Pharmacy-Based Model Enabling Patient Self-Monitoring of Warfarin: Development and Evaluation

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## Acronyms

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<th>Explanation</th>
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<tr>
<td>ADR</td>
<td>Adverse Drug Reaction</td>
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<tr>
<td>AF</td>
<td>Atrial Fibrillation</td>
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<tr>
<td>GP</td>
<td>General Practitioner</td>
</tr>
<tr>
<td>HMR</td>
<td>Home Medicines Review</td>
</tr>
<tr>
<td>INR</td>
<td>Internationalised Normalised Ratio</td>
</tr>
<tr>
<td>NSW</td>
<td>New South Wales</td>
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<tr>
<td>PSM</td>
<td>Patient Self-Monitoring</td>
</tr>
<tr>
<td>POC</td>
<td>Point of Care</td>
</tr>
<tr>
<td>QA</td>
<td>Quality Assurance</td>
</tr>
<tr>
<td>QOL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>TTO</td>
<td>Time Trade Off</td>
</tr>
<tr>
<td>TTR</td>
<td>Time in Therapeutic Range</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
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<tr>
<td>UMORE</td>
<td>Unit for Medication Outcomes Research and Education</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
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<tr>
<td>VTE</td>
<td>Venous Thromboembolism</td>
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1. Introduction

Oral anticoagulation therapy is widely used for the prevention and treatment of thrombosis. Warfarin has been in widespread use since the 1950s and is currently the most commonly prescribed vitamin K antagonist worldwide.\(^1\),\(^2\) The use of warfarin is now increasing at a steady rate (approximately 10% per year),\(^1\),\(^3\) particularly in elderly patients, because of its proven benefits in atrial fibrillation (AF) and the increasing prevalence of this condition.\(^1\),\(^4\)-\(^8\) The prevalence of AF rises with age and increasing numbers of elderly patients are candidates for, and could benefit from, the use of anticoagulants.\(^9\) This is expected to result in current demand for oral anticoagulant therapy increasing up to six-fold by 2050.\(^10\)

The presence of AF has been found to be more than quadruple a person’s risk of stroke,\(^11\),\(^12\) and accounts for approximately 14% of all strokes in patients greater than 60 years old.\(^13\) It has been demonstrated that long-term anticoagulation therapy can reduce the annual risk of stroke by approximately 68% in patients with non-valvular AF; this makes it three times more effective than aspirin.\(^7\),\(^14\)-\(^21\) In elderly patients, who often possess multiple risk factors and are at higher baseline risk for stroke, the potential benefits of warfarin may be even greater.

Despite its proven benefits in preventing thromboembolic conditions, warfarin is well recognised as a high-risk drug for adverse drug events.\(^4\),\(^22\)-\(^28\) It is frequently cited as a leading drug involved in preventable serious adverse drug events\(^29\) and in primary care, warfarin belongs to one of the classes of medicines most commonly associated with fatal medication errors.\(^30\)

Not surprisingly, the major complication of anticoagulant therapy is bleeding.\(^31\),\(^32\) The average frequencies of fatal, major, and major or minor bleeding during long-term warfarin therapy are 0.6%, 3.0%, and 9.6% respectively; these frequencies are approximately five times those expected without warfarin therapy.\(^31\),\(^33\) Major independent risk factors for bleeding during long-term warfarin therapy include co-morbid conditions other than the indications for therapy, history of stroke, history of gastrointestinal bleeding, advancing age (greater than 65 years), and the intensity of anticoagulant therapy.\(^31\),\(^33\)-\(^35\)

Bleeding complications with anticoagulant drugs appear to occur more frequently in older patients than in younger individuals.\(^3\),\(^31\),\(^34\),\(^36\)-\(^39\) Older patients may be at an increased risk for anticoagulant-related bleeding because they generally have an increased incidence of adverse drug reactions, increased prevalence of comorbidity and polypharmacy, and increased vascular and endothelial fragility.\(^40\)

The effective use of warfarin is limited by the difficulty of managing it, the requirement for frequent monitoring and the necessity for dose adjustment to limit the adverse consequences of a narrow therapeutic window, multiple food and drug interactions, and variable pharmacology.\(^41\) Unexpected fluctuations of international normalised ratio (INR) values present further challenges to therapy management and can be attributed to numerous factors including changes in diet, poor compliance with medication, alcohol consumption, and drug-drug interactions.\(^42\)-\(^44\)

The aim of monitoring the INR is to maintain an intensity of anticoagulation capable of preventing thromboembolic events without increasing the risk of bleeding complications (Figure 1).\(^45\),\(^46\) The risk of these adverse events depends largely on the proportion of time during which the INR is outside the therapeutic range.\(^47\) Therefore optimal management of anticoagulant therapy with warfarin is inextricably linked to the proportion of time that patients spend in their target INR range.\(^48\) In well conducted clinical trials, time in therapeutic range (TTR) is usually only 60% to 65%,\(^49\)-\(^53\) with some studies estimating that patients on warfarin may be in their therapeutic range as little as one-third of the time.\(^54\) TTR is closely correlated with clinical outcomes, and improvements in TTR of as little as 10% have been shown to convey a significant improvement in all-cause mortality.\(^48\),\(^55\)-\(^58\) Therefore, maintenance of the INR in the therapeutic range, and achievement of a high TTR, is the primary goal of warfarin management.\(^59\)
Poor control of warfarin therapy within the target INR range, particularly in the elderly, is a common cause of adverse drug reactions (ADRs) in Australia. Recent data shows that anticoagulants are one of the major causes of ADRs, and the rate of anticoagulation-related ADRs has increased dramatically in recent years. Optimal control of INR would be expected to prevent 1750 episodes of bleeding and 700 ischaemic strokes each year in Australia.

Maintaining the INR within the target range is a time consuming process for physicians and has been cited as one reason for non prescription of warfarin. It can reduce patient compliance and increase the risks associated with treatment, especially in people who are housebound, live far from a monitoring site, or who have a regular job and find it difficult to attend regular appointments. The majority of people taking warfarin are managed in traditional general practice settings. The management process often involves frequent collection of venous blood samples and visits to the doctor’s practice or pathology laboratory. There is concern over standardisation of laboratories, and problems with patient-physician communication inherent in this process. The process is labour intensive and costly for the physician and the patient, respectively, as it requires two separate interactions with each monitoring event. The need for regular laboratory visits and subsequent follow up for dose adjustment is inconvenient and causes many patients to feel an unwanted dependence on health care practitioners.

Recently, portable monitors capable of INR monitoring have become available. Traditional testing methods require venous access, a relative large volume of blood, and the testing process may take several hours. On the other hand, portable monitors can measure INR values from a capillary finger stick sample with results in minutes. They are simple to use and their accuracy and reliability in a number of settings has been well documented.
Self-monitoring allows the rapid provision of results which can facilitate better clinical decision making, improved patient adherence, and greater patient satisfaction, all of which lead to improved clinical outcomes. Patients with diabetes have been self-monitoring and self-managing their insulin therapy for decades. Warfarin monitoring is not as intense as blood glucose monitoring, but it still requires frequent assessment of the INR. Patient self-monitoring (PSM) of warfarin therapy involves a patient (or carer) performing an INR measurement and reporting the results to a health care provider who decides an appropriate dose and the timing of the next measurement.

The increasing number of patients on warfarin and concerns over the ability of conventional health care services to cope with the corresponding increase in workload are the reasons for the expansion of PSM as a strategy worldwide for the management of oral anticoagulation. PSM of anticoagulation is primarily based upon the premise that more frequent testing will lead to tighter anticoagulation control and thus improved clinical outcomes. Data indicates that the mortality of patients taking warfarin is related to control of the INR; that is, an INR range of 2-3 is associated with the lowest rate of mortality. Increasing rates of mortality are equally associated with both under- and over-anticoagulation, neither is acceptable for the patient on warfarin. It has also been shown that the time in the therapeutic range correlates strongly with clinical outcomes (bleeding and embolic) and that more frequent testing increases the time in the therapeutic range.

Interestingly, PSM of warfarin therapy has also been demonstrated to improve thromboembolic and haemorrhagic outcomes, with only a slight increase in the percentage of INR tests in the therapeutic range when compared to control patients. It was noteworthy that in this particular study the improvement in clinical outcomes was achieved without an improvement in INR control; thus, the benefits of PSM extend beyond improved INR control to increasing patient empowerment, improving adherence and improving patient awareness of their health status. By minimising hospital or primary care visits for blood sampling and providing close monitoring with an optimal higher test frequency and less discomfort for the patient, point of care (POC) devices provide more flexible procedures for INR measurement and have been shown to improve the quality of life.

The concept of PSM with dose-adjustment of anticoagulation, based on physician-derived guidelines, was first tested in 1974 by Erdman et al. in patients with prosthetic heart valves. Self-managed patients demonstrated a greater degree of satisfactory anticoagulation control (95%) compared to a retrospective survey of standard patients who only achieved 71% adequate anticoagulation.

Ansell et al. analysed the results of PSM with dose-adjustment over seven years with 20 patients. These patients performed their own INR testing and adjusted their own warfarin dose based on physician guidelines. The results from this group were compared with a matched group being treated by an anticoagulation clinic. The self-managed patients were found to be in the therapeutic range for around 89% of the determinations, compared to 68% for the control subjects. They also found the study group had fewer dosage changes (11% vs. 28%) and complication rates did not differ between the groups. Patient satisfaction with this model of therapy was found to be very high.

In a retrospective study, Berardo reported on self managed patients over six years. He found that INR results were in the target range 83% of the time. These results were compared with a group of traditionally managed patients and it was found that the self-managed patients had a trend for fewer haemorrhagic events and fewer embolic events. Patients in the study by Sidhu et al. reported greater personal convenience, increased confidence in their therapy, and they enjoyed the ability to widely travel with less fear of deviation from the therapeutic range while away from home.

Siebenhofer et al. conducted a systematic review of studies of self-management of oral anticoagulation, evaluating RCTs from 1966 to 2003. Four studies were eligible for inclusion. These studies showed that self-management can improve the quality of oral anticoagulation. This was reflected by an increased number of INR values in the target range and a reduction in the risk of thromboembolism and bleeding complications. Self-management of oral anticoagulation was found by these studies to be safe, improving patient satisfaction and treatment-related quality of life.

The results of 14 published and unpublished randomised controlled trials involving PSM with and without warfarin dose-adjustment compared to routine management underwent meta-analysis recently. Pooled analysis of these studies demonstrated significant reduction in major bleeding (OR 0.45, 95% CI 0.30-0.68), all-cause mortality (OR 0.61, 95% CI 0.38-0.98) and major haemorrhage (OR 0.65, 95% CI 0.42-
0.99) in the self-monitored patients. There were some differences in clinical outcomes for patients who self-managed their warfarin rather than self-monitored in the clinical trials. Self-managed patients had a significantly lower risk of thromboembolic events (OR 0.27, 95% CI 0.12-0.59) and all-cause mortality (OR 0.37, 95% CI 0.16-0.85), but not major bleeding (OR 0.93, 95% CI 0.42-2.05) compared to usual care. Self-monitored patients had a significantly lower risk of thromboembolic events (OR 0.57, 95% CI 0.35-0.93) and major bleeding (OR 0.56, 95% CI 0.34-0.93), but not all-cause mortality (OR 0.81, 95% CI 0.44-1.49) compared to usual care. In the studies that reported INR control, either the TTR or the proportion of tests in range improved in all cases in the order of 3% to 21%. In a systematic review of anticoagulation control, patient groups performing PSM spent a significantly higher proportion of time within the therapeutic range compared to patients managed in other settings (72% compared to 63%).

To supplement the beneficial effect of PSM on mortality for patients involved in initial trials as demonstrated by meta-analysis, the long-term survival benefits of self-management have been recently established. In a follow-up study of the Early Self-Controlled Anticoagulation Trial, 930 patients were followed for up to 12 years following the initial study. According to both intention to treat analysis and per protocol analysis, the self-management group was associated with a 10-year improved survival of 23% (95% CI 0.58-1.0) and 33% (95% CI 0.51-0.89), respectively, on multivariate analysis, compared to patients in the usual care group.

In a recent 12 month trial in the UK, which was published following the systematic review, 617 patients aged over 18 and receiving warfarin were randomised to intervention (self-monitoring of INR twice a week and a simple dosing chart to interpret the dose of warfarin) or routine care. No significant differences were found in the TTR between self-management and routine care (70% vs. 68%). Self-managed patients with poor control before the study showed an improvement in control that was not seen in the routine care group. It was concluded that with appropriate training, self-management is safe and reliable for a sizeable proportion of patients receiving oral anticoagulation treatment. It was noted that PSM might also improve the TTR for patients with initially poor control. In a trial to evaluate the clinical effectiveness of PSM with dosage adjustment compared to routine care outside of trial conditions, 38 patients from this study performing PSM were matched with 40 controls whose warfarin was managed in primary care. In a 12-month period, the TTR was 70% for patients performing PSM and 57% for control patients, demonstrating that PSM with dosage adjustment is effective compared to usual care outside of trial conditions. An ongoing RCT of self-management of warfarin in elderly patients (over 60 years of age) recently presented data from the first year of the study. These preliminary results indicate that INR control with patients performing PSM is superior to routine care in this cohort of elderly patients.

Ultimately, self-monitoring by patients with or without self-dosage adjustment has a great potential to maximise the safety of anticoagulant therapy. It allows patients to assume responsibility for their own therapy, which can lead to improvements in patients' self-worth, closer adherence to treatment, and increased control of treatment with warfarin. It has been demonstrated that self-monitored patients are less anxious about their therapy. Other advantages of PSM include patients having the ability to conduct testing at home, saving travel and time to visit a clinic/doctor, and that they are less dependent on the health care system to manage their therapy.

In summary, studies have shown PSM to be feasible, accurate, associated with a greater time in therapeutic range, and an improved quality of life for the patients. International research has established that PSM represents the gold-standard for warfarin management for suitable individuals, and that patients who perform PSM have been shown to spend a greater proportion of their time within the target INR range, have a lower incidence of haemorrhagic and thromboembolic events and also have a lower risk of mortality compared to patients undergoing usual care. PSM has been noted as an effective method of monitoring oral anticoagulation therapy, providing outcomes at least as good as, and possibly better than, those achieved with anticoagulation clinics or usual care. However, PSM is currently not well established in Australia, despite the availability of portable INR monitors that have been demonstrated to be accurate and easy to use. PSM may not be a unanimously appealing option as it requires special training to implement, and there are still many variables, such as patient selection criteria and testing frequency, that need optimisation. A number of criteria relating to patient selection and potential capability to undertake PSM have been identified in many studies. These include a long
term indication for warfarin, being an adult or supervised by an adult, a willingness to learn the testing procedure and perform PSM, and a basic understanding of, or capability to understand the condition for which warfarin is prescribed. Studies suggest that the majority of patients who are able to lead an independent life should be capable of PSM, irrespective of educational or social status. Patients or their carers also require sufficient manual dexterity and acuity of vision to operate the testing device. A contraindication to participation in PSM is the presence of antiphospholipid syndrome (including lupus anticoagulant) as the test strips are inaccurate in the presence of these antibodies.

The therapeutic benefits of warfarin are highly dependent on maintaining the INR within the therapeutic range. Poor compliance, variable dietary intake, inadequate knowledge, and miscommunication between the patient and physician have all been cited in the literature as potential causes for fluctuations in the INR. Successful anticoagulation treatment is dependent on the patient's knowledge of warfarin, and there is a generalised acceptance in the medical literature that patients who have a good understanding of warfarin therapy will experience fewer complications with therapy. Knowledge, drug compliance, and anticoagulation control all improve after patient education becomes part of the management plan.

Recent studies have shown that patient knowledge of warfarin in a community setting is often poor. Studies have generally shown an inverse relationship between patient knowledge and adverse outcomes of warfarin therapy, primarily major bleeding. Positive outcomes have been recorded where patients have had increased participation in their care and where they were encouraged to communicate more effectively with doctors and other health professionals about drug interactions and changes in lifestyle or diet. This is likely to be because knowledge has been cited as a strong determinant of anticoagulation control. 

Patient education regarding anticoagulation therapy and patient empowerment are therefore important elements in improving quality of treatment and patient awareness and could also be a major factor for improving patient compliance. Compliance with warfarin is essential to maintaining good anticoagulant control and to preventing unnecessary dosage changes. Barcellona et al. linked the level of knowledge to compliance. They found patients who stated they sometimes missed a daily dose of their anticoagulant did not understand the need to take the therapy every single day and as such spent substantially less time within their therapeutic range. They concluded that greater emphasis should be given to educational courses for anticoagulation patients in an attempt to improve knowledge levels, and in turn improve compliance. Other studies have also identified a lack of patient knowledge regarding the important aspects of warfarin therapy as a determinant of non-adherence to therapy.

In addition to increasing compliance, education has also been attributed to reducing adverse events during warfarin treatment. The risk of bleeding due to warfarin therapy is closely related to the adequacy of warfarin control. Written and verbal education has been shown to improve control of the level of anticoagulation in a number of studies. Roddie and Pollock showed that 85% of patients with a good understanding of warfarin had a well controlled and stable INR, compared to only 63% in the poor-understanding group. Generally, patients’ knowledge, therapy compliance and anticoagulant control all improve after patient education becomes part of a structured management program.

Successful, safe anticoagulation depends on patient education, good compliance and communication with the patient and between health professionals responsible for their clinical care. The rate of warfarin-related hospitalisation for bleeding is substantially lower for patients who reported receiving medication instructions from a physician, nurse or pharmacist; however, literature reports the quality of the provision of educational materials to hospitalised patients started on warfarin is generally poor. Improving patient knowledge may improve control, reduce complications and therefore reduce the burden on health services. General practitioners and community pharmacists should take a key role in reinforcing knowledge regarding anticoagulation to reduce the risk of complications of anticoagulant therapy. Warfarin training should be tailored to suit the level of education and age of the patient. Education of elderly and illiterate patients may require special consideration and include the use of visual aids.
Adequate patient education and training is essential to the success of PSM. In all trials involving anticoagulation self-monitoring, consumers have undertaken comprehensive training programs, and the training process has been identified as critical in achieving the benefits of PSM. Most studies have involved multiple training sessions, involving training on the use of the equipment and instructions on dosage adjustments. Some studies are not specific about their methods or requirements. Ansell et al. simply had their patients instructed on the use of the INR monitor and in dosage-adjustment guidelines by an anticoagulation nurse over a two-week period. Other researchers have placed more importance on the training programs their patients undergo in order to self-monitor. Common elements appear in many of the suggested programs. In most training programs, patients receive an overview of oral anticoagulant therapy, including the effect of certain factors, such as alcohol, on anticoagulation control. Patients also receive information on the importance of bleeding and thromboembolic events, and how to recognise the signs of over- and under-coagulation. As well as theoretical information, it is suggested patients receive intensive supervised training on the use of POC monitors, and instruction in adjustment of warfarin dose (if required). Some programs give patients the opportunity to practice obtaining consistent INR results at home between training sessions.

