about their warfarin compliance. From their initial education sessions, they also knew that they would be followed-up and that their INR blood test results would be an objective measure of their true warfarin compliance rates.

In summary, even though the trends for the ‘Medication-Taking-Measures’ (MTM) questionnaire (APPENDIX 18) scores were higher for the intervention group patients than for the control group patients, both immediately and after three months of therapy, t-tests ascertained that these scores were not significantly different. There was, however, a significant improvement in the ‘Medication-Taking Measures’ (MTM) questionnaire scores for both groups over the three-month period, suggesting that they had become significantly more confident with their warfarin compliance over time. The patients’ comments received during this time mainly reflected their fears about being careless or forgetting to take their warfarin medication, which may also be representative of their improved understanding about the importance of good warfarin compliance.
6.4.4 ‘Warfarin Knowledge’ questionnaire (APPENDIX 19) results.

6.4.4.1 Introduction

The ‘Warfarin Knowledge’ questionnaire (APPENDIX 19) was used to estimate the patients’ warfarin knowledge and understanding following the education sessions. In the absence of a validated or reliable instrument in the literature this questionnaire was drafted from several different warfarin studies performed over the past three decades (Scalley, Kearney et al. 1979; Witte, Gurwich et al. 1980; Wyness 1989), the ‘Warfarin Education Program Objectives’ (APPENDIX 14) and the contents of the new warfarin information booklet (APPENDIX 12). The answers to the ‘Warfarin Knowledge’ questionnaire (APPENDIX 19) were coded as True (for correct answers) and False (for incorrect answers). Adding the number of correct responses in the questionnaire gave a score out of 26. The ‘Warfarin Knowledge’ questionnaire scores were then further subdivided into the following categories (score ≥ 22.0 excellent; 19.0-21.9 good; 16.0-18.9 average; ≤15.9 poor) to allow for a more meaningful analysis and discussion.

6.4.4.2 t-test used to compare the mean ‘Warfarin Knowledge’ questionnaire scores for the intervention and control groups

To establish whether or not there was a difference in the warfarin knowledge scores between the intervention and the control groups, a t-test was performed on the mean ‘Warfarin Knowledge’ questionnaire scores recorded immediately and three months after initiation of warfarin therapy. The mean score for the immediate ‘Warfarin Knowledge’ questionnaire for the intervention group was 21.0 (80.8 percent) and 19.0 (73.0 percent) for the control group, both of which were classified as good warfarin knowledge scores. A t-test indicated that there was a significant difference in the scores between the groups with a p-value equal to 0.0173*. This result identified that the intervention group patients had a significantly higher immediate ‘Warfarin Knowledge’ questionnaire score than did the control group patients. In other words, the new program improved
the patients’ warfarin knowledge and understanding more so than did the customary program, immediately after the initial warfarin education session.

The mean ‘Warfarin Knowledge’ questionnaire scores three months after the initial warfarin education session was 18.04 (69.4 percent) for the intervention group, and 17.04 (65.5 percent) for the control group. These results show a deterioration in the mean ‘Warfarin Knowledge’ scores for both groups over the three month period. Both the intervention and control group mean scores were therefore reclassified, falling from good to average. A p-value equal to 0.1805 for the t-test, used to compare the mean scores for both groups, indicated that there was no significant difference between scores achieved by both groups after three months. This demonstrates that, the initial positive influence of the new warfarin education program on the patients’ warfarin knowledge and understanding had become less significant over time.

6.4.4.3 Chi-Squared tests used to assess whether or not there was a relationship between the patient group and the correct answer to questions in the ‘Warfarin Knowledge’ questionnaire.

A chi-squared test was used to assess whether or not there was a relationship between the patient group (intervention or control group) and the correct answers for each of the questions in the ‘Warfarin Knowledge’ questionnaire (APPENDIX 19). The chi-squared test performed on the ‘Warfarin Knowledge’ questionnaire completed immediately after the initial warfarin education session produced p-values below 0.05 for the following six questions, suggesting a relationship between the patient group (intervention or control) and the correct answers to these questions.

- Q.1 Which brand of warfarin is prescribed for you? (p-value 0.0049**)
- Q.2. Why is the warfarin prescribed for you? (p-value 0.0262*)
- Q.7a. What should you do if you forget to take a dose of warfarin? (p-value 0.0045**)
- Q.8b. Can you suggest two things, which you could use to remind you about taking your warfarin tablets (if necessary)?
  (p-value 0.0012**)  
- Q.11a What are FOUR signs of bleeding from too much warfarin?
  (p-value 0.0149*)  
- Q.15 Are there any foods which can affect how warfarin works?
  (p-value 0.0122*)

The direction of the relationship between these questions and the patient group is summarised in table 13, which shows that a larger proportion of the intervention group patients correctly answered Questions 2, 7a, 8b, 11a and 15, as compared to the control group patients. A greater proportion of the control group patients, however, correctly answered Question 1. Initially, therefore, the intervention group patients had a better understanding about: why warfarin was prescribed for them; what to do if they forgot to take a dose of warfarin; how to remind themselves about their warfarin dose; what side effects to look out for as a result of too much warfarin; and which foods could interact with their warfarin medication. The control group patients, on the other hand, were more knowledgeable about the brand name of their warfarin medication.

Table 13 Percentage of intervention and control group patients to correctly answer ‘Warfarin Knowledge’ (APPENDIX 19) questions 1, 2, 7a, 8b, 11a and 15 immediately after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Question from the ‘Warfarin Knowledge’ questionnaire (APPENDIX 19)</th>
<th>Intervention patients (n=50) who answered question correctly</th>
<th>Control patients (n=52) who answered question correctly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q.1</td>
<td>30% (15)</td>
<td>57.7% (30)</td>
</tr>
<tr>
<td>Q.2</td>
<td>94% (47)</td>
<td>76.9% (40)</td>
</tr>
<tr>
<td>Q.7a</td>
<td>72% (36)</td>
<td>42.3% (22)</td>
</tr>
<tr>
<td>Q.8b</td>
<td>52% (26)</td>
<td>19.2% (10)</td>
</tr>
<tr>
<td>Q.11a</td>
<td>94% (47)</td>
<td>75% (39)</td>
</tr>
<tr>
<td>Q.15</td>
<td>92% (46)</td>
<td>73.1% (38)</td>
</tr>
</tbody>
</table>
The chi-squared tests performed on the questions in the ‘Warfarin Knowledge’ questionnaire completed after three months, found that only the correct answer to one question differed significantly between the two groups. This was Question 10 “What is your target INR blood test range?” with a p-value of 0.008*. For this particular question, 72 percent (36) of the intervention group patients, as compared to 44.2 percent (23) of the control group patients, answered the question correctly. This means that a significantly greater proportion of the intervention group patients knew what their therapeutic International Normalised Ratio (INR) blood test ranges should be during their warfarin treatment, as compared to the control group patients.

6.4.4.4 Two-way ANOVA test to assess whether or not there was a relationship between the patients’ group, educational level and ‘Warfarin Knowledge’ questionnaire score.

Two-way ANOVA tests were used to determine whether or not the patients’ warfarin knowledge scores, immediately and after three months were affected by their group (i.e. intervention or control) and educational level. The ANOVA test was used in place of the t-test because three variables; group, educational level and warfarin knowledge score were being assessed in place of two variables. The ANOVA test is more appropriate in this instance because it can compare means between the two groups taking into account several factors. The results from the two-way ANOVA tests produced a p-value equal to 0.0058* immediately, and a p-value equal to 0.0278* for the three-month follow-up scores. These results suggest that there was a significant difference between the mean ‘Warfarin Knowledge’ questionnaire scores (calculated from the General Linear Models (GLM) procedure for the Least Square Means), taking into account their group (intervention or control) and their educational level, as per Table 14. In other words, the more educated patients in both the intervention and control groups achieved higher mean scores for their ‘Warfarin Knowledge’ questionnaires.
Table 14: Summary of intervention and control group patients’ mean GLM ‘Warfarin Knowledge’ questionnaire scores immediately and three months after the initial warfarin education session, based on education level.

<table>
<thead>
<tr>
<th>Level of Education</th>
<th>Mean WK score for intervention patients (n=50)</th>
<th>Mean WK score for control patients (n=52)</th>
<th>Mean WK score for intervention patients (n=50)</th>
<th>Mean WK score for control patients (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ Grade 6</td>
<td>19.8 (16)</td>
<td>17.7 (10)</td>
<td>16.6 (16)</td>
<td>15.0 (10)</td>
</tr>
<tr>
<td>Grade 7-9</td>
<td>21.1 (16)</td>
<td>18.2 (26)</td>
<td>18.3 (16)</td>
<td>16.0 (26)</td>
</tr>
<tr>
<td>≥ Grade 10</td>
<td>22.0 (18)</td>
<td>21.5 (16)</td>
<td>19.1 (18)</td>
<td>20.0 (16)</td>
</tr>
</tbody>
</table>

(In the table: Mean scores were calculated from the General Linear Models (GLM) procedure for the Least Square Means; WK = ‘Warfarin Knowledge’ questionnaire; immediate = WK scores achieved immediately after the initial warfarin education session; 3-month follow-up = WK scores achieved three months after the initial warfarin education session)

Based on the warfarin knowledge score classifications (WK scores ≥ 22.0 excellent; 19.0-21.9 good; 16.0-18.9 average; ≤15.9 poor), the results in table 14 indicate that immediately after the initial warfarin education session, the intervention group patients educated at all three levels (i.e. ≤ grade 6, between grade 7-9, and, ≥ grade 10) achieved higher mean scores than did the control group patients educated at the same levels. The immediate score for the intervention group patients educated at or below 9 levels, including those educated at or below grade 6 levels, were good, compared to average for control group patients educated at the same level. Similarly, the immediate mean score for intervention group patients educated at or above grade 10 levels was excellent, compared to good for control group patients in the same education category. This indicates that the new warfarin education program was initially more effective than the customary education program in educating patients from all different educational backgrounds about their warfarin therapy and improving their warfarin knowledge and understanding.

Table 14 also shows that after three months of warfarin therapy the mean ‘Warfarin Knowledge’ scores were much lower than the initial scores for both groups. The mean scores for the intervention group patients educated at or below grade 6 levels, and between grade 7-9 deteriorated to average scores,
and the scores for those educated at or above grade 10 levels deteriorated to good scores. The mean scores for the control group patients educated at the different levels also deteriorated, with those educated at or below grade 6 levels achieving poor scores, the lowest recorded for all patient participants. It could be argued, therefore, that the customary warfarin education program did not appropriately cater for the needs of the patients with low literacy skills (educated at or below a grade 6 level), which is why their warfarin knowledge scores were the lowest recorded.

Interestingly, the only mean scores for the ‘Warfarin Knowledge’ questionnaire achieved by the control group patients which were higher than those achieved by the intervention group patients, were the three-month follow-up scores achieved by patients educated at or above grade 10 level (20.0 versus 19.1). Importantly, however, these scores were not significantly different which means that both programs were equally effective at educating patients with educational levels at or above grade 10 about their warfarin therapy.

Overall, therefore, the intervention group patients achieved higher mean ‘Warfarin Knowledge’ questionnaire scores than did the control group patients, immediately and three months after the commencement of warfarin therapy. In fact, the immediate scores were significantly higher for the intervention group patients than they were for the control group patients. Not surprisingly, the more educated patients in both groups achieved the higher mean warfarin knowledge scores and those educated at or below a grade 6 level achieved the lowest mean scores. The control group patients educated at or below a grade 6 level achieved the lowest mean ‘Warfarin Knowledge’ questionnaire scores.

6.4.4.5 Paired t-tests used to compare the immediate ‘Warfarin Knowledge’ questionnaire score against the three-month follow-up ‘Warfarin Knowledge’ questionnaire score.

Paired t-tests were used to assess whether or not the deterioration in the ‘Warfarin Knowledge’ (WK) questionnaire scores over the three-month period for both groups was significant. Table 15 provides a summary of the paired t-test
results and suggests that there was a significant difference between the immediate and three-month follow-up scores for both groups. The three-month follow-up ‘Warfarin Knowledge’ questionnaire scores for the intervention group patients were on average 2.9 marks lower than the immediate scores (p-value less than 0.0001***). Similarly, the three-month follow-up scores for the control group patients were on average 2.12 marks lower than the immediate scores (p-value 0.0019*). Thus there was a significant deterioration in the mean ‘Warfarin Knowledge’ questionnaire scores over the three-month period for both groups. This deterioration in warfarin knowledge and understanding could have serious implications for patients on long-term warfarin therapy.

Table 15: Paired t-test results comparing intervention and control group patients ‘Warfarin Knowledge’ mean scores immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Difference between WK scores (WK₁-WK₂)</th>
<th>Lower CL Mean</th>
<th>Mean</th>
<th>Upper CL Mean</th>
<th>Degrees of Freedom (df)</th>
<th>t value</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention group (WK₁-WK₂)</td>
<td>1.76</td>
<td>2.9</td>
<td>4.04</td>
<td>49</td>
<td>5.10</td>
<td>&lt;0.0001***</td>
</tr>
<tr>
<td>Control group (WK₁-WK₂)</td>
<td>0.82</td>
<td>2.12</td>
<td>3.41</td>
<td>51</td>
<td>3.28</td>
<td>0.0019**</td>
</tr>
</tbody>
</table>

(In the table: WK = ‘Warfarin Knowledge’ questionnaire; WK₁ = immediate mean ‘Warfarin Knowledge’ questionnaire score; WK₂ = three-month follow-up mean ‘Warfarin Knowledge’ questionnaire score; CL = 95% confidence interval of the difference)

6.4.4.6 Summary

In summary, a number of tests were performed to evaluate the results of the ‘Warfarin Knowledge’ questionnaire (APPENDIX 19). The results of t-tests indicated that the new warfarin education program, used to educate the intervention group patients, significantly improved warfarin knowledge and understanding immediately after the initial warfarin education session, as compared to the customary warfarin education program used to educate the control group patients. This significant improvement, however, was not maintained because there was no significant difference identified between the
‘Warfarin Knowledge’ questionnaire scores achieved by both groups after three months of warfarin therapy.

Chi-squared tests identified relationships between the patient group (intervention or control) and the correct answers to several questions in the initial, and only one question in the three-month follow-up ‘Warfarin Knowledge’ questionnaire. Compared to control group patients more intervention group patients had a better understanding about: why warfarin was prescribed; how to manage and improve warfarin compliance; how to recognise serious side effects; and possible food interactions. A two-way ANOVA test also identified that the more educated patients in both groups achieved higher mean scores for their ‘Warfarin Knowledge’ questionnaires. Finally, paired t-tests confirmed that the three-month follow-up ‘Warfarin Knowledge’ questionnaire scores for both groups were significantly lower than their immediate scores, suggesting that warfarin knowledge had deteriorated over time.

Overall, therefore, the new warfarin education program improved the patients’ warfarin knowledge and understanding, especially immediately after the initial warfarin education session, more so than did the customary warfarin education program. Notably, the low literacy skilled patients educated at or below a grade 6 level, who received the customary warfarin education program, achieved the lowest mean ‘Warfarin Knowledge’ questionnaire scores after three months of warfarin therapy. This suggests that the new warfarin education program, as compared to the customary warfarin education program, more effectively improved warfarin knowledge and understanding in all patients, including those with low literacy skills.

6.4.5 t-tests to compare the mean scores for the ‘Self-Management,’ ‘Medication-Taking-Measures’ and the ‘Warfarin Knowledge’ questionnaires

6.4.5.1 Introduction

t-tests were used to evaluate whether or not a number of different factors affected the mean scores for the ‘Self-Management’, ‘Medication-Taking-
Measures’ and ‘Warfarin Knowledge’ questionnaires (Appendices 17-19) immediately and three months after the initial warfarin education session. The factors assessed included patient participants: having prior warfarin knowledge; coming from non-English speaking backgrounds; being elderly (aged 65 years and over); having a carer and/or family member present during the initial warfarin education session; and seeking more warfarin information. The results of these t-tests will now be discussed.

6.4.5.2 Comparing mean scores for the various questionnaires for participating patients with and without prior warfarin knowledge

In order to establish whether or not prior warfarin knowledge affected the mean ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaire scores immediately and three months after the initial warfarin education session, t-tests were performed on each of these scores. The t-tests were carried out on the scores of intervention and control group patients with and without prior warfarin knowledge.

The results of these t-tests for the intervention group patients’ mean questionnaire scores are summarised in table 16, which shows that no p-values were below 0.05. Thirty percent (15) of the intervention group patients who had prior warfarin knowledge, achieved mean scores for the ‘Self-Management’, the ‘Medication-Taking-Measures’ and the ‘Warfarin Knowledge’ questionnaires which were not significantly different to the mean scores achieved by the 70 percent (35) of the intervention group patients who had no prior warfarin knowledge. Thus, the intervention group patients with and without prior warfarin knowledge were equally confident about their warfarin management and compliance at home, and they had similar levels of warfarin knowledge and understanding.
Table 16: t-test results comparing mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires of intervention group patients with and without prior warfarin knowledge immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Mean score for intervention patients with prior warfarin knowledge (n=15)</th>
<th>Mean score for intervention patients with no prior warfarin knowledge (n=35)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM score (immediate)</td>
<td>19.133</td>
<td>19.057</td>
<td>0.8615</td>
</tr>
<tr>
<td>SM score (3-month follow-up)</td>
<td>19.933</td>
<td>19.886</td>
<td>0.6488</td>
</tr>
<tr>
<td>MTM score (immediate)</td>
<td>2.6</td>
<td>3.0571</td>
<td>0.3603</td>
</tr>
<tr>
<td>MTM score (3-month follow-up)</td>
<td>3.8</td>
<td>3.6571</td>
<td>0.5002</td>
</tr>
<tr>
<td>WK score (immediate)</td>
<td>20.333</td>
<td>21.229</td>
<td>0.4022</td>
</tr>
<tr>
<td>WK score (3-month follow-up)</td>
<td>18</td>
<td>18.086</td>
<td>0.9418</td>
</tr>
</tbody>
</table>

(In the table: SM score = ‘Self-Management’ questionnaire score (maximum score =20); MTM score = ‘Medication-Taking-Measures’ questionnaire score (maximum score=4); WK score = ‘Warfarin Knowledge’ questionnaire score (maximum score= 26); immediate = questionnaire completed immediately after the initial warfarin education session and 3-month follow-up = questionnaire completed three months after the initial warfarin education session)

Table 17 also shows that there were no p-values below 0.05 for the t-tests carried out on mean scores for the control group patients with and without prior warfarin knowledge. The 48.1 percent (25) of control group patients with prior warfarin knowledge did not achieve significantly different mean scores to the 51.9 percent (27) of control group patients with no prior warfarin knowledge. Therefore, the mean scores for the ‘Self-Management ’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires, completed immediately and three months after the initial warfarin education session, were similar for the control group patients with and without prior warfarin knowledge. Here again, the control group patients with and without prior warfarin knowledge were equally confident about their warfarin management and compliance at home, and they had similar levels of warfarin knowledge and understanding.
Table 17: t-test results comparing mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires of control group patients with and without prior warfarin knowledge immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Mean score for control patients with prior warfarin knowledge (n=25)</th>
<th>Mean score for control patients with no prior warfarin knowledge (n=27)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM score (immediate)</td>
<td>18.96</td>
<td>17.963</td>
<td>0.2022</td>
</tr>
<tr>
<td>SM score (3-mth follow-up)</td>
<td>19.56</td>
<td>19.889</td>
<td>0.1904</td>
</tr>
<tr>
<td>MTM score (immediate)</td>
<td>3.2</td>
<td>2.8519</td>
<td>0.3663</td>
</tr>
<tr>
<td>MTM score (3-mth follow-up)</td>
<td>3.68</td>
<td>3.3704</td>
<td>0.2278</td>
</tr>
<tr>
<td>WK score (immediate)</td>
<td>20</td>
<td>18.333</td>
<td>0.1492</td>
</tr>
<tr>
<td>WK score (3-mth follow-up)</td>
<td>17.16</td>
<td>16.889</td>
<td>0.8115</td>
</tr>
</tbody>
</table>

(In the table: SM score = ‘Self-Management’ questionnaire score (maximum score =20); MTM score = ‘Medication-Taking-Measures’ questionnaire score (maximum score=4); WK score = ‘Warfarin Knowledge’ questionnaire score (maximum score= 26); immediate = questionnaire completed immediately after the initial warfarin education session and 3-month follow-up = questionnaire completed three months after the initial warfarin education session)

The combined results for both groups, as shown in tables 16 and 17, indicate that patients who had prior warfarin knowledge did not achieve significantly different mean scores for any of the questionnaires, as compared to the patients without prior warfarin knowledge. Hence, prior warfarin knowledge did not seem to positively impact upon the patients’ confidence to manage or comply with their warfarin therapy at home, nor did it improve warfarin knowledge and understanding. Possibly the most important aspect of these results is that even though the participating patients’ confidence about their warfarin management and compliance improved over time, their warfarin knowledge and understanding deteriorated over time.
6.4.5.3 Comparing mean scores for the ‘Self-Management’ ‘Medication-Taking-Measures’ and the ‘Warfarin Knowledge’ questionnaires for participating patients from English and non-English speaking backgrounds.

t-tests were used to evaluate whether or not coming from an English speaking background or a non-English speaking background affected the mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires completed immediately and three months after the initial warfarin education session. The t-test results for the intervention group patients are summarised in table 18 and in table 19 for the control group patients.

As shown in table 18, the English speaking background intervention group patients, as opposed to the non-English speaking background intervention group patients, achieved higher mean scores for each of the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires. The only significant differences between the two were achieved for the immediate ‘Self-Management’ questionnaire score with a p-value of 0.0047**, and the immediate ‘Warfarin Knowledge’ questionnaire score with a p-value of 0.0248*. The English speaking background intervention group patients, as compared to the non-English speaking background intervention patients, appeared to be more confident about their warfarin management at home and had a better warfarin knowledge and understanding immediately after their initial warfarin education session. Notably, even though these results were expected, the small number of non-English speaking background intervention group patients in this sample (n=9) makes it difficult to draw any firm conclusions from the data.
Table 18: *t*-test results comparing mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires of intervention group patients from English and non-English speaking backgrounds immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Mean score for intervention patients from English speaking backgrounds (n=41)</th>
<th>Mean score for intervention patients from non-English speaking backgrounds (n=9)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM score (immediate)</td>
<td>19.4</td>
<td>17.7</td>
<td>0.0047**</td>
</tr>
<tr>
<td>SM score (3-month follow-up)</td>
<td>19.9</td>
<td>19.8</td>
<td>0.3361</td>
</tr>
<tr>
<td>MTM score (immediate)</td>
<td>3.1</td>
<td>2.3</td>
<td>0.229</td>
</tr>
<tr>
<td>MTM score (3-month follow-up)</td>
<td>3.7</td>
<td>3.6</td>
<td>0.4857</td>
</tr>
<tr>
<td>WK score (immediate)</td>
<td>21.5</td>
<td>18.67</td>
<td>0.0248*</td>
</tr>
<tr>
<td>WK score (3-month follow-up)</td>
<td>18.3</td>
<td>16.8</td>
<td>0.2608</td>
</tr>
</tbody>
</table>

(In the table: SM score = ‘Self-Management’ questionnaire score (maximum score =20); MTM score = ‘Medication-Taking-Measures’ questionnaire score (maximum score=4); WK score = ‘Warfarin Knowledge’ questionnaire score (maximum score= 26); immediate = questionnaire completed immediately after the initial warfarin education session and 3-month follow-up = questionnaire completed three months after the initial warfarin education session)

Table 19 summarises the results for the control group patients. Again, the English speaking background control group patients achieved higher mean scores overall for each of the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires, than did the non-English speaking background control group patients. In this instance, none of these questionnaire mean scores were significantly different between the English speaking and the non-English speaking background control patients. Based on the small number of control group patients from non-English speaking backgrounds (n=6) however, these results cannot be considered to be conclusive.
Table 19: t-test results comparing mean scores for the 'Self-Management', 'Medication-Taking-Measures' and ‘Warfarin Knowledge’ questionnaires of control group patients from English and non-English speaking backgrounds immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Mean score for control patients from English speaking backgrounds (n=46)</th>
<th>Mean score for control patients from non-English speaking backgrounds (n=6)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM score (immediate)</td>
<td>18.6</td>
<td>17.5</td>
<td>0.396</td>
</tr>
<tr>
<td>SM score (3-month follow-up)</td>
<td>19.8</td>
<td>19.2</td>
<td>0.0899</td>
</tr>
<tr>
<td>MTM score (immediate)</td>
<td>3.1</td>
<td>2.5</td>
<td>0.337</td>
</tr>
<tr>
<td>MTM score (3-month follow-up)</td>
<td>3.5</td>
<td>3.8</td>
<td>0.3781</td>
</tr>
<tr>
<td>WK score (immediate)</td>
<td>19.33</td>
<td>17.67</td>
<td>0.3614</td>
</tr>
<tr>
<td>WK score (3-month follow-up)</td>
<td>17.4</td>
<td>14.0</td>
<td>0.0504</td>
</tr>
</tbody>
</table>

(In the table: SM score = 'Self-Management' questionnaire score (maximum score=20); MTM score = 'Medication-Taking-Measures' questionnaire score (maximum score=4); WK score = 'Warfarin Knowledge' questionnaire score (maximum score=26); immediate = questionnaire completed immediately after the initial warfarin education session and 3-month follow-up = questionnaire completed three months after the initial warfarin education session.)

In summary, tables 18 and 19 showed that English speaking background patients in both the intervention and control groups achieved higher mean scores overall for each of the questionnaires (Appendices 17-19), than did the non-English speaking background patients. When tables 18 and 19 were compared to each other, it was also identified that the non-English speaking backgrounds intervention group patients, as compared to the non-English speaking backgrounds control group patients, achieved higher mean scores for the ‘Self-Management’ and ‘Warfarin Knowledge’ questionnaires (Appendices 17 and 19), immediately and after three months of warfarin therapy. On the other hand, the non-English speaking background control group patients achieved slightly higher mean scores for the immediate and three-month follow-up ‘Medication-Taking-Measures’ questionnaire scores. These results suggest that the new warfarin education program improved the non-English speaking background patients’ confidence about their warfarin management at home, as
well as their warfarin knowledge and understanding, whereas the customary warfarin education program improved the non-English speaking background patients’ confidence with their warfarin compliance. Unfortunately, the number of non-English speaking background patients, in both groups, was too small to analyse statistically and conclusively.

6.4.5.4 Comparing mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and the ‘Warfarin Knowledge’ questionnaires for participating patients aged above and below 65 years.

$ t $-tests were used to analyse whether or not being elderly (aged 65 years and over) affected the mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires. At first, the $ t $-tests were conducted on the mean scores achieved by all the patient participants in both groups aged 65 years and over, and compared to the scores achieved by all patient participants in both groups aged below 65 years. There were no significant differences found for the mean scores of the ‘Self-Management’ and ‘Medication-taking-Measures’ questionnaires. However, there were significant differences in the immediate and three-month follow-up ‘Warfarin Knowledge’ questionnaire mean scores.