In Germany, a nationally approved, formalised training program developed by Sawicki et al. is in place. This structured educational program aims to help patients assume increased responsibility for disease management based on systemic INR self-monitoring and self-adjustment of the warfarin dose. The training course covers theoretical and pharmaceutical aspects of anticoagulation, a demonstration of the equipment to be used by the patients, and a practical session using near patient testing systems.

Fitzmaurice et al. have also developed a training program for patients in UK studies of PSM. Their training course involves two workshops of up to two hours, conducted a week apart. These workshops are conducted within practice settings and cover theoretical and practical aspects of anticoagulation management, including the procedure for performing testing, the use of testing devices, quality control procedures, and managing the INR result using a specified algorithm. Between sessions patients are asked to practice with the POC device, recording at least six results and any problems. The research team individually assesses each patient to determine whether they are competent to self-manage.

Community pharmacists are in a unique position to help patients manage chronic illness in view of their expertise, their regular contact with patients and their accessibility. Overseas, pharmacist involvement in warfarin management has been shown to result in significantly better control of the INR.

There is clear evidence that better strategies are required to optimise warfarin therapy in Australia. New strategies have been implemented elsewhere in the world and have been demonstrated to improve clinical outcomes, and consumer satisfaction and quality of life. The underuse of PSM is now evidence of a practice gap in Australian healthcare and represents a clear opportunity for pharmacists to participate in reducing the harm and maximising the benefits associated with warfarin therapy. The adoption of PSM of warfarin therapy to achieve appropriate outpatient anticoagulation and prevent complications was ranked in the top 10 clear opportunities to improve patient safety in a report prepared by the US Agency for Healthcare Research and Quality. The implementation of PSM in Australian healthcare is an example of an intervention that would address a number of principles to improve the management of warfarin therapy through improved access to monitoring, improve consumer awareness of monitoring requirements, and empower consumers and enhance their understanding of their chronic disease and warfarin therapy.

1.1 Aims and objectives:

The primary aim of this study was to develop, implement and evaluate a pharmacy-centred pathway to enable Australians who take warfarin to monitor their own therapy (Figure 2). To achieve this aim, a number of intermediate objectives were identified:

- Development of training packages to enable pharmacists to train consumers and to enable consumers to self-monitor;
- Implementation of a model to enable PSM in collaboration with consumers, other healthcare professionals, and industry representatives;
- Evaluation of the model to allow for refinement; and
• Demonstration of the benefits of PSM for consumers.

This report presents the results of this research, and their implications for the widespread implementation of PSM of warfarin therapy in Australia.

Figure 2: Inclusive model of warfarin management
2. Methods

2.1 Development of self-monitoring model

Members of the research team attended two different training courses at the University of Birmingham to assist in the development of a self-monitoring model suitable for the Australian healthcare environment. One course was aimed at training patients to manage their own warfarin therapy, while the other focussed on training health professionals to use POC INR monitors and manage oral anticoagulation therapy. Both courses were valuable in the development of the final design and in the development of the educational materials discussed below.

It was felt that it was important to consult a wide range of stakeholders in the design of the PSM pathway and on the development of project materials and resources to ensure a model which was seen as acceptable and feasible to participants at every step of the process. To this end, a Project Advisory Group was formed by inviting a wide range of stakeholder organisations to put forward a representative to participate in project discussions. The function of the Project Advisory Group was to inform and guide the research team to ensure optimal implementation of the project.

The Project Advisory Group’s role was to:

• provide advice regarding the feasibility of the implementation strategy of PSM in Australia;
• oversee and monitor the progress of the project against the project plan and timeline and provide those directly involved on the project with guidance on project issues;
• ensure effort and expenditure was appropriate to stakeholder expectations;
• identify and reduce barriers and risk to project implementation ensuring reconciliation of differences in opinion and approach, if disputes arose; and
• ensure that the requirements and perspectives of the participants were considered and that ethical guidelines were followed.

Individual reference group members were asked to act as ‘knowledge brokers’ within their organisation to assist the implementation of the project.

Consumers, other healthcare professionals and industry were represented on the Project Advisory Group through input from:

• The National Stroke Foundation;
• The National Prescribing Service;
• The Royal Australian College of General Practitioners;
• The Australian General Practice Network;
• The Australian Medical Association;
• The Australian Association of Consultant Pharmacy;
• The Pharmaceutical Society of Australia;
• The Pharmacy Guild of Australia;
• The Society of Hospital Pharmacists of Australia; and
• The Royal College of Pathologists of Australasia.

Colleagues from the Universities of Sydney, Wollongong, and South Australia were also consulted and the project team engaged the services of a consultant haematologist to enable the development of the PSM pathway and accurate and usable project tools.

The Project Advisory Group had extensive input into the content of educational materials and the structure of the Home Medicines Review (HMR) used in the pilot model. It was felt that a quality assurance (QA) aspect was imperative to safely and successfully implement PSM in Australia. QA was included in the model in the form of two comparison INR tests initially and further comparison tests three to six monthly to ensure accuracy of self-obtained results. The comparison INR tests are to be
performed within four hours of a venous sample being taken and must be within 15% of one another to be considered acceptably accurate.

The final clinical pathway developed for this project utilised the existing HMR model and is shown in Figure 3. Community pharmacists are ideally placed to screen consumers taking warfarin for their suitability to monitor their own therapy, and were used to identify suitable patients for this study. Under existing funding structures, pharmacists referred these patients to their GP to discuss the concept, with the view to referring them to an HMR-accredited pharmacist for specialised training, delivered as part of an HMR. The Australian Association of Consultant Pharmacy accredits a specialised sub-group of Australian pharmacists to undertake HMRs for suitable patients. A number of these accredited pharmacists were trained using a train-the-trainer program, to teach suitable consumers to monitor their own therapy using training materials developed for this purpose.

Figure 3: Clinical pathway to enable self-monitoring of warfarin therapy

The educational HMR consisted of a medication review, warfarin education, and hands on training in the use of the CoaguChek®XS INR monitor. The education component of the HMR covered background on warfarin, risk of bleeding, diet, and the INR. The practical component covered a practical demonstration of using the monitor and other aspects, such as quality control and the storage and handling of test strips.
Once trained, a ‘run-in’ phase where patients completed two INR tests on the CoaguChek®XS in conjunction with two pathology tests to compare for accuracy ensured that the research team, the GP, and the patient were satisfied that the monitor provided accurate results and could be used effectively. If the comparison tests were not within 15% further instruction was provided. If further comparisons were subsequently not within 15%, the patient was excluded from the trial.

Once consumers had been trained to perform PSM and completed the ‘run-in’ phase, they were asked to use the CoaguChek®XS to measure their INR once every two weeks (or more often if requested by their GP) and report the result to their GP, as arranged, for dosage adjustment. The decision to alter warfarin doses was made by the consumer’s GP on the basis of the INR result. GPs were remunerated for the time involved in dosage adjustments informed by consumer obtained POC INR results.

2.2 Development of educational materials

2.2.1 Train-the-trainer

A train-the-trainer package previously developed by the lead investigator was used to train the accredited pharmacists participating in this project. This package included a training booklet to enable accredited pharmacists to provide suitable patients who are taking warfarin with the knowledge and resources to successfully monitor their own therapy (the table of contents of this booklet can be seen in Appendix 1). The booklet comprehensively covers anticoagulation theory, with topics ranging from the mechanism of action of warfarin and thrombosis to the therapeutic uses of warfarin and managing warfarin therapy. It covers the POC INR testing and the INR as well as the accuracy of POC INR devices and the need for quality assurance. Finally, the book covers the evidence behind patient self-monitoring of warfarin and training of patients to perform PSM. This resource was designed to be used as part of a training package that includes practical demonstration of the CoaguChek®XS monitor and one-on-one demonstrations. The booklet can be considered as support material for the oral presentations and as a reference for accredited pharmacists training patients to monitor their own warfarin therapy. This tool was offered to the Project Advisory Group for independent review and refinement for use in this study. Additional tools were created to assist GPs and community pharmacists to identify suitable candidates for PSM – these were incorporated into a flyer to encourage recruitment of consumers into project (Appendix 2).

2.2.2 Train-the-consumer

As a component of the train-the-trainer package described above, the project team had also developed training materials for accredited pharmacists to use when training consumers to perform PSM. The consumer booklet is divided into two sections (the table of contents of this booklet can be seen in Appendix 3). The first covers coagulation, how warfarin works, its therapeutic uses, the INR and the evidence behind self-monitoring and the POC devices. The second section covers quality assurance and is designed to incorporate the hand-on training session with the INR monitor. This package also underwent refinement before being offered to the Project Advisory Group for review. Additional resources for consumers participating in the study were developed; including an INR record book and warfarin identification wallet cards (Appendix 4 and Appendix 5).

2.2.3 Web-based anticoagulation resources

A website (www.anticoagulation.com.au) was developed to promote PSM and the safe use of warfarin in Australia, to provide anticoagulation information for all interested people and to house the educational tools. Information for the content of the site was gathered from a variety of literature and online sources. Content was written according to recommendations for writing health literature, and the readability of content was kept at or below Flesch-Kincaid Grade Level 7 to enable accessible content for a wide demographic audience. The information was reviewed and refined by members of the Project Advisory Group to ensure content accuracy and accessibility.

A number of interface designs were considered and assessed on both aesthetic and practical features. A member of the project team attended a website usability course to assist in producing a user-friendly...
site design. The likely audience was considered in designing layout, with the aim to produce a site that was easy to read (both in terms of content and font sizes) and easy to navigate.

The project team enlisted the assistance of a professional web developer to produce the framework for the site.

The website has been well received since its launch in October 2008. It received almost 500,000 hits in the twelve month period. Large amounts of positive feedback and requests for information have been received through the site. A summary of the website statistics, feedback, and information requests can be seen in Appendix 6.

The final website design can be seen in Appendix 7.

2.3 Recruitment of study participants

2.3.1 Pharmacy recruitment

Pharmacies in southern Tasmania who had previously expressed an interest in participating in UMORE projects were sent an invitation to participate in this study. A group of pharmacies in the Riverina region of NSW who had recently contacted UMORE about participating in research projects were also approached to participate. Ten community pharmacies approved to claim for HMRs in the Hobart region of Tasmania and five in the Riverina region were engaged to participate and recruit consumers for the implementation phase.

Pharmacists from each of the participating pharmacies attended a training evening prior to the commencement of recruitment. Educational evenings were held in Tasmania in August 2008 and in Wagga Wagga in December 2008. This evening provided community pharmacists with a refresher on anticoagulation theory, a background to self-monitoring as a strategy for warfarin management, and training on what was required from them during the project period. The community pharmacists were also given a demonstration of the CoaguChek®XS device which was followed by a hands on session to ensure they fully understood the testing procedure they would be referring their consumer to undertake.

Participating pharmacies were responsible for facilitating an HMR with a trained accredited pharmacist, via referral from the GPs. Pharmacies were provided with a list of trained accredited pharmacists in their area. Many of the NSW pharmacies had trained accredited pharmacists on staff.

Throughout the intervention, community pharmacists provided participants with support and ongoing education, as well as facilitating the ongoing supply of study materials to the consumer from the project team.

2.3.2 Accredited pharmacist recruitment

Accredited pharmacists who had previously attended training sessions at ConPharm conferences and who serviced the areas surrounding recruited pharmacies were contacted directly and invited to participate. Two accredited pharmacists in the Hobart region and one accredited pharmacist in the Riverina region responded. In Hobart, one accredited pharmacist made themself available to perform all necessary HMRs. An additional training session was held in Wagga Wagga in December 2008 to upskill an additional five accredited pharmacists in this area.

Training sessions followed the contents of the train-the-trainer booklet, as described above, and covered anticoagulation theory and the evidence behind POC INR testing. This was accompanied by a practical training session on the use of the CoaguChek®XS device and included each pharmacist demonstrating their capability to obtain an INR result.

Accredited pharmacists were required to provide HMR reports to the pharmacy and GP, as is standard practice, and to make a recommendation on the consumer’s suitability to self-monitor based on a post-training assessment.
2.3.3 Recruitment of consumers

Consumers were invited to participate by their community pharmacy. These people had been taking warfarin for at least six months and had a long-term indication for warfarin therapy. Community pharmacists were given criteria to assist them to select potential candidates for PSM (Appendix 2).

The participating community pharmacists identified consumers filling prescriptions for warfarin who they thought may be capable of and interested in self-monitoring their warfarin therapy. Consumers with carers were not excluded from participating if they had an interest in self-monitoring and they had a carer who was willing and able to undergo training and perform INR testing on the consumer’s behalf.

A range of strategies were used to identify consumers, with some community pharmacists approaching consumers when they presented in store, some posting letters to people they thought would be interested, and some choosing to work collaboratively with local GPs to identify potential participants. Consumers then contacted the project team, or asked their pharmacist to contact the project team on their behalf.

Once the consumer consented to be involved in the study, the research team contacted the patient’s GP informing them of the study and their patient’s interest in participating. An information form and consent form were then sent to the GP. For a consumer to be involved in the trial, their GP must also have provided consent.

2.4 Implementation of PSM model

2.4.1 Experimental design and analysis of results

This project was a proof of concept study regarding the implementation of pharmacist involvement in PSM of warfarin therapy in the community. The main outcomes were feedback from GPs, consumers, and pharmacists regarding the training program and the clinical pathway developed. This was obtained using evaluation questionnaires featuring visual analogue scales (The questionnaires, together with accompanying results and comments are attached in Appendix 8 to Appendix 13) and qualitative interviews conducted by a consultant social science researcher (full report Appendix 14). The level of warfarin knowledge and quality of life (QOL) was determined before commencement of the training program and following the intervention. Warfarin knowledge was also measured in the post-training period. Data on clinical outcomes, such as minor and major bleeding, were collected, but it was not anticipated that improvements would be observed in this study due to a small sample size and relatively short time-frame. Minor bleeding was defined as bleeding that was reported but not requiring additional tests, referrals and visits, while major bleeding was categorised as including fatal or life threatening bleeding, or bleeding associated with a defined drop in haemoglobin and requiring transfusion.

Once training was complete and quality assurance achieved, participants tested their INR approximately once per fortnight, or more frequently if required by their GP, for a period of at least six months. The TTR and proportion of tests within target range of INR were determined for each patient during the trial. This was compared to their previous level of control determined in the six months immediately prior to the commencement of the intervention phase (provided at study entry with the participant’s consent). A function to calculate the TTR was based on the method originally proposed by Rosendaal et al. Based on this calculation, the TTR for each participant was determined for available pre-intervention and intervention data. Data regarding TTR and proportion of tests in range approached normality and as such was treated as parametric. Paired t-tests were used for these comparisons. Due to the small sample size, all other data was treated as non-parametric and Wilcoxon signed rank sum tests were used for comparisons. Wilcoxon signed rank sum tests were also used to determine if any significant change in knowledge had occurred compared to baseline. Statistical significance was set at \( p \) less than 0.05.

The study was not powered to detect clinical outcomes, although their occurrence was documented as a matter of course. It should be emphasised that the over-arching objective of the study was to demonstrate that the proposed clinical pathway for PSM was feasible and consumers, pharmacists and GPs were satisfied with this model of care. The primary outcome for the analysis of the implementation
phase of the project was TTR. Secondary outcomes included improvement in warfarin knowledge and QOL.

2.4.2 Quality of life

Due to the difficulties associated with quantifying the benefits of an intervention program, a common unit of measurement for benefit, QOL, was utilised. QOL was measured using the EQ5D instrument (Appendix 15), which comprises five dimensions of health (mobility, personal care, usual activities, pain/discomfort, anxiety/depression) with respondents being offered the choice of three ‘level’ under each dimension (‘no problems’, ‘some/moderate problems’, and ‘extreme problems’). The questionnaire was conducted with each patient twice, at entry into the study and following the intervention. The results for the participant’s EQ5D were entered into a database. The UK ‘Time Trade Off’ (TTO) data set was utilised to calculate a utility weight for each participant before and after PSM. No Australasian data set is currently available, and the UK TTO data set has used previously in the Australian context.\textsuperscript{143} (Note: TTO involves asking a person to imagine living in a specified health state for 10 years and then asking them to specify the amount of time they would be willing to give up to live in ‘full health’ instead)\textsuperscript{144} Participants’ pre- and post-PSM utility weight results were compared using the Wilcoxon Signed Ranks Test. Statistical significance was set at \( p < 0.05 \).

2.4.3 Warfarin knowledge

Participants completed the Oral Anticoagulation Knowledge Test\textsuperscript{145} (Appendix 16). The questionnaire was completed at study entry, in the post-training period, and again on completion of the study. Scores were calculated as a percentage and Wilcoxon signed rank sum tests and Friedman tests for non-parametric data were used to compare warfarin knowledge levels. Statistical significance was set at \( p < 0.05 \).

2.4.4 Qualitative analysis

An independent social science researcher was enlisted to conduct interviews with a selection of participants to evaluate the model. The research adopted a qualitative approach as is appropriate to achieve exploratory objectives. Telephone depth interviews were conducted with project participants following the intervention period by experienced qualitative researchers. The sample of participants for the telephone interviews was selected independently by the qualitative researchers and included a convenience sample of 8 consumers, 8 GPs, and 6 pharmacists who had been involved in the selection of consumers for the trial or in their training.

The objectives of the qualitative research were to:

- Develop an understanding of the patients’ connection with INR testing to manage anticoagulation therapy. This included:
  - The weaknesses and strengths of laboratory and POC INR testing;
  - Patient expectations for the management of anticoagulation therapy;
  - Initial and ongoing acceptance of POC INR testing and specifically any reasons for apprehension;
  - Drivers and barriers of PSM; and
  - Effects of POC INR testing on the patient-GP/patient-pharmacist relationship.
- Determine the level of satisfaction with POC INR training provided in the study. This included:
  - Convenience of sessions and preferences;
  - Appropriateness and comprehension of material provided; and
  - Satisfaction with the training model used and suggestions for improvement.
- Determine the GP/pharmacist thoughts on the viability of a nationally conducted PSM programme.
- Ascertain any issues with training patients to perform PSM.
2.4.5 Sample size

A sample size of 20 to 30 patients was deemed to be adequate to demonstrate the feasibility of this model of warfarin management. Participants involved in the study were required to have had at least six months of warfarin therapy prior to the study, and INR results from this period were provided to the research team as part of the patient enrolment in the trial. It was presumed that participants would have had six to twelve INR results in this period. During the study period, participants were anticipated to complete at least 12 INR results. For 30 patients, 360 pre-study INRs and 360 in-study INR results were anticipated. The literature suggests that patients in the community spend 50-60% of their time within the target range.49 It was envisaged that this could be improved to 70% with weekly testing and improved education, although an improvement of 5-10% has been proposed as a clinically important goal.45 At a power of 80% and statistical significance set at 0.05, 175 INR results per group were required.

2.4.6 Handling of data

All data was treated confidentially and anonymously. The names of participating patients were not stored with questionnaires or data files on computer.

2.4.7 Statistical analysis

All information was stored and analysed using SPSS 16.0 for Windows (SPSS Inc. Chicago, Illinois, USA)

2.4.8 Ethical approval

This project received ethical approval from the Human Research Ethics Committee (Tasmania) Network and the Human Research Ethics Committee (University of Sydney) and was registered with the Australian Clinical Trials Registry (ACTRN 12608000374369)
3. Results

3.1 Participants
Twenty-eight consumers completed the initial training program and were evaluated for control of their INR. A further four consumers approached the project team to participate but were not successfully recruited into the project. Reasons for non-recruitment were:

- In two cases the patient’s GP refused consent;
- One consumer underwent training but withdrew prior to commencing PSM as they didn’t feel confident with the responsibility of performing testing; and
- One consumer was found during the HMR to have a diagnosis of lupus anticoagulant which is a contraindication to using the POC INR device due to potential inaccuracies with this condition.

Thirty different GPs were involved in the management of the recruited patients, though some GPs were responsible for multiple patients and some patients had multiple GPs during the trial period. Patients were recruited through thirteen community pharmacies – ten in Tasmania and three in New South Wales.

Two patients were unable to continuing self-monitoring for the six month duration. One patient was unable to be contacted and was removed from the study, the other passed away during the intervention period due to unrelated causes. No patients were excluded from entering the trial because they were incapable of completing training or using the monitor. Similarly, no patients were excluded by their GP once the study commenced. One elderly patient had a carer present at the training session whom they preferred to perform the testing procedure on their behalf.

3.1.1 Patient Characteristics
Table 1 displays the patient characteristics for enrolled patients. The majority of patients (60.7%; 17/28) were male. AF was the most common indication for warfarin therapy and a target INR range of 2.0-3.0 was the most common.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>17 (60.7)</td>
</tr>
<tr>
<td>Age (median)</td>
<td>66.5 ± 16.0</td>
</tr>
<tr>
<td>Indication for warfarin</td>
<td></td>
</tr>
<tr>
<td>AF</td>
<td>18 (64.3)</td>
</tr>
<tr>
<td>Recurrent VTE</td>
<td>8 (28.6)</td>
</tr>
<tr>
<td>Heart valve</td>
<td>6 (21.4)</td>
</tr>
<tr>
<td>Other</td>
<td>9 (32.1)</td>
</tr>
<tr>
<td>Target INR range</td>
<td></td>
</tr>
<tr>
<td>2.0-3.0</td>
<td>22 (78.6)</td>
</tr>
<tr>
<td>2.5-3.5</td>
<td>3 (10.7)</td>
</tr>
<tr>
<td>Other</td>
<td>3 (10.7)</td>
</tr>
</tbody>
</table>
Consumers involved in the study were required to have taken warfarin for at least six months prior to self-monitoring. At commencement of self-monitoring the median duration of warfarin therapy was 5.3 years (range 0.5 to 16.0 years).

### 3.2 Proportion of time within target INR range

Complete INR data sets were available for 23 participants. The mean TTR at baseline was 57.8% (95% CI 42.6% to 72.9%). A total of 183 INR tests were provided, with a median of 7 (range 2 to 22) tests per patient in the six months prior to the initiation of PSM.

Patients performing PSM subsequently spent a mean proportion of time within target range of 72.5% (95% CI 65.6% to 79.5%). The median number of results per patient was 24 (range 4 to 60); 677 home tests were completed by the group. The median duration of self-monitoring was 263 days (range 178 to 333). The improvement in TTR when patients performed PSM was not statistically significant (p=0.11). These results are shown in Table 2.

#### Table 2: Quality of anticoagulation pre- and post-intervention

<table>
<thead>
<tr>
<th>Quality control indicators</th>
<th>Mean (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-intervention TTR</td>
<td>57.8% (42.6-72.9%)</td>
<td></td>
</tr>
<tr>
<td>Post-intervention TTR</td>
<td>72.5% (65.6-79.5%)</td>
<td>0.11</td>
</tr>
<tr>
<td>Tests per patient pre-intervention</td>
<td>7 in 6 months (2-22)</td>
<td></td>
</tr>
<tr>
<td>Tests per patient post-intervention</td>
<td>24 in 6 months (4-60)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Of the 23 consumers for whom pre-intervention and intervention INR data is available, 14 (60.9%) showed an improvement in TTR, with an average improvement of 29.3%. Nine (39.1%) didn’t show an improvement in TTR.

### 3.3 Proportion of tests within target INR range

Fifty-six percent (102/183) of all pre-intervention INR tests were within patients’ therapeutic ranges. This improved to 68.4% (463/677) of tests during the intervention. On an individual basis, the mean proportion of tests in range for each patient was 55.2% (95% CI 41.4% to 68.9%) in the six months prior to self-monitoring. This increased to a mean of 71.7% (95% CI 65.2% to 78.2%), which was statistically significant (p=0.03). These results are shown in Table 3.

#### Table 3: Proportion of tests in range during the study

<table>
<thead>
<tr>
<th>Proportion of tests in range</th>
<th>Mean (95% CI)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-intervention tests in range</td>
<td>55.2% (41.4-68.9%)</td>
<td>0.03</td>
</tr>
<tr>
<td>Post-intervention tests in range</td>
<td>71.7% (65.2-78.2%)</td>
<td></td>
</tr>
</tbody>
</table>

### 3.4 Testing frequency

The frequency of INR testing was a median of 1.2 tests per month (range 0.3 to 3.3 tests) in the six months prior to self-monitoring. During the self-monitoring period the frequency of testing significantly increased to a median of 2.7 tests per month (range 0.7 to 7.0 tests; z=-3.954, n=23, p<0.001). These results are shown in Table 4.
Table 4: INR testing frequency

<table>
<thead>
<tr>
<th>Tests per month</th>
<th>Median (range)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-intervention testing frequency</td>
<td>1.2 (0.3 – 3.3)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-intervention testing frequency</td>
<td>2.7 (0.7 – 7.0)</td>
<td></td>
</tr>
</tbody>
</table>

3.5 Accuracy of the CoaguChek®XS portable INR monitor

A total of 108 comparison INRs (CoaguChek®XS and Pathology INR within 4 hours of each other) were completed either on entry into, or during the trial, by participants. The CoaguChek®XS INR values were significantly correlated with the laboratory INR values (\( r=0.86, p<0.001 \); Figure 4). The mean difference in INR (laboratory minus CoaguChek®XS) was 0.07 ± 0.02 INR units (\( t=3.71, df=107, p<0.001 \)). As a requirement of entry into the trial, patients were required to complete two comparison INRs, with the values being within 15%. The Bland-Altman style plot is shown in Figure 5. The CoaguChek®XS showed only slight variation compared with laboratory testing, with a mean variation of 6.9% ± 0.54%.

Figure 4: Relationship between CoaguChek®XS and laboratory INR values
3.6 Warfarin knowledge

Participants were awarded a warfarin knowledge score based on their responses to the questionnaire. Repeated warfarin knowledge questionnaire responses were available for 22 participants. Table 5 shows the median scores (and ranges) of participants at baseline, following the education and training session, and at the conclusion of the intervention period.

Table 5: Warfarin knowledge scores during the study

<table>
<thead>
<tr>
<th>Knowledge scores</th>
<th>Median (range)</th>
<th>( p )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-self-monitoring</td>
<td>80.0 (35.0-100.0)</td>
<td>} 0.01</td>
</tr>
<tr>
<td>Following education and training</td>
<td>90.0 (55.0-100.0)</td>
<td>} 0.36</td>
</tr>
<tr>
<td>Conclusion of PSM period</td>
<td>80.0 (45.0-100.0)</td>
<td></td>
</tr>
</tbody>
</table>

Comparison of the test results at the three time intervals using Friedman testing demonstrated a significant difference between the scores (\(X^2=8.716, \text{ df}=2, p=0.01\)). Further investigation using the Wilcoxon signed rank sum tests comparing pre-self-monitoring to post-education, post-education to post-intervention, and pre-self-monitoring to post-intervention demonstrated that there was a significant increase in knowledge scores seen prior to self-monitoring training and following education and training (\(Z=-2.86, n=22, p<0.001, \text{ two-sided} \)).

Although the median warfarin knowledge score dropped between the post-education period and the conclusion of the PSM period, this fall was not statistically significant (\(p=0.36\)).

3.7 Quality of life

Participants completed the EQ5D QOL questionnaire at baseline and on completion of the intervention phase, with median QOL utilities of 1.0 (range 0.6 to 1.0) and 0.9 (range -0.2 to 1.0). There were no significant changes in the quality of life of participants during the self-monitoring period (\(p=0.37\)).
3.8 Clinical outcomes
No clinical outcomes (events of major bleeding or thromboembolism) were observed during the intervention.

There was one death during the intervention period due to an unrelated cause (acute myocardial infarction secondary to alcoholic liver disease). The INR of this patient a few days prior to death was within range at 2.1.

3.9 Evaluation questionnaire
A summary of the responses to the evaluation questionnaire is shown in Table 6.

Table 6: Summary of evaluation responses

<table>
<thead>
<tr>
<th>Question summary</th>
<th>Median GP score /11</th>
<th>Median consumer score /11</th>
<th>Median Pharmacist score /11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valuable service</td>
<td>9.0</td>
<td>11.0</td>
<td>11.0</td>
</tr>
<tr>
<td>Confidence managing/taking/identifying warfarin</td>
<td>7.0</td>
<td>11.0</td>
<td>10.0</td>
</tr>
<tr>
<td>Feedback and training</td>
<td>9.0</td>
<td>11.0</td>
<td>10.0</td>
</tr>
<tr>
<td>Confidence in accuracy of CoaguChek®XS</td>
<td>10.0</td>
<td>11.0</td>
<td>-</td>
</tr>
<tr>
<td>Ease of use of monitor</td>
<td>-</td>
<td>11.0</td>
<td>-</td>
</tr>
<tr>
<td>Home-monitoring preference</td>
<td>-</td>
<td>11.0</td>
<td>-</td>
</tr>
<tr>
<td>Feasibility of model</td>
<td>11.0</td>
<td>-</td>
<td>10.0</td>
</tr>
</tbody>
</table>

3.9.1 General Practitioner
A total of 13 GP evaluation questionnaires were completed. Participants were asked to rate their responses to given statements out of eleven with one being strongly disagree and eleven being strongly agree. General practitioners believed that their patients found the self-monitoring method to be a worthwhile service and that their patients coped well with the model, with statements receiving median scores of 9.5 (range 6.0-11.0) and 9.5 (range 6.0-11.0), respectively. They felt 10% to 70% (median of 50%) of people taking warfarin would benefit from this service. Sixty-two percent of GPs reported previously utilising an HMR in their practice, and many found the HMR recommendations regarding warfarin to be valuable in their patient care and would consider referring patients on warfarin for an HMR in the future (median scores of 8.5 (range 6.0-11.0) and 10.0 (range 9.0-11.0), respectively. GPs also expressed confidence in the accuracy of the CoaguChek®XS INR monitor, with the statement scoring a median of 10.0 (range 8.0-11.0). Comments received included satisfaction with improving compliance and empowering patients to take greater care of their management, and the benefits of using this method of monitoring in patients with poor venous access and limited mobility, but emphasis was placed on the importance of selecting an appropriate patient group. A selection of comments is shown in Table 7.
Table 7: General Practitioner Comments

<table>
<thead>
<tr>
<th>Compliance/patient empowerment</th>
<th>Benefits of self-monitoring</th>
<th>Patient selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>“He feels improved and more likely to be compliant”</td>
<td>“It’s a great service for: 1) people with limited mobility; and 2) people who have difficult veins”</td>
<td>“Good for certain patient groups”</td>
</tr>
<tr>
<td>“Patient ownership of management causes the patient to take more care with their management”</td>
<td>“It’s instantaneous”</td>
<td>“Need to select patients carefully”</td>
</tr>
<tr>
<td>“My patient felt empowered to guide his own health”</td>
<td>“Gave the patient more autonomy and was easier for him”</td>
<td>“Home monitoring for INR is not suitable for all patients – we need to choose the proper patient”</td>
</tr>
</tbody>
</table>

A visual representation of the full set of GP responses is provided in Appendix 8 and comments can be seen in Appendix 9.

3.9.2 Consumer

A total of 24 consumer evaluation questionnaires were completed. All feedback regarding the service was extremely positive, with all median scores for statements being 11.0 out of 11.0. Despite the results of the EQ5D, consumers did report that their overall quality of life had improved as a result of being able to monitor their warfarin therapy at home, awarding the statement a median score of 11.0 (range 8.0-11.0). Consumers expressed a preference to monitoring their INR at home and found the CoaguChek®XS device simple to use and had confidence in its accuracy, with median scores of 11.0 (range 7.0-11.0), 11.0 (range 8.0-11.0) and 11.0 (range 10.0-11.0), respectively. Participants reported self-monitoring to be a valuable way of monitoring their therapy and found the initial training to be beneficial, including improving their warfarin knowledge. These statements received median scores of 11.0 (range 8.0-11.0), 11.0 (range 6.0-11.0) and 11.0 (range 5.0-11.0), respectively. Comments included satisfaction with the education and training component of the model and with the flexibility, speed of testing, and huge time and cost savings associated with this method of testing compared to laboratory testing. Consumers suggested implementation may need to accompanied by a Government subsidy and that it would be beneficial to have someone following their progress. A selection of comments is shown in Table 8.

Table 8: Consumer Comments

<table>
<thead>
<tr>
<th>Benefits of self-monitoring model</th>
<th>Implementation suggestions</th>
</tr>
</thead>
<tbody>
<tr>
<td>“The whole scheme is a very positive step in helping to manage the problem”</td>
<td>“Maybe more calls more often”</td>
</tr>
<tr>
<td>“Flexibility, speed of testing and huge time and cost savings”</td>
<td>“Email/telephone contact to check if everything is going smoothly”</td>
</tr>
<tr>
<td>“Self-testing is especially beneficial in pre-operative situations”</td>
<td>“Personal contact is very important to the patient”</td>
</tr>
<tr>
<td>“Saving of time. I can do the test quickly at a time that is convenient and not having to waste time sitting in waiting rooms”</td>
<td>“Would be cheaper overall for Government if they subsidised machines and strips. Reduced GP visits and reduced Medicare expenses”</td>
</tr>
<tr>
<td>“Allows me much more control of my INR levels. MUCH SAFER”</td>
<td></td>
</tr>
<tr>
<td>“The education helped me to understand my problems and how to solve them”</td>
<td></td>
</tr>
<tr>
<td>“Freedom to travel away from known localities”</td>
<td></td>
</tr>
<tr>
<td>“Being able to keep check with my own health, particularly when travelling”</td>
<td></td>
</tr>
<tr>
<td>“Allows instant monitoring of INR if unusual factors occur”</td>
<td></td>
</tr>
<tr>
<td>“The ease of checking my INR without seeing a doctor or pathology dept”</td>
<td></td>
</tr>
<tr>
<td>“You do not need as much blood”</td>
<td></td>
</tr>
</tbody>
</table>
A visual representation of the full set of consumer responses is provided in Appendix 10 and comments can be seen in Appendix 11.

### 3.9.3 Community pharmacists

A total of 8 community pharmacist questionnaires were completed. All feedback was positive, with the lowest median score for a statement being 9.5 out of 11. Community pharmacists felt that the self-monitoring service had a positive impact on their relationship with their patients and that more patients could benefit from this service, with statements scoring a median of 9.5 (range 7.0-11.0) and 10.5 (range 10.0-11.0) respectively. They felt that 25% to 75% (median of 45%) of people taking warfarin would benefit from this service. Community pharmacists felt that the self-monitoring model is a valuable service to patients, a feasible way to manage patients on warfarin and they felt confident about identifying patients who may be suitable for this model of care, with statements receiving median scores of 11 (range 8.0-11.0), 10.0 (range 10.0-11.0) and 10.0 (range 8.0-11.0), respectively. Comments received included satisfaction with being able to provide a better service and empowering patients, improvements in the pharmacist’s warfarin knowledge and counselling skills, and patients appreciating not having to go to the doctor for INR measurements. Pharmacists also commented on the potential benefits of government subsidies to wider self-monitoring implementation. A selection of comments is shown in Table 9.

#### Table 9: Community Pharmacist Comments

<table>
<thead>
<tr>
<th>Patient convenience</th>
<th>Benefits of self-monitoring</th>
<th>Implementation suggestions</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Made patient take their own control of monitoring and less reliance on travelling long distances to pathology”</td>
<td>“Improved my knowledge. Patient was happier they were doing the right thing”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>“Improved my warfarin counselling skills”</td>
<td>“More rollout with more promotional materials”</td>
</tr>
<tr>
<td></td>
<td>“Better service and empowering of patients”</td>
<td>“Government subsidy of monitor and strips to make the service more readily available to more people”</td>
</tr>
<tr>
<td>“Patients loved not having to fo to the Dr for INR measurements”</td>
<td></td>
<td>“Subsidy for tests from a National Anticoagulation Service”</td>
</tr>
</tbody>
</table>

A visual representation of the full set of community pharmacist responses is provided in Appendix 12 and comments can be seen in Appendix 13.