The participating patients aged 65 years and over achieved an immediate ‘Warfarin Knowledge’ mean score of 19.16 (73.7 percent) and a three-month follow-up score of 16.59 (63.8 percent). On the other hand, participating patients aged below 65 years achieved an immediate mean score of 21.5 (82.7 percent) and a three-month follow-up mean score of 19.105 (73.5 percent). The results of the $ t $-tests found a $ p $-value equal to 0.0012** for the immediate scores, and a $ p $-value equal to 0.0014** for the three-month follow-up scores. These results are indicative of the fact that the warfarin knowledge and understanding was poorer in all participating patients aged 65 years and over, as compared to those aged 65 years and under.

To investigate possible differences in the questionnaire mean scores within the two groups (intervention and control), further $ t $-tests were performed.
Firstly, t-tests were conducted on the mean scores of the intervention group patients aged above and below 65 years of age and the results of these tests are summarised in table 20. Secondly, t-tests were performed on the mean scores of the control group patients aged above and below 65 years and the results of this test are summarised in table 21.

Table 20: t-test results comparing mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires of intervention patients aged above and below 65 years and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Mean score for intervention patients aged 65 years and over (n=34)</th>
<th>Mean score for intervention patients aged below 65 years (n=16)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM score (immediate)</td>
<td>19.088</td>
<td>19.063</td>
<td>0.9608</td>
</tr>
<tr>
<td>SM score (3-month follow-up)</td>
<td>19.912</td>
<td>19.875</td>
<td>0.7743</td>
</tr>
<tr>
<td>MTM score (immediate)</td>
<td>2.971</td>
<td>2.813</td>
<td>0.7484</td>
</tr>
<tr>
<td>MTM score (3-month follow-up)</td>
<td>3.735</td>
<td>3.625</td>
<td>0.5965</td>
</tr>
<tr>
<td>WK score (immediate)</td>
<td>20.412</td>
<td>22.125</td>
<td>0.0991</td>
</tr>
<tr>
<td>WK score (3-month follow-up)</td>
<td>17.0</td>
<td>20.313</td>
<td>0.0026**</td>
</tr>
</tbody>
</table>

(In the table: SM score = ‘Self-Management’ questionnaire score (maximum score =20); MTM score = ‘Medication-Taking-Measures’ questionnaire score (maximum score=4); WK score = ‘Warfarin Knowledge’ questionnaire score (maximum score= 26); immediate = questionnaire completed immediately after the initial warfarin education session and 3-month follow-up = questionnaire completed three months after the initial warfarin education session.)

Table 20 shows that between intervention group patients aged above and below 65 years, the only significant difference in scores was in the three-month follow-up ‘Warfarin Knowledge’ questionnaire scores (p-value 0.0026**). In this questionnaire, the results show that elderly intervention group patients (aged 65 years and over) achieved significantly lower scores than those intervention group patients aged less than 65 years. This demonstrates that after three months of warfarin therapy, elderly patients who have received the new warfarin
education program had significantly less warfarin knowledge and understanding than did their younger counterparts.

Table 21: t-test results comparing mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires of control patients aged above and below 65 years immediately and three months after the initial warfarin education session.

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Mean score for control patients aged 65 years and over (n=30)</th>
<th>Mean score for control patients aged below 65 years (n=22)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM score (immediate)</td>
<td>18.967</td>
<td>17.727</td>
<td>0.1236</td>
</tr>
<tr>
<td>SM score (3-month follow-up)</td>
<td>19.633</td>
<td>19.864</td>
<td>0.3484</td>
</tr>
<tr>
<td>MTM score (immediate)</td>
<td>3.233</td>
<td>2.727</td>
<td>0.1986</td>
</tr>
<tr>
<td>MTM score (3-month follow-up)</td>
<td>3.6</td>
<td>3.409</td>
<td>0.4642</td>
</tr>
<tr>
<td>WK score (immediate)</td>
<td>17.733</td>
<td>21.045</td>
<td>0.0034**</td>
</tr>
<tr>
<td>WK score (3-month follow-up)</td>
<td>16.133</td>
<td>18.227</td>
<td>0.0640</td>
</tr>
</tbody>
</table>

(In the table: SM score = ‘Self-Management’ questionnaire score (maximum score =20); MTM score = ‘Medication-Taking-Measures’ questionnaire score (maximum score=4); WK score = ‘Warfarin Knowledge’ questionnaire score (maximum score = 26); immediate = questionnaire completed immediately after the initial warfarin education session and 3-month follow-up = questionnaire completed three months after the initial warfarin education session.)

Table 21 shows that between control group patients aged above and below 65 years, the only significant difference was in the immediate ‘Warfarin Knowledge’ questionnaire’ (p-value 0.0034**). These results suggest that the elderly control group patients (aged 65 years and over) achieved significantly lower mean scores than those control group patients aged below 65 years, immediately after the initial warfarin education session. This demonstrates that the elderly patients who received the customary warfarin education program had significantly less warfarin knowledge and understanding than did the younger patients from the initiation of their warfarin therapy.

Comparing tables 20 and 21 also identified that the mean scores achieved by the elderly intervention group patients were, on the whole, higher than the average mean scores achieved by the elderly control group patients. According
to t-tests results, however, only the immediate ‘Warfarin Knowledge’
questionnaire scores were significantly higher for the elderly intervention group
patients compared to the elderly control group patients (p-value 0.0092**). This
demonstrates that the new warfarin education program, as compared to the
customary warfarin education program, significantly improved the elderly
patients’ warfarin knowledge and understanding immediately after the initial
warfarin education program. The higher mean scores achieved by the elderly
intervention group patients compared to the elderly control group patients for the
‘Self-Management’ and ‘Medication-Taking-Measures’ questionnaires, also
suggests that the new program was more effective than the customary program,
in promoting warfarin self-management and compliance at home for elderly
patients.

In summary, the elderly patient participants (aged 65 years and over)
achieved lower overall mean scores for the ‘Self-Management’, ‘Medication-
Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires, than did the patient
participants aged below 65 years. Statistical analysis, however, found that only
the elderly patient participants’ ‘Warfarin Knowledge’ questionnaire scores were
significantly lower than those of the younger patient participants. These results
demonstrate, that the customary warfarin education program was less effective
at educating the elderly patients than the younger patients from the beginning,
whereas the new warfarin education program lost its initial benefit over time.
Interestingly, the new warfarin education program, as compared to the customary
warfarin education program, was more effective at improving elderly patients’
warfarin knowledge and understanding, as well as their overall confidence with
warfarin management and compliance.
6.4.5.5 Comparing mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and the ‘Warfarin Knowledge’ questionnaires for participating patients with and without the presence of a carer and/or family member during the initial warfarin education session.

T-tests were used to analyse whether or not having a carer and/or family member present during the education session had an effect on the patients’ mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires (Appendices 17-19), completed immediately and three months after the initial warfarin education session. P-values for both the intervention and the control groups were all above 0.05 indicating that there was no difference in results based on having a carer and/or family member present during the initial warfarin education session. Nor did it have an apparent effect on the patients’ confidence to manage and comply with their warfarin therapy at home, or affect their warfarin knowledge and understanding. However, this result does not provide any indication of the role of the carer – whether those with a carer present were better off than those without a carer present. It was not possible to address this question in the present study.

6.4.5.6 Comparing mean scores for the three-month follow-up ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires for patients seeking more warfarin information from their general practitioners, medicines information telephone lines, the internet, etc.

In order to analyse whether or not the patients who had sought more warfarin information achieved different mean scores for their ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires (Appendices 17-19) compared to those who did not, t-tests were performed. These t-tests were performed on the mean scores for each of these questionnaires completed after three months of warfarin therapy (it was assumed that they did not seek information before their initial warfarin education sessions). The results for the intervention and control group patients, who did and didn’t
seek more warfarin information, are summarised in tables 22 and 23, respectively.

As shown in table 22 the only mean score which was significantly different for the intervention group patients who sought more warfarin information compared to those who did not was the ‘Warfarin Knowledge’ questionnaire (p-value 0.0072**). Arguably the most interesting point to make here is that the average mean ‘Warfarin Knowledge’ questionnaire score for the intervention group patients who had sought more information was lower than the mean score achieved by intervention group patients who did not. In reality, this result may not be considered conclusive because of the small number of intervention group patients who sought more warfarin information, 16 percent (8). Alternatively, it may also reflect that the quality and readability of the warfarin information available from these other sources is poor and/or incomprehensible, making them more confused about their warfarin therapy.

**Table 22: t-test results comparing the mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires of intervention group patients who sought more warfarin information compared to those who did not.**

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Mean scores for intervention patients who sought more warfarin information (n=8)</th>
<th>Mean scores for intervention patients who did not seek more warfarin information (n=42)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM score</td>
<td>19.75</td>
<td>19.929</td>
<td>0.5053</td>
</tr>
<tr>
<td></td>
<td>(3-month follow-up)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTM score</td>
<td>3.75</td>
<td>3.6905</td>
<td>0.8226</td>
</tr>
<tr>
<td></td>
<td>(3-month follow-up)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WK score</td>
<td>17.452</td>
<td>21.25</td>
<td>0.0072**</td>
</tr>
<tr>
<td></td>
<td>(3-month follow-up)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(In the table: SM score = ‘Self-Management’ questionnaire score (maximum score =20); MTM score = ‘Medication-Taking-Measures’ questionnaire score (maximum score=4) and WK score = ‘Warfarin Knowledge’ questionnaire score (maximum score= 26))

Table 23 shows that the only significant difference in any of the mean scores for the questionnaires completed by the control group patients, who did and did not seek more warfarin information, was the ‘Medication-Taking-Measures’ (MTM) questionnaire (p-value 0.0004***). In this case, all 7.7 percent
(4) of the control group patients who sought more warfarin information had a perfect MTM score equal to 4, as compared to the mean MTM score of 3.4792 for the 92.3 percent (48) control group patients who did not seek more warfarin information. Once again, given that only a small number of control group patients actually sought more warfarin information and that the MTM mean scores were representative of ‘high’ compliance scores in both instances, it cannot be concluded that the patients who sought more warfarin information were truly more confident about their warfarin compliance, than were patients who did not.

Table 23: t-test results comparing the mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires of control group patients who sought more warfarin information compared to those who did not.

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Mean scores for control patients who sought more warfarin information (n=4)</th>
<th>Mean scores for control patients who did not seek more warfarin information (n=48)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>SM score</td>
<td>19</td>
<td>19.792</td>
<td>0.4874</td>
</tr>
<tr>
<td>(3-mth follow-up)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MTM score</td>
<td>4</td>
<td>3.4792</td>
<td>0.0004***</td>
</tr>
<tr>
<td>(3-month follow-up)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WK score</td>
<td>20.75</td>
<td>16.708</td>
<td>0.0534</td>
</tr>
<tr>
<td>(3-month follow-up)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(In the table: SM score = ‘Self-Management’ questionnaire score (maximum score =20); MTM score = ‘Medication-Taking-Measures’ questionnaire score (maximum score=4) and WK score = ‘Warfarin Knowledge’ questionnaire score (maximum score= 26))

Importantly, tables 22 and 23 indicate that only a small proportion of the intervention group patients (16 percent (8)) and control group patients (7.7 percent (4)), actually sought more warfarin information. Therefore, it is not possible to generalise that the results in these data are representative of the general warfarin prescribed patient population. It could be argued, however, that because both of the education programs were so effective and informative, many patient participants did not feel the need to seek more warfarin information.
6.4.5.7 Summary

In summary, the results of the t-tests did not show a significant difference in either of the groups for the ‘Self-Management’, ‘Medication-Taking-Measures’ or the ‘Warfarin Knowledge’ questionnaire scores when patient participants’ had prior warfarin knowledge or when they had a carer and/or family member present during the initial warfarin education session. Compared to English speaking background patient participants, non-English speaking background patient participants were found to have poorer warfarin knowledge and less confidence with their warfarin management and compliance. The data indicated, however, that the non-English speaking background patients who received the new warfarin education program had a better understanding of their warfarin knowledge and were more confident about their warfarin management, than were the non-English speaking background patients who received the customary warfarin education program. Similarly elderly patient participants (aged 65 years and over) had poorer warfarin knowledge and less confidence with their warfarin management and compliance, than did the younger patients. Here again, the elderly intervention group patients who received the new warfarin education program had a better understanding of their warfarin knowledge and were, overall, more confident about their warfarin management and compliance, than were elderly control group patients who received the customary warfarin education program. The new warfarin education program, therefore, seemed to be more effective than the customary warfarin education program at improving these ‘high risk’ participating patients’ warfarin knowledge and understanding, as well as confidence with their warfarin management and compliance.

Given the small number of patient participants who sought more warfarin information, it is difficult to draw and real conclusions from the data. However, the fact that so few patient participants did actually seek more warfarin information may be an indication that both the new and the customary warfarin education programs provided patients with sufficient warfarin information.
6.4.6 ‘Satisfaction with Information about Medicines Scale’ (SIMS) (APPENDIX 20) results

6.4.6.1 Introduction

The patients’ satisfaction with the warfarin information they were given was measured with the established and validated ‘Satisfaction with Information about Medicines Scale’ (SIMS) (APPENDIX 20) (Horne, Hankins et al. 2001). Questions 1 - 9 were used to analyse the patients' satisfaction with the information they received about warfarin’s action and usage and questions 10 - 17 were used to analyse their response to the information they received about warfarin’s potential problems. The following rating criteria were used:

a) too much
b) about right
c) too little
d) none received
e) none needed

6.4.6.2 Analysis of questions 1-9 of the ‘Satisfaction with Information about Medicines Scale’ (SIMS) questionnaire.

Analysis of questions 1-9 of the SIMS data collected immediately after the initial warfarin education session showed that both groups rated highly the information they received for questions 1 - 4, 6 and 8 of the scale, as per APPENDIX 20. These questions refer to warfarin’s name, indication, action, and duration of therapy. More than 90 percent of both groups rated the information they received for these questions as about right (b). The ratings for questions 5, 7 and 9 of the questionnaire, however, varied somewhat and a summary of the findings is listed below.

- Question 5 How long warfarin will take to act.
  100 percent (50) of the intervention group patients and 86.5 percent (45) of the control group patients felt that the information they received about
question 5 was about right (b). However, 11.54 percent (6) of the control group patients felt that too little information (c) was received, and 1.92 percent (1) felt that no information had been received (d).

These results show that the intervention group patients were more satisfied with the information they received about how long it takes for warfarin to act.

- **Question 7 How long you will need to be on your medicine.**

92 percent (46) of the intervention group patients and 88.46 percent (46) of the control group patients felt that they had received the right amount of information (b) for question 7. However, 8 percent (4) of the intervention group patients and 7.69 percent (4) of the control group patients felt that they had received too little information (c), and, 3.85 percent (2) of the control group patients felt that they had not received any information (d).

This shows that the intervention group patients appeared to be more satisfied than the control group patients about the information received regarding how long they would need to be on warfarin therapy.

- **Question 9 How to get a further supply**

86 percent (43) of the intervention group patients and 67.31 percent (35) of the control group patients felt that they had received the right amount of information (b) for question 9. However, 8 percent (4) of the intervention group patients and 21.15 percent (11) of the control group patients felt that they had received too little information (c), whereas 9.4 percent (2) of the intervention group patients and 7.69 percent (4) of the control group patients felt that they had received no information (d). Interestingly, 2 percent (1) of the intervention and 3.85 percent (2) of the control group patients felt that they hadn’t needed any information (e) about question 9.

Intervention group patients therefore appeared to be much more satisfied than control group patients with the information about how to obtain further supplies of warfarin tablets.
Overall, for each of these initial SIMS (APPENDIX 20) warfarin action and usage questions, the intervention group patients were more satisfied than the control group patients about the information they received. It would be fair to say however, that even though the satisfaction scores were high for both groups, educating patients about: how long warfarin takes to work; how long warfarin needs to be taken; and where to get further supplies, would help to improve patients’ satisfaction with the current customary warfarin education program given to TACT patients.

The three-month follow-up SIMS data found that 96 percent (98) of the 102 participating patients in both groups felt that all the information given to them about warfarin’s action and usage (Questions 1-9 of APPENDIX 20) was about right (b). This demonstrates that their satisfaction scores improved over time.

6.4.6.3 Analysis of questions 10-17 of the ‘Satisfaction with Information about Medicines Scale’ (SIMS) questionnaire

Focus will now turn to Questions 10 - 17 of the data, which analysed patients’ satisfaction with information they received about warfarin’s potential problems. Once again, the overall results were high with over 90 percent of the participating patients immediately - and over 95 percent of patients after three months - describing the information they received for Question 12 to 15 in APPENDIX 20 was about right (b). These questions referred to their satisfaction with the information they received about: what to do if they experienced unwanted side effects; whether or not they could drink alcohol while on warfarin therapy; whether or not other medicines interacted with warfarin; and what they should do if they forgot to take a dose.

The questions which did not highly satisfy the participating patients were questions 10 and 11 initially, and questions 16 and 17 both initially and after three months of warfarin therapy. The following is a brief summary of the immediate satisfaction scores for questions 10 and 11 of the SIMS questionnaire (APPENDIX 20).
Question 10 Whether the medicine has any unwanted effects (side effects).

Ninety-eight percent (49) of intervention group patients and 88.46 percent (46) of control group patients felt that they had received the right amount of information (b) about side effects. However, 2 percent (1) of the intervention and 9.62 percent (5) of the control group patients felt that they had received too little information (c), and only one control patient or 1.92 percent, indicated that no information had been received (d).

Intervention group patients were slightly more satisfied than the control group patients with the initial information they received about warfarin’s side effects.

Question 11 What are the risks of you getting side effects?

Ninety-two percent (46) of the intervention group patients and 76.92 percent (40) of the control group patients felt that they received the right amount of information (b) about their risks of suffering side effects. However, 6 percent (3) of the intervention group patients and 21.15 percent (11) of the control group patients felt that they had received too little information (c), and one intervention patient, or 2 percent, and one control patient, 1.92 percent, indicated that they had not received any information (d) about the risk of side effects.

Once again, intervention group patients appeared more satisfied than control group patients about the information they received concerning the risk of suffering from warfarin-related side effects.

More than 60 percent (72) of the participating patients were not satisfied with the information referred to in Questions 15 and 16 of the SIMS questionnaire (APPENDIX 20), either immediately or after three months of warfarin. The satisfaction results were low, primarily because warfarin has no major effects on drowsiness or normal heterosexual sexual behaviour and hence these issues were not discussed during the education sessions. These results are not
surprising because prior to the research study it was decided to use the SIMS questionnaire (APPENDIX 20) in its entirety inclusive of these two questions which were not considered to be highly relevant to warfarin therapy.

6.4.6.4 Chi-square test results and patient comments used to compare and contrast the ‘Satisfaction with Information about Medicines Scale’ (SIMS) questionnaire scores for both groups.

Chi-squared tests, in place of the inappropriate t-tests, were used to identify significant differences between the two groups’ satisfaction scores for questions 5, 7, 9, 10, 11, 16 and 17 of the ‘Satisfaction with Information about Medicines Scale’ (SIMS) (APPENDIX 20), identified above. A significant difference in the scores was only identified for Question 5 with a p-value of 0.027*. Therefore, the intervention group patients’ satisfaction with the information they received about how long it takes for warfarin to act was significantly better than the control group patients’ satisfaction with this information. It should be noted however, that this satisfaction score was significantly better immediately, as compared to three months after the initial warfarin education session. This shows that patients in the new warfarin education program were more satisfied than those in the customary program with information provided in the first education session about how long warfarin takes to act.

Patients’ comments were once again encouraged during this data collection period and, as a result, several comments were documented. These comments were similar for both groups and reflected their satisfaction with being educated at home and having the information reinforced in a simple and easy-to-understand manner. Some examples of these comments included:

- **Intervention 2** “Good to get info at home…”
- **Intervention 28** “I like the simplicity of the booklet…”
- **Control 16** “Boots booklet and information from TACT is extremely useful and easy to understand…”
Control 16 “I found answering the questions reassured my knowledge ..”

6.4.6.5 Summary

In summary, a key arbiter of the quality of medicines information given to patients is the extent to which individuals perceive that it has met their needs and they are satisfied (Horne, Hankins et al. 2001). Overall, the satisfaction scores were high for both groups in relation to the information provided about warfarin’s action, usage and potential problems. The ‘Satisfaction with Information about Medicines Scale’ (SIMS)(APPENDIX 20) data however identified that the new warfarin education program addressed the information about how long warfarin will take to act significantly better than did the customary warfarin education program.

6.4.7 ‘Outcome Measures of the Warfarin Education Program’ questionnaire (APPENDIX 21) results

6.4.7.1 General practitioner visits

To identify whether or not general practitioner visits affected patients’ ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaire scores, a correlation coefficient test was used. The correlation coefficient test calculated whether or not there was a relationship between the mean three-month follow-up questionnaire scores and the number of general practitioner visits (a coefficient of 0 indicates no linear relationship between two variables, whereas a coefficient of 1 indicates a linear relationship between two variables). The general practitioner visits averaged about 7 visits per patient for both the intervention and the control group patients. Interestingly however, the general practitioner visits varied between 0 to 30 visits for the intervention patients, and 2 to 16 visits for the control patients. The results of the correlation coefficient test scores are summarised in table 24.
Table 24: Pearson correlation coefficient scores assessing any relationship between ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaire scores and the number of general practitioner visits after three months.

| Questionnaire score | Intervention Group (n=50) |  | Control Group (n=52) |  |
|---------------------|---------------------------|---------------------------------|---------------------------------|
|                     | Pearson Correlation Coefficient | p-value | Pearson Correlation Coefficient | p-value |
| SM score (3-month follow-up) | -0.14704 | 0.3082 | -0.30512 | 0.0278* |
| MTM score (3-month follow-up) | 0.01807 | 0.9009 | 0.17809 | 0.2065 |
| WK score (3-month follow-up) | -0.04010 | 0.7822 | -0.43277 | 0.0014** |

(In this table: SM score = ‘Self-Management’ questionnaire score; MTM score = ‘Medication-Taking-Measures’ questionnaire score and WK score = ‘Warfarin Knowledge’ questionnaire score; 3-month follow-up = questionnaires scores three months after the initial warfarin education session)

According to the results in table 24, only the control group’s ‘Self-Management’ (SM) questionnaire scores (p-value 0.0278*) and ‘Warfarin Knowledge’ questionnaire (WK) scores (p-value 0.0014**) had coefficients significantly different to zero, three months after the initial warfarin education session. In both these cases, even though correlations were poor, there was a direct relationship between the ‘Self-Management’ and ‘Warfarin Knowledge’ questionnaire scores and the number of general practitioner visits. Interestingly, the coefficients for both of these scores were negative, indicating a negative relationship or a reduction in the mean scores for both questionnaires as the number of general practitioner visits increased. In other words, as the number of general practitioner visits increased for the control group patients, their confidence with their warfarin management and their warfarin knowledge deteriorated. A possible implication of this finding is that the control group patients who had poor self-management skills and poorer warfarin knowledge visited their general practitioners more frequently during the initial three months of warfarin therapy.
6.4.7.2 Hospital visits

Eighteen percent (9) of the intervention group patients and 21.2 percent (11) of the control group patients visited hospital within the first three months of their warfarin therapy. The reasons for hospital visits are listed below, with the number of patients who presented from each group shown in brackets;

<table>
<thead>
<tr>
<th>Intervention Patients (n=9)</th>
<th>Control Patients (n=11)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atrial fibrillation (1)</td>
<td>Heart key hole surgery (1)</td>
</tr>
<tr>
<td>Chemotherapy (1)</td>
<td>Chemotherapy (2)</td>
</tr>
<tr>
<td>Chest pain (3)</td>
<td>Shortness of breath (1)</td>
</tr>
<tr>
<td>Osteomyelitis (1)</td>
<td>Surgical procedures (5)</td>
</tr>
<tr>
<td>Pain management (1)</td>
<td>Pacemaker inserted (1)</td>
</tr>
<tr>
<td>Surgical procedures (2)</td>
<td>Transient ischaemic attacks (1)</td>
</tr>
</tbody>
</table>

These results suggest that similar proportions of patients from both the intervention and control groups visited hospital during their first three months of their warfarin therapy for reasons which were not related to poor warfarin therapeutic outcomes or warfarin-related adverse drug events.

6.4.7.3 Emergency department visits

Sixteen percent (8) of the intervention group patients and 11.54 percent (6) of the control group patients visited the emergency department during the first three months of their warfarin therapy. The reasons for their emergency department visits are listed below with the number of patients from each group once again represented in brackets;

<table>
<thead>
<tr>
<th>Intervention Patients (n=8)</th>
<th>Control Patients (n=6)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allergic reaction to antibiotics (1)</td>
<td>Asthma attack (1)</td>
</tr>
<tr>
<td>Atrial fibrillation (1)</td>
<td>Burst blood vessel in eye (1)</td>
</tr>
<tr>
<td>Chest pain (2)</td>
<td>Chest pain (1)</td>
</tr>
<tr>
<td>Minor bleeding (3)</td>
<td>Falls (2)</td>
</tr>
<tr>
<td>Shortness of breath (1)</td>
<td>Worried post stroke (1)</td>
</tr>
</tbody>
</table>
Of the patients in both groups who presented to the emergency department during the first three-month period, only 6 percent (3) of the intervention and 1.9 percent (1) of the control group patients had minor bleeds associated with possible warfarin-related adverse events. In total therefore, 3.92 percent (4) of the participating patients presented to the emergency department suffering from minor bleeds potentially due to warfarin therapy which did not require hospitalisation.

6.4.7.4 Warfarin-related adverse drug events

Very few patients in both groups reported any possible warfarin-related adverse drug events. Six percent (3) of the intervention group patients and 4 percent (2) of the control group patients reported possible minor bleeding. All of the intervention group patients reported to the emergency department for medical advice, whereas only one of the two control group patients presented to the emergency department for advice. Importantly, only 4.9 percent (5) of the patient participants experienced minor possible warfarin-related adverse drug events and none of them experienced major possible warfarin-related adverse drug events during the three-month follow-up period.

6.4.7.5 Possible drug-to-drug interactions between warfarin and complementary medicines

Twenty-four percent (12) of the intervention group patients and 19 percent (10) of the control group patients were found to be taking complementary medicines. Of the 21.6 percent (22) of participating patients who took complementary medicines, approximately half of these (10) admitted that their general practitioners were unaware of their use of complementary medicines. It was only after having been shown the ‘Potential drug-to-drug warfarin interaction sheet’ (APPENDIX 27) that they realised the possibility of an interaction and agreed to either cease taking the complementary medicines or to continue taking them after consultation with their general practitioners.
6.4.7.6 International Normalised Ratio (INR) stability

The results indicated that there was an inconsistency in the number of International Normalised Ratio (INR) blood tests processed per patient during the three-month follow-up period. Even though participating patients in both the intervention and control groups had an average of 11 INR blood tests, the range of INR blood tests processed was between four and 26 over the three-month period.

In order to evaluate the number of patients in both groups who had achieved a therapeutic International Normalised Ratio (INR) score (within the 2.0-3.5 therapeutic range), their therapeutic INR scores were calculated as a percentage of their total number of INR blood tests processed during the three-month period. This calculation was used because of the inconsistent number of blood tests processed per patient during the study period. The following formulae were used to calculate the percentage of INR scores within therapeutic range (INR=2-3.5) and outside therapeutic range (INR = <2 or >3.5).

\[
\text{The percentage of INRs (within therapeutic range)} = \frac{\text{Total number of INR scores between 2 and 3.5}}{\text{Total number of INR scores}}
\]

\[
\text{The percentage of INRs (outside therapeutic range)} = \frac{\text{Total number of INR scores outside 2 and 3.5}}{\text{Total number of INR scores}}
\]

Using these formulae it was found that on average, 71.86 percent of the intervention group patients’ INR scores, and 69.42 percent of the control group patients’ INR scores, were within therapeutic ranges: Thus, 28.14 percent of the intervention group patients’ and 30.58 percent of the control group patients’ INR scores were outside therapeutic ranges. These results suggest that patients who received the new warfarin education program had a slightly higher percentage of therapeutic INR scores during the initial three-month period of their warfarin
therapy, than did the patients who received the customary warfarin education program.

A t-test was then used to analyse whether or not there was a significant difference in the percentage of therapeutic INR scores between the two groups. A p-value of 0.5568 suggested that there was no statistically significant difference in the percentage of intervention and control group patients' therapeutic INR scores for the first three months of warfarin therapy.

A Pearson correlation coefficient test was used to investigate whether or not there was a relationship between the percentages of INR scores inside and outside the therapeutic range (INR=2.0-3.5) and the actual mean scores for the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires (Appendices 17-19). The results of these correlation coefficient tests are summarised in tables 25 and 26 below.

Table 25 summarises the correlation coefficient test results used to identify a relationship between the questionnaire scores and the percentage of INR scores within therapeutic range. This table shows that after three months of warfarin therapy, only the intervention group patients’ mean ‘Medication-Taking-Measures’ (MTM) questionnaire score (p-value 0.0328*) had a linear relationship with the percentage of therapeutic INR scores (INR = 2.0 - 3.5). The positive correlation coefficient for this score suggests that as the MTM questionnaire scores increased, so too did the percentage of therapeutic INR scores. In other words, as the intervention group patients’ confidence with their warfarin compliance increased, so too did their percentage of therapeutic INR scores.
Table 25: Pearson correlation coefficient results assessing any relationship between the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaire scores and the percentage of therapeutic INR results after three months

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Intervention Group (n=50)</th>
<th>Control Group (n=52)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pearson Correlation Coefficient</td>
<td>p-value</td>
</tr>
<tr>
<td>SM score (3-month follow-up)</td>
<td>0.07542</td>
<td>0.6027</td>
</tr>
<tr>
<td>MTM score (3-month follow-up)</td>
<td>0.30243</td>
<td>0.0328*</td>
</tr>
<tr>
<td>WK score (3-month follow-up)</td>
<td>0.00438</td>
<td>0.9759</td>
</tr>
</tbody>
</table>

(In this table: SM score = ‘Self-Management’ questionnaire score; MTM score = ‘Medication-Taking-Measures’ questionnaire score and WK score = ‘Warfarin Knowledge’ questionnaire score; the 3-month follow-up = questionnaire results three months after the initial warfarin education session; therapeutic INR = 2.0 – 3.5)

Table 26 summarises the correlation coefficient test results used to identify a relationship between the questionnaire scores and the percentage of INR scores outside the therapeutic range. Not surprisingly, this table shows that only the intervention group patients’ ‘Medication-Taking-Measures’ questionnaire mean score had a linear relationship with the percentage of INR scores outside the therapeutic range (p-value 0.0408*). The negative correlation coefficient in this instance, suggested that as MTM questionnaire scores decreased the percentage of INR scores outside the therapeutic range increased. Therefore, when the intervention group patients’ confidence about their warfarin compliance deteriorated, they experienced an increase in the percentage of INR scores outside of the therapeutic range.
Table 26: Pearson correlation coefficient results assessing any relationship between the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaire scores and the percentage of non-therapeutic INR results after three months.

<table>
<thead>
<tr>
<th>Questionnaire score</th>
<th>Percentage INR results outside therapeutic range (INR&lt;2.0 or &gt;3.5)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intervention Group (n=50)</td>
<td>Control Group (n=52)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pearson Correlation Coefficient</td>
<td>p-value</td>
<td>Pearson Correlation Coefficient</td>
</tr>
<tr>
<td>SM score (3-month follow-up)</td>
<td>-0.07005</td>
<td>0.6288</td>
<td>-0.10190</td>
</tr>
<tr>
<td>MTM score (3-month follow-up)</td>
<td>-0.29040</td>
<td>0.0408*</td>
<td>0.14101</td>
</tr>
<tr>
<td>WK score (3-month follow-up)</td>
<td>-0.00747</td>
<td>0.9589</td>
<td>-0.07807</td>
</tr>
</tbody>
</table>

(In this table: SM score = ‘Self-Management’ questionnaire score; MTM score = ‘Medication-Taking-Measures’ questionnaire score and WK score = ‘Warfarin Knowledge’ questionnaire score; the 3-month follow-up = questionnaires results three months after the initial warfarin education session; non-therapeutic INR = INR< 2.0 or >3.5)

The combined results of the Pearson correlation coefficient tests (Tables 25 and 26), show that as the intervention group patients’ confidence with their warfarin compliance increased so too did their therapeutic INR scores (INR = 2.0-3.5). Therefore, as expected, the reverse was also true because as the intervention group patients’ confidence with their warfarin compliance deteriorated there was an increase in their percentage of INR scores outside the therapeutic range (INR scores <2 and/or >3.5). Notably, however, the percentage of therapeutic INR scores was relatively high for both groups, 71.86 percent for the intervention group and 69.42 percent for the control group. In other words, both warfarin education programs empowered patient participants with the knowledge and confidence to achieve good warfarin therapeutic control.
6.5 Summary

In summary, according to the results of the readability tests the new warfarin information booklet (APPENDIX 12) was much easier to read than the Boots warfarin information booklet (2003) because it was written between a grade 6 - 8 level as compared to a grade 8.9 –14 level. The higher scores for the ‘Suitability Assessment Materials’ (SAM) (Doak, Doak et al. 1985), the ‘Bernier Instructional Design Scale’ (BIDS) (Bernier 1996) and the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) also indicated that the new warfarin information booklet, as compared to the Boots warfarin information booklet (2003), was a better quality booklet, produced at a higher standard, catering for the needs of a wider patient population, inclusive of the ‘high risk’ group.

Data collection commenced in February 2003 and was completed within 12 months with a total of 102 of the 114 patient participants providing fully completed questionnaires. Fifty intervention patients received the new warfarin educational program and 52 control patients received the customary warfarin education program delivered to warfarin-prescribed TACT patients. The participating patients in both groups were referred to The Ambulatory Care Team (TACT) from similar sources and for similar diagnoses, the most common of which was deep venous thrombosis. Many of the participating patients came from the ‘high risk’ patient population with: 62.8 percent (64) aged 65 years and over; 25.5 percent (26) educated at or below a grade 6 level; and 14.71 percent (15) coming from non-English speaking backgrounds.

Although the research data suggest that patients receiving the new warfarin education program achieved higher mean scores than patients receiving the customary warfarin education program in the ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires (Appendices 17-19), statistical analysis found that only the immediate ‘Warfarin Knowledge’ questionnaire scores were significantly better for those receiving the new warfarin education program. The difference in the ‘Warfarin Knowledge’ questionnaire scores became less significant over time, with the scores
significantly deteriorating for both groups over the three-month period of data collection. Interestingly as ‘Warfarin Knowledge’ scores deteriorated in both groups ‘Self-Management’ and ‘Medication-taking-Measures’ scores significantly improved. This could have serious implications for patients on long-term warfarin therapy because they may not have the warfarin knowledge and understanding to achieve optimal therapeutic outcomes, even though they may feel confident about their warfarin management and compliance at home.

The ‘high risk’ patients in both groups which included - the elderly (aged 65 years and over), those with low literacy skills (education at a level ≤ grade 6) and those from non-English speaking backgrounds - achieved lower mean scores than other participants for the ‘Self-Management’, ‘Medication-Taking-Measures’ and the ‘Warfarin Knowledge’ questionnaires. However, the trend in the data found that intervention group ‘high risk’ patients achieved higher mean scores for these questionnaires than did the control group ‘high risk’ patients. These results, and especially the higher mean scores for the immediate ‘Warfarin Knowledge’ questionnaire, suggest that the new warfarin education program more effectively educated the ‘high risk’ patients about their warfarin therapy.

Although data from the ‘Satisfaction with Information about Medicines Scale’ (SIMS) (APPENDIX 20) showed that all patient participants were highly satisfied with the warfarin information they received, the intervention group patients were more satisfied with the information they received about how long warfarin will take to act than were the control group patients.

Similar results for both groups of patients were achieved for the outcome measures during the three-month follow-up period. Both groups had similar numbers of general practitioner, hospital, and emergency department visits, with only a small percentage of patients (4.9 percent) experiencing minor possible warfarin-related adverse drug events. The high percentage of therapeutic INR scores (INR = 2 and 3.5) for both groups are indicative of the effectiveness of both education programs in empowering the patient participants with the knowledge and confidence to achieve good therapeutic control.
Overall, therefore, the new warfarin information booklet (APPENDIX 12) was written in a better quality, easier-to-read format, than was the Boots warfarin information booklet (2003). Comparing and contrasting the new warfarin education program against the customary warfarin education program found that it was more effective in terms of improving the patients’ warfarin knowledge, management and compliance, knowing when to look for medical assistance, as well as improving their overall satisfaction with the information received. Similar results were also found for the ‘high risk’ patients, including the elderly, those with low literacy skills and those from non-English speaking backgrounds.
CHAPTER 7
Discussion, Limitations and Recommendations

7.1 INTRODUCTION

For almost two decades, the efficacy of warfarin education programs has been the subject of significant debate. Fifteen years ago, Wyness (1989) examined the need for clear program design and, some nine years later, Haines (1998) proposed a more structured education program for better outpatient anticoagulant management. It appears that such calls for a more structured education program have been largely ignored. This is evident in the ever-increasing reports of warfarin knowledge deficiencies in patients prescribed warfarin, and particularly the ‘high risk’ patients (Cheah and Martens 2003; Lambert and Wynne 2003; Nadar, Begum et al. 2003; Tang, Lai et al. 2003; Wilson, Racine et al. 2003).

The research study, therefore, focused on developing and evaluating a new, home based warfarin education program to help improve warfarin knowledge, management and compliance in a wider patient population, inclusive of the ‘high risk’ group. This ‘high risk’ group includes the elderly, those with low literacy skills and those from non-English speaking backgrounds. The conceptual framework for the new program incorporated interventions and strategies which targeted the five key elements of an effective patient education program. Importantly, this framework can be used as a blueprint for other patient medication education programs in both hospital and community settings.

The impact of this new warfarin education program was compared and contrasted with the customary home-based warfarin education program used by The Ambulatory Care Team (TACT) at Illawarra Health. Evaluations included comparing and contrasting the participating patients’ warfarin knowledge and understanding, as well as their ability to manage and comply with their warfarin therapy at home. Warfarin knowledge was evaluated using the ‘Warfarin
Knowledge’ questionnaire (APPENDIX 19) and the participants’ ability to manage and comply with warfarin therapy at home was evaluated using the ‘Self-Management’ and ‘Medication-Taking-Measures’ questionnaires (APPENDIX 17 and 18). Patient participants’ satisfaction with the warfarin information they received was measured by using the ‘Satisfaction with Information About Medicines Scale’ (SIMS) (APPENDIX 20), and outcome measures (therapeutic INR scores and healthcare visits) were used as objective measures to analyse and compare the effectiveness of both programs.

This chapter discusses the data in relation to the patient participants’ warfarin knowledge, management and compliance, as well as their therapeutic outcomes based on the interventions and strategies used in the conceptual framework. The five key elements targeted by interventions and strategies in the conceptual framework included: health professional/patient communication and partnerships; warfarin compliance; simple, easy-to-read warfarin information; the continuity of care between hospital and community settings; and patient follow-up. The impact of the new warfarin education program was assessed both generally across the wider population and more specifically in respect to the ‘high risk’ patient populations. Based on the results of the study recommendations are made for both current and future practice in patient warfarin education programs. Finally, limitations are acknowledged and conclusions are drawn from the study results and, when necessary, from evidence available in the literature.

The implications of this study are that the incorporation of the five key elements of an effective patient education program into a warfarin education program will benefit all patients, including those from the ‘high risk’ group. These patients will be empowered to confidently manage and comply with their warfarin therapy because of their improved warfarin knowledge, which in turn will help them to optimise their therapeutic outcomes and minimise adverse drug events.
7.2 OVERVIEW OF THE PARTICIPATING PATIENTS’ WARFARIN KNOWLEDGE AND UNDERSTANDING, RESULTING FROM THE WARFARIN EDUCATION PROGRAMS.

7.2.1 Introduction

From an educational perspective, good knowledge and understanding of warfarin therapy underpins optimum therapeutic outcomes (Barcellona, Contu et al. 2002) and a reduction in warfarin-related adverse drug events (Kagansky, Knobler et al. 2004). Inadequacies in existing warfarin education programs (Connor 1998) and consequent patient knowledge deficiencies (Cheah and Martens 2003; Tang, Lai et al. 2003), highlight the urgent need for a new more effective warfarin education program.

The new education program developed and tested in this research study was based on five aforementioned key elements of education. These methods were incorporated with the specific aim of improving warfarin knowledge and understanding. However, during the course of the study, several of these specific strategies and interventions were also incorporated into the customary warfarin education program following directions from the area health service management. This unforeseen action was out of the control of the researcher. It had the potential to affect findings of the research, particularly the overall patients’ warfarin knowledge and understanding results. However, because many of these intervention were perceived to be best practice with the potential to reduce the incidence of adverse drug events and improve overall therapeutic outcomes (Australian Council for Safety and Quality in Health Care 2002; Bhasale, Miller et al. 1998; Mullen, Simons-Morton et al. 1997), the area health service management recommended that they be included into the customary practice for TACT.
### 7.2.2 Participating patients’ warfarin knowledge and understanding

Data from the ‘Warfarin Knowledge’ questionnaires (APPENDIX 19) indicate that higher mean scores were achieved by the intervention group patients compared to the control group patients. The initial mean scores were 21.0 (80.8 percent) for the intervention group patients versus 19.0 (73 percent) for the control group patients. After three months, the mean scores were 18.04 (69.4 percent) for the intervention group patients and 17.04 (65.5 percent) for the control group patients. These results suggest that the new warfarin education program educated patients and improved their warfarin knowledge and understanding more effectively than the customary warfarin education program.

Shortcomings in current warfarin education programs are evident in the literature which has identified that patients prescribed warfarin often have deficiencies in their warfarin knowledge (Cheah and Martens 2003; Lambert and Wynne 2003; Roche-Nagle, Chambers et al. 2003; Tang, Lai et al. 2003). In the absence of a validated warfarin knowledge questionnaire, each of these studies used a different instrument to measure the patients’ warfarin knowledge, making it difficult to compare them against each other and against the data collected in this research study. The average percentage of correct warfarin knowledge answers achieved by the intervention and control group patients in this study, both initially (80.8 percent intervention and 73.0 percent control) and after three months (69.4 percent intervention and 65.5 percent control), were higher than the 46.9 percent achieved by patients in a study by Cheah et al (2003), the 48 percent achieved in a study by Tang et al (2003) and the 61.1 percent achieved in study by Nadar et al (2003). These results suggest that the new warfarin education program more effectively educated patients and improved their warfarin knowledge and understanding, than not only the customary warfarin education program but also many other available warfarin education programs. Further studies need to be undertaken, using a common warfarin knowledge questionnaire, to contrast the effectiveness of the new warfarin education program with other warfarin education programs, available in both Australia and overseas.
Another explanation for the improved warfarin knowledge and understanding of the patient participants in both the intervention and control groups of this study is that they had to complete the warfarin knowledge questionnaires on two occasions during the study. On both occasions, immediately and after three months of warfarin therapy, when and if they answered a question incorrectly, their answers were documented and the correct answers were reinforced. The higher than average warfarin knowledge scores and therapeutic INR scores achieved by patients in both groups, as well as comments such as “I found answering the questions reassured my knowledge” concur with the results of a recent study (Barcellona, Contu et al. 2002) which found that patients who completed a warfarin knowledge questionnaire spent more time in the therapeutic range. A recommendation based on these results is that a standardised warfarin knowledge questionnaire should be developed and completed by all patients receiving warfarin education. Not only would the questionnaire help to reinforce warfarin information, it would also help to identify deficits in the patients’ knowledge, which could then be addressed by the educating health professional.

Further analysis of the data collected from the initial ‘Warfarin Knowledge’ questionnaire found that the intervention group patients had a better knowledge and understanding of certain aspects of their warfarin therapy, than did the control group patients. These findings suggest that the new program, more so than the customary program, improved the intervention patients awareness about why their warfarin was prescribed, how to manage missed doses and how to recognise side effects and possible drug and/or food interactions with their warfarin.

Pharmacists, nurses, medical practitioners and carers should be aware of the difference between the reality of what the patient actually knows and what the patient thinks they know (Barat, Andreasen et al. 2001). It is important to understand that patients can be overwhelmed by the information they receive and often forget what has been communicated to them (Ansell, Buttaro et al. 1997). The intervention and control group patients’ deterioration in warfarin
knowledge over the three-month follow-up period agrees with the literature reporting warfarin knowledge deficits following discharge from hospital (MacDonald 1998). These results highlight the importance of continuous reinforcement of warfarin information (Haynes, McDonald et al. 2002a) which according to the data should occur every three months.

In summary, based on the ‘Warfarin Knowledge’ questionnaire (APPENDIX 19) data, it would appear that the new warfarin education program is better placed than the customary and other available warfarin education programs to improve patients’ warfarin knowledge and understanding. The new program has provided patients with a better understanding about why warfarin was prescribed for them, possible drug and/or food interactions, how to manage missed doses and which side effects to look out for. According to the overall high warfarin knowledge scores achieved by all the patient participants, a recommendation has been made to develop a standardised warfarin knowledge questionnaire to be completed by all patients prescribed warfarin, which will help to reinforce and reassure them about their warfarin information. The significant deterioration in patients’ warfarin knowledge over time highlights the importance of continuous patient follow-up and information reinforcement.

**7.2.3 ‘High risk’ patients’ warfarin knowledge and understanding**

**7.2.3.1 Introduction**

The patient populations at ‘high risk’ of experiencing poor warfarin-related therapeutic outcomes and adverse drug events because of poor warfarin knowledge and understanding include the elderly, those with low literacy skills (Lambert and Wynne 2003; Tang, Lai et al. 2003) and people from non-English speaking backgrounds (Nadar, Begum et al. 2003). The research study’s participating patient population had a good representation of these ‘high risk’ patient population with 62.74 percent (64) of the patients aged 65 years and over, 25.5 percent (26) educated at or below grade 6 level, and 14.7 percent (15) coming from non-English speaking backgrounds.
7.2.3.2 Warfarin knowledge and the elderly patient participants

Poor quality warfarin education is a common risk factor for poor warfarin-related therapeutic outcomes and adverse drug events among the elderly (Kagansky, Knobler et al. 2004). Current warfarin education programs do not cater for elderly patients, aged 65 years and over, who typically score poorly, or less than 50 percent for their warfarin knowledge questionnaire scores (Cheah and Martens 2003; Lambert and Wynne 2003; Tang, Lai et al. 2003). Interestingly, in this study the mean scores for the 'Warfarin Knowledge' questionnaire achieved by the elderly patient participants in both groups were higher than the 50 percent average reported in the literature (Cheah and Martens 2003; Tang, Lai et al. 2003).

The elderly intervention group patients initially scored 20.4 (78.5 percent) out of a possible 26, compared to the elderly control group patients who scored 17.7 (68.2 percent) for their 'Warfarin Knowledge' questionnaire. After three months of therapy, the elderly intervention group patients scored 17.0 (65.4 percent), compared to the elderly control group patients who scored 16.1 (62.05 percent). These results suggest that even though the new program more effectively improved warfarin knowledge in the elderly patients than did the customary program, both programs improved warfarin knowledge and understanding in elderly patients more so than did other available warfarin education programs.

Notably, the deterioration in warfarin knowledge scores over the three-month period in the study was more significant for all the elderly participating patients than it was for the younger participating patients, aged below 65 years. Not only does this agree with evidence in the literature (Lambert and Wynne 2003; Taylor, Ramsay et al. 1994) but it also highlights the need to provide elderly patients with regular follow-up and reinforcement of their warfarin information.

These results suggest that the new warfarin education program more effectively improved warfarin knowledge and understanding in elderly patients, than did the customary warfarin education program. Importantly however, both
programs appear to be more effective at improving warfarin knowledge and understanding in elderly patients compared to other available warfarin education programs. To confirm this possibility further studies with a much larger sample size of elderly patients would need to conducted, comparing the new warfarin education program to other available warfarin education programs.

7.2.3.3 Warfarin knowledge and patient participants with low literacy skills

According to the literature a significant relationship exists between the patients' literacy level and warfarin knowledge (Barcellona, Contu et al. 2000; Estrada, Martin-Hryniewicz et al. 2004; Wilson, Racine et al. 2003). It is not surprising therefore, that all patient participants educated at or above grade 10 levels achieved the highest mean scores for the 'Warfarin Knowledge' questionnaires and those educated at or below grade 6 levels achieved the lowest mean scores.

Overall, the intervention group participants with low literacy skills (educated at or below a grade 6 level) achieved higher mean scores for the 'Warfarin Knowledge' questionnaire, than did the control group patients with low literacy skills, both initially (19.8 versus 17.7); and after three months of warfarin therapy (16.6 versus 15.0). Importantly, there were more intervention group patients with low literacy skills (n = 16) than there were control group patients with low literacy skills (n = 10), which may have negatively impacted on the final results. This means that the final results may not be a true indication of the positive impact of the new warfarin education program on warfarin knowledge of patients with low literacy skills. Based on the study results however, it could be suggested that the new warfarin education program more effectively educated patients with low literacy skills about their warfarin therapy, than did than the customary warfarin education program. Further studies examining the impact on warfarin knowledge of this new program, for a much larger sample size of patients with low literacy skills, would need to be undertaken to verify this possibility.
Warfarin knowledge and patient participants from non-English speaking backgrounds

Recent studies have found that non-English speaking background (NESB) patients have significant gaps in their warfarin knowledge (Nadar, Begum et al. 2003; Wilson, Racine et al. 2003). The results of this study suggest that the needs of the NESB patients are being met to some degree by the new warfarin education program, as compared with the customary warfarin education program. The NESB intervention group patients achieved higher mean scores for the ‘Warfarin Knowledge’ questionnaire than did the NESB control group patients, both initially (18.7 versus 17.7), and after three months of warfarin therapy (16.8 versus 14.0). These results suggest that the new program, more so than the customary program, improved warfarin knowledge in the NESB patients. It cannot be denied, however, that these results were based on a small sample size of NESB patient participants (n=14) in total. Further investigations on a much larger sample size of NESB patients would therefore need to be conducted to assess the true impact of the new warfarin education program on warfarin knowledge of NESB patients, as compared to other available warfarin education programs.

Interestingly, only 5 of the 9 NESB intervention group patients, compared to 5 of the 6 NESB control group patients, had a carer and/or family member present during the initial warfarin education session. In view of the fact that carers and/or family members can help with overcoming possible language and cultural barriers (Davidhizar and Brownson 1999; Minas, Lambert et al. 1996), it is even more impressive that the NESB intervention group patients still managed to achieve higher mean warfarin knowledge scores than did the NESB control group patients.

Summary

The data implied that compared to the customary warfarin education program, the new warfarin education program more effectively improved warfarin knowledge in the ‘high risk’ group, which included the elderly, those with low
literacy skills and those from non-English speaking backgrounds. The data also suggested that the mean warfarin knowledge scores achieved by the ‘high risk’ patients in both groups were higher than the mean score of 50 percent achieved by patients from the general population in other recent studies (Cheah and Martens 2003; Tang, Lai et al. 2003). Unfortunately, this cannot be stated conclusively because the other studies used different warfarin knowledge questionnaires. Further research is needed, therefore, on a much larger sample size of patients from the ‘high risk’ group, to test the effectiveness of the new warfarin education program against other available warfarin education programs, with regard to improving warfarin knowledge and understanding.

7.2.4 Summary of the participating patients’ warfarin knowledge and understanding

The research study focused on developing a new structured home-based warfarin education program to help improve warfarin knowledge and understanding in a wider patient population, inclusive of the ‘high risk’ group. This new program, based on a conceptual framework targeting five key elements, was then compared and contrasted with the customary warfarin education program delivered to patients admitted to Illawarra Health’s The Ambulatory Care Team.

The higher mean scores for the ‘Warfarin Knowledge’ questionnaires (APPENDIX 19) achieved by the intervention group patients, compared to the control group patients, suggests that the new warfarin education program more effectively educated patients, including the ‘high risk’ patients, about their warfarin therapy. In fact, based on the high mean scores achieved by all the patient participants, it could be argued that both warfarin education programs more effectively improved warfarin knowledge and understanding than do other available warfarin education programs. Notably, the ‘Warfarin Knowledge’ questionnaire used in this study differed to the questionnaires used in other studies (Cheah and Martens 2003; Nadar, Begum et al. 2003; Tang, Lai et al. 2003) making it difficult to state categorically that the new warfarin education program was the most effective. Therefore, further research, using a
standardised warfarin knowledge questionnaire is recommended to compare and contrast the effectiveness of the new program with other available programs.

An important finding of the research study was the deterioration in warfarin knowledge for patients in both groups, and especially elderly patients, over the three-month period. This in itself highlights the need to continuously follow-up and reassure patients about their warfarin therapy, especially if they are elderly and on long-term therapy. Based on the results of this study it is recommended that warfarin information be reinforced every three months.

With the inadequacies in current warfarin education programs (Connor 1998) leading to gaps in patients knowledge (Cheah and Martens 2003; Lambert, Stoll, Singy, Zobel, Molina and Guex 1999; Nadar, Begum et al. 2003), and in the absence of a best practice model for home-based warfarin education programs, it would be reasonable to recommend the new program as a best practice model for an effective warfarin education program. Importantly, this new home-based program could be readily adapted to other hospital and community based settings.