### 3.10 Qualitative analysis

To evaluate the implementation of the PSM model, qualitative interviews were conducted with participants and stakeholders to gain feedback on the experience. The results are based on these interviews: eight with GPs, eight with consumers taking warfarin and six with pharmacists involved in the trial. Results were generally positive and can be seen in detail in the full report in Appendix 14.
4. Discussion

4.1 Participants
Of the 32 consumers who consented to participate in the pilot study, 28 (87.5%) completed all training requirements and went on to monitor their own warfarin therapy. The proportion of patients that did not complete training is less than, but similar to, that reported by Murray et al. in a training program to enable PSM in the UK. We defined reasons for dropout during training as either self-exclusion of patients themselves or exclusion by the researcher. Of the patients, one excluded themselves due to a lack of confidence with the responsibility of performing testing. Researchers excluded one patient during training due to a diagnosis of lupus anticoagulant, which is a contraindication to using a POC INR monitor due to potentially inaccurate results with this condition. The remaining 2 consumers were excluded as their GPs refused to consent to their participation. The patients who completed the training had a median age of 66 years – older than those trained by Murray et al. and Sawicki et al.

4.2 Training for PSM
While PSM is widespread in some countries (it is estimated that 400,000 patients manage their own anticoagulation in Germany) its use is virtually non-existent at present in Australia. Hence, there is a need to develop and implement a standardised training program to enable health professionals to train patients who are capable of self-monitoring. It is advantageous to have the opportunity to develop such a training program in Australia before the demand for self-monitoring becomes established. In Germany, a nationally approved, formalised training program is established. The Association of Self-Management of Anticoagulation in Germany has established a number of training centres across the country and organises seminars to train the trainers and patients.

Accredited pharmacists are especially suited to deliver training for PSM in the patient’s home. Suitable patients could be identified by the community pharmacist or GP and then be referred to an accredited pharmacist for training. This is the model that was satisfactorily trialled in this study. Qualitative feedback on the model suggests that GPs, pharmacists and consumers were all positive to a national program for INR self-monitoring and saw potential benefits to the community. The training and support piloted in this study were all accepted and there were minimal suggested changes to the materials, indicating that a national program for INR self-monitoring could feasibly be implemented using these materials and support model.

4.3 Accuracy of the CoaguChek®XS compared to the laboratory method
When comparing the accuracy of the CoaguChek®XS to the laboratory method for INR measurement, one problem is the lack of a gold standard for comparison. The laboratory method is not infallible and previous studies have found that the variation between portable coagulometers and laboratory was not larger than the variation between different laboratories measuring a single sample. However, for the purposes of this study, comparison to the laboratory must be treated as the gold standard. The CoaguChek®XS performed well in this study. In addition to being highly accurate, participants found it simple to use and both GPs and patients were highly satisfied with its performance. Despite the disadvantage of use by 28 different users, and comparison with multiple laboratories, the CoaguChek®XS was very accurate compared to the laboratory method, with a correlation coefficient above 0.86. In this study 98% (106 of 108) of CoaguChek®XS INR tests were within 20% and 99.1% (107 of 108) were within 0.5 units of the corresponding laboratory INR.

4.4 Quality of control of warfarin therapy
There is a strong relationship between TTR and clinical outcomes for patients taking warfarin. A number of peer-reviewed studies have used TTR as a primary outcome measure. The largest of these is the Managing Anticoagulation Services Trial and the decision to use TTR was approved by an external agency for research. The risk of anticoagulant-induced bleeding is determined by risk factors such as the length of anticoagulant therapy, patient characteristics, the concomitant use of drugs that
interfere with haemostasis, and the intensity of anticoagulant effect. Control of the INR within the therapeutic range is thus critical to the safety and efficacy of oral anticoagulant use. Better INR control ultimately results in improved clinical outcomes with fewer thromboembolic or bleeding events. A number of studies have shown PSM to improve the TTR. In the view of Samsa et al., the TTR should be seen as a primary outcome, while clinical events should be regarded as secondary outcomes. Literature suggests that patients in the community spend 50-60% of their time within the target range.

Results from the present study would indicate, albeit in a small number of patients willing to self-monitor, where routine control of anticoagulation was better than expected from the literature, that there is scope for improvement in control. While the improvement in TTR in the small study population was not statistically significant, the mean TTR rose from 57.8% to 72.5% with PSM. Literature suggests that TTR is closely correlated with outcomes, and improvements in TTR of as little as 10% have been shown to convey a 29% improvement in all-cause mortality. An improvement in TTR of 5-10% has been proposed as a clinically important goal, and was achieved by the study population.

The proportion of tests within range is often biased, although simple to calculate. It tends to be biased because it is affected by a tendency for physicians to perform repeated tests soon after an out-of-range INR. This bias is likely to increase as the interval between test increases. For monthly testing intervals, data suggests that the magnitude of the bias is approximately 10%. In our study, in the six months prior to the intervention, consumers recorded a mean of 55.2% of tests were in the target range. This improved to a mean of 71.7% during PSM, a result which was statistically significant. In a recent trial involving POC INR monitoring performed in GP practices in Australia, control and intervention patients recorded percentage tests in range of 57.6% and 55.8% respectively. The control population in this study had a similar percentage tests in range to the group in the study by Bubner et al. POC INR monitoring (in the form of PSM) produced a greater increase in percentage of tests in range in the intervention group in this study, suggesting that POC INR monitoring is most effective when used by the patient themselves. This may suggest that the improvements are due to a number of patient related factors, such as improved knowledge and patient empowerment, than simply due to the use of the POC device.

The TTR marker of quality of control of warfarin therapy rewards tests that are only slightly out of range with a portion of time in the therapeutic range if the prior INR is within range. It is likely that the short duration of the self-monitoring phase, and the six-month comparison period, make it more problematic to compare these measures of warfarin control. This is because some patients had only a small number of tests in the pre-trial period so one test in or out of range had more of an impact on their control than in the PSM period. When comparing the control of participants in this study prior to the intervention, with that noted in other studies, it compared well. Approximately 50-60% of tests in range are the norm for patients attending anticoagulation clinics in the UK, it is again apparent from this measure that the pre-intervention control of enrolled patients was very good.

A number of studies support the notion that increased frequency of INR testing leads to an increased TTR, and improved outcomes. Perhaps the most important evidence illustrating the benefits of more frequent testing arose from Horstkotte where patients went from long to short testing intervals and both outcomes and patient satisfaction improved. Participants in this study recorded a significant increase in frequency of testing during the intervention period, increasing from a median of 1.2 to 2.7 INR tests per month. Even in the absence of any improvements in INR control the improvement in frequency would suggest improved outcomes for study participants.

4.5 Warfarin knowledge

Many studies have demonstrated a link between improved warfarin knowledge and outcomes. Participants’ warfarin knowledge improved significantly from baseline following the education session delivered as part of the training program. This improvement was sustained over the course of the intervention with no significant change in warfarin knowledge between the post education period and the conclusion of the PSM phase.
4.6 Quality of life
Using the EQ5D instrument, participants had a mean baseline QOL utility of 1.0 (zero tantamount to death, one optimal), which did not change significantly as a result of the intervention. A larger sample size would be required to demonstrate a significant improvement in QOL with PSM.

4.7 Evaluation questionnaire

4.7.1 General practitioners
The GPs who were involved in the study and completed an evaluation questionnaire found it to be a valuable service for their patients. Opinion was divided as to whether they would feel more confident in managing patients on warfarin if this was a regular service; however they all reported finding the HMR recommendations regarding their patient’s warfarin therapy valuable in their patient care. The doctors agreed that more patients could benefit from this type of service and the proportion of patients they felt suitable for this system ranged from 10% to 70%. GPs agreed that their patients found the PSM model to be a worthwhile service and also that they coped well with the trial requirements. When asked about their confidence with the accuracy of the CoaguChek®XS, GPs strongly agreed that they were confident with its accuracy. GPs commented on the importance of appropriate patient selection if self-monitoring were to become a more widespread model of patient care. They expressed satisfaction with self-monitoring as an alternative model of care with the potential for improving patient compliance, particularly in patients with limited mobility and poor venous access.

4.7.2 Consumers
Consumers found the PSM model to be a valuable service that made them feel more confident about their warfarin therapy. They found the initial training to be beneficial and also agreed that their warfarin knowledge had improved as a result of the training. Participants all strongly agreed that their overall quality of life had improved as a result of being able to monitor their own warfarin therapy at home and preferred home testing to pathology testing. They found the CoaguChek®XS easy to use, and importantly, strongly agreed that they were confident in the accuracy of the device. Consumers suggested implementation may need to be accompanied by a Government subsidy to make it more accessible, particularly as they felt that self-monitoring represented a cost saving to the healthcare system. They expressed satisfaction with the education and training component of the proposed self-monitoring model and with the flexibility, speed of testing, and huge time and cost savings to consumers associated with this method of testing.

4.7.3 Community pharmacists
The community pharmacists who were involved in the study and completed the evaluation questionnaire were all very positive about the self-monitoring model. They strongly agreed that the PSM model was a valuable service to their clients and felt that the proposed PSM pathway was a feasible way to manage patients on warfarin. Importantly, they all felt confident to identify potentially suitable candidates for PSM and felt more patients could benefit from this model of care. The proportion of patients that community pharmacists felt could benefit ranged from 25% to 75%. Pharmacists also suggested that the implementation of a self-monitoring model would benefit from some form of government subsidy to make it more accessible to patients. They expressed professional satisfaction arising from improvements in their knowledge, skills and service provision.

4.8 Qualitative analysis
Feedback from the qualitative analysis was generally positive and supportive of the model for the implementation of PSM that was proposed and trialled in this study. The full report arising from the interviews can be found in Appendix 14. The qualitative researchers drew a number of conclusions from the interviews. These were:

• Self-monitoring of INR is a viable option for some consumers able to cope with the self-testing procedure;
• Consumers adapt to the testing procedure quickly and without clinical problems given appropriate selection, training and support;
• Once adapted to PSM, consumers are very positive towards the experience and eager to continue;
• PSM has no detrimental effect on the GP/consumer relationship;
• GPs can be reluctant to move consumers to PSM because they perceive that many consumers are unsuitable. GPs are often content with their existing arrangements for INR monitoring and see no reason to change;
• The training and support provided in this study was well accepted and there were minimal suggested changes to the materials;
• The results indicated that a national program for PSM could be implemented using these materials and support model; and
• GPs’ attitudes towards patients monitoring their own INR levels could present a barrier to the acceptance of a national program. These attitudes could be addressed through the development of a communication strategy to inform and educate on the advantages of PSM and to whom it would be best suited.

4.9 Feasibility of the proposed model
The primary aim of this study was to develop, implement and evaluate a pharmacy-centred pathway to enable Australians who take warfarin to monitor their own therapy. To this end a wide range of training and educational resources were developed and used to pilot the model. The materials have been well received by all participants and received positive reviews from stakeholder organisations. Only minor modifications to the developed resources have been proposed, suggesting these materials are appropriate for use in a national program to enable PSM. Feedback on the proposed model from participants and stakeholders has also been positive. The proposed pathway has been demonstrated to enable the successful selection of suitable candidates for PSM, to deliver appropriate, consumer-centred education and training, and to ensure quality control procedures are in place. The model has also been shown to clinically improve measures of INR control, as well as improve other aspects important to warfarin management such as consumer knowledge. Qualitative and quantitative feedback suggests that the proposed clinical pathway for PSM is likely to a feasible model to implement within the Australian healthcare setting.

This model could be implemented in Australia under existing funding structures, with community pharmacists in an ideal position to screen and refer patients to their GP to discuss the concept of PSM. This discussion would occur with the view to referring the patient to a trained accredited pharmacist for specialised training, delivered as part of an HMR. Materials developed by this project and another funder under the Rural Pharmacy Small Project Funding Scheme (Development and implementation of a flexible anticoagulation monitoring service for rural community pharmacies) could be utilised to facilitate the implementation of this model widely within the Australian community pharmacy setting. These materials include an implementation toolkit to upskill community pharmacists in anticoagulation management and suggestions for incorporating this and other anticoagulation services into community pharmacy practice. Accredited pharmacist training is again being offered through workshops at accredited pharmacist conferences and has the potential to be offered through more flexible delivery methods to increase the number of accredited pharmacists able to access training.

4.10 Limitations of the study
This study was designed as a historically controlled proof of concept trial to determine the feasibility of a model of care involving a pharmacist-centred model of warfarin self-monitoring. While the study involved only 28 patients, it was sufficiently powered to detect an improvement in TTR. Potential limitations of the study include the method of selection of patients, the small sample size, non-randomised design, and the relatively short duration of the intervention. Patients were selected in a similar way to other trials involving PSM of warfarin therapy, but involved community pharmacists identifying participants and inviting them to participate instead of primary care physicians. GPs indicated that in any program
involving PSM they would need to be the gatekeepers and the ones who are responsible for deciding which consumers could participate in PSM.

As with other trials of PSM,\textsuperscript{99, 102} participants in this study were hand selected by their health professional. They were a highly motivated group of patients who had an interest in becoming more involved in their healthcare, and as such cannot be expected to be representative of the general population of people taking warfarin. This is not strictly a limitation as it has never been suggested that PSM is a model of management suitable for all patients, but rather it is a management strategy that improves patient adherence, satisfaction, and clinical outcomes in those patients who wish to undertake self-monitoring.\textsuperscript{104}

Participants in the study obtained much of their support from the research team during phone calls to follow up on INR results. In a program to implement PSM more broadly consumers would need to obtain this support from their community pharmacist or GP, and health professionals would need to be educated to provide this support.

4.11 Conclusions

This study was successful at demonstrating the feasibility of the proposed clinical pathway to enable PSM of warfarin therapy. Measures of INR control and consumer outcomes were improved during the PSM phase. The level of satisfaction expressed by all groups of participants in regard to both the study materials and the method of management was very high, supporting the implementation of a national program to enable INR self-monitoring in Australia.

4.11.1 Recommendations

PSM is a rapidly evolving area and Australian consumers have access to monitoring devices with no access to training, support, or appropriate follow-up. Implementation of a program such as the pathway piloted in this study is critical to improve the safety of consumers who take warfarin.

A number of recommendations have arisen from this study to inform implementation of the piloted clinical pathway as part of a national program to enable PSM:

- Implementation of PSM needs to be supported by health promotional activities to raise the awareness of the availability of point-of-care INR devices, of their place in therapy, and the usefulness of PSM as a warfarin management model. Awareness should be raised among all stakeholder groups, especially among consumers, GPs and pharmacists.

- Raised awareness should be supported by information and education to enable implementation of PSM. The web-based resource developed in this study may be an appropriate platform to raise awareness and provide access to educational materials.

- The training materials refined for use in this study have been reviewed by stakeholder organisations and piloted in the study population. It would now be appropriate for stakeholder organisations to formally endorse these materials for use in a national program.

- The screening tool used in this project should be refined and converted to a checklist to enable the selection of appropriate consumers for PSM.

- A funding model should be developed to support the proposed pathway. Recommendations include:
  - The training program developed in this study should be funded and implemented on a national level. Funded training programs should cover the training program to credential accredited pharmacists and the training program to train consumers.
  - An incentive scheme could be implemented to complement the rollout of accredited pharmacist training to ensure a critical mass of accredited pharmacists is available to deliver the training service. This could be done in a manner similar to the incentive schemes that have been used in the Diabetes Medication Assistance Service and Pharmacy Asthma Management Service.
- It may be appropriate to consider government subsidies for portable INR monitoring devices and/or consumables to consumers. It may be appropriate for conditions regarding training and ongoing QA to be attached to theses subsidies.

- Training and credentialing of accredited pharmacists to provide the PSM training service needs to be coordinated by a professional pharmacy organisation.

- Any national program to enable PSM should be accompanied by appropriate quality assurance measures, including initial and ongoing comparison pathology tests and an annual HMR. A partnership with the Royal College of Pathologists of Australasia may be appropriate to ensure ongoing QA is completed.
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Warfarin Education Program:
Accredited Pharmacist Training to Enable Patient Self-Monitoring of Warfarin

Dr Luke Bereznicki
Dr Shane Jackson
Professor Gregory Peterson
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Appendix 2: Flyer for Recruiting Candidates for Self-Monitoring

Warfarin Self-Monitoring

Who is suitable?

Adults

Long term indication for warfarin*

Interest in learning more about warfarin and monitoring their INR

Sufficient manual dexterity to operate a point of care monitor (or have a carer who is willing to do so for them)

anticoagulation.com.au

The University of Tasmania School of Pharmacy, in conjunction with the University of Sydney, is offering a small number of patients the opportunity to monitor their INR as part of an implementation pilot program. For more information, or to register your patients’ interest, email info@anticoagulation.com.au or call the School on (03) 6226 1068

* An indication for warfarin of 6 months or greater is necessary to participate in self-monitoring. Conditions which may require this duration of anticoagulation include prosthetic heart valves, atrial fibrillation, deep vein thrombosis or pulmonary embolism. Unfortunately patients with antiphospholipid syndrome are unable to self monitor their therapy as the point of care device is unable to produce accurate results in this condition.
Appendix 3: Consumer Training Booklet (table of contents)

Warfarin Education Program: Self-Monitoring Education Manual for Consumers

Dr Luke Bereznicki
Dr Shane Jackson
Professor Gregory Peterson
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11. If you miss a dose: Take the missed dose as soon as possible. If you do not remember until the next day, skip the missed dose. Only take the next dose as directed.

10. If you miss a dose:

• Severe headache
• Easy bruising
• Heavy bleeding from cuts or wounds that does not stop
• Unusually heavy menstrual bleeding
• Red or dark-brown-colored urine
• Rapid or weak or delayed heartbeat
• Coughing up blood
• Bleeding from the gums or nose

You should report the following to your doctor immediately:

9. Work:

8. Warning:

7. You should carry an identification card that shows you are taking warfarin. The test is called an INR, and it measures how fast your blood clots compared to normal. It is very important to have regular blood tests while taking warfarin.