7.3 HEALTH PROFESSIONAL/PATIENT COMMUNICATION AND PARTNERSHIPS

7.3.1 Background

Poor health professional/patient communication and partnerships have been identified as major contributors to poor warfarin-related therapeutic outcomes and adverse drug events (Bhasale, Miller et al. 1996; Gandhi, Weingart et al. 2003). The patient populations most likely to have problems with communication and establishing partnerships include the elderly, those with low literacy skills and patients from non-English speaking backgrounds (Bhasale, Miller et al. 1998).

The new warfarin education program placed special emphasis on the improvement of patient/health professional partnerships and communication to help patients make educated decisions about their warfarin compliance and
management. Interventions of an administrative nature included: one-on-one education sessions with the patients and/or their carers at home; follow-up; communication directly with the patients, their carers and allied health professionals; as well as availing the patients of other important resources (for example interpreters for non-English speaking background patients, blister packs for the elderly). Other interventions of a more abstract nature included: ensuring that the home environment was conducive to learning by making certain that all televisions, radios and stereo players were turned off; speaking in an encouraging, reinforcing and reassuring manner; asking lots of questions; and encouraging feedback from the patients and/or their carers.

The Ambulatory Care Team (TACT) staff members were also keen to incorporate many of these interventions, to help improve health professional/patient communication and partnerships, into the customary warfarin education program. The very nature of the service provided by TACT and the pride of the team members in providing an excellent service, meant that professionally it was inevitable that these interventions would be incorporated in the customary program. This dynamic made it very difficult to compare the customary warfarin education program with the new warfarin education program and could be viewed as a limitation of the study. However, in light of recent reports identifying that poor health professional/patient communication and partnerships contribute to poor warfarin-related therapeutic outcomes and adverse events (Dantas, Thompson et al. 2004; Gandhi, Weingart et al. 2003) it could be argued that it would have been unconscionable not to have included them into the customary program.

Discussions will now focus on comparing the effectiveness of the new and customary warfarin education programs in the area of health professional/patient communication and partnerships.
7.3.2 Comparing the effectiveness of the new and customary warfarin education programs in the area of health professional/patient communication and partnerships

One of the first indications that good health professional/patient communication and partnerships had been established was that all patients admitted to TACT for anticoagulation therapy from January 2003 to October 2003 consented to be part of the study. Of the 114 consenting patients who were eligible, only one withdrew from the study voluntarily, while the other 11 were no longer eligible because of warfarin cessation, death or simply because they could not be re-contacted for evaluation follow-up. In other words, all the patient participants who consented to be part of the study initially were happy to continue being part of the study, until its completion, without feeling threatened or coerced.

Data from the ‘Satisfaction with Information about Medicines Scale’ (SIMS) (APPENDIX 20) found that most patient participants (over 90 percent) were very satisfied with the information they received about warfarin’s action, usage and potential problems. Statistical analysis found that only the information about how long it takes for warfarin to act significantly satisfied more of the intervention group patients than the control group patients (p-value 0.027). It could be argued that the similar interventions to improve health professional/patient communication and partnerships used in both warfarin education programs may have contributed to fewer significant differences between the two. Both education programs equally satisfied and met the needs of all patient participants who were satisfied with the collaborative interchange between themselves and their health professional.

Improved health professional/patient communication and partnerships for both programs can also be inferred from the high mean scores for the ‘Self-Management’ and ‘Medication-Taking-Measures’ questionnaires (Appendices 17-18), which will be discussed later in this chapter. Further studies need to be conducted to assess the extent to which the new warfarin education program, in particular, improves health professional/patient communication and partnerships compared to other available warfarin education programs.
Another limitation of the study was that several interventions and strategies targeting the key elements, which included health professional/patient communication and partnerships, were introduced into both warfarin education programs at the same time. This makes it difficult to analyse the impact of improved health professional/patient communication and partnerships alone. Future studies should therefore focus on identifying the impact that improving health professional/patient communication and partnerships alone has on warfarin knowledge, management and compliance, as well as long-term warfarin-related therapeutic outcomes and adverse drug events.

The literature identifies that even though patients were satisfied with the information they received there were gaps in their warfarin knowledge (Lambert and Wynne 2003; Nadar, Begum et al. 2003). In the present study, data from the ‘Satisfaction with Information about Medicines Scale’ (SIMS)(APPENDIX 20) and the high mean scores in the ‘Warfarin Knowledge’ questionnaire scores (APPENDIX 19), suggest that the new warfarin education program, as compared to the customary warfarin education program, satisfied more of the patients’ needs and improved their level of warfarin knowledge. Further research is needed to establish whether or not the new warfarin education program does in fact improve patients’ warfarin knowledge and their satisfaction with the information provided, as compared to other available warfarin education programs.

Based on the promising results of this study, especially with regard to patient satisfaction and improved warfarin knowledge, it could be recommended that all warfarin education programs should target improved health professional/patient communication and partnerships. In doing so, these programs would not only improve patients’ warfarin knowledge, management and compliance, but they would also help to promote optimal therapeutic outcomes and minimise adverse drug events.
7.3.3 Summary of the effectiveness of health professional/patient communication and partnerships in the study

Several interventions were incorporated into both the new and the customary warfarin education programs to help improve health professional/patient communication and partnerships. These interventions included: home based one-on-one education sessions; offering the patients and/or their carers encouragement, reinforcement, reassurance and feedback; asking lots of questions; and providing an interpreter when necessary.

The high mean scores achieved by all participating patients in the ‘Self-Management’, ‘Medication-Taking-Measures’ and the ‘Warfarin Knowledge’ questionnaires, as well as the ‘Satisfaction with Information about Medicines Scale’ (SIMS) (Appendices 17-20), suggest that both warfarin education programs improved patients’ warfarin knowledge, management and compliance as well as their satisfaction with the information received. These results imply that both programs achieved good health professional/patient communication and partnerships which is an improvement on many other available programs identified in the literature (Cox, Stevenson et al. 2004; Dantas, Thompson et al. 2004; Elwyn, Edwards et al. 2003).

7.4 WARFARIN COMPLIANCE

7.4.1 Introduction

Research has shown that poor warfarin compliance contributes significantly to poor therapeutic outcomes (Arnsten, Gelfand et al. 1997) and adverse drug events (Brigden, Kay et al. 1998; Hirri and Green 2002). Several interventions were incorporated into the new warfarin education program based on ‘best evidence’ to improve medication compliance (Haynes, McDonald et al. 2002a). These interventions included: educating the patients, their carers and/or family members about the importance of taking warfarin on a regular basis; explaining the implications of not complying with regular warfarin dosage;
recommending compliance aids when and if required; offering reinforcement, reassurance and telephone follow-up; and undertaking medication reviews.

Data collected from the ‘Self-Management’ (APPENDIX 17) and ‘Medication-Taking-Measures’ (APPENDIX 18) questionnaires, as well as the percentage of therapeutic International Normalised Ratio (INR) scores, were used to evaluate the patient participants’ warfarin compliance. These results for the intervention and control group patients were compared and contrasted to analyse the impact of both warfarin education programs on the patients’ compliance.

7.4.2 ‘Self-Management’ questionnaire

The ‘Self-Management’ questionnaire scores for both the intervention and the control group, tested immediately and after three months of therapy, were high and well within the highly confident range. These high scores suggest that both education programs promoted patient confidence to manage and comply with their warfarin therapy at home.

The ‘Self-Management’ questionnaire scores significantly improved over the three-month period for both groups (p-value equal to 0.0009*** for the intervention group and p-value equal to 0.0024** for the control group), suggesting that all patient participants became increasingly confident about their warfarin management over time. The trend for the mean ‘Self-Management’ questionnaire scores was found to be higher for the intervention group patients than the control group patients. Even though these scores were not significantly different between the two groups, they do suggest that the new warfarin education program encouraged the patients to be more confident about their warfarin management, than did the customary warfarin education program.

The ‘Self-Management’ questionnaire used in this study was adapted from Lorig et al’s ‘Self-Efficacy Questionnaire’ (1996 p.41-44), making it difficult to directly compare these results with other studies. Indirectly, however, it could be argued that both warfarin education programs promoted good warfarin management at home, which is known from the literature (Lorig and Gonzales
2000; Lorig, Ritter, Stewart, Sobel, Brown, Bandura, Gonzalez, Laurent and Holman 2001) to contribute to good therapeutic outcomes in patients with chronic disease. Future research should endeavour to test the impact of the new warfarin education program against other community and/or warfarin education programs for its impact on the patients’ confidence to manage their warfarin therapy at home.

It is worrying that the significant increase in confidence to manage warfarin therapy over the three month period was accompanied by a significant decrease in the patients' warfarin knowledge, as per the 'Warfarin Knowledge' questionnaire scores already discussed. Similar results were also found in other studies which showed that even though patients were confident and satisfied with the warfarin information they received, they had deficiencies in their warfarin knowledge (Lamber and Wynne 2003; Nadar, Begum et al. 2003). This is a major concern because deficiencies in warfarin knowledge can predispose patients to poor therapeutic outcomes and adverse drug events (Haines 1998; Kagansky, Knobler et al. 2004). This research study was too short to investigate this anomaly any further, however future research studies should investigate the possible impact of such changes over at least a six to 12 month period with a view to assessing the importance of regularly following-up patients, as well as reassuring them and reinforcing their warfarin information.

The deterioration in warfarin knowledge accompanied by improved confidence in warfarin management over time gives rise to one other possibility for further investigation – patient complacency. Certainly the literature identifies that poor compliance (Haynes, McDonald et al. 2002a), especially in the ‘high risk’ patient population (Barat, Andreasen et al. 2001; Davidhizar and Brownson 1999; Esposito 1995; Feifer 2003), leads to poor therapeutic outcomes and increased adverse drug events. It would be interesting, therefore, to investigate whether or not the patients become complacent with their warfarin therapy and what impact this could have on their therapeutic outcomes over time.

In summary, the high mean scores for the 'Self-Management' questionnaires indicate that both warfarin education programs, and especially the
new program, empowered all patients, including those from the ‘high risk’ group, to feel confident about managing their warfarin therapy at home. Importantly, however, this improved confidence was accompanied by a deterioration in warfarin knowledge, highlighting the need to follow-up, reassure and reinforce warfarin information on a regular basis.

7.4.3 ‘Medication-Taking-Measures’ questionnaire

Intervention group patients achieved higher scores in the ‘Medication-Taking-Measures’ (MTM) questionnaire (APPENDIX 18) than control group patients. Intervention group patients achieved more ‘high compliance’ scores than control group patients, both initially (62 percent versus 53.85 percent) and after three months (80 percent versus 71.15 percent). Although statistical analysis did not find these results to be significantly different, they suggest that the new warfarin education program promoted better warfarin compliance among patients than did the customary warfarin education program. This is also evident in the positive correlation coefficient test (p-value equal to 0.0328*), which found that as the intervention group patients’ MTM scores increased, so too did their percentage of therapeutic INR scores. In other words, as the intervention patients’ confidence about their warfarin compliance improved, so too did their therapeutic control of warfarin.

Analysis of the MTM data after a three-month period showed significant increases in the scores for both groups (p-value equal to 0.0017** for the intervention group and p-value equal to 0.0243* for the control group). In fact, the follow-up scores for both groups were approximately 20 percent higher than the initial scores, suggesting that, from the patients’ perspective, compliance improved over time. The three-month follow-up ‘high compliance’ MTM scores for the intervention and control groups (80 percent versus 71.15 percent) were considerably higher than the average 50-65 percent medication compliance rates reported in the literature for long-term medications (Haynes, McDonald et al. 2002a; Haynes, McKibbon et al. 1996). These results suggest that both warfarin education programs, and especially the new program, were more effective at
promoting good compliance than were other available medication education programs. Further investigations over a longer period of time, however, would need to be carried out to ensure that the patients’ compliance with long-term warfarin therapy remained stable.

It is also worth noting, that the initial comments made by many of the patient participants in both groups were that they did not take regular medications prior to their warfarin being prescribed. It could be argued, therefore, that the significantly higher MTM scores after three months were due in part to the effectiveness of both programs in encouraging patients to be compliant with their warfarin therapy. The most worrying aspect of the significantly improved MTM scores over the three-month period was the concurrent deterioration in the patients’ warfarin knowledge. Future studies need to research the effects that this deterioration has on the patients’ warfarin compliance over time (at least 6-12 months). It would also be useful to investigate what elements of ‘warfarin knowledge’ are critical to maintain good compliance and which could be left out, although this could be difficult to research ethically.

When the three-month MTM scores were compared to the percentage of INR scores within therapeutic range, an interesting observation was made. Similar to the findings in a study by Barcellona et al (2002), the intervention group patients in this study who were highly compliant also achieved the highest therapeutic control, probably because they understood the relationship between regular compliance and good therapeutic control. In this study, the intervention group patients who declared a high level of compliance (MTM=4) achieved the highest mean percentage for therapeutic INR scores (73.7 percent). Whereas, the intervention group patients who declared a low level of compliance (MTM=1) achieved a lower mean percentage for therapeutic INR scores (64.7 percent). In contrast, however, the control group patients who declared a high level of compliance (MTM=4) achieved the lowest mean percentage for therapeutic INR scores (66.2 percent), and the control group patients who declared a low level of compliance (MTM=1) achieved the highest mean percentage of therapeutic INR scores (72 percent). These results suggest that the new warfarin education
program was more effective than the customary warfarin education program in educating patients about the importance of regular warfarin compliance, which improved their therapeutic control. Further research is needed, to confirm that the new warfarin education program does in fact promote better warfarin compliance resulting in improved therapeutic control over prolonged periods of time, as compared to other warfarin education programs.

In addition to the positive impact of both education programs, another possible explanation for the significantly higher MTM scores after three months of therapy for both groups was that since patient participants knew that they were being followed-up, they were more diligent with their warfarin compliance. This result is consistent with evidence in the literature which states that patient follow-up does help to improve medication compliance (Waterman, Milligan et al. 2001). There will be more discussion about the impact of patient follow-up later in this chapter.

In summary, the ‘Medication-Taking-Measures’ (MTM) questionnaire (APPENDIX 18) scores were high for both programs and especially the new warfarin education program. These results suggest that even though both programs promoted good warfarin compliance, the new program promoted it more effectively than did the customary warfarin education program. The significantly higher MTM scores after three months indicated that both programs continued to effectively promote warfarin compliance over time. Interestingly, the intervention group patients who were most confident about their warfarin compliance also achieved the highest therapeutic control. Further research is needed to analyse the long-term benefits of the new program with regard to warfarin compliance and therapeutic control over time.
7.4.4 International Normalised Ratio (INR) scores

7.4.4.1 Discussion of the INR results

An important aspect of both the ‘Self-Management’ and ‘Medication-Taking-Measures’ (MTM) questionnaires was that they relied on the patients’ own reporting if their confidence levels for management and compliance at home. International Normalised Ratio (INR) blood tests, on the other hand, are laboratory results, which give an objective measure of the patients’ warfarin compliance.

The high percentage of therapeutic INR scores (69 percent) corresponded with the high mean scores for the ‘Self-Management’ and ‘Medication-Taking-Measures’ questionnaires for both groups. These results imply that patient participants who were confident with their warfarin management and compliance also achieved good therapeutic control. The association between the MTM scores and the INR scores has already been discussed and will not be revisited. The association between the ‘Self-Management’ and INR scores will be discussed now.

The data revealed that as the ‘Self-Management' scores increased for both the intervention and control group patients, so too did the percentage of therapeutic INR scores. The ‘highly confident’ patients in both groups achieved a higher percentage of therapeutic INR scores, 70.9 percent for the intervention group and 71.8 percent for the control group, whereas the less confident patients in both groups achieved a lower percentage of therapeutic INR scores, 67.8 percent for the intervention group and 66.7 percent for the control group. These results suggest that both the new and the customary warfarin education programs effectively empowered a large proportion of the patients to feel confident about managing and complying with their warfarin medication, which in turn resulted in better therapeutic control. Both programs also appear to be more effective than other available programs, based on the fact that they both achieved higher than average therapeutic INR scores, 69 percent, as compared to the 30 percent to 60 percent average reported in the literature (Gray,

The finding that improved confidence with compliance and management promotes improved therapeutic control, is also evident in the literature (Beyth, Quinn and Landefeld 2000). This finding emphasises the importance of incorporating interventions and strategies to improve patients’ confidence with their warfarin compliance and management, which in turn will help to improve therapeutic control. Similar results achieved by both the new and customary warfarin education programs may have been due to the inclusion of similar interventions to target improved warfarin compliance. Further research is needed to establish which of the following interventions most effectively improve warfarin compliance, especially for elderly patients taking life-long warfarin therapy: educating the patients and/or their carers; compliance aids; general encouragement, reinforcement, reassurance and follow-up; and/or medication reviews.

7.4.4.2 A structured self-management warfarin education program

Even though therapeutic control for both programs was good overall, there still remains the problem of the 30 percent of INR scores which were outside the therapeutic range. These are a problem because they could potentially cause adverse drug events (Gallus, Baker et al. 2000). One of the ways in which to remedy this would be to combine the new warfarin education program with a self-monitoring program, often referred to as a self-management program. Patients could be educated about their warfarin therapy with the new warfarin education program and taught how to adjust their own warfarin doses according to their INR results. Recent studies examining the therapeutic control of patients performing self-monitoring have found that they spend significantly more time within therapeutic range compared with patients who do not self-monitor (Ansell, Jacobson, Levy, Voller and Hasenkam 2005; McCahon, Fitzmaurice, Murray, Fuller, Hobbs, Allan and Raftery 2003; Sawicki 1999). The researcher recommends further research into the benefits of combining the new warfarin
education program with a structured self-management (self-monitoring) program. If the evaluation for this new structured self-management warfarin education program was good, it could be recommended as a best practice model for a home-based warfarin self-management program.

7.4.4.3 Best practice guidelines for the number of INR blood tests

Analysis of the INR data revealed that there was no consistency with the number of INR blood tests ordered by the patient participants’ general practitioners. An average of 11 INR blood tests, ranging from 4 - 26 INR blood tests, were ordered by the patient participants’ general practitioners during the three month period after their discharge from TACT.

There is abundant literature which provides information about the importance of therapeutic INR monitoring (Ansell, Hirsh, Dalen, Bussey, Anderson, Poller, Jacobson, Deykin and Matchar 2001; Dzung The Le 1994). However, there is limited information (AMH 2003) about the recommendations for the frequency of these blood tests. Evidence suggests that 50 - 60 percent of patients will remain within therapeutic range if monitoring of INR occurs monthly, 77 - 85 percent if monitored weekly and up to 92 percent if monitored every third day (Oral Anticoagulation Monitoring Study Group 2001). Best practice guidelines about the number of INR blood tests which should be ordered need to be developed and distributed to all health professionals prescribing warfarin. Also, with the evolving trend for patients to self-monitor their INR at home using especially designed devices (Ansell, Jacobson et al. 2005; Fitzmaurice and Machin 2001; Koertke, Minami, Bairaktaris, Wagner and Koerfer 2000), guidelines need to be given to patients about how often to test their INR. In other words, they also need to be provided with best practice guidelines about how often their INR should be tested to achieve optimal therapeutic control.
7.4.5 Carers and/or family members

Over 50 percent of both intervention and control group patients, many of whom were from the ‘high risk’ group, had a carer and/or family member present during the initial warfarin education session. Based on the high proportion of therapeutic INR scores (above 70 percent) and the low incidence of minor potential warfarin-related adverse drug events (4.9 percent), it could be argued that these patients benefited from the assistance of their carers and/or family members.

There is ample evidence to support the benefits of carers and/or family members being in attendance during medication education sessions to help improve medication compliance (Haynes, McDonald et al. 2002a), memory recall (Doak, Doak et al. 1998) and overcoming possible language, cultural, cognitive and/or physical barriers (Davidhizar and Brownson 1999; Minas, Lambert et al. 1996). These benefits, however, are not reflected in higher scores for the three-month follow-up ‘Self-Management’, ‘Medication-Taking-Measures’ and ‘Warfarin Knowledge’ questionnaires. This suggests that participating patients who had a carer present during the initial warfarin education session were not more confident about their warfarin management and compliance, nor did they have a better warfarin knowledge and understanding than did the participating patients without a carer present. One of the possible reasons for these unexpected results is that the follow-up questionnaires were completed over the telephone by the patients themselves. This could be seen as a limitation of the study because if the carer and/or family member had been responsible for the patients’ warfarin management then they should have been asked to complete the evaluation questionnaires. In order to investigate this further, future research needs to focus on the impact that carers and/or family members have on warfarin management, by having all the evaluation questionnaires completed by the person responsible for administering and managing the warfarin therapy at home, whether it be the patient, carer and/or family member. Other important factors to investigate in future studies would be whether or not carers and/or family members actually do improve warfarin knowledge, management and compliance.
Although the literature identifies that carers and/or family support can play a significant role in assisting with medication compliance (Schlenk, Dunbar-Jacob et al. 2004), very little attention has been paid to the role of families, their knowledge and/or expressed emotion toward medication compliance (Sellwood, Tarrier, Quinn and Barrowclough 2003). Another recommendation for future research would therefore be to compare warfarin management and compliance for all patients, especially the ‘high risk’ patients, with and without the physical and emotional support of a carer and/or family member.

7.4.6 Compliance aids

Based on the evidence that compliance aids help to improve medication compliance (Levings, Szep et al. 1999; Wong and Norman 1987) several aids, including dosette boxes, alarm clocks and calendars, were strongly recommended, especially for the ‘high risk’ patients, as part of the new warfarin education program. These aids were also recommended in the customary warfarin education program, making it difficult to compare and assess their effectiveness.

During data collection, most patient participants could readily suggest two aids (for example dosette box, alarm clock) to help them with their warfarin compliance. This suggests that both programs effectively increased the patients’ awareness of compliance aids, which they could readily use to assist them with their warfarin compliance when and if they felt it was necessary. In the past, single strategies employed to improve long-term medication compliance such as compliance aids have not been found to be very effective (Haynes, McKibbon et al. 1996; McDonald, Garg et al. 2002; Roter, Hall et al. 1998), which is why these aids were recommended as one of several strategies. This, however, made it difficult to evaluate the impact of aids on warfarin compliance in the study. Future research should therefore focus on evaluating the impact that a single compliance aid such as a dosette box actually has on warfarin compliance, especially in the long term for ‘high risk’ patients.
7.4.7 Medication reviews

Complex and complicated medication regimens can impact upon medication compliance, especially in patients over 65 years of age (Col, Fanale et al. 1990). In this research study, a significant proportion (62.74 percent) of the patient participants were aged 65 years and over, and although warfarin itself may not be considered a complex and complicated medication regimen, it has the potential to be when combined with other medications. Importantly, therefore, pharmacists in both groups conducted medication reviews on all patient participants, including the elderly, to ensure that medication regimens were simplified as much as possible. Home medication reviews became incorporated into both programs because they were perceived to be best practice and were highly promoted by the local division of general practice (Australian Government Department of Health and Ageing 2001). Once again, common practices in both programs made it difficult to compare the effect that the medication reviews had on the patients' warfarin compliance for the new and customary warfarin education programs.

Both programs achieved higher than the ‘norm’ warfarin compliance scores over the three-month period - above 70 percent as compared with the 50-60 percent reported in the literature (Haynes, McDonald et al. 2002a; Haynes, McKibbon et al. 1996). It could be argued that these results were in part due to the benefits of the medication reviews, which ensured that warfarin was taken appropriately without any potential drug-to-drug interactions. A recommendation for all home-based warfarin education programs, therefore, is to incorporate home medication reviews as part of overall strategies to improve warfarin compliance.

7.4.8 Summary of the effectiveness of the interventions used to improve warfarin compliance

Several interventions were incorporated into both the new and the customary warfarin education programs, based on 'best evidence' to improve
medication compliance (Haynes, McDonald et al. 2002a; McDonald, Garg et al. 2002). These interventions included: educating the patients, carers and/or family members; offering reinforcement, reassurance and follow-up; recommending compliance aids; and undertaking medication reviews.

The high mean scores achieved for the ‘Self-Management’ and ‘Medication-Taking-Measures’ questionnaires (APPENDIX 17-18), as well as the high proportion of therapeutic International Normalised Ratio (INR) scores, suggest that these interventions contributed to improving the participating patients’ confidence to manage and comply with their warfarin therapy at home, resulting in good warfarin therapeutic control. Unfortunately, because several interventions were incorporated simultaneously, it was not possible to identify which ones were the most effective with regard to improving warfarin compliance in both programs.

Several recommendations arose from the study results. Firstly, there is a clear need to develop best practice guidelines for the number of INR blood tests required by patients to ensure good therapeutic control. Secondly, given the trend towards self-monitoring (often referred to as self-management), there is a need to develop a good practice model for a structured warfarin self-management program, based on the new warfarin education program. Finally, medication reviews should be incorporated into all home-based warfarin education programs to reduce the risk of drug-to-drug interactions.

7.5 SIMPLE, EASY-TO-READ WARFARIN INFORMATION

7.5.1 Introduction

The amount of information presented to patients beginning anticoagulant medication can be overwhelming (Ansell, Buttaro et al. 1997). It has been found that on average 40 percent of patients forget the information given to them (Prochaska and DeClementi 1986). Based on this knowledge, during the initial new warfarin education session the decision was made to verbally communicate only the important points as per the ‘Warfarin Counselling Checklist ’ (APPENDIX
13) and to provide each patient with the new written warfarin information booklet (APPENDIX 12) for written and visual reinforcement. The contents of both the checklist and the warfarin information booklet were based on ‘best evidence’ about what patients taking warfarin need to know in order to help optimise warfarin therapeutic outcomes (Ansell, Buttaro et al. 1997; Gallus, Baker et al. 2000; Haines 1998; Witte, Gurwich et al. 1980)

Health professionals have a duty of care to provide information which is easy-to-read and understand (Wilson, Racine et al. 2003). A number of strategies were used to ensure that the new warfarin information booklet (APPENDIX 12) was easily read and understood by most patients, including those with low literacy skills. These strategies included using readability instruments such as SMOG (McLauglin 1969), the Fry readability formula (Fry 1968) and the Microsoft Word 2000 computerised Flesch-Kincaid test to ensure that the booklet was written at a suitable level. Other strategies included adhering to guidelines such as those in the ‘Toolkit for producing patient information’ (The United Kingdom Department of Health 2002) (APPENDIX 2) and the ‘Guidelines for writing patient information’ (Doak, Doak et al. 1996b) (APPENDIX 3) to ensure that the booklet was written in a simple, easy-to-read format with culturally-sensitive illustrations. Prior to the commencement of the research study, changes were also made to the new booklet, as discussed in chapter 5, based on the comments and recommendations made by literacy experts, pharmacists, TACT staff, Illawarra Health interpreters and the 10 pilot study participants.