6. Target INR range:

<table>
<thead>
<tr>
<th>Lower Limit</th>
<th>Upper Limit</th>
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<tr>
<td>1.9</td>
<td>3.1</td>
</tr>
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</table>

5. Watermark:

4. Pharmacy name:

3. Phone number:

2. Surgery name:

1. Doctor name:

If you are experiencing problems with:

www.ancobergen.com.au

If you have questions about warfarin, or need assistance, call us at: 1800 645 619

RCN self-referral number:

For further information about warfarin, or other medications, please contact the pharmacy support line: 1800 645 619.
Quick guide to warfarin treatment

1. Warfarin belongs to a class of medications called anticoagulants ("anticoagulating medicines"). Warfarin keeps blood clots from forming or getting larger.
2. Many medications can change the way warfarin works. Ask your doctor or pharmacist about using any other medication, including over-the-counter medications, vitamins and herbal products.
3. Make sure your doctor or pharmacist knows if you are taking aspirin or aspirin-like medications, such as medications for pain relief and the common cold.
4. Avoid drinking large amounts of alcohol.
5. Certain foods will change the way warfarin works. Do not change your diet while taking warfarin. Foods that contain vitamin K (such as lettuce, spinach, broccoli, cabbage, cauliflower or liver) decrease the anti-clotting effect of warfarin. If you eat foods that have vitamin K, do not change the amount of these foods that you normally eat per week. The main point regarding diet is to eat a consistent amount of foods per week that contain vitamin K.

Tips for INR self-testing

1. Warm hands under warm running water prior to test
2. "Milk" the finger – avoid squeezing
3. Don't prick finger until monitor is ready
4. Avoid calloused areas
5. Prick the side of the finger pad
6. Hold elbow up to promote blood flow to fingertips
7. Touch the drop to the test strip – not the finger to the test strip
8. Never use the same puncture if the first attempt is unsuccessful – try a different finger.
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<th>Mon</th>
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Recommended Waiting Dose

Next Appointment

Date

NEXT

INR
<table>
<thead>
<tr>
<th>Date</th>
<th>INR</th>
<th>Recommended Warfarin Dose</th>
<th>Next appointment</th>
</tr>
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<tr>
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<th>Thu</th>
<th>Fri</th>
<th>Sat</th>
<th>Sun</th>
<th>Next Appointment</th>
<th>Recommended Waiting Dose</th>
<th>INR</th>
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Appendix 5: Warfarin ID Wallet Cards

WARFARIN ID CARD

Name: ..............................................................
Address: ............................................................
Ph: .................................................................
Doctor: ..............................................................
Ph: .................................................................

I am taking a medicine which causes me to bleed more easily and for longer than normal. In case of an emergency, please call an ambulance on 000 and tell them I am taking warfarin.

WARFARIN ID CARD

Name: ..............................................................
Address: ............................................................
Ph: .................................................................
Doctor: ..............................................................
Ph: .................................................................

I am taking a medicine which causes me to bleed more easily and for longer than normal. In case of an emergency, please call an ambulance on 000 and tell them I am taking warfarin.

WARFARIN ID CARD

Name: ..............................................................
Address: ............................................................
Ph: .................................................................
Doctor: ..............................................................
Ph: .................................................................

I am taking a medicine which causes me to bleed more easily and for longer than normal. In case of an emergency, please call an ambulance on 000 and tell them I am taking warfarin.

WARFARIN ID CARD

Name: ..............................................................
Address: ............................................................
Ph: .................................................................
Doctor: ..............................................................
Ph: .................................................................

I am taking a medicine which causes me to bleed more easily and for longer than normal. In case of an emergency, please call an ambulance on 000 and tell them I am taking warfarin.

Statistics summary

Usage Statistics

In Brief:
- Average length of stay per visit to the site: **462 seconds**
- Total number of resources downloaded: **6430**
- Total number of hits: **420111**

Visitors from: **49 different countries**

- Number 1 search result in Google (in Australia)
- Over 200 subscribers to the newsletter

Requests for information

**Phone calls/emails from pharmacists regarding:**
- Interaction information (2)
- Where to source warfarin information booklets (4)
- Information to support not switching brands (1)
- Information regarding the importance of timing of dose on INR (1)
- Request for self-monitoring training booklet (3)
- Availability of promotional materials for consumers (3)

**Phone calls/emails from consumers regarding:**
- Requests for paper copies of newsletter to be posted (3)
- Interaction information (1)
- Dietary advice (4)
- Identification advice (e.g. MedicAlert) (1)
- Management process in Australia (consumer emigrating from UK) (1)
- Dose adjustment advice (1)

**Phone calls/emails from GPs/Pathology regarding:**
- Self-monitoring (1)
- Availability of promotional material for patients (1)

**Comments:**
- “The warfarin website is great - easy to use and very clear.”
- “One of the best pharmacist resources available.”
- “I enjoyed reading your site which I found very informative and easy to use.”
Appendix 7: Final Website Design*

* The images shown in this report are screen shots of the final design of the web site as it was developed for this project. The web site has been since been redeveloped for use in another Guild funded project and no longer looks as it appears in these images.

www.anticoagulation.com.au Home Page
www.anticoagulation.com.au Content (i)

www.anticoagulation.com.au Content (ii)
Appendix 8: Evaluation Questionnaire: General Practitioners

Warfarin Home Monitoring Study
General Practitioner Evaluation

Responses to the GP Evaluation Questionnaire (median values, with range lines plotted). Other results are shown in red.

1. I found self-monitoring to be a valuable way of managing my patient(s) therapy.

   - Strongly disagree
   - Strongly agree

   Unsure 1 (7.7%)

2. I would feel more confident in managing patients on warfarin if this was a regular service.

   - Strongly disagree
   - Strongly agree

   Unsure

3. I received adequate feedback and assistance from the support staff.

   - Strongly disagree
   - Strongly agree

   Unsure

4. I believe that more patients would benefit from this type of service.

   - Strongly disagree
   - Strongly agree

   Unsure 1 (7.7%)

5. If so, what proportion of all patients on warfarin do you feel would benefit? 50% (range 10%-70%)

   Unsure: 2 (15.4%)

   Unsure 1 (7.7%)

   - Strongly disagree
   - Strongly agree

   Unsure 1 (7.7%)
6. My patient coped well with the Warfarin Home Monitoring model.

[Scale for Strongly disagree to Strongly agree]

[] Unsure

7. I am confident with the accuracy of the CoaguChek XS portable INR monitor that my patient/s used.

[Scale for Strongly disagree to Strongly agree]

[] Unsure

8. I found the Home Medicines Review (HMR) recommendations regarding warfarin to be valuable in my patient care.

[Scale for Strongly disagree to Strongly agree]

[] Unsure 2 (15.4%)

9. Have you previously utilised an HMR in your practice?

[] Yes: 61.5%  [] No: 38.5%

10. I would consider routinely referring warfarinised patients for HMRs in the future.

[Scale for Strongly disagree to Strongly agree]

[] Unsure 1 (7.7%)

11. My study patient(s) had a lower rate of warfarin related adverse events than patients receiving usual care.

[Scale for Strongly disagree to Strongly agree]

[] Unsure 2 (15.4%)

12. My study patient(s) spent more time in the target INR range than patients receiving usual care.

[Scale for Strongly disagree to Strongly agree]

[] Unsure 3 (23.1%)

13. My study patient(s) had improved levels of warfarin knowledge than patients receiving usual care.

[Scale for Strongly disagree to Strongly agree]

[] Unsure 1 (7.7%)
14. I feel that this project has had a positive impact on my relationship with my patient(s).

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

☐ Unsure

1 (7.7%)

Please comment:

_________________________________________________________________________________________________________________________________________
_________________________________________________________________________________________________________________________________________
_________________________________________________________________________________________________________________________________________

15. I feel that this project has had a positive impact on my relationship with local pharmacist(s).

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

☐ Unsure

3 (23.1%)

Please comment:

_________________________________________________________________________________________________________________________________________
_________________________________________________________________________________________________________________________________________
_________________________________________________________________________________________________________________________________________

16. I see this model of care as a feasible way for me to manage suitable patients on warfarin.

<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
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<tr>
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</table>

☐ Unsure

17. Are there any aspects about this service you particularly liked (use back of page if more space is required)?

_________________________________________________________________________________________________________________________________________
_________________________________________________________________________________________________________________________________________
_________________________________________________________________________________________________________________________________________
18. Are there any ways you feel this service could be improved (use back of page if more space is required)?

.................................................................................................................................................................
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19. Any other comments about the service would be appreciated (use back of page if more space is required).

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## Appendix 9: Evaluation Questionnaires: General Practitioner Comments

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<tr>
<th>Question</th>
<th>Comments</th>
<th>Comments</th>
<th>Comments</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>14. I feel that this project has had a positive impact on my relationship with my patient(s).</td>
<td>Has made no difference</td>
<td>Save the patient more autonomy, easier for him</td>
<td>No comment</td>
<td>Need to select patients carefully</td>
</tr>
<tr>
<td>15. I feel that this project has had a positive impact on my relationship with local pharmacist(s).</td>
<td>We already get along well</td>
<td>It's instantaneous</td>
<td>No</td>
<td>I Like it</td>
</tr>
<tr>
<td>16. Patient ownership of management causes the patient to take more care with their management</td>
<td>No effect that I'm aware of</td>
<td>No comment</td>
<td>No comment</td>
<td>No comment</td>
</tr>
<tr>
<td>17. Are there any aspects of this service you particularly liked?</td>
<td>No contact since initiation of home testing</td>
<td>Good service for certain patient groups</td>
<td>Main concern is over very limited contact with patient - only once did he phone in since commencing in March, therefore unsure as to compliance and control. Whose responsibility if any problems?</td>
<td>I cannot afford the time to keep chasing him up. Overall I would prefer in this case for him to come in here to be tested.</td>
</tr>
<tr>
<td>18. Are there any ways you feel this service could be improved?</td>
<td>He feels improved and more likely to be compliant</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
</tr>
<tr>
<td>19. Any other comments about the service would be appreciated.</td>
<td>Minimal change</td>
<td>No real impact</td>
<td>(no comment)</td>
<td>(no comment)</td>
</tr>
<tr>
<td></td>
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<td></td>
<td>This patient home managed her INR's and I had no feedback on her INR levels, dosages etc. As a result I felt a little disconnected from her care. She used the POC self testing to allow herself to control her own therapy with no reference to myself. I do not believe this is necessarily a good thing!</td>
</tr>
<tr>
<td>20. No better than with previous warfarin testing</td>
<td>No change</td>
<td>1. I didn't need to see the patient in my room therefore a spare appointment for other patrons 2. I can't get blood out of Mr B very easily</td>
<td>No</td>
<td>It's a great service for: (1) people with limited mobility and (2) people who have difficult veins</td>
</tr>
<tr>
<td>21. My patient felt empowered to guide his own health but I try to encourage this approach in all patients</td>
<td>No significant effect other than working with the pharmacists running the trial</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
</tr>
<tr>
<td>22. Home monitoring for INR is not suitable for all patients, we need to choose the proper patient</td>
<td>No comment</td>
<td>Including Nursing home patients</td>
<td>(no comment)</td>
<td>(no comment)</td>
</tr>
<tr>
<td>23. We had a sensible patient, who was home test savvy due to testing for diabetes</td>
<td>We've never had a bad relationship with a pharmacist (nothing needed to change!)</td>
<td>We started with a cognitively intact, &quot;finger-pricker&quot; aware patient - it was bound to succeed in</td>
<td>(no comment)</td>
<td>(no comment)</td>
</tr>
</tbody>
</table>
Appendix 10: Evaluation Questionnaire: Consumers

---

### Warfarin Home Monitoring Study

**Patient Evaluation**

*Responses to the Pharmacist Evaluation Questionnaire (median values, with range lines plotted). Other results are shown in red.*

---

1. I found testing my own INR to be a valuable way of monitoring my therapy.

   - [ ] Strongly disagree
   - [ ] Strongly agree
   - [ ] Unsure
   - [ ] 1 (4.2%)

2. I would feel more confident about taking warfarin if this was a regular service.

   - [ ] Strongly disagree
   - [ ] Strongly agree
   - [ ] Unsure
   - [ ] 2 (8.3%)

3. I found the initial training on warfarin therapy beneficial.

   - [ ] Strongly disagree
   - [ ] Strongly agree
   - [ ] Unsure
   - [ ] 1 (4.2%)

4. I feel that my knowledge regarding warfarin therapy and my condition requiring warfarin has improved due to my involvement in the Warfarin Home Monitoring study.

   - [ ] Strongly disagree
   - [ ] Strongly agree
   - [ ] Unsure
   - [ ] 1 (4.2%)

5. I feel confident in recognising the signs of side effects of warfarin (e.g. unusual bleeding).

   - [ ] Strongly disagree
   - [ ] Strongly agree
   - [ ] Unsure
   - [ ] 2 (8.3%)

6. I feel confident in knowing what lifestyle factors (such as diet or other medications) may affect my INR.

   - [ ] Strongly disagree
   - [ ] Strongly agree
   - [ ] Unsure

---

Page 1 of 5

---
7. I understand the importance of taking my medication as per my doctor's instructions.

[Strongly disagree] [Strongly agree] [Unsure]

8. I was satisfied with the way I communicated my INR results to my doctor and they communicated the appropriate dosage directions to me.

[Strongly disagree] [Strongly agree] [Unsure] 1 (4.2%)

Please comment:

__________________________________________________________________________________________

__________________________________________________________________________________________

9. There is the potential for communication between you and your GP to be done using an internet model. Would you be interested in using such a service in the future?

[Yes: 62.5%] [No: 37.5%] [Unsure: 3 (12.5%)]

10. I feel that my overall quality of life has improved as a result of being able to monitor my own warfarin therapy at home.

[Strongly agree] [Strongly agree] [Unsure] 2 (8.3%)

11. I would prefer to monitor my warfarin therapy at home rather than through pathology testing.

[Strongly disagree] [Strongly agree] [Unsure]

12. The CoaguChek XS was simple to use.

[Strongly disagree] [Strongly agree] [Unsure]

How many test strips, on average did you need to use to get a result? 1 (range 1-4) test strips
(unsure: 1 (4.2%))

Initially in the trial I used 2 (range 1-7) strips per result (unsure: 3 (12.5%))

By the end of the trial I used 1 (range 1-2) strips per result (unsure: 3 (12.5%))
13. I am confident with the accuracy of the CoaguChek XS portable INR monitor that I have used.

[Scale with options: Strongly disagree, Unsure, Strongly agree]

14. I received adequate ongoing support from the support staff.

[Scale with options: Strongly disagree, Unsure, Strongly agree]

15. I was satisfied with my GP's involvement in the trial.

[Scale with options: Strongly disagree, Unsure, Strongly agree]

16. I feel that this project has had a positive impact on my relationship with my general practitioner.

[Scale with options: Strongly disagree, Unsure, Strongly agree]

Please comment:

________________________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________________________

17. I feel that this project has had a positive impact on my relationship with my pharmacist(s).

[Scale with options: Strongly disagree, Unsure, Strongly agree]

Please comment:

________________________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________________________
18. What features did you like best about the training session you received?

________________________________________________________________________________________________________________

________________________________________________________________________________________________________________

________________________________________________________________________________________________________________

________________________________________________________________________________________________________________

19. What features did you like least about the training session you received?

________________________________________________________________________________________________________________

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________________________________________________________________________________________________________________

________________________________________________________________________________________________________________

20. Are there any other features you would like to see in the training session (use back of page if more space is required)?

________________________________________________________________________________________________________________

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________________________________________________________________________________________________________________

21. Are there any aspects about this service you particularly liked (use back of page if more space is required)?

________________________________________________________________________________________________________________

________________________________________________________________________________________________________________

________________________________________________________________________________________________________________
22. Are there any ways you feel this service could be improved (use back of page if more space is required)?

23. Any other comments about the service would be appreciated (use back of page if more space is required).
### Appendix 11: Evaluation Questionnaires: Consumer Comments

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<tr>
<th>Question</th>
<th>Comment 1</th>
<th>Comment 2</th>
<th>Comment 3</th>
<th>Comment 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;I was satisfied with the way I communicated my INR results to my doctor and they communicated the appropriate dosage directions to me.&quot;</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>Personal, simple and easy directions</td>
<td>None</td>
</tr>
<tr>
<td>&quot;I send my results by email &amp; he replies quite promptly. This is easier than having to ring his administration staff and wait for a reply.&quot;</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>Not long enough</td>
<td>None</td>
</tr>
<tr>
<td>&quot;He is interested in the outcomes of this trial &amp; how it has affected my lifestyle to the good.&quot;</td>
<td>The pharmacist who provided me with the initial training is not my usual pharmacist. I have only had essential contact with her but she has been helpful on those occasions.</td>
<td>It was at my home at a time that was suitable to me</td>
<td>I would have liked to have the opportunity to read the literature before the ‘hands on’ training. That way I could have the time to organise my timing about appropriate questions.</td>
<td>None</td>
</tr>
<tr>
<td>&quot;My only problem was the test strips. In approximately 4 cases the drop of blood did not flow up the test strip to the required spot.&quot;</td>
<td>(no comment)</td>
<td>Strongly agree if we are talking about my pharmacist from UTAS. Ensure if the Chemist Shop</td>
<td>(no comment)</td>
<td>None</td>
</tr>
<tr>
<td>&quot;Allows me much more control of my INR levels. MUCH SAFER.&quot;</td>
<td>Interaction with GP positive. Allows instant monitoring of INR if unusual factors occur.</td>
<td>Don’t interact with pharmacist much</td>
<td>More detailed knowledge of warfarin chemistry and interactions</td>
<td>Nothing</td>
</tr>
<tr>
<td>&quot;Doctor patient understanding is very positive.&quot;</td>
<td>Understanding/trust of judgment very positive.</td>
<td>Very helpful with good advice on interactions with other substances</td>
<td>The whole scheme is a very positive step in helping to manage the problem</td>
<td>(no comment)</td>
</tr>
<tr>
<td>&quot;My doctor is very supportive of me being involved in the home monitoring programme.&quot;</td>
<td>See previous comment</td>
<td>I have not discussed this with my pharmacist.</td>
<td>The pharmacist was very patient and helpful and made sure I felt confident in doing the tests.</td>
<td>All features were OK</td>
</tr>
<tr>
<td>&quot;(In reference to Questions 8, 9, 15 &amp; 16) have never had an established doctor until recently. I have had doctors who that are learning from the loyal that come to this medical centres. I don’t blame them but they should not begin patients like me if you know what I mean. Before the medical centre changed hands I never had any trouble that’s why I am unable to answer those questions I refer to.&quot;</td>
<td>See previous comment</td>
<td>if it were not for my pharmacist I would never have known that I was being prescribed the wrong tablets (eg coumadin) instead of warfarin (my warfarin book my original doctor cancelled our coumadin by putting a cross on that section)</td>
<td>That you do not need as much blood (as pathologist use to get result!)</td>
<td>(no comment)</td>
</tr>
<tr>
<td>&quot;Never discussed with GP. My readings I considered to be more accurate as result instantly.&quot;</td>
<td>(no comment)</td>
<td>Not involved.</td>
<td>(no comment)</td>
<td>(no comment)</td>
</tr>
<tr>
<td>Question</td>
<td>Improvement</td>
<td>Communication</td>
<td>Relationship</td>
<td>Features</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------</td>
<td>---------------</td>
<td>--------------</td>
<td>----------</td>
</tr>
<tr>
<td>8. I was satisfied with the way I communicated my INR results to my doctor and they communicated the appropriate dosage directions to me.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>This is the best thing that happened to me. Both parents had a stroke before turning 50. I had a stroke at 59.</td>
<td>Couldn't recommend it more. He has taken an interest from the first.</td>
<td>No problems they are all aware and helpful.</td>
<td>The education helped me understand my problems and how to solve them.</td>
<td>Nothing</td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>GP recently retired and had little involvement before. GP was very happy as my involvement with trial and team support for personal INR testing where user can afford cost of test strips.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>I am very pleased to be able to check my own INR. It is simple, safe and reassuring.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>It is very convenient to monitor at home and receive prompt advice from GP if necessary.</td>
<td>My GP has been most cooperative.</td>
<td>My pharmacist has occasionally enquired about the in home monitoring which is very positive support.</td>
<td>Very well presented</td>
<td>None</td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>Haven't asked</td>
<td>No comment has been made by pharmacist.</td>
<td>The training session was good but I referred to the book in case I forgot something.</td>
<td>Fully explained</td>
<td>Nil</td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>Very helpful, in need, only one phone call away.</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>20. Are there any other features you would like to see in the training session?</td>
<td>21. Are there any aspects about this service you particularly liked?</td>
<td>22. Are there any ways you feel this service could be improved?</td>
<td>23. Any other comments about the service would be appreciated.</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>Professional Caring Friendly</td>
<td>Maybe more calls more often (once a month) to check all is OK</td>
<td>(no comment)</td>
<td></td>
</tr>
</tbody>
</table>

A simple flowchart of essential prompts could enhance the development of competency. Overview of what error messages may show on screen. I did find them in the supplied literature but discussion earlier could have allayed my concerns.

| (no comment) | (no comment) | (no comment) | (no comment) |

The ease of checking my INR without seeing a doctor or pathology dept.