To assess the readability, quality and the patients’ satisfaction with the new warfarin information booklet (APPENDIX 12), it was compared and contrasted to the Boots warfarin information booklet (2003) used in the customary warfarin education program. The results of these analyses will now be discussed.
7.5.2 The overall effectiveness of the new warfarin education program compared to the customary program for patients with low literacy

The literature reports that patients with low literacy skills generally experience poor anticoagulation control because they cannot read or understand the information given to them (Estrada, Martin-Hryniewicz et al. 2004). The participating patients with low literacy skills in this study (educated at or above a grade 6 level) achieved a high proportion of therapeutic INR scores (69.5 percent intervention group and 69.2 percent control group), as well as high mean scores in the ‘Self-Management’ questionnaire (19.9 intervention group and 19.9 control group) and the ‘Medication-Taking-Measures’ questionnaire (3.8 intervention group and 3.8 control group). These results suggest that both programs equally promoted good therapeutic control and instilled confidence in patients with low literacy skills to manage and comply with their warfarin therapy at home. However, intervention group patients with low literacy skills achieved higher mean scores than the control group patients with low literacy skills in the ‘Warfarin Knowledge’ questionnaires, both initially (76.2 percent versus 68.1 percent) and after three months (63.9 percent versus 57.8 percent). As already discussed, these results suggest that the new warfarin education program was more effective than the customary warfarin education program, as well as other programs reported in the literature (Cheah and Martens 2003; Nadar, Begum et al. 2003; Tang, Lai et al. 2003) at improving warfarin knowledge in patients with low literacy skills.

Overall therefore, although the new warfarin education program was more effective at improving warfarin knowledge in patients with low literacy skills, both the new and customary programs equally promoted good therapeutic control and encouraged patients with low literacy skills to manage and comply well with their warfarin therapy. Interestingly, the high proportion of therapeutic INR scores (69.5 percent intervention group and 69.2 percent control group) achieved by the patient participants with low literacy skills in this study, were higher than the 30 percent to 60 percent average reported for the general population in the literature (Gray, Garabedian-Ruffalo et al. 1985; Khan, Kamali et al. 2004).
recommendation for future research would be to compare the new warfarin education program, inclusive of the new warfarin information booklet (APPENDIX 12), with other available warfarin education programs and written information, on a much larger sample size of patients with low literacy skills.

7.5.3 The effectiveness and readability of the new warfarin information booklet (APPENDIX 12) compared to the Boots warfarin information booklet (2003)

Unlike other currently available written warfarin information leaflets and booklets (Estrada, Hryniewicz et al. 2000; Tang, Lai et al. 2003), the new warfarin information booklet tried to address the needs of ‘high risk’ patient population. The ‘Toolkit for producing patient information’ (The United Kingdom Department of Health 2002) (APPENDIX 2) and the ‘Guidelines for writing patient information’ (Doak, Doak et al. 1996b) (APPENDIX 3) were used to help ensure that most patients, including those with low literacy skills, could read and understand the information.

The combined results of the SMOG test (McLaughlin 1969)(APPENDIX 4), the Fry test (1968) (APPENDIX 5) and the Microsoft Word 2000 computerised Flesch-Kincaid test found that the new booklet was written between grade 6 - 8 reading levels which complied with the recommendations for reading grade levels necessary for patients with low literacy skills (Buchbinder, Hall et al. 2001). This new booklet was found to be written at least 2 - 3 grades below the Boots warfarin information booklet (2003), as well as several reading grade levels below other available written warfarin information (Estrada, Hryniewicz et al. 2000). It could be argued that because these readability tests are not healthcare specific they may not be entirely accurate. In the absence of healthcare specific readability tools apart from RAIN (Singh 2002), which is time consuming and difficult to use, there were no other tools available for use in the study. The development of a healthcare-specific readability instrument would therefore be extremely valuable for all health professionals developing written patient healthcare information.
The patient demographic data collected in the research study indicated that 32 percent (16) of the intervention group patients and 19.2 percent (10) of the control group patients were educated at or below a grade 6 level. These patients with low literacy skills would have been able to read and understand the new warfarin information booklet (APPENDIX 12), but would not have been able to read and understand the Boots warfarin booklet (2003) or other available written warfarin information (Estrada, Hryniewicz et al. 2000; Estrada, Martin-Hryniewicz et al. 2004).

These results confirm the need to provide simple, easy-to-read warfarin information, which can be read and understood by a wider patient population, inclusive of those with low literacy skills. The new warfarin information booklet (APPENDIX 12) used in this research study was developed and written with these patients in mind. Based on the high evaluation scores for the intervention group patients with low literacy skills, the new booklet appears to have contributed to the effectiveness of the new program in empowering all patients, including those with low literacy skills, to make confident educated decisions about their warfarin therapy and management.

7.5.4 The quality and suitability of the new warfarin information booklet (APPENDIX 12) compared to the Boots warfarin information booklet (2003).

A patient's understanding and satisfaction with written information is influenced by factors such as format, colour, text, print size and the use of illustrations (Clark, AbuSabha et al. 1999). In this study the quality and the suitability of the two warfarin information booklets were assessed using the ‘Suitability Assessment Materials’ (SAM) (Doak, Doak et al. 1985), the ‘Bernier Instructional Design Scale’ (BIDS) (Bernier 1996) and the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) (see Appendices 6-8).

The SAM instrument (Doak, Doak et al. 1985) found the new warfarin information booklet (APPENDIX 12) to be superior to the Boots booklet (2003) in terms of content, literacy, demand, illustrations, layout, learning stimulation and
motivation. The BIDS instrument (Bernier 1996) identified that the new booklet contained more instructional design and learning principles than did the Boots booklet (2003). Also, the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) identified several potential deficiencies within the Boots booklet, but none in the new warfarin information booklet. Based on these tests, therefore, the new warfarin information booklet could be considered superior in terms of quality and suitability to the commonly used Boots warfarin information booklet (2003).

Even though the SAM instrument identified the superiority of the new booklet, it also identified some areas in which it could be improved to better meet the needs of patients with low literacy skills. The SAM instrument suggested that the booklet should limit its scope to essential warfarin information only and to develop a subsequent booklet to record blood test results and warfarin doses. The SAM instrument also suggested: changing some of the vocabulary (for example replace ‘binge eat’ with ‘over eat’); modifying the cover page to incorporate people from different cultures; and labelling the illustrations/lists more clearly. Unfortunately, the new booklet had already been printed when these results were identified which is why they were not incorporated into the booklet. These changes, however, have been incorporated in the revised edition of the new warfarin information booklet, which will be available in 2005.

7.5.5 The readability, quality and suitability of other written warfarin information sought by the patient participants

The small percentage of intervention group patients (16 percent) who sought more warfarin information achieved significantly lower mean scores for their ‘Warfarin Knowledge’ questionnaire after three months, than did the intervention group patients who did not. On the other hand, the small percentage of control group patients (7.7 percent) who sought more information achieved slightly higher mean ‘Warfarin Knowledge’ questionnaire scores, than did the control patients who did not. Even though these results were based on very small numbers of patients within both groups, they suggest that seeking more warfarin
information does not always improve warfarin knowledge and understanding. One of the reasons for this may be that the information available from these other sources is pitched at a level above the comprehension of many patients, as identified in the literature (Estrada, Hryniewicz et al. 2000; Estrada, Martin-Hryniewicz et al. 2004; Wilson, Racine et al. 2003), adding to their warfarin knowledge deficits and confusion. An interesting future study would be to investigate from where patients, especially those with low literacy skills, seek more warfarin information and what impact this information-seeking behaviour has on their warfarin knowledge, management and compliance in the long-term.

7.5.6 Non-English speaking background patients and written warfarin information

Diverse cultural groups interpret written material based on the values, rules of behaviour and healthcare practices consistent with their culture (Davidhizar and Brownson 1999; Guidry and Fagan 1999). For the purposes of this study, both the intervention and control group non-English speaking background (NESB) patients were offered a warfarin information booklet written in English and an accredited Illawarra Health interpreter to translate the relevant warfarin information to them.

As would be expected (Nadar, Begum et al. 2003), the non-English speaking background (NESB) patients achieved lower mean scores for each of the evaluation questionnaires, than did the English speaking background patients in both groups. The NESB intervention group patients, as compared to the NESB control group patients, achieved higher mean scores for the ‘Self-Management’ and ‘Warfarin Knowledge’ questionnaires. These results suggest that compared to the customary warfarin education program, the new warfarin education program improved the NESB patients’ knowledge and understanding of warfarin and their confidence to manage their therapy. However, the small number of NESB patients (9 intervention and 6 control), make it impossible to draw meaningful conclusions from these results. A recommendation for future research, therefore, would be to compare and contrast the new and customary
warfarin education programs on a much larger sample size of NESB patients. Also, in the absence of information in the literature, further research needs to be done regarding the language and cultural issues pertaining to written warfarin information available to patients from non-English speaking backgrounds.

One obvious limitation of the study was that the written warfarin information was only available in English. Unfortunately, restrictions in finances and time made it impossible for the information to be translated into the appropriate languages during this study. Future studies could evaluate the value of translating the new warfarin information booklet into different languages.

Additionally, the written information needs to be culturally sensitive (Wilson, Racine et al. 2003), as does the behaviour of health professionals educating patients from non-English speaking backgrounds (Lambert and Minas 1998; Minas, Lambert et al. 1996; Wilson, Racine et al. 2003). Prior to the study, the new warfarin booklet was circulated to Illawarra health service interpreters to ensure that it contained culturally sensitive graphics. In future, when the booklet is translated into different languages it would be appropriate to include graphics and photographs of patients who actually come from the different cultural backgrounds. Adherence to culturally-appropriate behaviours should become part of the everyday practice of all health professionals dealing with patients from diverse cultural communities (Wilson, Racine et al. 2003).

The researcher/TACT pharmacist providing the new warfarin education program had an advantage over the pharmacist providing the customary warfarin education program because she comes from a non-English speaking background. Even though this could be seen as a limitation of the study it must be taken into account that the study area is home to over 100 different nationalities, only 10 of which were represented in this research study. Notably, the study population did not include either Muslim or indigenous Australian patients. These cultures are especially important because Muslim patients often change their medication doses and intake time during Ramadan without seeking medical advice (Aadil, Houti and Moussamih 2004), and indigenous Australians often experience poor therapeutic outcomes based on communication, social and
cultural barriers (Morgan, Slade and Morgan 1997; Shannon 1994). In both cases, future research could focus on identifying cultural strategies, which could be adopted by all health professionals when trying to educate these patients about warfarin.

7.5.7 Summary

The issues of readability, quality and the suitability of written warfarin information were addressed in several ways throughout the research study. Several readability tests found the new warfarin information booklet (APPENDIX 12) to be written in a much simpler, easier-to-read format than the Boots warfarin information booklet (2003). Following evaluations with validated instruments, the new booklet was also found to be superior to the Boots booklet (2003) in terms of quality and suitability for a wider patient population, inclusive of those with low literacy skills.

The high proportion of therapeutic INR scores and the high ‘Warfarin Knowledge’ questionnaire scores achieved by the intervention patients with low literacy skills, suggests that the new program, including the new warfarin education booklet (APPENDIX 12), impacts favourably on warfarin knowledge and therapeutic control in patients with low literacy skills. Even though further research is needed to confirm this, these promising results imply that all patients should receive good quality, simple, easy-to-understand warfarin education programs and simple, easy-to-read written warfarin information.

Other recommendations borne out of the study are that readability tools such as SMOG (McLaughlin 1969) and Fry Test (Fry 1968)), as well as guidelines such as ‘The toolkit for producing patient information’ (The United Kingdom Department of Health 2002) and the ‘Guidelines for writing patient information’ (Doak, Doak et al. 1996b), should be used when preparing written patient information. In doing so, health professionals can ensure that information is available in a simple, easy-to-read format, which will appeal to a wider patient population. Prior to the distribution of the written patient information its quality and suitability should also be assessed by using instruments such as the
'Suitability Assessment Materials' (SAM) (Doak, Doak et al. 1985), the 'Bernier Instructional Design Scale' (BIDS) (Bernier 1996) and the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) (Appendices 6-8).

7.6 THE CONTINUITY OF CARE BETWEEN HOSPITAL AND COMMUNITY SETTINGS

Poor continuity of care between hospital and community settings has been reported to negatively impact upon poor therapeutic outcomes and adverse drug events (Australian Council for Safety and Quality in Health Care 2002; Balla and Jamieson 1994). To improve the continuity of care between hospital (ambulatory care in this instance) and community settings, the new warfarin education program followed the Australian Pharmaceutical Advisory Council (APAC) ‘National guidelines to achieve the continuum of quality use of medicines between hospital and community’ (1998). The strategies used to incorporate these guidelines have already been described in the methodology chapter of this thesis and will not be discussed here. It is important to note, however, that these guidelines, which can be seen to reflect best practice were also included into the customary warfarin education program during the course of the study. This may have impacted upon some of the results and made them less significantly different than expected.

The patient participants in the research study were referred to The Ambulatory Care Team (TACT) from the following three sources: emergency departments, hospital wards and general practitioners. The emergency department and hospital ward referrals outnumbered the general practitioner referrals at a ratio of 4:1. This highlights the need to prioritise the continuity of care between hospital and community settings to ensure that general practitioners know how to optimally continue monitoring their patients’ warfarin once discharged from the care of TACT.

Many of the interventions incorporated to improve the continuity of care were similar to those used to improve warfarin compliance. These interventions
included: encouraging carers and/or family members to be present during the initial education sessions; ensuring that an interpreter was available for patients from non-English speaking backgrounds; undertaking medication reviews; and encouraging the patients to be active participants in their warfarin management.

It is difficult, therefore, to accurately assess the impact that the continuity of care guidelines had on the therapeutic outcomes of the patient participants in this study. However, the high average warfarin knowledge scores (≥73 percent initially and ≥65.5 percent after three months), the high proportion of therapeutic INR scores (69 percent) and the low incidence of minor potential warfarin-related adverse drug events (4.9 percent) achieved by all patient participants in this study leaves little doubt about the benefits of adhering to the APAC guidelines. These results support the need to always incorporate APAC guidelines into ambulatory care services such as TACT because the timely transfer of information to patients, carers and/or their health professionals working in the community (Thornton, Simon and Mathew 1999) ultimately contributes toward optimising therapeutic outcomes and minimising adverse drug events.

A recommendation for future research would be to evaluate the direct impact of the APAC guidelines on ambulatory care services, assessing whether or not similar benefits and/or disadvantages are achieved. Some interesting aspects to focus on in these future studies would include: assessing the general practitioners preferred method of receiving patient information (email, fax, letter); their perceptions about the timeliness of the information; as well as the quality of the information that they received about their patient.

In summary, both programs appear to have successfully incorporated the APAC guidelines to improve the continuity of care between hospital (ambulatory care) and community settings. Even though further research is needed, preliminary data from this study indicate that when ambulatory care services like TACT adhere to these guidelines there is an improvement in patients achieving good therapeutic control with fewer warfarin-related adverse events.
7.7 PATIENT FOLLOW-UP

7.7.1 Introduction

Patient follow-up was used in the new warfarin education program because it has been identified as a key element of an effective patient education program (Dudas, Bookwalter et al. 2001; Haynes, McDonald et al. 2002a). The intervention patients received a follow-up telephone call one week after the initial warfarin education session. During this initial telephone follow-up they had their warfarin information reinforced and they were also encouraged to ask questions and make comments about their warfarin therapy. All the participating patients (intervention and control) then received telephone follow-up calls after three months, and, as initially informed, were asked to complete the evaluation questionnaires. During the three-month follow-up telephone calls, all the patient participants were also encouraged to ask questions and make any comments about their warfarin therapy and education programs.

7.7.2 Impact of patient follow-up on warfarin management and compliance

As already discussed, patients were possibly more diligent with their warfarin management and compliance because they were being monitored in the study. Evidence in the literature also supports the positive impact of patient follow-up on medication management, compliance and therapeutic control (Dudas, Bookwalter et al. 2001; Jackson, Peterson et al. 2004). It would be reasonable to conclude, therefore, that the telephone follow-up contributed to all patient participants achieving high mean scores for their ‘Self-Management’ and ‘Medication-Taking-Measures’ questionnaires, as well as the high proportion of therapeutic INR scores during the three-month study period. An interesting investigation in the future would be to examine the impact that long-term follow-up (at least 12-24 months) has on patients’ warfarin knowledge and understanding, their compliance, management and therapeutic outcomes.
7.7.3 Impact of patient follow-up on warfarin-related adverse drug events

Reports in the literature identify that follow-up after hospital discharge significantly reduces the incidence of adverse drug events requiring hospitalisation (Dudas, Bookwalter et al. 2001; Jackson, Peterson et al. 2004). Therefore, telephone follow-up in this study has almost certainly contributed to the very low incidence of minor warfarin-related adverse drug events, none of which required hospitalisation. Only 4.9 percent (5) of the patient participants in the study experienced minor possible warfarin-related bleeds, as compared with the 13.7 percent reported in the literature for other outpatient anticoagulation clinics (Wilt, Gums, Amhed and Moore 1995). These results promote the benefits of incorporating patient follow-up into a warfarin education program. To identify the benefits of patient follow-up alone, future studies would need to identify the long-term effects on warfarin-related adverse drug events in patients receiving regular follow-up, compared to those receiving no follow-up.

7.7.4 Impact of patient follow-up on warfarin knowledge

It is notable that even though the intervention group patients received follow-up telephone calls one week after their initial warfarin education session, their warfarin knowledge deteriorated at a similar rate as that of the control group patients during the study. This deterioration in warfarin knowledge could have serious implications for patients diagnosed with medical conditions requiring potentially lifelong warfarin therapy. Such diagnoses include: atrial fibrillation; transient ischaemic attacks; cerebrovascular accidents; and mechanical cardiac valves, which were found to exist in 41.2 percent (42) of the patient participants. More of a concern is that many of these patients were elderly, aged 65 years and over (62.8 percent), and therefore at a potentially greater risk of experiencing poor therapeutic outcomes and warfarin-related adverse events (Cheah and Martens 2003; Tang, Lai et al. 2003; Taylor, Ramsay et al. 1994; Wilson, Racine et al. 2003). A recommendation based on these results is to have regular patient follow-up, especially for elderly patients, reassuring them and reinforcing warfarin information on a three monthly basis.
Based on the three-month follow-up period of this study, it is difficult to predict the long-term effects of the warfarin knowledge deficits. Further studies, especially on elderly patients, need to investigate whether or not three monthly follow-up, reinforcement and reassurance improves warfarin knowledge, management, compliance and therapeutic outcomes over time.

7.7.5 Summary of the impact of patient follow-up

Patient follow-up was believed to contribute to the patient participants’ improved warfarin knowledge, management and compliance, as well as their good overall therapeutic control and low incidence of warfarin-related bleeds. No significant differences were found between the new and the customary warfarin education programs, probably because they both incorporated many similar strategies and interventions to target follow-up as a key element.

Based on the significant deterioration of all patients’ warfarin knowledge after three months, a quarterly follow-up scheme is recommended. The long-term consequences of patient follow-up on warfarin-related therapeutic outcomes and adverse drug events, are difficult to predict from the results of this short-term study, so further research is needed.

7.8 OTHER INTERESTING RESULTS FOUND IN THE RESEARCH STUDY

7.8.1 Introduction

Other interesting results identified in this study will now be discussed. Firstly, discussions will focus on the impact of prior warfarin knowledge and general practice visits. Secondly, the effects of the new and customary warfarin education programs on adverse drug events, hospitalisation and emergency department visits will be compared. Lastly, discussion will turn to the impact of written information pertaining to drug-to-drug interactions with warfarin, especially with regard to complementary medicines.
7.8.2 Prior warfarin knowledge

The research data indicated that the 39.2 percent (40) of participating patients (30 percent intervention and 48.1 percent control) who claimed to have prior warfarin knowledge, did not achieve higher mean scores for their ‘Self-Management’, ‘Medication-Taking-Measures’ or ‘Warfarin Knowledge’ questionnaires, than the participating patients with no prior knowledge. In other words, patients in both groups who claimed to have prior warfarin knowledge did not appear to be more confident with their warfarin management and compliance, nor did they have a better warfarin knowledge and understanding, than did the patients with no prior warfarin knowledge.

These results have important implications for warfarin education because many health professionals perform a quick overview of warfarin information for patients whom they believe to have prior warfarin knowledge (Haines 1998). It is therefore important for health professionals not to take for granted information which has been previously communicated to patients because, despite their best efforts, they can and do forget (Ansell, Buttaro et al. 1997). The results of this study imply that all patients receiving warfarin therapy - for the first time or not - should ideally receive a complete and thorough warfarin education program with continuous follow-up, reinforcement and reassurance to help promote good warfarin knowledge, management and compliance.

7.8.3 General practitioner visits

Following discharge from The Ambulatory Care Team (TACT), patient participants were cared for by their general practitioners. The data reveal that on average the patients in both groups visited their general practitioners approximately seven times each, during the three-month follow-up period. The intervention group patients who visited their general practitioners more frequently were more confident about their warfarin management and had a better warfarin knowledge, than did intervention group patients who visited their general practitioners less frequently. Conversely, control group patients who visited their general practitioners more frequently were less confident about their warfarin
management and had poorer warfarin knowledge, than did control group patients who visited their general practitioners less frequently. A possible explanation for these results given that both groups achieved similar overall therapeutic INR scores, is that the control group patients as opposed to the intervention group patients were more inclined to let their general practitioners manage their warfarin therapy for them. Similar to the results found by Dantas et al (2004), it appears that even though the control group patients were satisfied with the warfarin information they received and experienced few adverse drug events, they were more inclined to accept directives rather than be collaborative with their general practitioners. More research is needed to investigate this further.

7.8.4 Warfarin-related adverse drug events, hospitalisation and emergency department visits

Eighteen percent (9) of the intervention group patients and 21.2 percent (11) of the control group patients were hospitalised during the three-month follow-up period. Importantly, none of these hospitalisations were due to possible warfarin-related adverse drug events. Instead, 5.9 percent (6) in total for both groups were due to exacerbations of the disease for which the warfarin was initially prescribed.

Sixteen percent (8) of the intervention group patients and 11.5 percent (6) of the control group patients visited the emergency departments during the three-month follow-up period. In total, only 3.92 percent (4) of these emergency department visits were associated with minor bleeds potentially caused by warfarin therapy. These results compare well with reports in the literature claiming that in anticoagulation clinics, 2.8 percent of patients experience major bleeds and 18.3 percent of patients experience minor bleeds, and that in general practice settings, 10.9 percent of patients experience major bleeds and 17.6 percent of patients experience minor bleeds (Ansell, Buttaro et al. 1997). It could be argued that as this study was only conducted over a short period of time these results are not a true reflection of what may occur in the long-term. Given that most warfarin-related adverse events occur within the first few months of therapy
(Jackson, Peterson et al. 2004; Levine, Raskob, Landefeld and Kearon 2001; White, Beyth, Zhou and Romano 1999), initial indications of this study show that both the new and customary education programs are helping to reduce the number of such occurrences.

These results have important implications because not only have both programs reduced the incidence of possible warfarin-related adverse events, they have also reduced hospitalisation costs. With recent increases in warfarin-related hospitalisations (AIHW 2002; AIHW 2003), it would be fair to assume that current hospitalisation costs are well in excess of the 1992 estimation of $100 million per annum (Rigby, Clark et al. 1999). Further studies are therefore required to analyse the potential reductions in warfarin-related adverse drug events and healthcare costs associated with using the new warfarin education program.

The 4.9 percent (5) incidence of minor warfarin-related bleeds in this study is much lower than the 18.3 percent average reported in the literature for anticoagulation clinics (Ansell, Buttaro et al. 1997). These results and the absence of any major bleeds associated with warfarin therapy in this study may be a reflection of the small sample size, however they are noteworthy because they suggest that both programs potentially reduce the incidence of warfarin related adverse drug events.

7.8.5 Warfarin information on possible drug-to-drug interactions (including complementary medicines)

The increasing use of complementary medicines (Harris and Rees 2000; Shenfield, Atkin and Kristoffersen 1997; Welch 2001) potentially increases possible drug-to-complementary medicine interactions with warfarin (Myers 2002). This is why participating patients were educated and given the ‘Patient information on potential drug-to-drug warfarin interactions sheet’ (APPENDIX 27). This information sheet also contains information about interactions between warfarin and complementary medicines.
Upon receipt of the drug-to-drug interaction sheet (APPENDIX 27), 10 percent (10) of participating patients who had taken complementary medicines without their general practitioners’ knowledge either ceased to do so or continued after consultation with their general practitioners. Without this information, patients would have taken their complementary medicines without their general practitioners’ knowledge and potentially caused serious warfarin-to-complementary medicines interactions.

An important recommendation for future practice would be to ensure that all patients prescribed warfarin, as well as their health professionals, should be familiarised with the potential interactions between complementary medicines and warfarin. This could be done by ensuring that all patients and their health professionals were given relevant education and information such as the ‘Patient information on potential drug-to-drug warfarin interactions sheet’ (APPENDIX 27).

Current research is identifying an increasing number of potential interactions between warfarin and complementary medicines (Myers 2002). Future research needs to identify how much health professionals and patients need to know about these interactions to achieve optimal warfarin-related therapeutic outcomes and minimal adverse drug events.

7.8.6 Summary

The research study identified that patients who had prior warfarin knowledge did not necessarily have better warfarin knowledge, management, compliance and therapeutic outcomes than did those with no prior warfarin knowledge. Increased general practitioner visits did not always lead to improved warfarin knowledge and management, which confirms the need for regular patient follow-up, reinforcement and reassurance.

Many of the strategies and interventions incorporated in both warfarin education programs in this study have successfully contributed to the reduction in the incidence of warfarin-related adverse events, as well as in the number of emergency department and hospital visits. With the current increase in the use of
complementary medicines (Harris and Rees 2000; Shenfield, Atkin et al. 1997; Welch 2001), health professionals and patients need to be made fully aware of the potential warfarin-to-complementary medicines interactions to prevent further possible warfarin-related adverse drug events. The information sheet used in this study, ‘Patient information on potential drug-to-drug warfarin interactions sheet’ (APPENDIX 27) would be a good starting point. Importantly, each of these findings provides valuable information to help reduce the large and unresolved problem of warfarin-related adverse drug events (Halstead, Roughead et al. 1999).

7.9 RECOMMENDATIONS OF THE STUDY

Several recommendations to improve current practice in warfarin education arose from the research study. These recommendations include the provision of the following to all patients prescribed warfarin:

- the new warfarin education program should be considered suitable as a possible best practice model for effective home-based warfarin education program.’
- a good quality, simple, easy-to-read warfarin information booklet (APPENDIX 12).
- a warfarin counselling checklist to achieve specific objectives (APPENDIX 13).
- a validated ‘Warfarin Knowledge’ questionnaire to evaluate patients’ warfarin knowledge and understanding based on APPENDIX 19.
- a written information sheet about potential drug-to-drug interactions (including warfarin-to-complementary medicines interactions) such as the ‘Patient information on potential drug-to-drug warfarin interactions’ (APPENDIX 27).
- regular three-monthly follow-up sessions to reinforce and reassure patients about their warfarin information
best practice guidelines for the number of INR blood tests which are required to achieve optimal therapeutic control.

- a best practice model for home-based warfarin self-management programs which incorporates the new warfarin education program and a structured self-management (self-monitoring) program.

The following are recommendations for all health professionals developing and producing patient medication education programs:

- the regular use of readability tests such as SMOG (McLauglin 1969) and the Fry Test (Fry 1968) to ensure that patient information is written below a grade 8 level or preferably a grade 6 level.
- the need to develop an easy-to-use healthcare-specific readability instrument.
- the regular use of the ‘Toolkit for producing patient information’ (The United Kingdom Department of Health 2002) and the ‘Guidelines for writing patient information’ (Doak, Doak et al. 1966b) when developing new patient information to ensure that it is written in a simple, easy-to-read format.
- evaluation of the quality and suitability of written patient medication information by using instruments such as the ‘Suitability Assessment Materials’ (SAM) (Doak, Doak et al. 1985), the ‘Bernier Instructional Design Scale’ (BIDS) (Bernier 1996) and the ‘Checklist for print materials’ (Bidford Maine Area Health Education Center 1996) (Appendices 6-8).
- target the needs of the ‘high risk’ patient population.

These recommendations, in combination with the interventions and strategies used in the study to target the five key elements of an effective medication education program, should be used to improve current medication education practices, including warfarin education programs. The five key elements which
need to be improved include: patients/health professional communication and partnerships; warfarin compliance; simple, easy-to-read warfarin information; continuity of care between hospital and community settings; and patient follow-up.

7.10 LIMITATIONS OF THE STUDY

There were a number of limitations in the study, many of which have already been discussed. The following is a brief overview of these limitations.

One of the major limitations of the study was that the researcher/TACT pharmacist developed both the new and customary warfarin education programs, delivered to Illawarra Health’s The Ambulatory Care Team (TACT) patients. This, together with the fact that many of the strategies and interventions developed for the new warfarin education program were also absorbed into the customary warfarin education program during the course of the study, may have affected the results and made them less significantly different than expected. In hindsight, it would have been better to compare and contrast the new program with another home-based warfarin education program available within Australia, because the results of this study may have been a better indication of the benefits and/or deficits of the new program.

Another limitation of the study was that it was conducted over a three-month period and many long-term benefits could not be analysed. Regardless, long-term analysis would not have been possible in this study because many of the patient participants were diagnosed with a deep venous thrombosis (41.2 percent). These patients would only have been prescribed warfarin therapy for three months, making them ineligible for studies conducted over a longer period of time. Future, longer studies would need to be conducted on patients diagnosed with an illness such as atrial fibrillation, potentially requiring lifelong warfarin therapy.
The inclusion of patient participants from the general population could also be described as a limitation of this study. As a result, many of the benefits of the new warfarin program could not be assessed for their direct impact on the ‘high risk’ group – that is, on patients who were elderly, had low literacy skills and/or came from non-English speaking backgrounds. It would therefore be useful to conduct further studies exclusively on ‘high risk’ patients.

The use of readability tools such as the SMOG formula (McLauqlin 1969), the Fry readability formula (Fry 1968) and the Microsoft Word 2000 computerised Flesch-Kincaid test, which are not healthcare specific, may also be viewed as a limitation of the study. However, in the absence of a simple, easy-to-use healthcare specific readability tool there was no alternative in this instance. The development of such a tool is highly recommended.

For non-English speaking background patients, a limitation in the study was that the written warfarin information was only available in English. A recommendation for future studies is to supply each non-English speaking background patient with a booklet translated into their own native language.

A final imitation of the study was requiring all patient participants to answer follow-up questionnaires when, in some cases, carers and family members managed their warfarin therapy for them. Future studies should therefore ensure that the person responsible for managing the warfarin therapy answer all the evaluation questionnaires.

7.11 CONCLUSIONS

If current educational practices continue, recent increases in warfarin prescribing will almost certainly result in an increased incidence of poor warfarin-related therapeutic outcomes and adverse drug events (Gurwitz, Field et al. 2003; Halstead, Roughhead et al. 1999). The patients at ‘high risk’ of experiencing these poor therapeutic outcomes and adverse events include the elderly and those with low literacy skills (Estrada, Martin-Hryniewicz et al. 2004; Tang, Lai et
al. 2003), as well as non-English speaking background patients (Lambert and Wynne 2003; Nadar, Begum et al. 2003).

The basis of this thesis is good patient warfarin education, which is the key to improving warfarin knowledge, management and compliance (Haines 1998; Kagansky, Knobler et al. 2004). These in turn will help to optimise warfarin-related therapeutic outcomes and minimise adverse drug events by empowering patients to make educated decisions, as reported in the literature (Australian Council for Safety and Quality in Health Care 2002; Bhasale, Miller et al. 1998). The research study focused on developing and evaluating a new warfarin education program to improve warfarin knowledge, management and compliance in a wider patient population, inclusive of the ‘high risk’ group.

The new warfarin education program was founded on a conceptual framework which targeted five key elements of an effective patient education program. These elements were: health professional/patient communication and partnerships; warfarin compliance; simple, easy-to-read written warfarin information; improved continuity of care between hospital and community settings; and patient follow-up. Many similar strategies and interventions targeting these key elements were incorporated into both the new and the customary warfarin education programs during the course of the study and almost certainly affected the results by making them less significantly different than expected.

Overall, however, the trend in the results suggested that the new warfarin education program was more effective than the customary warfarin education program in educating patients, including ‘high risk’ patients, about their warfarin therapy. In other words, patients receiving the new warfarin education program had a better warfarin knowledge and understanding, and were more confident about their warfarin management and compliance at home.

Both the new and the customary warfarin education programs used in this study appeared to be more effective than other available warfarin education programs, achieving better warfarin knowledge scores and therapeutic outcomes, with fewer warfarin-related adverse drug events and healthcare visits.
It could be argued, therefore, that the interventions and strategies incorporated in both programs, which targeted the five key elements in the conceptual framework, successfully produced a new more effective warfarin education program.

Throughout the research study, interventions and strategies targeting the five key elements of an effective education program were applied to the home-based ambulatory care service TACT. There is no reason why this new home-based warfarin education program could not be applied to other hospital and community-based warfarin education programs, especially since the key to effective anticoagulant management is good patient warfarin education (Haines 1998).

Based on the success of the results in this study, the researcher contends that by targeting the five key elements of an effective warfarin education program, a wider patient population, inclusive of those from the ‘high risk’ group, will be effectively educated about their warfarin therapy. This in turn will help them to achieve optimum warfarin-related therapeutic outcomes and minimum adverse drug events.

One of the major benefits of this study is that the conceptual framework, with its five key elements, provides a blueprint for the development of other effective patient medication education programs in both hospital and community settings.
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APPENDIX 1

FLESCH Reading Ease Scale (Flesch 1948)

Step 1. Count the words.

Count the words in your piece of writing. Count as single words contractions, hyphenated words, abbreviations, figures, symbols and their combinations.

Step 2. Count the syllables.

Count the syllables in your piece of writing. Count the syllables in words as they are pronounced. Count abbreviations, figures, symbols and their combinations as one-syllable words. If a word has two accepted pronunciations, use the one with fewer syllables. If in doubt, check a dictionary.

Step 3. Count the sentences.

Count the sentences in your piece of writing. Count as a sentence each full unit of speech marked off by a period, colon, semicolon, dash, question mark or exclamation point. Disregard paragraph breaks, colons, semicolons, dashes or initial capitals within a sentence.

Step 4. Figure the average number of syllables per word.

Divide the number of syllables by the number of words.

Step 5. Figure the average number of words per sentence.

Divide the number of words by the number of sentences.

Step 6. Find your readability score.

Find the average sentence length and word length of your piece of writing on the chart (below). Take a straightedge or ruler and connect the two figures. The intersection of the straightedge or ruler with the centre column shows your readability score.
HOW TO USE THIS CHART
Draw a straight line from your measured "Words per Sentence" to your measured "Syllables per Word." The intersection of this line with the center column shows your readability score. The minimum score for Plain English is 60.
You can also use this formula:

Multiply the average sentence length by 1.015. Multiply the average word length by 84.6. Add the two numbers. Subtract this sum from 206.835. The balance is your readability score.

The scale shows scores from 0 to 100. Zero means practically unreadable and 100 means extremely easy. The minimum score for Plain English is 60, or about 20 words per sentence and 1 1/2 syllables per word. Conversational English for consumers should score at least 80, or about 15 words per sentence and 1 1/2 syllables per word.

<table>
<thead>
<tr>
<th>Score</th>
<th>School Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 to 100</td>
<td>5th grade</td>
</tr>
<tr>
<td>80 to 90</td>
<td>6th grade</td>
</tr>
<tr>
<td>70 to 80</td>
<td>7th grade</td>
</tr>
<tr>
<td>60 to 70</td>
<td>8th and 9th grade</td>
</tr>
<tr>
<td>50 to 60</td>
<td>10th to 12th grade (high school)</td>
</tr>
<tr>
<td>30 to 50</td>
<td>college</td>
</tr>
<tr>
<td>0 to 30</td>
<td>college graduate</td>
</tr>
</tbody>
</table>
APPENDIX 2

Toolkit for Producing Patient Information(The United Kingdom Department of Health 2002)

To make the text more inviting to read use the following;

- Short sentences-in general no more than 15 to 20 words long
- Lower case letters where possible as they are easier to read. Exceptions to this are proper names and the first letter in a sentence.
- Present and active tenses where possible.
- A question and answer format is helpful to divide up the test.
- Bulleted or numbered points to divide up complicated information.
- Small blocks of text. Do not use long paragraphs divide them using headings and new paragraphs.
- White space makes the information easier to read.
- Large bold font emphasises text. Avoid upper letters, italics and underlining as they make the text more difficult to read.
- Numbers from one to nine are easy to read if they are written in words, and numbers from 10 can be represented as numbers.
- A font size of no less than 12 point.
- Diagrams and pictures are very effective and should be in line with communication principles. Where appropriate, use them to illustrate the text, remember to label them and do not print over them. You should not use clipart as it does not add to the reputation of the professional organisation.

You should apply these principles to all documents, not just those for people with sight difficulties. A large number of patients using the NHS will be over 40, and clear, legible print with the lines not too close together will make documents easier to read.

- Font size: 12 point (minimum) to 14 point but if you are writing information for the elderly or people with sight difficulties always use 14 point or larger.
- Use a medium weight typeface for example Frutiger Roman.
- Contrast: use a light background with dark print.
- It is acceptable to use a dark background with white print (reversed out) for headings but not for large sections of the text.
- Use a sans serif font-Frutiger.
- Justify the text to the left only.
- Use one or two colours.
- Do not write text over background pictures or a design.
APPENDIX 3

Guidelines for writing patient information (Doak, Doak and Root 1996)
1. Write the way you talk; use active voice.
2. Use common words, and, on average, use short sentences.
3. Give examples to explain hard words.
4. Include interaction and reviews.

Guidelines for typography and layout
a) Type style and size
   • Use serif type and lowercase lettering, except where grammatically necessary to use capital letters.
   • Use 12-point type or larger.
   • Do not use large or stylised initial letters.
   • In general, do not use reverse print, that is, white on black.

b) Line length
   • Try to limit line length to 30 to 50 characters and spaces.
   • Make the left edge of lines rectified.
   • Leave right ends of lines ragged.

c) Layout of text on the page
   • Leave some white spaces on the page to avoid a look of solid text.
   • Use headers ("road signs") underlined or in bold print to introduce each new topic and to break up the appearance of a page of solid text.
   • Use an eye-catcher, a box or larger font or an indent, to draw readers’ eyes to the most important information.
APPENDIX 4

SMOG Formula (McLauiglin 1969)

1. Count 10 consecutive sentences near the beginning of the text to be assessed, 10 in the middle and 10 near the end. Count as a sentence any string of words ending with a period, question mark or exclamation point.

2. In the 30 selected sentences count every word of three or more syllables. Any string of letters or numerals beginning and ending with a space or punctuation mark should be counted if you can distinguish at least three syllables when you read it aloud in context. If a polysyllabic word is repeated, count each repetition.

3. Estimate the square root of the number of polysyllabic words counted. This is done by taking the square root of the nearest perfect square for example 95 is 100 which yields a square root of 10. If the count lies roughly between two perfect squares, choose the lower number. For instance, if the count is 110, take the square root of 100 rather than of 121.

4. Add 3 to the approximate square root. This gives the SMOG GRADE, which is the reading grade that a person must have reached if he is to understand fully the text assessed.
APPENDIX 5

Fry Readability Formula (Fry 1968)

1. Select three one-hundred-word passages from near the beginning, middle and end of the book. Skip all proper nouns.

2. Count the total number of sentences in each hundred-word passage (estimating to the nearest tenth of a sentence). Average these three numbers.

3. Count the total number of syllables in each hundred-word sample. There is a syllable for each vowel sound; for example car (1), blackbird (2), continental (4). Don’t be fooled by word size; for example polio (3), through (1). Endings such as –y, -ed, -el, or –le usually make a syllable, for example: ready (2), bottle (2). I find it convenient to count every syllable over one in each word and add 100. Average the total number of syllables for the three samples.

4. Plot on the graph the average number of sentences per hundred words and the average number of syllables per hundred words. Most plot points fall near the heavy curved line. Perpendicular lines mark off approximate grade level areas.

Graph from (Klug Redman 2001 The Practice of Patient Education 9th Edition page 57)
# APPENDIX 6

## SAM (The Suitability Assessment Materials) (Doak, Doak and Root 1985)

**SAM Scoring Sheet**

2 points for superior rating  
1 point for adequate rating  
0 points for non-suitable rating  
N/A if the factor does not apply to this material.

<table>
<thead>
<tr>
<th>FACTOR TO BE RATED</th>
<th>SCORE</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CONTENT</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Purpose is evident</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) Content about behaviours</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) Scope is limited</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(d) Summary or review included</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. LITERACY DEMAND</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Reading grade level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) Writing style, active voice</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) Vocabulary uses common words</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(d) Context is given first</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) Learning aids via &quot;road signs&quot;</td>
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<td></td>
</tr>
<tr>
<td>3. GRAPHICS</td>
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<td></td>
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<tr>
<td>(a) Cover graphic shows purpose</td>
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<td></td>
</tr>
<tr>
<td>(b) Type of graphics</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) Relevance of illustrations</td>
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<td></td>
</tr>
<tr>
<td>(d) Lists, tables, etc, explained</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(e) Captions used for graphics</td>
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<td></td>
</tr>
<tr>
<td>4. LAYOUT AND TYPOGRAPHY</td>
<td></td>
<td></td>
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<tr>
<td>(a) Layout factors</td>
<td></td>
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<tr>
<td>(b) Typography</td>
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</tr>
<tr>
<td>(b) Subheads (&quot;chunking&quot;) used</td>
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<td></td>
</tr>
<tr>
<td>5. LEARNING, STIMULATION, MOTIVATION</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Interaction used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) Behaviour are modelled and specific</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(c) Motivation and self-efficacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. CULTURAL Appropriateness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(a) Match in logic, language, experience</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(b) Cultural image and examples</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Total SAM Score: ____________  
Total possible score: ____________  
Percent score: ____________%
APPENDIX 7

Bernier Instructional Design Scale (BIDS) (Bernier 1996)

The rating scale:
0= Not met
1= Partially met
2= Met
NA= Not applicable

<table>
<thead>
<tr>
<th>Principle Scale</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. There is sufficient contrast between the ink and paper to make reading easy.</td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>2. The font or print size can be read easily by the target audience.</td>
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<tr>
<td>3. The type style is easy to read.</td>
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</tr>
<tr>
<td>4. Drawings/illustrations are recognizable to the target group with or without explanatory text.</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5. Drawings/illustrations are labeled clearly.</td>
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<td>6. Drawings/illustrations represent racial and ethnic groups appropriate to the target audience.</td>
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<td>7. Titles and subtitles are clear and informative</td>
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<td>8. The vocabulary of the PEM is one that reflects words commonly used by the target group.</td>
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<td>9. Necessary health terms are defined.</td>
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<td>10. Terms are used in a consistent manner throughout the PEM.</td>
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<td>11. The writing style is one that will actively engage the reader and stimulate active participation.</td>
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<td>12. The active voice is used (e.g. “Many persons with colostomies find it beneficial to be a member of an ostomy support group” is better than the passive voice “Many persons with colostomies have found that they benefited from an ostomy support group”).</td>
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<td>13. The use of double (or multiple negatives) is avoided (e.g. This sentence is confusing: There is no reason why a person with diabetes should not exercise when they are not ill).</td>
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<td>14. The purpose of the PEM is made clear to the target group.</td>
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<td>15. The relevance of the educational content to the target group is clearly stated.</td>
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<td>16. The learning objectives that are stated or implied and the educational content of the PEM relate to one another.</td>
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<td>17. The learning objectives that are stated or implied relate to the intended learning outcome that is stated or implied in the PEM.</td>
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18. Only the most essential information about the topic is presented, using not more than 3-4 main points.
19. The content is accurate.
20. The content is presented in concrete terms rather than abstract ideas and concepts.
21. The content is written in a style that is ‘patient-centered’ that is, in the perspective of the patient foremost.
22. The content is presented in a way that relates and integrates the new information to what is already known and understood by the target group.
23. Examples are used to bridge the gap between what the target group already knows and the content that is to be taught and learned.
24. The examples that are used contain the central characteristics of the ideas and concepts under discussion.
25. The content is presented in a manner, which is respectful of the customs and traditions of the target group.
26. The information load of the educational material is appropriate to the target group (The more unfamiliar the information, the smaller the amount to be presented at the time).
27. The content focuses on what the target group should do as well as know.
28. The main ideas of the PEM are divided into meaningful units of content.
29. The educational material moves from simple to more complex content in a manner that is organised and logical.
30. The educational content is current.
31. Specific, precise instructions are given if the target group is expected to carry out some health or self-care activity.
32. Important ideas and points of content are repeated as reinforcement throughout the PEM.
33. Sentences are kept in logical order and present a coherent structure for the information being conveyed in the PEM.
34. Summaries/synopses of the educational content being delivered are included throughout the PEM.
35. The PEM is written at a readability level that is appropriate to the target group (Materials intended for the general public should be written at the 6th – 8th grade level).
APPENDIX 8

Checklist For Print Materials (Bidford Maine Area Health Education Center 1996)

Title of Material: _____________________________________________

Directions: Place a check next to each item that meets the described attribute.

ORGANISATION
1. The cover is attractive. It indicates the core content and intended audience.
2. Desired behaviour changes are stressed. ‘Need to know’ information is stressed.
3. Not more than three or four main points are presented.
4. Headers and summaries are used to show organization and provide message repetition.
5. A summary that stresses what to do is included.

WRITING STYLE
6. The writing is in conversational style, active voice.
7. There is little or no technical jargon.
8. Text is vivid and interesting. Tone is friendly.

APPEARANCE
10. Lowercase letters used (capitals used only when grammatically needed).
11. There is a high degree of contrast between the print and the paper.
12. Print size is at least 12 point, serif type, and no stylized letters.
13. Illustrations are simple - preferably line drawings.
14. Illustrations serve to amplify the text.

APPEAL
15. The material is culturally, gender and age appropriate.
16. The material closely matches the logic, language, and experience of the intended audience.
17. Interaction is invited via questions, response, suggested action, etc.

**Principle 1:** It is the responsibility of the admitting institution to ensure the development and coordination of a medication discharge plan for each patient. The person responsible for coordinating the development, implementation, and monitoring of the medication discharge plan, including medication supply and medication information, should be identified as soon as practicable after admission.

**Principle 2:** Hospital staff should obtain an accurate medication history, including prescription and over-the-counter medicines and other therapies such as herbal products, at the time of admission.

**Principle 3:** Hospital staff should evaluate the current medication at the time of admission, in consultation with the patient’s general practitioner, with a view to:

- identifying the appropriateness and effectiveness of current medication and rationalising current medications if appropriate,
- paying particular attention to any problems associated with current drug therapy, including any possible relationship with the current medical condition, and
- documenting allergies and any previous adverse drug reactions.

**Principle 4:** During the hospital stay, treatment plans relating to the probable medication management during the stay and where applicable at discharge should be developed in consultation with the patient and/or carer. Hospital staff should negotiate with the patient issues relating to treatment and the development of a discharge plan, and these discussions should be documented in the patient’s notes. This plan should form part of the overall care plan or critical pathway.
- The use of interpreters may be required to ensure good communication with people from non-English speaking backgrounds.

- To enable the discharge process to be successful, there needs to be effective communication and coordination between all relevant parties in the hospital environment.

- Where appropriate, community health providers, especially the patient’s general practitioner, should be consulted.

- Carers should also be consulted where appropriate.

**Principle 5:** Prior to discharge, pre-discharge medication review and dispensing of adequate medication should take place in a planned and timely fashion. Adequate medication means sufficient medication to carry the patient through to the next arranged review (by their general practitioner, outpatient clinic, or some other arrangement), or to complete the course of treatment. If patients are discharged with inadequate supplies of medication, this can compromise quality of care for the patient. Supply of the medication from the hospital facility must be adequate to ensure continuity of medication is not interrupted by the inability to obtain further ongoing supplies if required, within a reasonable timeframe.

**Principle 6:** At the time of discharge, each patient should be provided with a discharge folio containing relevant information such as Consumer Medicine Information, a medication record, patient/carer plan, and information on the availability and future supply of medication.

**Principle 7:** No patient should be discharged from hospital until the details of the admission, medication changes (including additions/deletions) and arrangements for follow-up have been communicated to the healthcare provider(s) nominated by the patient as being responsible for his or her ongoing care.
APPENDIX 10

Information Required for the Initial New Warfarin Education Session

1. New warfarin information booklet (APPENDIX 12)
2. Warfarin counselling checklist (APPENDIX 13)
3. Warfarin pretest questionnaire (APPENDIX 15)
4. Patient demographic data sheet (APPENDIX 16)
5. ‘Self-Management’ questionnaire (APPENDIX 17)
6. ‘Medication-Taking-Measures’ questionnaire (APPENDIX 18)
7. ‘Warfarin Knowledge’ questionnaire (APPENDIX 19)
8. ‘Satisfaction with Information about Medicines Scale’ (SIMS) (APPENDIX 20)
9. NPS medicine information line fridge magnet
10. Patient information on potential drug-to-drug warfarin interactions (APPENDIX 27)
APPENDIX 11

Typical transcript of the initial new warfarin education session

Good morning/afternoon, my name is Judy Mullan and I am the pharmacist who has come to speak to you about your warfarin medication and to help you understand:

- What warfarin is, how it works and how to take it properly.
- What to do if you miss a dose.
- Why regular blood tests are important and what the results mean.
- What the possible side effects are and when to look for medical help.
- Why you need to tell other healthcare providers about your warfarin.
- What other factors such as medicine, food and alcohol can affect your warfarin dose.

Remember that we are working in a partnership and if you have any concerns or questions please ask me at anytime. Also, remember that if you follow our instructions, take your warfarin properly and refer to this booklet, you will help stop any problems developing from your warfarin therapy.

After the education session you will be expected to manage your own warfarin therapy at home. It is important for us to know whether you intend to take your warfarin tablets regularly and follow the recommendations you are about to learn?

- If Yes – continue with the education session
- If No - explain potential problems and make an appointment for them to speak to the medical practitioners

Before we begin the session, I would like to ask you a few questions about what you know about warfarin, so that I can get an idea about how much you may or may not already know.

Complete Warfarin pre-test questionnaire (Appendix 15).
The purpose of this questionnaire is also to evaluate the patients’ perceptions about warfarin and whether or not they have any fears associated with taking warfarin medication. If they do, attempts should be made to reduce their negative perceptions and/or fears by using encouragement, reassurance and reinforcement, as well as providing positive feedback. Giving examples of many similar cases to theirs, which have been successfully treated with warfarin therapy also often helps relieve anxieties and fears.

Once the patient is comfortable and confident with the idea of continuing with warfarin therapy, the education session resumes with the key points underlined in the new warfarin booklet, also provided as a visual guide.

Warfarin and how it works

Warfarin is an anticoagulant and is sometimes called a ‘blood thinner.’ It can save your life because it slows down the clotting process and stops harmful clots forming. Blood clots can be harmful because they can travel through blood vessels to other parts of the body, such as the lungs and brain. If a blood clot reaches the blood supply to the brain, it may cause a stroke.

Warfarin starts to work 24 hours after taking a dose, but its full effect may take between 72 and 96 hours. On the other hand, the effects of a single Warfarin dose can last between 2-5 days.

Patients are then informed about why their warfarin has been prescribed for them e.g. preventing harmful clots for atrial fibrillation, helping the body to dissolve a deep venous thrombosis etc. They are also reminded that although good warfarin compliance reduces the development of harmful clots, poor compliance can lead to the development of clots.

Warfarin Brands

Your doctor has ordered your warfarin dose in milligrams (mg). In Australia, there are two different brands of warfarin, known as ‘Coumadin’ and ‘Marevan.’ TACT has given you the ‘Coumadin’ brand (Tick the Coumadin box).
However, you need to know that the ‘Marevan’ brand is also available. Unless your doctor tells you to change brands in the future, you are to keep taking the ‘Coumadin’ brand of warfarin after you are discharged from our service. To make sure you are taking the right tablets always check the brand, colour and strength.

*Patients are then advised which dose of warfarin to take that night and reminded that the dose may vary, depending on the INR blood test results. To ensure that patients know how to manage their doses appropriately, they are asked to make up possible doses of 9mg, 8mg, 4mg and 3mg, using the warfarin 1mg, 2mg and 5mg tablets given to them.*

**How to take warfarin**

You should always take the exact warfarin dose ordered by your doctor at the same time every day. We recommend that you take your warfarin tablets in the evening, swallowed whole with a glass of water, either before or after food, whichever you prefer. Don’t stop taking the tablets or change the dose unless your doctor tells you to.

The most important thing to remember is to take your warfarin every day. If you think you will have trouble remembering to take your warfarin, we recommend that you use a reminder such as a calendar, an alarm clock, a mobile phone alarm or special tablet boxes.

*Patients will be asked what time of day they intend to take their warfarin therapy. If the patient is unsure or chooses an inappropriate time, then they will be encouraged to have an evening dose at approximately 6pm.*

**What to do if you miss a dose?**

If you forget to take a dose at the normal time but then remember within about three hours, you should still take the tablets. However, if you forget for a longer time do not take a dose, just take your next normal dose when it is due. Never take a double dose because this could thin the blood too much and cause
serious bleeding side effects. If this ever happens write down the date and time you missed your dose in this booklet and tell your doctor that you missed a dose at your next visit or when you have your blood test. Otherwise, contact your doctor or pharmacist if you are not sure what to do.

Why are regular blood tests important?

Different people need different warfarin doses to control their blood’s clotting power and the only way we can work out this dose is from your blood test results. The blood test is called an INR test or International Normalised Ratio test and it shows how long it takes your blood to clot. You will need to have regular INR blood tests so that your doctor can prescribe you the correct warfarin dose.