Initially more training with the machine before going solo.

None

| (no comment) | (no comment) | (no comment) | (no comment) |

Not having to travel to Rosny to get tested is a great benefit at my age

| (no comment) | (no comment) | (no comment) |

Interpersing a test by the pathologist to check accuracy of results. Say in 1 in 4, reducing as experience and own expertise increases.

Personal involvement of UTAS staff

| (no comment) | (no comment) |

Being able to monitor INR on demand. Cost Safety.

Would be cheaper overall for Government if they subsidised machines and strips. Reduced GP visits; reduced Medicare expenses e.g. strips 1 per week at $7 versus GP visit 1 per fortnight at $36

Fine as it is

| (no comment) | (no comment) |

Personal contact is very important to the patient, to instil confidence about treatment

Fine as it is

None

| (no comment) | (no comment) |

I liked the follow up phone calls and courtesy of the trainers

No, I think it is adequate and satisfactory

(no comment)
<table>
<thead>
<tr>
<th>20. Are there any other features you would like to see in the training session?</th>
<th>21. Are there any aspects about this service you particularly liked?</th>
<th>22. Are there any ways you feel this service could be improved?</th>
<th>23. Any other comments about the service would be appreciated.</th>
</tr>
</thead>
<tbody>
<tr>
<td>(no comment)</td>
<td>Yes, I believe home testing would decrease the chances of getting an infection. It is so simple, (like diabetics like me!) are prone to getting infected</td>
<td>I would think that someone like the UFAS Pharmacists notify your doctor and tell your doctor what's going on etc. But this depends on the medical centre, but I would think drop the doctor a line, that's providing you have a permanent doctor, not like I have had since the surgery changed hands, and my original doctor went back to England. The last one I had did not know how to work out the warfarin dosage, I don't blame those doctors I had they have to learn somewhere but they should not be used on patients like me being a diabetic does not make it any easier.</td>
<td>(no comment)</td>
</tr>
</tbody>
</table>

| (no comment) | (no comment) | (no comment) | (no comment) |

No, it’s fine

The attitude of all the people involved was great and helpful.

Not at the moment

Not at the moment

| (no comment) | (no comment) | (no comment) | (no comment) |

Perhaps little more tuition in landing procedure. I had problems getting enough blood for the test, until I increased progressively over several tests the Coag from 3 to 5

Flexibility, speed of testing and huge time and cost savings - vis-a-vis having to drive 12 kms to nearest town for pathology service to take blood samples, time involved and the times to get INR results. Self-testing is especially beneficial in a pre-operative situation e.g. I have to have a biopsy and I can present for same with INR test result taken just 2 hours previously.

A simplified INR results diary would be beneficial along lines

Test Date - Result – Current Dosage – Post Test Change – Next Test Date

Ready availability of expert advice if any problems are encountered is first class and reassuring

| (no comment) | (no comment) | (no comment) | (no comment) |

No

Being able to keep check on my own health particularly when travelling. I’ve had a number of disastrous blood tests done where the needle has gone through my veins with resulting pain and bruising (only in NSW though)

No

Very occasionally I had a no brainer day and used 4 strips!
<table>
<thead>
<tr>
<th>No</th>
<th>20. Are there any other features you would like to see in the training session?</th>
<th>21. Are there any aspects about this service you particularly liked?</th>
<th>22. Are there any ways you feel this service could be improved?</th>
<th>23. Any other comments about the service would be appreciated.</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>Regular follow-up by School of Pharmacy staff</td>
<td>No</td>
<td>Very pleased with all aspects of this programme</td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>Yes, it is DIY</td>
<td>(no comment)</td>
<td>I would like to keep going</td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td>(no comment)</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 12: Evaluation Questionnaires: Community Pharmacists

Warfarin Self-Monitoring Study
Community Pharmacist Evaluation

Responses to the Pharmacist Evaluation Questionnaire (median values, with range lines plotted). Other results are shown in red.

1. I found this to be a valuable service provided to my patient(s).
   
<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   
   [Scale]

2. I see this model of care as a feasible way to manage suitable patients on warfarin.
   
<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   
   [Scale]

3. I feel confident to identify patients who may be suitable for this model of care.
   
<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   
   [Scale]

4. I believe that more patients would benefit from this type of service.
   
<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   
   [Scale]

If so, what proportion of all patients on warfarin do you feel would benefit? *45% (range 25%-75%)*

Unsure: 2 (28.6%)

5. I believe that my patient(s) found this to be a worthwhile service.
   
<table>
<thead>
<tr>
<th>Strongly disagree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
   
   [Scale]
6. My patient coped well with the Warfarin Self Monitoring model.

[1-5 scale]  
Strongly disagree  Strongly agree  
☐ Unsure

7. I received adequate feedback from the support staff.

[1-5 scale]  
Strongly disagree  Strongly agree  
☐ Unsure

8. My study patients had improved levels of warfarin knowledge than patients receiving usual care.

[1-5 scale]  
Strongly disagree  Strongly agree  
1 (14.3%)

9. I feel that this project has had a positive impact on my relationship with my patient(s).

[1-5 scale]  
Strongly disagree  Strongly agree  
☐ Unsure

Please comment:

________________________________________________________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________________________________________________________

10. I feel that this project has had a positive impact on my relationship with the local general practitioner(s).

[1-5 scale]  
Strongly disagree  Strongly agree  
1 (14.3%)

Please comment:

________________________________________________________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________________________________________________________
11. Are there any aspects about this service you particularly liked (use back of page if more space is required)?

________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________

12. Are there any ways you feel this service could be improved (use back of page if more space is required)?

________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________

13. Any other comments about the service would be appreciated (use back of page if more space is required).

________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________

________________________________________________________________________________________________________________________________________
### Appendix 13: Evaluation Questionnaires: Community Pharmacist Comments

<table>
<thead>
<tr>
<th>Question</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. I feel that this project has had a positive impact on my relationship with my patient(s).</td>
<td>Improved my warfarin counselling skills. Those patients involved in the trial appreciated the pharmacies recruitment.</td>
</tr>
<tr>
<td>10. I feel that this project has had a positive impact on my relationship with the local general practitioner(s).</td>
<td>Not enough patients recruited to generate much impact with local GPs plus one GP initially involved left district.</td>
</tr>
<tr>
<td>11. Are there any aspects about this service you particularly liked?</td>
<td>Website very good - <a href="http://www.anticoagulation.com">www.anticoagulation.com</a> especially patient information download.</td>
</tr>
<tr>
<td>12. Are there any ways you feel this service could be improved?</td>
<td>More rollout with more promotional material for trial (no comment)</td>
</tr>
<tr>
<td>13. Any other comments about the service would be appreciated.</td>
<td>Patients loved not having to go to the Dr for INR measurement (no comment)</td>
</tr>
<tr>
<td></td>
<td>We enrolled patients and usually did an INR at the same time (no comment)</td>
</tr>
<tr>
<td></td>
<td>They want to keep their monitors (no comment)</td>
</tr>
<tr>
<td>Better communication during and after project</td>
<td>No feedback from GP (no comment)</td>
</tr>
<tr>
<td></td>
<td>Improved my knowledge. Patient happy that they were doing right thing</td>
</tr>
<tr>
<td></td>
<td>(no comment)</td>
</tr>
<tr>
<td>All work was outsourced from the usual pharmacy staff to a third party</td>
<td>I’m not sure that they really appreciate the work being done and are too busy to follow up adequately (no comment)</td>
</tr>
<tr>
<td></td>
<td>Better service and empowering of patients (no comment)</td>
</tr>
<tr>
<td></td>
<td>More interaction with the referring pharmacy (no comment)</td>
</tr>
<tr>
<td></td>
<td>A worthwhile project (no comment)</td>
</tr>
<tr>
<td>(no comment)</td>
<td>(no comment)</td>
</tr>
<tr>
<td></td>
<td>(no comment)</td>
</tr>
<tr>
<td>Medec patient take their own control of monitoring and less reliance on travelling large distances to pathology</td>
<td>(no comment)</td>
</tr>
<tr>
<td></td>
<td>One monitor per patient, availability of strips, monitoring process (no comment)</td>
</tr>
<tr>
<td></td>
<td>More patients in trial (no comment)</td>
</tr>
<tr>
<td>Very little ongoing involvement. Mainly managed by the AP.</td>
<td>Hard to say - no direct communication re this issue (no comment)</td>
</tr>
<tr>
<td></td>
<td>Gov’t subsidy of monitor &amp; strips to make the service more readily available to more people (no comment)</td>
</tr>
<tr>
<td>My patient likes self-monitoring very much and appreciates that we included him in the study</td>
<td>Did not have much/any direct feedback from the GP (no comment)</td>
</tr>
<tr>
<td></td>
<td>Subsidy for tests from NAS (cf glucose test strips) (no comment)</td>
</tr>
</tbody>
</table>
Research Report on Qualitative Findings

Patient Self-Monitoring

Of

Warfarin

September 2009
Prepared for: Ella Jeffrey
Unit for Medication Outcomes Research and Education
School of Pharmacy
University of Tasmania
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1 EXECUTIVE SUMMARY

This report covers one component of a project designed to develop and implement an educational and support program to enable consumers taking warfarin to monitor their own international normalised ratio (INR) levels.

Twenty-nine consumers requiring INR testing (10 Tasmania and 10 New South Wales) were selected, trained in INR self-monitoring, and provided with point of care (POC) INR monitoring devices (CoaguChek® XS). These consumers then self-monitored their INR for at least 6 months.

To evaluate the program, qualitative interviews were conducted with participants and stakeholders to gain feedback on the experience. The results described in this report are based on these interviews: eight with general practitioners (GPs), eight with consumers taking warfarin and six with pharmacists involved in the trial.

The conclusions arising from these interviews are:

- Self-monitoring of INR is a viable option for some consumers able to cope with the testing procedure;
- Consumers adapt to the testing procedure quickly and without clinical problems given appropriate selection, training and support;
- Once adapted to self-monitoring, consumers are very positive towards the experience and eager to continue;
- INR self-monitoring has no detrimental effect on the GP/consumer relationship;
- From the data collected there was no indication that the community pharmacy / consumer relationship changed as result of consumer self-monitoring;
- GPs can be reluctant to move consumers to INR self-monitoring because they perceive that many consumers are unsuitable. GPs are often content with their existing arrangements for INR monitoring and see no reason to change;
- The training and support provided in the study was well accepted and there were minimal changes suggested to the materials;
- The results indicate that a national program for INR self-monitoring could be implemented using these materials and support model, and
2 CONCLUSIONS

Patient Self-Monitoring (PSM) is a viable option for some patients who are able to cope with the testing procedure. The training and educational materials used in this study were well received by both consumers and pharmacists and could be used in a national roll out program for INR self-monitoring.

Caution does need to be taken with generalising from these results: the sample of consumers involved in the study was small and handpicked to exclude:

- People whose GP refused consent;
- Those with a short-term indication for warfarin (that is, with an expected duration of treatment of less than 6 months);
- People unable to use the device or lacking the required visual acuity to read the device output;
- People without access to a telephone in their home;
- Those who changed their mind and decided that they no longer wished to perform self-monitoring;
- Those with the presence of the lupus anticoagulant (as this is a contraindication for obtaining accurate results with the test strips);
- Non-English speaking people;
- People aged under 18 years;
- People with intellectual or cognitive impairment;
- People who were unwilling to undertake the training process; and
- People who were unable to use the CoaguChek XS device accurately.

The results therefore reflect the experiences only of the consumers in the study. The general population of people taking warfarin could potentially differ significantly in their attitudes and in their responses to training.
2.1 INR monitoring

Patients on warfarin therapy need to have their blood coagulation checked regularly.

- **Testing options**: There were three different ways consumers involved in these interviews could have their INR levels monitored:
  - **Laboratory testing**: Involved the taking of venous blood for later diagnostic testing by a pathology laboratory. The collection point for this service occurred either at GP surgeries (sometimes conducted by the GP on selected patients) or at a separate collection point established by a pathology service.
  - **GP point of care testing (POCT)**: Some GP surgeries provided POCT for their patients on warfarin therapy. Practice nurses often performed the tests and advised the GP of the results. Any necessary dose adjustments were made by the GPs immediately after testing.
  - **INR self-monitoring**: Patients who had access to INR monitoring devices were able to perform finger prick blood tests and measure their INR levels. The results were available to them in a few seconds. They would then contact their GP via telephone, email or SMS to advise the test results and receive updated dose instructions.

- **GP preferences**: GPs often had an established INR testing preference.
  - **GPs with POCT**: The GPs who had invested in the purchase of an INR POCT device saw no advantage in laboratory testing, and preferred that their patients continue to visit their surgeries for INR monitoring because of the efficiency of the process. The results were available immediately, necessary warfarin dosage alterations could be made while their patient was visiting and there was no need to contact patients later.
  - **Laboratory testing**: Some GPs favoured laboratory testing because of its perceived accuracy and efficient communication of results to the GP, typically by electronic transfer to patients' histories. It was additionally an integral part of their established warfarin management protocols. These GPs tended to perceive several risks associated with INR self-monitoring.
2.2 Consumers and INR self-monitoring

- **Drivers**: The drivers of INR self-monitoring were:
  - Living in remote areas;
  - Difficulties in arranging transport specifically for INR testing;
  - Fear of strokes due to uncontrolled INR levels; and
  - An expectation of greater convenience and freedom.

A potential driver would be an expectation of greater coagulation control with impromptu INR testing. This was an important benefit reported by consumers.

- **Barriers**:
  - *GP attitudes* were in some cases a significant barrier:
    - A desire for full control of patients’ care;
    - An inability to trust patients to follow procedures correctly, interpret results and to take appropriate action with out of range results;
    - A fear of patients becoming too confident and moving away from adequate supervision with consequent potential for medicolegal issues in the future; and
    - Perceived medical risk.
  - It should be noted however, that GPs’ concerns about self-monitoring represented potential difficulties, theoretical problems only, since their reality was that there were no problems encountered with INR self-monitoring. *Consumers’ initial apprehension* was a barrier to INR self-monitoring. This apprehension was related to several factors:
    - The responsibility of INR self-monitoring;
    - Fear of making a mistake in the INR testing procedure and perhaps as a result getting an inaccurate result; and
    - Fear that management of their INR would be compromised, and INR levels would go out of range.

- **Acceptance**
  - *Initial acceptance*: Initially most consumers experienced apprehension with INR self-monitoring. However this was quickly overcome with home training, home visits, telephone contact and practice in collecting blood samples and using the monitoring device.
Ongoing acceptance. Consumers were very positive to INR self-monitoring and many wanted to continue with the practice following trial cessation. Ongoing acceptance was supported by GP contacts and telephone reassurance. The overall effect of INR self-monitoring was for patients to feel empowered, to have a more active role in their health management and to have a better understanding of anticoagulation therapy and its control.

Training

- Appropriateness and comprehension: Consumers evaluated the training materials very positively. None said the materials were pitched too high a level. However it was thought the elderly may need more education reinforcement than others. The materials covered all necessary areas and consumers particularly liked the diet section, diagrams and the pictures illustrating the various sections. The CoaguChek® XS booklet was also well received.

- Session timing and preferences: Consumers preferred pharmacists’ home visits over GP training or training at community pharmacies. They liked the one on one contact, lack of distractions that allowed them to concentrate on the information and the relaxed familiar environment with no pressure or urgency. Delivery of training in the environment where the self-monitoring is to occur has clear benefits in terms of information retention. Consumers would consider group training but only if it was supplementary to any initial home based training. Timing of the training was positively regarded since it had been arranged to suit the consumer. There was high satisfaction amongst consumers and GPs for this home based approach. There was little support for pharmacy based training: most pharmacies were not set up for private conversations/training and pharmacists were often too busy to set aside 20 minutes or more for uninterrupted training.

- Overall satisfaction with training model: There were very high levels of satisfaction with the training model from all consumers and no adverse comments from GPs or pharmacists.

- Suggestions for improvement: There were some suggestions for improvement in the training materials. These included:
  - Additional diagrams illustrating the educational materials; and
- An abbreviated testing summary with little additional wording so it could be followed while performing the testing procedure.