Generally your INR results should be between 2 and 3. A low INR (below 2) means that your blood may not be thin enough and clots can continue to grow, whereas an INR above 3 (and in some situations above 3.5) may mean that your blood is a little too thin and the dose of warfarin needs to be lowered before any bleeding side effects occur.

You must always follow your doctor’s orders for regular INR blood tests, as well as writing down your INR blood test results on pages 18-21 of this booklet within 24 hours of the test.

Patients are reminded that their dose may need to be adjusted according to their INR blood results. Therefore, blood results outside of this therapeutic range (generally 2-3) need to be addressed immediately so that dosage adjustments can be made and optimal therapeutic outcomes achieved. Also, patients are reassured that regular blood tests, visits to the doctor and complying with the recommendations in the booklet will help to stop any of these problems developing.

The researcher/pharmacist takes the time to fill in the patient’s first few warfarin doses, on pages 18-21 of the new warfarin booklet. She also shows them where to fill in their own INR results, warfarin dosage and appointment times in the
future. Patients are encouraged to keep these records as valuable information for themselves, their medical practitioner and specialists.

Possible side effects and when to look for medical help

Warfarin does thin the blood and therefore can increase the incidence of bleeding and bruising which you will notice straight away. There are, however, some very important signs of serious bleeding, which you need to know about.

The early warning signs of serious bleeding include:

- nosebleeds
- bleeding gums
- dark red or dark brown urine
- red or black faeces (dark stools)
- cuts that bleed for a much longer time
- unexplained bruising or other bleeding

If you notice any of these, contact your doctor or local emergency department immediately because the earlier a problem is found, the easier it is to solve. You will also need to tell your doctor about any of the following symptoms; vomiting, diarrhoea, pain, swelling and shortness of breath, because these can also affect, or be the effects of, inadequate warfarin therapy.

Patients are reminded that even though the likelihood of serious bleeding complications are rare when the recommendations are followed and regular blood tests are performed, in the event that they should occur, immediate medical attention needs to be sought.

Inform other healthcare providers

Your will need to inform all your healthcare providers, including: specialists; doctors; dentists; pharmacists; nurses; physiotherapists; massage
therapists; other healthcare workers; friends and relatives who look after you, that you are taking warfarin tablets.

Explain to patients that this is important because these healthcare providers may want to undertake a procedure or give medications which could result in an adverse event (e.g. bleeding) when used in combination with the warfarin therapy.

You might like to consider wearing Medic Alert jewellery (e.g. bracelets or pendants) available from your pharmacy, to let others know that you take warfarin tablets.

This should especially be encouraged when patients are elderly, live alone and/or have any cognitive and physical limitations.

What else can affect your warfarin dose?

Other medicine(s), food and alcohol can affect how warfarin works. Tell your doctor if there are any big changes in the medicine, alcohol or food that you normally take because these can affect your warfarin dose.

Patients are then given the ‘Patient information on potential drug-to-drug warfarin interactions’ (Appendix 27), which is used as a visual guide while talking about the following possible interactions.

Some examples of medicines which can affect the way warfarin works include:

- Prescription medicines - old and new medicines, in particular antibiotics and heart medication such as Amiodarone.
- Non-prescription medicines – medicines bought in the chemist, supermarket or health food store.
  - pain relievers (e.g. aspirin and NSAID such as ibuprofen)
To ensure that patients have understood, the researcher/pharmacist asks them which medications they could take and which medications they should definitely avoid taking, if they develop a headache or pain while on warfarin therapy.

- Natural and Herbal Preparations
  Many natural or herbal products can affect the way warfarin works. You should therefore talk to your doctor or avoid taking: garlic supplements; gingko biloba; herbal teas, especially 'Green Tea'; Chinese herbs, especially “Dong Quai”; St. John’s Wort and many other herbal preparations referred to in the “Patient information on potential drug-to-drug warfarin interactions” (APPENDIX 27).

- Vitamin Supplements
  Also talk to your doctor before taking vitamin supplements, because vitamins C, E, and K (especially high doses) can affect the way your warfarin works. Eating a well-balanced diet will provide you with enough vitamin supplements.

Ask the patient whether or not they are taking any of these or any other complementary medicines. If the answer is yes, highlight the potential interactions on their copy of the ‘Patient information on potential drug-to-drug warfarin interactions’ (Appendix 27) and suggest that they either cease taking them or talk to their general practitioner about taking them.
The researcher/pharmacist should now perform a medication review on all the patients’ medications including their complementary medicines, to ensure that there are no drug-to-drug interactions with their warfarin therapy. Advice about the timing of their doses should subsequently be given to patients to minimise the chances of any interactions. Any recommendations for changes in medications should be done in collaboration with the patient’s medical practitioners and/or other members of The Ambulatory Care Team.

- **Alcohol**
  Since alcohol can affect the warfarin dose you can drink alcohol in moderation (no more than 2 units per day) and avoid binge drinking.

- **Your Diet**
  Do not crash diet or binge-eat because your warfarin dose will be balanced with your eating habits. Most importantly Vitamin K has the opposite effect to warfarin, which is why you should eat no more than normal amounts of vitamin K rich foods. These foods include: green leafy vegetables (spinach, broccoli, lettuce, cabbage, brussels sprouts, alfalfa), canola, soybean and olive oils. We highly recommend that you have a well balanced diet and take in consistently small amounts of vitamin K rich foods.

Other things to consider
As already mentioned, warfarin can cause increased bleeding and bruising which is why you should avoid contact sports such as basketball, football and kick boxing.

*Ask patients if they play any contact sport and advise them accordingly.*

Pregnancy must be avoided (*Only discuss this when and if appropriate*). If you decide to go away on a holiday while you are still on your warfarin therapy, you will need to check with you doctor. You should always take enough
warfarin tablets with you and if you intend to stay for more than two weeks, you will need to organise INR blood tests while you are away.

**Handy Hints**

These are some handy hints for you while you are on your warfarin therapy:

- Since warfarin causes increased bleeding and bruising, try to avoid cutting yourself or bumping yourself
- Use a non-slip bath mat when bathing
- Use a soft bristle toothbrush
- Use gloves when gardening
- Use an electric shaver when shaving

We’ve now come to the end of the education session and I was wondering whether or not you had any questions or concerns you would like to discuss with me.

*If “yes”, the patient’s questions are to be answered using positive encouragement, reinforcement and reassurance.*

*If “no”, remind the patient that they can contact the TACT office, seven days a week between 8.30am and 9.30pm, if they have any concerns or queries regarding their warfarin therapy. The TACT telephone number on the back of the TACT information leaflet should be underlined.*

*Alternatively, recommend that patients contact the National Prescribing Service (NPS) medicines information line on 1300 888 763, Monday to Friday between 9am to 6pm (The fridge magnets containing these details should now be issued to the patients). Also inform patients of the relevant internet sites listed at the back of the warfarin information booklets; [http://www.nps.org.au](http://www.nps.org.au); [http://www.coumadin.com](http://www.coumadin.com) and [http://www.warfarininfo.com](http://www.warfarininfo.com)*

The researcher/pharmacist once again reinforces the key points of the education session as per the ‘Warfarin Counselling Checklist’ (APPENDIX 13) offering the
reassurance that if the warfarin therapy is taken properly, it will be safe and effective.

To make sure that you have understood what you have been taught, I would like to ask you a few questions.

- Why is it important not to miss a dose of warfarin and what should you do if you miss a dose?
- What brand of warfarin have you been given?
- What dosage of warfarin will you be taking today?
- Why is it important to have regular INR blood tests and what is your expected INR range?

Upon completion of these questions by the patients they are reminded about having to complete their questionnaires, both immediately and in three months time over the telephone.

Finally the patients are informed that the new warfarin booklets have been especially designed and printed for use in Judy Mullan’s Ph.D. project ‘To develop and trial a new warfarin education program to help improve warfarin knowledge, management and compliance in a wider warfarin prescribed population’ and if they would like further information regarding the project, to please contact:

Ms Judy Mullan
Graduate School of Public Health
Faculty of Health and Behavioural Science
University of Wollongong NSW 2500
Phone 02 4221 4274
APPENDIX 12

Warfarin
Information Booklet for Patients and their Carers
The purpose of this booklet is to help you understand:

- What is warfarin and how does it work?
- How to take warfarin?
- What to do if you miss a dose?
- Why are regular blood tests important?
- What are the possible side effects and when to look for medical help?
- Why you need to tell other healthcare providers about your warfarin?
- What other factors such as medicine, food and alcohol can affect your warfarin dose?

Remember that you are working in partnership with your doctor, pharmacist and any other healthcare providers.

By following your healthcare providers’ instructions, and referring to this booklet, you will help avoid any problems.
What is warfarin and how does it work?

- **Warfarin is an anticoagulant** (sometimes called a "blood thinner") which slows down the clotting process and stops harmful clots forming.

- **Blood clots can be harmful** because they can travel through blood vessels to other parts of the body, such as the lungs and brain.

- If a blood clot reaches the blood supply to the brain, it may cause a **stroke**.

- **Warfarin** begins to work within 24 hours after taking the drug. The **full effect may take 72 to 96 hours**. The anticoagulant effects of a single dose of Warfarin last 2-5 days.
Warfarin Brands

• Your doctor has ordered your warfarin dose in milligrams (mg).

• Warfarin tablets come in two different brands in Australia, Coumadin and Marevan

• Your doctor and pharmacist will tell you which brand to take.

• Always use the same brand - do not change brands unless your doctor tells you

• Take the right tablet by checking the brand, colour & strength
Doctor or Pharmacist to tick the brand prescribed for the patient – cross out the irrelevant brand

**Coumadin**

Coumadin tablets come in 3 different strengths, each has a separate colour and mg dose

- light tan 1mg
- lavender 2mg
- green 5mg

**Marevan**

Marevan tablets come in 3 different strengths, each has a separate colour and mg dose

- light brown 1mg
- light blue 3mg
- pink 5mg
How to take warfarin

Dosage:

• Take the exact warfarin dose ordered by your doctor.

• Do not stop taking the tablets or change the dose unless your doctor tells you to.

• Take the tablet(s) every day at the same time.

• Swallow whole warfarin tablet(s) with a glass of water.

• Warfarin can be taken with or without food.

If you have trouble remembering to take your warfarin, you can use reminders such as a calendar, an alarm clock, a mobile phone alarm or special tablet boxes.
What to do if you miss a dose

- **If you forget** to take a dose at the normal time but then
  - remember **within about three hours**, you should still **take the tablets**.
  - If you **forget for a longer time** do not take a dose, just take your next dose when it is due.
  - **Never take a double dose**

- Write down the date and time you missed your dose on page 19 and 20 of this booklet

- Tell your doctor that you missed a dose at your next visit or when you have your blood test.
  
  or

- Contact your doctor or pharmacist if you are unsure of what to do.
Why are regular blood tests important!

- Different people need different warfarin doses to control their blood’s clotting power.

- Your doctor will organize for you to have regular blood tests

- The blood test is called an INR or International Normalised Ratio test.

- The INR blood test shows how long it takes your blood to clot.

- The INR blood test results help your doctor to prescribe your correct warfarin dose
INR blood test results and the warfarin dose

Your warfarin dose is balanced according to your INR blood test results.

Low INR
“blood may be too thick”

INR RANGE

High INR
“blood may be too thin”

Remember to:

• Follow your doctor’s orders for regular INR blood testing.

• Call your doctor or laboratory within 24 hours of the test (or as instructed) to find out your result.

• Write down the test results on pages 18-19 of this booklet.
Possible side effects and when to look for medical attention

Contact your doctor or local emergency department if you notice any of these early bleeding warning signs:

• nosebleeds
• bleeding gums
• dark red or dark brown urine
• red or black faeces (dark stools)
• cuts that bleed for a much longer time
• unexplained bruising or other bleeding

Because the earlier a problem is found the easier it is to solve

Also tell your doctor immediately if you start:

• feeling sick (e.g. vomiting, diarrhoea, infection, fever) as this may affect the warfarin dose that you need.
• having any unusual symptoms such as pain, swelling, dizziness, discomfort or difficulty breathing.
Inform other healthcare providers.....

You should inform your:
- doctors, including specialists
- dentists
- pharmacists
- nurses
- physiotherapists
- other health workers and assistants
- friends & relatives who look after you

that you are taking warfarin especially before undergoing any procedure or surgery.

Optional: You can wear MedicAlert jewelry (e.g. bracelets and pendants available from your pharmacy.)
What else can affect the warfarin dose?

Other medicine(s), food and alcohol can affect how warfarin works. Tell your doctor if there are any big changes in the amount of medicine, food or alcohol that you normally take because these can affect your warfarin dose.

1. Other medicines which can affect the way warfarin works include:

- **Prescription medicines** - old and new medicines (e.g. antibiotics)

- **Non-prescription medicines** - you can buy in the chemist, supermarket or health food store including:
  - pain relievers (e.g. aspirin & ibuprofen)
  - cough & cold medicines
  - stomach remedies (e.g. antacids)
  - laxatives
  - some creams for tinea and rubs
  - vitamins
Before taking **ANY** medicine, you **MUST ASK** your doctor or pharmacist:

“**Is it OK for me to take this medicine while I am on Warfarin?**”
2. Natural & Herbal Preparations

Talk to your doctor before taking any natural or herbal products.
Avoid:
- Garlic supplements
- Gingko Biloba
- Herbal teas, especially ‘Green Tea’
- Chinese herbs, especially "Dong Quai"
- St. John’s Wort
- Other herbal products

3. Vitamin Supplements

Talk to your doctor before taking vitamin supplements.
**Vitamins C, E, and K** can affect the way your warfarin works.
Eating a well-balanced diet will provide you with enough vitamin supplements.

4. Alcohol

- Drink alcohol in moderation (no more than 2 units per day)
- Avoid binge drinking.
- Discuss with your doctor a safe amount to suit you
5. Your Diet
Eat a well balanced diet

Do not crash diet or binge eat - your warfarin dose will be balanced with your eating habits.

Vitamin K has the opposite effect to warfarin.

Eating regular normal amounts of vitamin K is the key to good control of your warfarin dose.

Eat normal amounts of vitamin K rich foods, which include: green leafy vegetables (spinach, broccoli, lettuce, cabbage, brussels sprouts, alfalfa).

Canola, Soybean and Olive oils are also rich in vitamin K
5. Your Diet

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# Patient Details

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<td>Name of Doctor</td>
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### Details of Therapy

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<th>Target INR (Normally 2.0-3.0)</th>
<th>Other details or special instructions</th>
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<th>Sat</th>
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<th>Next Visit or Test</th>
<th>Dose prescribed (mg)</th>
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Useful Sites for Further Information

The NPS medicines Line
1300 888 763
Independent information
Monday to Friday 9am to 6pm

http://www.nps.org.au
http://www.coumadin.com
http://www.warfarininfo.com

This information booklet has been designed specifically for use in the project:

"To develop and trial a new warfarin educational program which will improve warfarin compliance and understanding for a warfarin prescribed population"

For further information regarding the project, please contact:

Ms Judy Mullan
Graduate School of Public Health
Faculty of Health and Behavioural Science
University of Wollongong NSW 2500
Phone 02 42 214 274
Acknowledgements:

This booklet has been adapted with permission from the information booklet "Warfarin Medication information Booklet for Patients and their Carers " produced by Beata Bajorek for her PhD thesis "Stroke prevention in elderly patients with atrial fibrillation ".

The pictures included in the booklet were copied with permission from Jonathon Ellis from the DraxGroup Agency; http://www.woolworths.com; http://www.sos-talisman.com and http://www.epill.com

References:


Krass I & Bajorek B. (2002) "Have trouble explaining INR to warfarin patients?" Retail Pharmacy, April: 29-30

Mott Health Topics (2002). Coumadin (Warfarin), University of Michigan Health System.


APPENDIX 13

Warfarin Counselling Checklist (adapted from Witte, Gurwich et al 1980)

☐ Reason for anticoagulation (e.g. PE, DVT, AF, others)
☐ Explanation about what warfarin is and how it works
☐ Patient’s regimen
  Identification of warfarin brand, colour and strength
  Dosage, route and frequency of warfarin tablets
  Importance of compliance
  What to do if a dose is missed
☐ Emphasise the importance of regular INR blood tests
☐ Alert patients to warfarin-related side effects
  Bleeding/bruising
  Possible signs of warfarin toxicity
  Proper action to take in case of an emergency
☐ Tell all their healthcare practitioners about their warfarin regimen
  Encourage medical bracelets
☐ Inform patients about factors which can affect warfarin dosage
  Other medications - prescribed
  - non-prescribed
  - complementary
  Alcohol
  Diet
  Exercise
  Avoid Pregnancy - when and if applicable
☐ Note that patients should use:
  Non-slip mats in the bath/shower
  Soft bristle toothbrush
  Garden gloves
  Electric razor instead of blades
☐ Reassurance
  Warfarin therapy, when taken properly, is safe and effective
  Careful monitoring is essential: regular INR blood tests; visits to the GP;
  and documentation of all INR results
APPENDIX 14

New Warfarin Education Program Objectives (Witte, Gurwich, Anzalone and Campagna 1980; Wyness 1990; Haines 1998)

Overall Goal: The patient takes warfarin effectively and safely.

1. Understands what the warfarin does
   1.1 explains the action of the warfarin
   1.2 explains the reason for taking the warfarin
   1.3 explains how quickly the drugs works

2. Understands how to take the warfarin safely
   2.1 explains how to take the warfarin
   2.2 explains the frequency of taking the warfarin
   2.3 predicts the optimum time of day for taking the warfarin
   2.4 explains use of an aid (e.g. calendar, alarm device) to remember to take warfarin and to record INR results
   2.5 identifies the action to take if a dose is missed or may have been missed
   2.6 explains that warfarin may be prescribed using generic and trade names
   2.7 explains the reason the same brand of the drug should be used consistently
   2.8 explains who will prescribe the warfarin and when
   2.9 explains the importance of identifying the correct tablet by checking the brand, colour and strength in milligrams

3. Understands facts about the INR test
   3.1 describes the term INR (International Normalised Ratio)
   3.2 states the need to go to a laboratory for regular INR tests
   3.3 explains the reason INR is measured
   3.4 explains the relationship of INR to amount of drug prescribed
   3.4 describes the procedure for obtaining INR results and recording them appropriately
   3.5 explains the goal international normalised ratio
   3.6 explains the reasons accurate drug-taking is essential
   3.7 explains potential consequences associated with a low INR
   3.8 explains potential consequences associated with a high INR

4. Understands possible side effects and what should be done if they occur
   4.1 identifies signs of bleeding to report
   4.2 explains bruises may occur easily and indications for reporting
   4.3 identifies any symptoms or illness to report
   4.4 identifies all health care workers e.g. dentist, pharmacist and podiatrist as individuals to notify
   4.5 identifies the need to inform all health professionals prior to surgery
4.6 identifies the benefits for carrying identification card and wearing Medic Alert tag

5. Understands factors affecting anticoagulant dosage

5.1 Other medications

5.1.1 identifies prescription medicines new and old can alter the effects of warfarin

5.1.2 identifies nonprescription medicines (including complementary medicines) can alter the effects of warfarin

5.1.3 explains that prior to taking any medication (prescribed or non-prescribed) the patient should check with their doctor or pharmacist

5.1.4 explains that many natural and herbal preparations can alter the effects of warfarin

5.1.5 explains that vitamin supplements, especially vitamins C; E and K, can alter the effects of warfarin

5.1.6 explains the effect of alcohol

5.2 Diet

5.2.1 explains the reason for maintaining a similar day-to-day dietary intake

5.2.2 explains the effect of vitamin K on action of warfarin

5.2.3 gives examples of foods high in vitamin K

5.3 Lifestyle

5.3.1 explains hazards of physical injury when taking oral anticoagulants

5.3.2 identifies activities such as sewing, gardening, kitchen activities, sports, use of power tools, as areas for caution

5.3.3 identifies activities of daily living that may need to be modified to prevent injury

5.3.4 explains action to take if travel is planned

5.3.5 identifies the dangers of pregnancy whilst prescribed warfarin

6. Demonstrates commitment to ongoing knowledge and safety.

6.1 proposes adaptations to be made in lifestyle as necessary

6.2 suggests other possible sites for gathering warfarin information

6.3 states expected duration of the warfarin regimen
APPENDIX 15

Pretest Questionnaire
(Circle one response Answered by patient carer patient and carer)

Question 1
Have you ever taken warfarin before?

Question 2
Do you know anything about warfarin? Yes or No.

If No. Go directly to education session
If Yes.

a. How does warfarin work?

b. Does warfarin have any side effects?

c. How and when should warfarin be taken?

d. What else do you know about warfarin?
APPENDIX 16

Patients Demographic Data Sheet

Date…………………………………

Client ID……………………………Intervention/Control .

Family Name…………………………… Given Name …………………

Address……………………………………………………………………………………

Suburb…………………………………Telephone…………………………………………

DOB……………… Sex  M / F Weight…………………………

Occupation………………………………………Educational Level………………

Allergies……………………………………

Other Medications

……………………………………………………………………………………………………

……………………………………………………………………………………………………

……………………………………………………………………………………………………

Referral source……………………………GP Name…………………………

Date of Commencement……………………………………………………………………

Referral Diagnosis…………………………………………………………………………

Past Medical Surgical History……………………………………………………………

……………………………………………………………………………………………………

Relevant Investigation and results (e.g. Doppler) ………………………………………

Next of Kin/Carer…………………………Present at Educational Session  Yes/No

Language spoken at home…………………………Country of Birth…………………

Interpreter needed Yes/ No

Aboriginal or Torres Strait Islander Yes / No
APPENDIX 17

‘Self-Management’ Questionnaire (adapted from Lorig, Stewart, Ritter, Gonzales, Laurent and Lynch 1996)

(Circle one response Answered by patient carer patient and carer)

1. How confident are you that you can take warfarin tablets correctly?

Not at all confident  1  2  3  4  5  Totally confident

2. How confident are you that you can recognise serious bleeding side effects which need medical help?

Not at all confident  1  2  3  4  5  Totally confident

3. How confident are you that you can self-manage your warfarin at home? (hint: especially with regard to your diet, alcohol and/or other medications)

Not at all confident  1  2  3  4  5  Totally confident

4. How confident are you that you know and understand the information given to you about warfarin?

Not at all confident  1  2  3  4  5  Totally confident

5. Are you worried about taking warfarin tablets?

( ) No ( ) Yes

If yes

I. What is it about taking warfarin tablets that worries you?

II. Has the warfarin education program affected your worries about taking warfarin tablets?

III. Other comments

6. Ask the carer (if present) for any comments about the education program or their concerns about the warfarin tablets.
Appendix 18

‘Medication-Taking-Measures’ Questionnaire (Morisky, Green and Levine 1986)

(Circle One response Answered by patient carer patient and carer)

Please circle “Yes” or “No” for each question:

1. Do you ever forget to take your medicine? Yes No

2. Are you careless at times about taking medicine? Yes No

3. When you feel better do you sometimes stop taking your medicine? Yes No

4. Sometimes if you feel worse when you take the medicine, do you stop taking it? Yes No

Comments

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

Scoring: This scale is designed to test medication compliance. To score, code “Yes”=0, “No”=1. The sum of the answers is the score. A score of 4 is considered high compliance, 3 is moderate compliance, and 2 or less is low compliance.
APPENDIX 19

‘Warfarin Knowledge’ Questionnaire *(adapted from Scalley, Kearney and Jacobs 1979; Witte, Gurwich et al. 1980; Wyness 1990; Horne, Hankins and Jenkins 2001)*

(Circle one response Answered by  patient  carer  patient and carer)

Question 1
Which brand of warfarin is prescribed for you?

Question 2
Why is the warfarin prescribed for you?

Question 3
How does the warfarin work?

Question 4
What are the different strengths and colours of your warfarin tablets?

Question 5
How will you know what dose of warfarin to take?

Question 6
How and when should you take your dose of warfarin?

Question 7
What should you do if you forget to take your dose of warfarin?

Question 8
Can you suggest two things which you could use to remind you about taking your warfarin tablets if necessary?

Question 9
Why should you have regular INR (International Normalised Ratio) blood tests?

Question 10
What is your target INR blood test range?

Question 11
1. What are FOUR signs of bleeding from too much warfarin?
2. What should you do if you notice any of these side effects?
**Question 12**
Why is it necessary to tell your doctor about starting or stopping any other medicines, including prescribed medicines (e.g. antibiotics), non-prescribed medicines (e.g. cold and flu tablets) and herbal or vitamin preparations?

**Question 13**
1. Do you need to tell your dentist that you are taking warfarin?
2. Should you tell any of your other healthcare providers that you are taking warfarin?

**Question 14**
Which medicine could you take for pain relief (e.g. a headache) while taking warfarin?

**Question 15**
Are there any foods that can affect how warfarin works?

**Question 16**
Is it safe to drink alcohol while taking warfarin?

**Question 17**
Name TWO activities or things you need to be careful doing while taking warfarin?
APPENDIX 20

Satisfaction with Information About Medicines Scale (SIMS)

(Horne, Hankins et al. 2001)

We would like to ask you about the information you have received about your medicines. Please rate the information you have received about each of the following aspects of your medicines. If you use more than one medicine, please give your overall feeling about information you have received about all your medicines.

(Rated: too much, about right, too little, none received, none needed).

1. What your medicine is called.
2. What your medicine is for.
3. What it does.
4. How it works.
5. How long it will take to act.
6. How you can tell if it is working.
7. How long you will need to be on your medicine.
8. How to use your medicine.
9. How to get a further supply.
10. Whether the medicine has any unwanted effects (side effects).
11. What are the risks of you getting side effects?
12. What you should do if you experience unwanted side effects.
13. Whether you can drink alcohol whilst taking this medicine.
14. Whether the medicine interferes with other medicines.
15. Whether the medication will make you feel drowsy.
16. Whether the medication will affect your sex life.
17. What you should do if you forget to take a dose.

Other information (please specify below)
APPENDIX 21

Outcome Measures Of The Warfarin Education Program Questionnaire
(adapted from Lorig, Stewart et al. 1996 page 53-55)

1. In the past three months have you tried to find out more information about your warfarin therapy? ( ) No ( ) Yes

   If yes:
   i. Where did you go for this information? e.g. general practitioner, NPS medicines number, internet, etc
   ii. How many hours did you spend looking for this information?
       1 = None
       2 = 1 - 5 hours
       3 = 6 - 10 hours
       4 = 11 or more hours

2. In the past three months how many times did you visit your doctor?

   How many visits _______________

3. In the past 3 months how many times did you stay in a hospital overnight or longer?

   ( ) None _____ times

   How many nights in total did you stay in a hospital?
   ( ) None _____ nights

   Reason for hospitalisation ____________________________________________

4. In the past three months did you visit the emergency department?

   ( ) None How many visits __________

   Reason for emergency department visit (s) ____________________________

5. In the past three months have you had any warfarin related side effects (e.g. nose bleeds, blood in urine)? ________________________________

6. Record your INR values over the three-month period.
APPENDIX 22

DISCERN

(Charnock, Sheppard et al 1999; Shepperd and Charnock 2002)

SECTION 1: Is the publication reliable?