- **Impact on GP relationship**: There was some initial GP reluctance towards INR self-monitoring due to a perceived need to change established routines and potentially fewer GP visits. However, this did not result in any reduction in the quality of the GP/consumer relationship. For those with existing concomitant conditions there was no change in the frequency of GP visits. In some cases, the relationship was seen as improved because the self-monitoring was empowering for consumers and allowed them to be able to work with GPs in a more direct and collaborative manner.

- **Impact on community pharmacy relationship**: The composition of the pharmacist sample precluded a true assessment of the consumer/pharmacy relationships. Two thirds of the pharmacists sampled were either accredited pharmacists who provided training or were part-time pharmacists who had little regular contact with consumers. Thus the likelihood of ongoing relationships with consumers was minimal and little comment could be made. In retrospect, greater attention might have been given to the community pharmacists working full time.

2.3 Viability of National program for INR self-monitoring

All stakeholders involved in the study were positive to a national program for INR self-monitoring and saw potential benefits to the community. However, GPs and pharmacists held some reservations. These concerns related to the selection of appropriate candidates, the type and process of selection, the financial burden on consumers and the risks of INR self-monitoring. There were questions raised about the need for INR self-monitoring given the emergence of new anticoagulation therapies and the availability of POCT in some GP surgeries.

- **Target segments**: There was a high degree of consistency between GP and pharmacists on the selection of candidates for self-monitoring. They need to be: manually dextrous, motivated to be involved in their own health management, cognitively capable, confident, responsible, able to be trusted to perform testing to GP directions and have regular GP contact.

- **For better acceptance by GPs**: To facilitate support for a national INR self-monitoring program, a communication strategy aimed at GPs could be developed encompassing:
Demonstration of the need for and the benefits of INR self-monitoring;

Education on INR self-monitoring advantages, the accuracy of POC INR machines compared to laboratory testing, the appropriate selection of patients, ways this management model can be incorporated into their practice; and

Case histories of consumer’s experiences.

From comments made by GPs it was evident that they would need to be involved in the selection of candidates. GPs were the gatekeepers on the decision of who was appropriate for self-monitoring. This was not to discount a role for community pharmacy in suggesting to consumers that they consider INR self-monitoring and to consult their GP.

3 INTRODUCTION

The availability of the INR (international normalized ratio) monitoring device has allowed consumers on warfarin treatment to directly monitor their own INR results. There are a number of important benefits of self-monitoring including optimised control of INR, greater patient motivation and empowerment as well as improved knowledge regarding warfarin.

In countries where warfarin self-monitoring has been established, programs exist to facilitate the process. Studies involving self-monitoring have shown that patient education regarding warfarin therapy has been an integral component of the program.

In the local context it is estimated that approximately 25% of the 200,000 Australians who take warfarin would be willing and able to perform self-monitoring. However, there is currently no pathway in place to enable those on warfarin therapy to be trained and provided with ongoing support. Nor is there any method or algorithm to establish who would be best suited to self-monitoring of INR levels.

Community pharmacists are uniquely positioned to take on the roles of identification and training of individuals who are suitable for patient self-monitoring (PSM) and to provide them with ongoing support. They have the requisite expertise, regular contact with consumers taking warfarin and are sufficiently accessible to represent a valuable resource in any INR self-monitoring program. Providing the one-on-one education required for the implementation of self-monitoring is a role suited to specially trained accredited pharmacists.

This paper describes outcomes of a PSM proof of concept trial, in which pharmacist-selected consumers were trained in PSM by a group of trained accredited pharmacists. Training
materials were developed to assist the accredited pharmacists to educate consumers to self-monitor their INR levels.

Twenty-nine consumers taking warfarin (10 Tasmania and 19 New South Wales) were selected, trained in INR self-monitoring, and provided with INR monitoring devices (CoaguChek®XS). These consumers then monitored their anticoagulation therapy for at least 6 months.

This study examines the experiences of a sample of these consumers and where possible, their general practitioners and the pharmacists involved in selecting or training those consumers.

4 RESEARCH OBJECTIVES

The objectives of the qualitative research were to:

- Develop an understanding of patients’ connection with INR testing to manage anticoagulation therapy. This includes:
  - The weaknesses and strengths of laboratory and point of care (POCT) INR testing;
  - Patient expectations for the management of anticoagulation therapy;
  - Initial and ongoing acceptance of POCT and specifically any reasons for any apprehension;
  - Drivers and barriers of patient self-monitoring of INR by POCT, and
  - Effects of POCT on the patient General Practitioner or community pharmacist relationship.

- Ascertain the level of satisfaction with POCT training provided in the study. This includes:
  - Convenience of sessions and preferences;
  - Appropriateness and comprehensiveness of material provided; and
  - Satisfaction with the training model used and suggestions for improvement.

- Determine the General Practitioner and pharmacist thoughts on the viability of a nationally conducted POCT programme.

- Ascertain any issues associated with training patients.
5 RESEARCH APPROACH

5.1 Methodology

The research adopted a qualitative approach as is appropriate to achieve exploratory research objectives. Telephone depth interviews were conducted with the research participants in August - September 2009 by experienced qualitative researchers. All consumers, GPs and pharmacies had previously signed consent forms.

5.2 Sample

5.2.1 Sample selection

From the consumers involved in the self-monitoring trial, a convenience sample of eight consumers participated in the interviews. In addition eight general practitioners plus six pharmacists who had been involved in the selection of consumers for the trial or in their training were also selected to be interviewed.

5.2.2 Sample structure

Exhibit 1 outlines the sample structure used in this research. Respondents were all from either southern Tasmania or the Riverina region of New South Wales.

Exhibit 1: Sample structure

<table>
<thead>
<tr>
<th>Respondent classification</th>
<th>State</th>
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</thead>
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<tr>
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</tr>
<tr>
<td>General practitioners</td>
<td>4</td>
<td>4</td>
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</tr>
<tr>
<td>Consumers</td>
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<tr>
<td>Total</td>
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6 RESULTS

6.1 General practitioners

6.1.1 GP background

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<td>M</td>
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<td>Rural</td>
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<td>Suburb</td>
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<td>25</td>
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<td>32</td>
<td>30</td>
<td>12</td>
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<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Main INR testing procedure</td>
<td>POCT</td>
<td>POCT</td>
<td>Lab but GP takes blood</td>
<td>POCT</td>
<td>Lab²</td>
<td>POCT</td>
<td>Lab</td>
<td>Lab</td>
</tr>
<tr>
<td>Percentage self-monitoring patients to total # req. INR testing</td>
<td>3%</td>
<td>15%</td>
<td>17%</td>
<td>8%</td>
<td>8%</td>
<td>3%</td>
<td>3%</td>
<td>8%</td>
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<tr>
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<td>1</td>
<td>2</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>

1 POCT – point of care testing at GP surgery
2 Lab – laboratory testing
Of the eight GPs in the sample, four worked in general practices in southern Tasmania and four were from the Riverina region, NSW. Three of the GPs in NSW had patients who were included in the consumer sample.

Most of the sampled GPs had worked more than 15 years in general practice; the average time in practice was 22 years (range 3 to 43 years). This demonstrated that this sample of GPs had considerable experience within the general practice context.

The number of patients requiring INR testing varied by GP, from 6 to 36 patients. Those with relatively high warfarin patient numbers attributed this to an elderly patient population.

All had less than 20% of their regular INR patients using self-monitoring. Most had only one patient self-monitoring.

### 6.1.2 Coagulation testing

- **Target INR levels**: GPs were asked to provide target INR levels across conditions in which warfarin was prescribed; their responses are shown below.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Target range</th>
<th>INR range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>2.0</td>
</tr>
<tr>
<td>Pulmonary embolus DVT</td>
<td>2.0 to 3.0</td>
<td></td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>2.0 to 2.5 or 2.0 to 3.0</td>
<td></td>
</tr>
<tr>
<td>Mechanical heart valve</td>
<td>2.5 to 3.5</td>
<td></td>
</tr>
</tbody>
</table>

The table demonstrates that among these GPs there was a general agreement concerning INR targets by indication. GPs used a target of 2 to 3 in most conditions. The exception to this was in cases of mechanical heart valves when the target range was a little higher, around 2.5 to 3.5, which is consistent with the target INR range recommended for mechanical heart valves in practice guidelines.
• **Frequency of INR testing**: Frequency of INR testing varied according to expected duration of therapy as well as stability of INR levels.
  
  o **Short term anticoagulant therapy**: Patients having short term anticoagulant therapy for instance after operations or following DVT, were tested frequently, up to every second day.
  
  o **Initiation of treatment**: While warfarin dose was being titrated and until INR levels were stabilised, testing INR was typically conducted every 2 – 4 days.
  
  o **Long term anticoagulant therapy**: Once the INR levels were stabilised, testing frequency was slowly reduced. GPs liked to maintain patients on typically 4, but up to 6 weekly testing.
  
  o **Non negotiable**: The frequency of INR testing was specified and controlled by GPs, sometimes on specialists’ recommendation, and was not open for negotiation by patients. The reason for the inflexibility was fear of patients’ INR levels going out of range with potentially serious sequelae. The potential for catastrophic outcomes and medico legal issues ensured GPs gave specific testing times to patients with little flexibility for frequency negotiation.

• **Laboratory testing - strengths**: GPs in the sample were asked the strengths of laboratory testing. A few perceived no strengths of laboratory testing of INR levels because their patients did not attend a pathology lab or collection point, but were tested in the GP rooms with POCT as part of the consultation. Other GPs did perceive some positives to lab testing as detailed below:
  
  o **Reliable and accurate**: The test results were always reliable and accurate because of quality control checks undertaken at laboratories.
  
  o **Results well communicated**: In most cases INR test results were transmitted electronically to GPs every day. The results could then be imported into patient’s histories for later reference. If an INR level was outside the required range then laboratory staff call GPs to allow quick action.
  
  o **Little or no cost to patient**: INR test costs were covered by Medicare so there was minimal cost to patients.
- **GP paid for service**: GPs who took their patients’ blood (venesection) generally received a consultation fee. This payment helped to subsidise any time given for warfarin dosing and associated paperwork.

- **Constant contact between GP and patient**: Visits by patients to GPs for blood sampling ensured regular contact between patient and GP.

- **Laboratory testing – weaknesses**: The GPs were able to discuss a number of problems they perceived with laboratory based testing from three perspectives: their own, their patients and the health system.

- **Inconvenient for patients**: Patients need to travel for a venous sample to be taken.

- **No coverage over weekend**: Few laboratories provide services over the weekend. This means that if testing was required past midday on Saturday, sampling was not possible until Monday. Samples taken late on Friday also came back on Monday. So over weekends there was a significant time lag between blood sampling and the test results. This could be an issue if INR levels were considerably outside the target range.

- **Possible high total health cost**: If blood sampling is conducted at a GP clinic, then there are a number of fees involved including the consultation, sample collection and the pathology testing.

- **Slow results**: In comparison with self-monitoring, the blood test results were slow to return to GPs which was not preferable if an INR level was out of range.

- **Invasive**: Having a blood test was considered as a more invasive procedure than having a finger prick test. Many patients dislike blood tests either because of associated pain or needle fear.

- **Difficult to obtain sample**: With some patients it was difficult to obtain a sample due to poor veins. An adequate sample was often dependent on the skill level of the particular person taking the sample.

- **Patient follow-up slow**: If an INR test level was outside the expected range, the onus was then on the GP to contact the patient immediately. In some cases this was time consuming as patients may not be easily contacted for a dose change.
• **INR self-monitoring - strengths:** GPs were asked to discuss what they considered to be the strengths of self-monitoring by patients. While the majority had minimal exposure to this practice, all provided patient-centric responses:

  o **Greater patient involvement:** Most GPs saw high value in patients being involved in their own care. As a result patients feel more in control and more likely to comply with therapy in the longer term.

  o **Greater patient understanding:** Additional to the point above, GPs felt that self-testing of INR levels resulted in a greater level of understanding, both of the patient’s own health as well as the objectives of INR monitoring and warfarin treatment.

  o **More convenient for patients:** One of the key strengths of self-monitoring by patients was seen as convenience for patients. This was expressed in terms of avoiding both the need to travel and the need to wait, either at the GP clinic or another collection point. The point was that self-monitoring can be done whenever and wherever it suits patient.

  o **Instant results:** Results were available within minutes. Thus patients need not wait nor worry about what their INR level might be.

  o **Allow patients to be mobile:** Another big positive of self-monitoring was that it provides patients with freedom and mobility. This means some, for the first time would be able to travel away from home and/or their local GP. Testing can be undertaken anywhere.

• **INR self-monitoring – weaknesses:** GPs were asked to discuss what they considered to be the weaknesses of self-monitoring of INR levels by patients. These weaknesses tended to be theoretical rather than based on their experiences. The majority of GPs were quite happy with their own patients’ abilities to conduct INR testing in the home. The key issues raised were:

  o **Not for everyone:** Self-monitoring of INR was clearly limited to those patients who were cognitively capable of understanding both the test procedure and the rationale for warfarin therapy. Patients who were irresponsible about their health, who were unwilling to take control or who were lacking manual dexterity were considered to be unsuitable candidates.
Costs: Several GPs believed that the current high cost of self-monitoring devices and the test strips meant the self-testing option was financially out of reach of most patients.

Needs adequate training for patient: An issue raised by one or two GPs was the amount of time and effort needed to bring patients up to speed with self-monitoring. This time and effort represented a financial burden to the health system.

Need for regular checks: One GP saw the need for regular laboratory tests to ensure comparability with patient's results.

Prevent adequate medical supervision: One GP raised the issue that self-monitoring can allow reluctant patients to effectively escape from medical care, even to the extent of warfarin dosing without GP assistance. Usually GPs have the opportunity to check on other medical conditions when the patient comes in for INR testing. Self-monitoring could mean that the GP loses this opportunity to see the patient as frequently; a scenario with potentially serious consequences.

Risk of abuse or misuse: Some concern was expressed that self-monitoring could have serious consequences if patients were not diligent with testing and maintaining contact with their GPs. There was the potential for problems to arise if the test was not being correctly performed or if testing was less frequent than recommended. This point underscored the need to take care in patient selection.

Testing preferences: GPs preferences for INR testing were as follows:

(i) GP Rooms - point of care testing: Three GPs (2 x NSW and 1 x Tas) preferred point of care INR testing in their own rooms, with a practice nurse. Typically these GPs had purchased a CoaguChek®XS machine. This form of testing had several advantages: the tests results were known immediately, patients were able to be advised of their next doses without recourse to telephoning the GP later, efficiency and no venous blood sample requirement. For these GPs preferring to conduct testing in their rooms, point of care testing prevented many medico legal and medical risks as consumers were not trusted to be able to self-monitor as accurately and frequently as GPs. It was ultimately the GP's responsibility to dose patients appropriately with warfarin. By testing the INR
themselves, error as a result of patients incorrectly self-monitoring was eliminated.

(ii) Self-monitoring by some: Three GPs (2 x NSW and 1 x Tas) expressed a preference for self-monitoring but only when the patient was able to cope with the process and responsibility. These GPs saw it was critical that prospective self INR testers were carefully selected.

(iii) Laboratory testing: Two GPs, both in Tasmania, preferred laboratory testing as it was very much part of the routine of warfarin therapy management. The results were received electronically so a history of INR test results was available for review. However, one of these GPs also thought that selected patients could be suitable for self-monitoring.

“I would lean towards self testing if all else was equal.”

“Self testing is too risky for patients if they get things wrong and in the end I am responsible for their well being.”

6.1.3 Transition to INR self-monitoring

Overall, there were low issues raised in relation to patients moving over to self-monitoring INR levels.

- **Training:** The GPs in the sample had not been involved in patient training so most could not comment. However, they were aware that training had occurred and were very supportive of the at home training provided by accredited pharmacists.

- **Run in phase:** All GPs thought the run-in phase where two CoaguChek®XS results were compared to laboratory tests was sufficient. The comparative results were very close so this offered a lot of comfort for them and their patients. GPs who were testing INR in their practices had high confidence in the reliability of the machine as it was the same as used in their rooms.

- **Patient concerns with self-monitoring:** Most patients were comfortable about the thought of self-monitoring, and in several instances were reported as being happy with the prospect. In only a minority of cases were there any reports of initial fears or generalised concern. Those fears related to lack of confidence in the ability to do the test
correctly from the start. The point was made that not all patients would be as happy to
self-monitor as those selected for the trial.

- Overcoming barriers: Patients were assisted in overcoming any initial fears mainly
through the training provided by pharmacists together with reassurance and close contact
from their GP. In several cases the practice nurse also helped to overcome barriers
through demonstrating the procedure and explaining when to contact the GP.
Overcoming resistance to self-monitoring was a short-term issue, taking less than a week
or the time needed to conduct a few tests. None of the GPs saw the process as onerous;
most took a minimal role and viewed their input as a normal part of patient care.

- Suggestions to overcome barriers: Because of the ease with which patients become
comfortable with self-monitoring there were few suggestions made. Education was
considered to be key to successful self INR testing and most suggestions made
involved educational activities. Examples were coaching, a simple instructional DVD and
clear directions regarding when to contact the GP. The other issue raised as a way to
overcome barriers to self-monitoring was financial: one GP wanted assistance provided to
patients to help them meet the initial and ongoing costs.

6.1.4 INR self-monitoring - effect on health professional relationships

- No difference to quality: The majority of GPs reported that the introduction of self-
monitoring had made no difference to the quality of their relationship with the patients
involved. Some patients were grateful to the GP for agreeing to participate in process.
Only in one outlier case was there a report of an alteration in the relationship: specifically
the patient had disappeared from care.

- Fewer consultations - typical outcome: Most GPs reported a decrease in the frequency
of visits. This was generally considered in a positive light due to decreased Medicare
costs and increased patient satisfaction as some patients appreciate fewer visits. One
GP was concerned however, that reduced visits precluded the opportunity to monitor
other significant health issues. Another had not seen the patient since she began self-
monitoring and had no idea of the status of the warfarin treatment or her other health
issues.
• **Same number of consultations**: Two GPs reported that there had been no change in frequency of consultations as a result of patient self-monitoring. The reason for continuing to see the patient as frequently was the need to monitor concurrent conditions. The continuation of past consultation patterns was viewed in a very positive light.

“It saves them coming into the clinic. The relationship is probably more direct as I receive an SMS and then respond."

“I have to say there is not much difference.”

6.1.5 Satisfaction with INR self-monitoring

Almost all GPs were happy with the way that patients in the trial had managed the move to self-monitoring.