1. Are the aims clear?

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Hint: Look for a clear indication at the beginning of the publication:
- What it is about
- What it is meant to cover (and what topics are meant to be excluded)
- Who might find it useful

If the answer to Question 1 is “No”, go directly to Question 3

2. Does it achieve its aims?

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Hint: Consider whether the publication provides the information it aimed to as outlined in Question 1

3. Is it relevant?

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Hint: Consider whether:
- The publication addresses the questions that readers might ask
- Recommendations and suggestions concerning treatment choices are realistic or appropriate

4. Is it clear what sources of information were used to compile the publication (other than the author or producer)?

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Hint:
- Check whether the main claims or statements made about treatment choices are accompanied by a reference to the sources used as evidence e.g. a research study or expert opinion
- Look for a means of checking the sources used such as a bibliography/reference list of the addresses of the experts or organisations quoted, or external links to the online sources
Rating Note: In order to score a full ‘5’ the publication should fulfill both hints. Lists of additional sources of support and information (Question 7) are not necessarily sources of evidence for the current publication.

5. Is it clear where the information used or reported in the publication was produced?

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Hint Look for:
- Dates of the main sources of information used to compile the publication
- Dates of any revisions of the publication (but not dates of reprinting in the case of print publications)
- Date of publication (copyright date)

Rating note: The hints are placed in order of importance - in order to score a full ‘5’ the date relating to the first hint should be found.

6. Is it balanced and unbiased?

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Hint: look for:
- A clear indication of whether the publication is written from a personal or objective point of view
- Evidence that a range of sources of information were used to compile the publication e.g. more than one research study or expert
- Evidence of an external assessment of the publication

Be wary if:
- The publication focuses on the advantages or disadvantages of one particular treatment choice without reference to other possible choices
- The publication relies primarily on evidence from single cases (which may not be typical of people with this condition or of responses to a particular treatment)
- The information is presented in a sensational, emotive or alarmist way

7. Does it provide details of additional sources of support and information?

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Hint: look for suggestions for further reading or for details of other organisations providing advice and information about the condition and treatment choices.
8. Does it refer to areas of uncertainty?

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Hint:
- Look for discussion of the gaps in knowledge or differences in expert opinion concerning treatment choices
- Be wary if the publication implies that treatment choice affects everyone in the same way, e.g. 100% success rate with a particular treatment

SECTION 2: How good is the quality of information on treatment choices?

N.B. The questions apply to the treatment (or treatments) described in the publication. Self-care is considered a form of treatment throughout this section.

9. Does it describe how each treatment works?

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Hint: Look for a description of how a treatment acts on the body to achieve its effect

10. Does it describe the benefits of each treatment?

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Hint: Benefits can include controlling or getting rid of symptoms, preventing recurrence of the condition and eliminating the condition, both short-term and long-term

11. Does it describe the risks of each treatment?

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Hint: Risks can include side effects, complications and adverse reactions to treatment, both short-term and long-term

12. Does it describe what would happen if no treatment is used?

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Hint: Look for a description of the risks and benefits if postponing treatment, of watchful waiting (i.e. monitoring how the condition progresses without treatment) or of permanently forgoing treatment
13. Does it describe how the treatment choices affect overall quality of life?

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Hint: Look for

- Description of the effects of the treatment choices on day-to-day activity
- Description of the effects of the treatment choices on relationships with family, friends and carers

14. Is it clear that there may be more than one possible treatment choice?

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Hint: Look for:

- A description of who is most likely to benefit from each treatment choice mentioned, and under what circumstances
- Suggestions of alternatives to consider or investigate further (including choices not fully described in the publication) before deciding whether to select or reject a particular treatment

15. Does it provide support for shared decision-making?

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Hint: Look for suggestions of things to discuss with family, friends, doctors or other health professionals concerning treatment choices

SECTION 3: Overall rating of the publication

16. Based on the answers to all of the above questions, rate the overall quality of the publication as a source of information about treatment choices

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<td>1</td>
<td>2</td>
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<td>Potentially important but not serious shortcomings</td>
<td>4</td>
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<tr>
<td>Minimal shortcomings</td>
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APPENDIX 23

UNIVERSITY OF WOLLONGONG

Research Information Sheet For Illawarra Health Staff

RESEARCHER: Judy Mullan (Ph.D. student)
SUPERVISORS: Assoc Professor Heather Yeatman  
Professor Patrick Crookes
DEPARTMENT: Graduate School of Public Health

My name is Judy Mullan and I am undertaking research toward my Ph.D. in the Graduate School of Public Health at the University of Wollongong. I am employed by Illawarra Health as a part-time pharmacist with The Ambulatory Care Team (TACT). My background in pharmacy has led to a special interest in patient education, especially with regard to warfarin, which is the focus of this research.

The purpose of this research study is to develop and trial a new patient warfarin education program based on a conceptual framework, which reflects ‘best evidence’ with regard to patient medication education programs. The new program will be compared and contrasted against the customary warfarin education program delivered to TACT patients who are prescribed the oral anticoagulant warfarin.

This comparative analysis will assist with the evaluation of the new program and its impact on warfarin knowledge, management and compliance for the wider warfarin prescribed population. This population includes the ‘high risk’ patient populations such as the elderly, those with low literacy skills and those from non-English speaking backgrounds.

Overview of the Research Study

- **Eligible Participants:** Patients admitted to TACT, who are newly prescribed warfarin, or who have recommenced on warfarin after at least 15 years, will be considered eligible participants. They will be made aware of the fact that their participation in the research study is voluntary and that they are free to withdraw from the study at any time. They will also be notified that their refusal to participate in the study or their withdrawal from the study will not detrimentally affect their Illawarra Health TACT service in any way.

- **Participant Demographic Data:** Routinely collected by the TACT pharmacists from the patients, their notes and the Dracis database will provide important patient medical information which can be used to ensure optimal therapeutic management and outcome evaluation. An analysis of the demographic patient information will also help establish whether or not demographic variables have impacted on the outcomes of the different patient warfarin education programs.
Throughout the research process the patients’ names will be coded and all the demographic data will remain confidential and locked in a secured cabinet at the University of Wollongong.

- Warfarin Education Sessions: These will take place in the patients’ homes, or at an alternative place specified by the patient. The 50 intervention patients will receive the new warfarin education program and the 50 control patients will receive the customary warfarin education program, each of these education sessions will take approximately 30 minutes.

Evaluation of the Patient Participants

- Immediately and three months after the initial warfarin education session, all consenting patient participants will be asked to complete four questionnaires which will take approximately 20 minutes. The initial questionnaires will be answered immediately after the education session and the three-month follow-up questionnaires will be answered over the telephone. These questionnaires relate to warfarin self-management, warfarin compliance, warfarin knowledge and understanding, as well as satisfaction with the warfarin information provided.

- During the three-month telephone follow-up, patients will be asked to complete their evaluation questionnaires, as well as their outcome measures questionnaire. The latter asks questions about INR results and health care visits (e.g. general practitioner, hospital and emergency department visits.)

If you have any enquiries about the research, please contact myself or my supervisors and we will gladly help with any questions or concerns pertaining to this research.

Researcher: Judy Mullan (e-mail jmullan@uow.edu.au, mobile 0412175029)

Supervisors: Associate Professor Heather Yeatman (02) 4221 3555
Professor Patrick Crookes (02) 4221 3123

Looking forward to your cooperation with this research,

Judy Mullan
APPENDIX 24
Suggested Dialogue for Patient Recruitment and Obtaining Consent

"Judy Mullan, one of the TACT pharmacists, is currently researching ways in which to improve the warfarin education delivered by TACT. This involves obtaining information from our patients that will assist with improving the educational services we deliver. If you are interested in participating in the research study I will provide you with an information sheet and explain the process to you. Would you like me to give you more information?"

*If the answer is No*—thank them for their kind consideration and inform them that their care will not be compromised in any way.

*If the answer is YES*—give the patient a ‘Patient Participant Information Sheet’ and proceed.

“This is the information sheet that has all the details of the research study. You can keep this for your own reference, however I will now read through the details with you” *(read through and explain the information on the sheet).*

*On completion of reading the ‘Patient Participant Information Sheet’ continue with:*

“Because this is a research study, your written consent is required for you to be an active participant and so the information you provide can be used. This is the consent form which is written in the standard format for Illawarra Health and the University of Wollongong” *(show patients the ‘Patient Participant Consent Form’ and then read through and explain the information on the consent form).*

*If the patient gives verbal consent, ask them to sign in the space provided, also enter the date. Ensure that the patient receives and keeps the ‘Patient Participant Information Sheet’.*

“A TACT pharmacist will contact you by telephone to make an appointment for the warfarin education session which will take place in your own home, or an alternative place which you prefer, at a time that suits you.”

“Do you have any questions about the research study?” *(Answer if possible, if not assure them that the pharmacists will address any of their concerns).*

“Thank you for your support and cooperation.”
APPENDIX 25

UNIVERSITY OF WOLLONGONG
Patient Participant Information Sheet

RESEARCHER: Judy Mullan
SUPERVISORS: Associate Professor Heather Yeatman
Professor Patrick Crookes
DEPARTMENT: Graduate School of Public Health,
The University of Wollongong

Judy Mullan is a pharmacist working for Illawarra Health’s The Ambulatory Care Team (TACT), doing research toward her Ph.D. in the Graduate School of Public Health at the University of Wollongong. Her background in pharmacy has led to a special interest in patient information, especially with regard to warfarin, which is the focus of this research.

The research study aims to provide a new warfarin education program, which will help to improve warfarin knowledge, management and compliance for a wider warfarin prescribed population. To gain this information, she is inviting you to take part in the study where you will be given either the customary or the new warfarin education program. The education session will be given at a time and place you choose, preferably your own home, and throughout the study your name and everything you say and write will remain confidential.

At the completion of the education session you will be asked to complete four questionnaires on two separate occasions, immediately and three months after the education session. The initial education session and the questionnaires will take approximately 30 minutes each and the answers will be recorded and evaluated with your approval. You will be contacted by telephone to complete the three-month follow-up questionnaires and you will also be asked a few questions
relating to your health outcomes. The health outcome questions will be about your INR results, general practitioner visits, hospital visits and possible warfarin-related adverse drug events.

Your participation in this research study is voluntary and you are free to withdraw at any time. If you choose to participate in the research study you will be asked to give your permission for the researcher to view your medical records, including the information available on the Dracis database, as well as your blood test results from your pathology service if you do not have your own records available. Also, if you choose to withdraw from the research study at any time, you will be allowed to withdraw all your personal data if you so wish. Upon withdrawal from the research study your refusal to participate or withdrawal of consent will not in any way affect the service provided to you by The Ambulatory Care Team (TACT).

If you have any enquiries about the study, please contact Judy Mullan or her supervisors and they will gladly help you with any queries or concerns you may have in relation to this research study.

Researcher/ Pharmacist Judy Mullan 0412175029 (mobile) 
e-mail jmullan@uow.edu.au

Supervisors: Associate Professor Heather Yeatman 02 4221 3555
Professor Patrick Crookes 02 4221 3123.

If you have any concerns or complaints regarding the way the research study is or has been conducted, you can contact the Complaints Officer, Human Research Ethics Committee, University of Wollongong on (02) 4221 4457.

Looking forward to your involvement in this research, 
Judy Mullan
APPENDIX 26

UNIVERSITY OF WOLLONGONG

Patient Participant Consent Form

RESEARCHER: Judy Mullan (0412175029; e-mail: jmullan@uow.edu.au)

SUPERVISORS: Associate Professor Heather Yeatman (02 4221 3555)
Professor Patrick Crookes (02 4221 3123)

DEPARTMENT: The Graduate School of Public Health

TITLE: To develop and trial a new warfarin education program which will help to improve warfarin knowledge, management and compliance for a wider warfarin prescribed population.

I have been given information about the proposed study and have discussed the research project ‘To develop and trial a new warfarin education program which will help to improve warfarin knowledge, management and compliance for a wider warfarin prescribed population’ with a TACT staff member. I understand that this research is being conducted as part of a Ph.D. study in the Graduate School at the University of Wollongong.

I understand that if I consent to participate in the project, I will be expected to participate in a warfarin education program, complete evaluation questionnaires and a telephone questionnaire within a 3-month period. I have been informed that my responses will be recorded and evaluated. I have also been informed that anything I say will be kept confidential and my name will not be revealed to anyone. I have been advised of the potential risks and burdens associated with this research and have had an opportunity to ask the TACT staff member about any questions I may have with regard to the research and my participation.
I understand that my participation in this research is voluntary, which means that I am free to refuse to participate and I am free to withdraw from the research at any time. My refusal to participate or my withdrawal of consent will not affect my treatment or health care in any way.

I am aware that if I have any enquiries about the research study, I can contact Judy Mullan, Associate Professor Heather Yeatman and Professor Patrick Crookes (4221 3555) for further information. Alternatively, if I have any concerns or complaints regarding the way the research is or has been conducted, I can contact the Complaints Office, Human Research Ethics Committee, University of Wollongong on 02 4221 4457.

By signing below I am indicating my consent to participate in the research entitled ‘To develop and trial a new warfarin education program which will help to improve warfarin knowledge, management and compliance in a wider warfarin prescribed population’ conducted by Judy Mullan, as it has been described to me in the information sheet and in discussion with me. I understand that the data collected from my participation will be used for the purpose of a thesis, conference presentations and journal publications, and I consent for it to be used in this manner.

Signed………………………………………………Date………………………
Name (please print)……………………………………………………………………
APPENDIX 27
Patient Information on drug-to-drug warfarin interactions

<table>
<thead>
<tr>
<th>Medicines Which Can Affect Warfarin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibiotics</td>
</tr>
<tr>
<td>Antifungals</td>
</tr>
<tr>
<td>Antiplatelet Agents</td>
</tr>
<tr>
<td>Aspirin (Solprin, Disprin, Astrix)</td>
</tr>
<tr>
<td>Clopidogrel (Iscover, Plavix)</td>
</tr>
<tr>
<td>Dipyridamole (Persantin)</td>
</tr>
<tr>
<td>Ticlopidine (Ticlid)</td>
</tr>
<tr>
<td>Non-Steroidal Antiinflammatory Drugs (NSAIDs)</td>
</tr>
<tr>
<td>including Cox 2 inhibitors</td>
</tr>
<tr>
<td>Celecoxib (Celebrex)</td>
</tr>
<tr>
<td>Diflunisal (Dolobid)</td>
</tr>
<tr>
<td>Ibuprofen (Brufen, Nurofen)</td>
</tr>
<tr>
<td>Indomethacin (Indocid)</td>
</tr>
<tr>
<td>Piroxicam (Feldene)</td>
</tr>
<tr>
<td>Rofecoxib (Vioxx)</td>
</tr>
<tr>
<td>Tenoxicam (Tilcotil)</td>
</tr>
<tr>
<td>Tiaprofenic Acid (Surgam)</td>
</tr>
<tr>
<td>Salicylate Creams, Ointments and Liniments</td>
</tr>
<tr>
<td>Deep Heat</td>
</tr>
<tr>
<td>Dencorub</td>
</tr>
<tr>
<td>Metsal</td>
</tr>
<tr>
<td>Tramadol (Tramal)</td>
</tr>
</tbody>
</table>

Please Note: This is not a comprehensive or exhaustive list. Contact your pharmacist for further information.
COMPLEMENTARY MEDICINES WHICH CAN AFFECT WARFARIN

<table>
<thead>
<tr>
<th>↑ Effect of warfarin (↑ INR)</th>
<th>↓ Effect of warfarin (↓ INR)</th>
<th>↑ Bleeding risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Danshen (salvia miltiorrhiza)</td>
<td>• Coenzyme Q_{10}</td>
<td>• Feverfew (tanacetum parthenium)</td>
</tr>
<tr>
<td>• Devil’s claw (harpagophytum)</td>
<td>• Ginseng</td>
<td>• Ginko (ginkgo biloba)</td>
</tr>
<tr>
<td>• Dong Quai (angelica sinesis)</td>
<td>• Green Tea</td>
<td>• Ginger (zingiber officinalis)</td>
</tr>
<tr>
<td>• Garlic (allium sativum)</td>
<td>• St John’s Wort (hypericum perforatum)</td>
<td>• Korean ginseng (panax ginseng)</td>
</tr>
<tr>
<td>• Ginkgo (ginko biloba)</td>
<td>• Vitamin C</td>
<td>• Liquorice (glycyrrhiza glabra)</td>
</tr>
<tr>
<td>• Papain (papaya extract)</td>
<td>• Vitamin K</td>
<td></td>
</tr>
<tr>
<td>• Vitamin E</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Many herbs contain coumarins that may increase the activity of warfarin

• Alfalfa (medicago sativa)
• Angelica (angelica archangelica)
• Aniseed (pimpinella anisum)
• Arnica (arnica Montana)
• Asafoetida (ferula spp.)
• Bedstraw (galium Odoratum)
• Celery (apium graveolens)
• Fenugreek (trigonella foenum-graecum)
• German chamomile (matricaria recutita)
• Horse chestnut (aesculus hippocastanum)
• Prickly ash (zanthyoxylum americana,z.clava-herculis)
• Quassia (picrasma excelsa) Red clover (trifolium pratense)
• Roman chamomile (anthemis nobilis) Sweet clover (melilotus spp)

Please Note: This is not a comprehensive or exhaustive list. Contact your pharmacist for further information

References:
http://www.clinical.caregroup.org/altmed/interactions/Drugs/Warfarin.html;
http://altmedicine.about.com/library/bl092400warfrain.html
Hello my name is Marion Townsend and I am one of the TACT pharmacists. I have come to talk to you about your warfarin medication. Firstly, I would like to assure you that warfarin has been proven to be effective in conditions such as yours, *(add in patients diagnosis)*. These and many other people take warfarin and get benefit from it without any problems.

Warfarin does, however, have some disadvantages in that:

- it takes a while to have its full effect.
- blood tests called the INR are necessary to see if it is working properly and the dose adjusted accordingly. The tests are done daily to start with, after the third dose of warfarin has been taken. As the INR stabilises, to between two and three, the frequency of blood tests reduces. However, as long as you are on warfarin, the INR must be tested at regular times.

There are two brands of warfarin ‘Coumadin’ and ‘Marevan’ and you have been started on the ‘Coumadin’ brand, so we recommend that you do not take the ‘Marevan’ brand, unless it is recommended by your doctor *(put a cross on the Marevan page)*.

The dose of Coumadin that will be prescribed for you is in milligrams (mg) and as you can see, tablets come in three different strengths and three different colours; 5mg is green, 2 mg is lavender and 1 mg light tan. The label on the bottle and its lid also match the colour of the tablets to help with identification.

You have been given warfarin to take because it stops harmful blood clots from forming. Warfarin is an anticoagulant and for warfarin to work properly you have to follow our and your doctor’s instructions, and tell us or your doctor about any changes in your condition.
What is an Anticoagulant

Anticoagulant drugs like warfarin help to prevent or treat thrombosis by decreasing the clotting power of the blood. The objective of your treatment is only to slow down the clotting process; if the blood was prevented from clotting altogether this would cause bleeding.

In order to do this safely and effectively, a careful check must be kept on the effect of the anticoagulant on your blood so that your doctor can prescribe the dosage that will keep the clotting process at the correct level.

Different people require different amounts of warfarin. Therefore, the dosage is tailored to you according to your blood test results and your blood tests are very important.

While on warfarin your doctor will ask you to have an INR blood test regularly. An INR test indicates how long blood takes to clot. A ‘normal’ INR i.e. the INR of a person not taking an anticoagulant, is approximately 1. When you take anticoagulants, the higher your INR, the longer your blood takes to clot. The lower your INR is toward 1, the closer it is to ‘normal’ blood. Changes in your warfarin dose will change your INR; however, these changes may not happen immediately. It can take four to five days before you have the full impact of a dose change on your INR. Your INR levels are very important as they help your doctor maintain the dose that suits you.

The three things to remember about INR testings are:

- have the INR test done every time it is ordered by your doctor.
- call your doctor or laboratory as instructed or within 24 hours of the test in case the warfarin dose needs adjusting.
- record the test results in the record section provided in this book.

Taking Warfarin

You must take your tablets at approximately the same time everyday as specified by your doctor. Warfarin can be taken before, during or after meals. By getting into the daily routine of marking a calendar after you have taken warfarin and not relying on your memory, you will be unlikely to miss a dose.
Missing a dose

If you forget to take a dose and then remember within two to three hours, you can still take your tablets. If you forget for a longer time, do not take the tablets to catch up, but take your next dose when it is due and tell your doctor or laboratory. Do not take a double dose.

Changes to your INR

Different things in your life affect how warfarin works on your blood. These things include; whether you are eating properly, other medicines you take, the amount of alcohol you drink and a new illness. The most important thing to remember is that when there is a big change to any of these things you must tell your doctor. The times these big changes usually occur is when you leave hospital and go home (make sure you arrange for a blood test soon after leaving hospital) and when you go away on holidays.

Other Medicines

The use of other medicines may interfere with the way warfarin works, therefore, keep in mind the following:

- Before taking any medicines, even prescribed by a doctor (or dentist), be certain to check with the doctor who is monitoring your warfarin dose.
- When we talk about medicines, we mean not only prescription medicines but anything you might buy (in a chemist or food store) for common colds, aches, pains and so on.
- It is especially important to check with your doctor or pharmacist before taking common medicines such as: aspirin; paracetamol or other pain medications; rubs and liniments; cold or cough preparations; certain stomach remedies (eg. antacids); laxatives; multivitamins containing vitamin K; and herbal medicines.
- Check with you pharmacist before buying any of these as they may affect your INR.
- If in the past you have been taking any drugs, even prescription medications such as the "Pill", be sure to check with your doctor
before taking them now because they might affect your response to warfarin.

**Diet Principles**

A well-balanced and varied diet is essential to everyone to maintain health and vitality, whether they are taking warfarin or not. This means that your diet should include: breads, cereals, fruit, vegetables, milk, cheese, yoghurt, lean meat, poultry, fish, legumes, nuts and eggs. Your diet should consist of only small amounts of sugar, butter, margarine and oil.

While taking warfarin you should maintain a well-balanced and consistent diet. You should avoid crash dieting and binge eating. As your dosage of warfarin has been adjusted to match your current eating pattern and lifestyle, it is important that any major changes be talked over with your doctor. You should also stabilise your intake of vitamin K because warfarin is affected by vitamin K. A high vitamin K intake in your diet can affect your response to warfarin and lower your INR significantly. You should therefore keep your intake of vitamin K-containing food relatively constant. This does not mean cutting these foods out of your diet but eating them in small to moderate quantities regularly (about half a cup or two to four tablespoons a serve).

The foods that are highest in vitamin K include the leafy green vegetables (not peas or green beans), soya beans, canola and olive oil.

**Vitamin and Herbal Supplements**

If you are taking dietary supplements check to see that they do not contain vitamin K. Large amounts of vitamin C (more than 5gms per day) and vitamin E greater than 400IU per day can also affect your response to warfarin. Herbal supplements and remedies often contain substances which may upset your INR balance by increasing your bleeding or increasing your risk of clotting while you are taking warfarin. You must discuss taking any supplements or herbal remedies with your doctor before starting them. Once you and your doctor decide the supplement is suitable for you, it is important that you take it regularly every day to maintain a stable INR. It is also important to let your doctor know if you stop taking any supplements as this may also affect your INR.
**Alcohol**
Use in moderation and avoid binge drinking. Discuss with your doctor a safe amount to suit you.

**Other important things for you to remember**

There are several additional things for you to keep in mind while working with your doctor to maintain the INR which is best for you.

- Take the exact number of anticoagulant tablets prescribed by your doctor.
- Don’t stop taking warfarin or change the dose unless your doctor tells you.
- Take the prescribed dose at approximately the same time each day. Try to connect taking it with something you do regularly e.g. meal time, bed time and use your calendar to keep track of the doses you take.
- If you forget to take a dose, call your doctor for advice.
- Tell your doctor right away if you develop any illness (for example diarrhoea, vomiting, infection or fever) as this may affect your dosage requirements. Also tell your doctor if you develop any unusual symptoms such as pain, swelling or discomfort.
- Well before undergoing any treatment, surgery or dental work be certain to inform the doctor or dentist performing the procedure that you are taking warfarin. This includes emergency treatment following any injury. Also, tell the doctor who is supervising your anticoagulation therapy.
- Remember that because you are taking an anticoagulant you may have an increased tendency towards bleeding. Therefore, you should check with your doctor before beginning any sport activities. Avoid situations with a high risk of injury.
- Warfarin can seriously affect an unborn baby. All women who may become pregnant should discuss with their doctor the possible risks and available means of reducing those risks. If a woman becomes pregnant she must discuss this with her doctor at the earliest opportunity. However, there have been no reports of the sperm from a man taking warfarin affecting an unborn child.
• Contact your doctor before you start on any extended trips and while travelling try to keep your diet and level of activity as close to normal as possible. You may need a laboratory test while you are away which is not hard to arrange. Ensure the information written on page 20 is up to date and take this book with you. Advise the doctor you see while you are away of this information. Make sure you take enough tablets with you to last the entire trip.

Handy Hints

You may need to change some of your activities to minimise the possibility of problems occurring. Some changes to consider are:

• Using a non-slip bath mat when bathing
• Using a soft bristle toothbrush
• Using gloves when gardening and having a clean bandage with you in case you scratch yourself and begin to bleed.
• Using an electric shaver when shaving

Reducing the Chances of Problems

In prescribing your warfarin dosage the doctor aims for the level of anticoagulation which prevents abnormal clot formation and does not permit excessive bleeding. Although people who are not taking anticoagulants can ignore occasional slight bleeding (e.g. a nosebleed) in your case this could be the result of excessive anticoagulation. Therefore, it’s important for you to be extra careful in looking for certain signs. You should therefore look for obvious signs of bleeding. These obvious signs of bleeding include:

• Cuts may bleed for a longer time.
• Occasional nosebleeds may occur.
• Heavier bleeding during periods or other vaginal bleeding.
• Bleeding gums.

The less obvious signs of bleeding include:

• Dark red or brown urine.
• Dark or black bowel movements
• Bruising
A bruise occurs when you bleed under the skin. If you notice you are bruising for unknown reasons or more than normal, tell your doctor right away. As you continue to take warfarin, it’s very important that you be constantly on the lookout for the signs we’ve been talking about and if any of these signs should appear, call your doctor immediately.

Remember that the purpose of this booklet and the warfarin therapy is to help you lead a normal life. By following your warfarin directions and the guidelines given in this booklet, you will reduce the risk of complications. If you do experience any problems, tell your doctor immediately so the problems can be handled promptly and effectively. Finally, use good judgment throughout your therapy program and if you have any questions be sure to ask your doctor or pharmacist.