• **Patient selection key reservation**: Generally the GPs had few if any reservations about self-monitoring with the caveat that the patients be appropriately selected. Several GPs did not believe that many patients would be able to manage self-monitoring because of what they saw as the cognitive complexity of the task and subsequent interpretation of the INR as abnormal or normal. Some GPs saw potential problems occurring if patients were unsuitable: with the INR testing itself, its interpretation and recognition of the need to seek medical assistance. One or two GPs indicated by their comments that they could not trust patients to do the correct thing, they felt patients may stop testing and not tell their GP.

• **High satisfaction overall**: The majority of GPs was very satisfied with the move to self-monitoring on the part of the selected patients. Not only were the patients happy and in control but also the GPs had minimal requirements of them in terms of training or general support. Most were unable to find any negative aspects to self-monitoring with the particular selected patient and indeed several would like to extend the trial to include other patients. The solo dissatisfied GP had not seen the patient since the trial started and assumed that the patient was self-adjusting the warfarin dose.

“I don’t think I can give a negative view on self testing. It looks positive and so I could give it 55%.”

“I’ve got no complaints at all… the patient is managing very well and phones me every 3-4 weeks.”
6.1.6 Viability of a nationally conducted INR self-monitoring program

- **Benefit to community**: Most GPs considered that there would be significant benefits to the community if self-monitoring of warfarin was rolled out nationally. Indeed a few have considered it in the past, viewing it in a similar way to testing for blood sugars. There was a high level of confidence in the accuracy of the machines since a number were successfully using similar ones in their own practices.

- **Uncertain cost benefit**: A small number of GPs queried the cost benefit of self-monitoring given the high initial cost of the CoaguChek® machines and consumables.

- **Attendant risks**: One or two expressed concern regarding the narrow therapeutic range of warfarin. The issue was that there were serious health consequences if dosages were not kept within the correct range.

- **New therapy - no need**: One GP believed that there would be no need to bring in such a program given the imminent availability of new oral anticoagulants. This would mean the end of warfarin and the need for INR testing.

- **Not for all patients**: All GPs were at pains to point out that self-monitoring was not suitable for all warfarin patients and that the program would need to be restricted to those willing to take control of their health.

- **Target segments**: Patient types considered suitable for inclusion in a national program were:
  - Cognitively capable;
  - Confident;
  - Dextrous;
  - With regular GP contact;
  - Motivated;
  - Interested in own healthcare; and
  - Responsible and able to be trusted to carry out testing on a regular basis.
“Absolutely there is no reason why not. If it is a national program there will need to be a cost benefit and someone will have to contend with the College of Pathology.”

“I lobbied for INR self-monitoring 10 years ago. The AMA was for it.”

“It depends on the cost of the tests and machines. I am in favour but the only risk is if patients don’t test themselves enough or if they get a bad reading and don’t come into the clinic.”

“Providing they do the tests properly and as often as needed. I don’t have issues about accuracy.”

“It’s not for everyone.”
### 6.2 Consumers

#### 6.2.1 Respondent characteristics

The consumer sample was split between respondents in the Riverina region of NSW and southern Tasmania, as indicated in the table below. Of the eight consumers, five were male and three female. Ages of these consumers ranged from 43 to 80. All were secondary educated; 3 had proceeded to tertiary study but only 3 were currently employed. There was diversity in terms of their distance from the nearest hospital (2.5 to 60km) and from blood testing site (0.5 to 20km).

<table>
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<td>4 yrs</td>
<td>6 yrs</td>
<td>13 yrs</td>
<td>12 yrs</td>
</tr>
</tbody>
</table>
Consumers were asked to outline the diagnoses which lead to treatment with warfarin. All were able to provide a history of their treatment and why and when it had started. The consumers suffered from the following conditions:

- Arrhythmias X 2
- Atrial Fibrillation X 3
- Severe thyroid problem
- Heart valve replacement

6.2.2 Anticoagulation therapy

Respondents were asked about their feelings towards anticoagulation therapy with the following findings:

- **Little concern over warfarin**: In the consumer sample there was little to no concern over warfarin (as a drug) with only a few patients describing an initial concern when they first commenced therapy. Any initial concerns often could be attributed to friends and family making disparaging remarks about warfarin therapy. Most realised that if their coagulation was maintained within set limits then warfarin therapy did not warrant concern.

  “People worried me to start with as they treated me like I was walking on egg shells so I felt I was on my back foot all the time.”

  “I may have been hesitant 25 years ago when I commenced warfarin therapy.”

- **Worry over poorly managed coagulation**: The fear of another stroke or severely fluctuating INR levels was a concern to many. All wanted to ensure they were within the INR range set by their medical practitioner. Some had difficulty controlling their INR levels due to a variety of reasons which included: idiopathic, diet, other medications and missing doses.

  "If I miss a dose I get a rapid plunge and it is a long time to get back to my normal levels."

- **Knowledge of blood clotting**: During the discussion the interviewers informally assessed the consumers for their general knowledge of blood clotting. All consumers in the sample were deemed to have an ‘average to very good’ general knowledge of blood
Clothing with most having 'good' knowledge. This was sufficient for these consumers to understand anticoagulation therapy and which external influences could affect INR levels.

'I have studied it and understand the basics of the mechanism. I understand the reason for INR testing.'

'I have researched the topic and have read all the reading material with the coag machine.'

6.2.3 Coagulation monitoring

- **Target INR levels**: the ranges of INR levels targeted by consumers under directions from their medical practitioners were:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Target range</th>
<th>INR range</th>
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<tbody>
<tr>
<td></td>
<td>range 2.0</td>
<td>2.5</td>
</tr>
<tr>
<td>Glomerular nephritis</td>
<td>2.0</td>
<td>X</td>
</tr>
<tr>
<td>Arrhythmia including atrial fibrillation</td>
<td>2.0 to 3.0</td>
<td></td>
</tr>
<tr>
<td>Post stroke</td>
<td>2.9 to 3.5</td>
<td></td>
</tr>
<tr>
<td>Mechanical heart valve</td>
<td>3.0 to 3.5</td>
<td></td>
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</table>

Most respondents aimed for an INR reading between 2.0 and 3.0. Exceptions were in the cases of a mechanical replacement heart valve or following a previous stroke when the target INR range was between 2.9 and 3.5.

- **Frequency of INR testing**: Consumers were asked to comment on the frequency of their INR testing.

  - **Set by medical practitioner**: In all cases, the frequency of INR testing was set by the consumers’ medical practitioners. None mentioned that there was any negotiation on the frequency as most abided by their doctors' recommendations on testing frequencies.

  - **Time period**: Initially testing would be every one or two days until the INR levels had stabilised, then the testing frequency would extend to fortnightly or monthly. Should the INR become unstable or move away from the targeted range then the
testing frequency would increase to every second day until levels were re-established.

6.2.4 Usual care (laboratory and point of care testing)

Consumers had a range of experiences with INR testing. Many have INR testing conducted at doctors’ surgeries and some in the laboratory setting.

- **Testing experience:** Prior to PSM all consumers travelled outside their residences for INR testing. In some cases, especially in Wagga Wagga, their local GP staff performed the testing with a point of care monitor (similar to that used in the trial) and test strips. All others had travelled to a pathology collection point. Within the sample, INR testing had been occurring for as long as the warfarin therapy: from 2 to 25 years.

- **Laboratory testing - strengths:** Consumers were asked to comment on the strengths of laboratory INR testing. Their comments were:
  - **Nothing:** Half the sample perceived lab testing as having no strengths;
  - **Other tests:** Some consumers needed other diagnostic tests conducted so while blood was taken a number of other tests could be conducted;
  - **Cheaper cost to consumer:** Laboratory testing was cheaper to consumers as it was reimbursed by Medicare; and
  - **Reassurance of laboratory tests:** Laboratory testing could provide a check for self-monitoring results.

- **Laboratory testing - weaknesses:** Consumers were asked to comment on the weaknesses of laboratory INR testing. Their comments were:
  - **Inconvenient:** Laboratory facilities required consumers to travel to the site. In some cases this also required transport to be arranged. Both were inconvenient;
  - **Time wasting:** Time was wasted when travelling to and from the laboratory and waiting in line for their turn. Added to this was the time required to get ready to leave the house (out of work or gardening clothes) and arrange suitable transport;
  - **Delayed results:** It took some time for the INR results to be available (up to 24hrs). This could especially be a problem over a weekend when some patients had to wait
until Monday before learning of their test results. This was worrying for consumers, especially when their coagulation times were fluctuating and they were worried about the possible consequences out of range INR levels; and

- **Venipuncture issue**: Some did not like to have blood taken for tests because the withdrawal of blood from a vein was difficult. This was attributed to their 'poor veins' and sometimes multiple venipunctures were required to obtain the necessary amount of blood.

### 6.2.5 INR self-monitoring

As part of the trial consumers were supplied with a CoaguChek®XS device and test strips for monitoring their own INR levels. This is a summary of their comments regarding patient self-monitoring after self testing INR levels for at least 6 months.

- **Self-monitoring**
  - **Impetus to self-monitor**: Most consumers decided to self-monitor after being asked by their local pharmacist or GP practice nurse to consider participating in the trial. A few learnt of the trial from advertising.
  - **Performance of self testing**: All consumers but one performed their own INR testing. The exception was the consumer with a carer.
  - **Competency**: While some had initial problems with the testing machine operation and blood collection, all felt they had become adequately proficient with self-monitoring after some practice. At the time of the interviews all participants were comfortable performing their own tests. The exception was the participant with the carer. In this case, the carer was comfortable with the testing procedure.

- **Drivers for self-monitoring**: Consumers were asked to list the reasons why they decided to try self-monitoring. The reasons were:
  - **Remote residence**: Two consumers lived in remote areas that were over 12 kilometres from the nearest laboratory testing site or collection depot so testing was inconvenient due to the travelling time;
- **Difficulty travelling for INR testing**: One patient needed a carer and another was a carer for his wife so both had trouble leaving their residences for testing reasons.

- **Working full time**: Two of the three who worked full time found INR testing inconvenient and one needed to travel for work and found testing while travelling difficult.

- **Fear of strokes**: Two feared strokes and wanted the security of knowing their INR levels at any time. Of these, one had recently suffered a stroke despite having good INR control.

- **Expectation of greater convenience and freedom**: Some consumers were very excited about the prospect of self-monitoring INR levels as they did not need to travel for testing and therefore it was more convenient. One recent stroke victim felt self-conscious going to the pathology laboratory due to some residual paralysis; and

- **Expectation of greater coagulation control**: Some liked the prospect of being able to perform tests whenever they were concerned about their INR levels.

*Also mentioned, however they were not drivers:*

- **Nothing to lose**: Some had the view that there was nothing to lose in self-monitoring INR levels; it could only be a bonus; and

- **Familiarity with CoaguChek®S**: Some consumers had their INR tests performed at their GPs' surgeries so the concept was familiar to them. It was a small transition to do it themselves.

“My pharmacist suggested that I go on the trial so I thought why not, there is nothing to lose.”

“It is so much more convenient and I feel safer.”

“I was interested in it (self-monitoring) was going to help me.”

“I felt a bit self-conscious going so regularly to the path lab as I only had a stroke 2 months ago.”

“I heard about the trial on the news and I immediately rang and asked to go on the trial.”

“I am able to do it now without reading any instructions.”
• **INR self-monitoring - strengths:** Consumers provided a wide range of positive aspects of self-monitoring.

  o **Health empowerment:** Consumers spoke of being more in control of their own health and felt empowered by this. One outcome of this was that they often became more interested in their health and understood their medical conditions more than previously;

  o **Convenient:** There were a number of reasons that consumers found self testing convenient;

    ⇒ **No travelling** - Travelling away from home or work for INR testing was a inconvenience for consumers and an unwelcome intrusion;

    ⇒ **No waiting** - Consumers did not have to wait at GPs or pathology laboratory;

    ⇒ **Testing at convenient times** – Testing could be conducted at convenient times of the day: outside testing often suited the testing site and not the consumer; and

    ⇒ **Good if isolated:** For those in isolated locations, there was no need to travel long distances for testing INR levels.

  o **Simple to operate machine:** With a little practice the CoaguCheck®XS machine was easy to use;

  o **Immediate results:** The results were immediate so there was no delay between testing and results and no need to coordinate a telephone call to the GP for the results;

  o **Reassurance:** When fears arose that INR levels may be outside the target ranges, self-monitoring provided reassurance that there was no potential problem, removing the need to attend the GP to have INR checked;

  o **INR levels more consistent:** Some considered their INR levels were more consistent since moving to self-monitoring. This could have been related to the next point;
- **Better knowledge**: There was a better understanding on how food and other external factors influenced INR levels. Consumers spoke of a greater depth of knowledge concerning warfarin therapy than they had previously.

- **Freedom to travel**: It was difficult to find testing facilities when consumers travelled, especially overseas. Self-monitoring facilitated travel. Results could be emailed to GPs from anywhere in the world and the dosage could then be emailed back. It was a simple system which worked very well and gave consumers freedom.

- **Simpler system**: Self-monitoring was regarded as simpler than the complexity of pathology testing. No planning was required, nor were there any time constraints. When combined with current telecommunications to inform the GP of results, self-monitoring also was simple in that it removed the need to call the GP after the pathology results were available; and

- **GP and patient happier**: Some thought both GPs and patients were happier with self-monitoring as it was easier to manage.

  "In fact since using it, my INR levels have been more consistent."
  "If I have doubts about my INR levels then I can test it and it reassures me."
  "I now better know the relationship between food and INR levels... Prior to self-monitoring I could never work it out."
  "Now I can go on a trip with comfort..."
  "If I have a problem then I can ring my GP in Wagga and tell him my results. I don't need a special trip..."
  "When I travel I can get remote assistance from my GP with email. It works very well."
  "I don't have to rely on path labs."
  "If something should happen I can do a test. I don't have to wait to go to the lab for a test."
  "If I have forgotten to take a tablet then I can do a test to check."

- **INR self-monitoring - weaknesses**: Few weaknesses were expressed by consumers regarding self-monitoring.
None: Many stated there simply were no weaknesses with self-monitoring.

Machine affected by temperature: At extreme temperatures the CoaguChek®XS did not operate. One consumer related how the machine needed to be placed in a refrigerator to cool it down before it would work. Others mentioned that extreme cold affected the operation of the battery, producing error messages.

Practice required: Some consumers required practice with the process before they could perform it without mistakes. Most problems related to collecting enough blood and loading the blood on the test strip.

Comprehension: A few thought the reading and comprehension of the machine’s instructions may be too detailed for some people; and

Test strips out of date: Should test strips go out of date then that may affect INR readings and consumers may not be aware the machine was reading incorrectly. However it should be noted that the device will produce an error message and not display an INR result if the test strips were out of date.

“I had to redo the first ones a couple of times as I had trouble picking up the blood.”

“At the beginning the results were a little higher than the lab results. If I had 2.0 the lab had 2.7. But now I know it doesn’t matter.”

“I had a nursing background and have been self injecting Cleuran® for some time so it was easy.”

“There are no weaknesses that I can see.”

6.2.6 Testing preferences

All consumers in the sample wanted to continue self-monitoring and not return to their previous mode of INR testing. Some were very definite with their desire to continue and wondered what was to happen at the end of the study. The findings are best illustrated with the consumers’ own words.
“Originally I was a bit uncomfrotable about the machine and the trial. But now after 6 months I would love to stay with the machine.”

“Self-testing is easy to do it is a breeze.”

“I much prefer to do it myself. I can go places as often as I want and I don’t have to ring my doctor for results. I don’t have to go to sleep wondering about my levels if my GP hasn’t got back to me.”

“Absolutely without doubt I want to do it myself…”

“It is brilliant I want to buy the machine. I am very happy.”

“I prefer to self because of the convenience. I am able to do it any time of the day. Anytime it suits me and not my GP. I don’t have to make an appointment and my results are there immediately.”

“I prefer self-testing as I am a carer and it is difficult to get out of home.”

“They are going to have to fight to get their machine back.”

6.2.7 Transition to INR self-monitoring

• **Feelings at commencement**: the feelings of consumers at the commencement of the study were a mix of apprehension and excitement.
  
  - **Concerns of responsibility and understanding**: Some were apprehensive when it came time to conduct their own INR tests as they had to learn the testing steps and did not want to make a mistake. In this way, it was daunting for a few to be in control of their INR testing. These concerns were transient, once they were fully trained and had used the machine all became comfortable with self-monitoring.

  - **Some excitement**: The realisation that their lives were about to change, they would be freer and have less inconvenience made some feel excited.

    “I was excited and relieved when I started. I knew something about the machine and knew the freedom it would give me.”

    “I was excited about it as I was used to doing my wife’s blood sugars.”

    “My main concern was the potential of doing something wrong and then getting too much warfarin.”
• **Training:** Most training for the trial was conducted in consumers’ homes by accredited pharmacists. One visit was conducted in a training room at the local hospital. Visits were timed to be convenient to consumers and the training materials were covered at a good pace for the audience. Most issues or questions were answered at this time.

“Carl the chemist sat in the tea room (hospital) and I did one in front of him and I didn’t have a problem. There were only a couple of times I had to redo them and that was all to do with picking up a drop of blood.”

• **Run in phase:** Consumers were required to conduct two tests with the CoaguChek®XS machine and compare these results with two laboratory samples taken within four hours of each other. This was completed in all cases and was regarded as appropriate without the need for more comparative tests.

“I had dad’s blood (INR levels) with his results... I knew the INR average and where he was. All I needed to do was make sure the reading stayed between 2 and 3. It went off one week and the dose was changed. I knew if he was behaving.”

• **Initial concerns with self-monitoring:** Consumers in the sample were asked about any initial barriers to self-monitoring. Their comments were:
  
  o **Mostly no concern:** Most consumers in the sample had no to few concerns about moving to self-monitoring;

  o **Different readings:** Some consumers were initially concerned with slight differences in readings between their usual testing and self-monitoring. However with a little more knowledge and experience with self testing they realised that this was not a real concern; and

  o **Capability issues:** Some had concerns about their ability to perform self-monitoring satisfactorily. The specific concerns mentioned were; performing a finger prick on themselves, collecting adequate blood for the test strips and finishing the testing process within the recommended time. Only one consumer (who did not perform the testing themselves) indicated that they had been initially a little panicked by the testing procedure.
"There was only one difference between the GP machine and my reading. They said that was pretty good so I was happy after that."

"I did not have any concerns however I had to get used to getting the right amount of blood on the strip. At the start I probably wasted one in five strips."

"I remember that I had to do the test in 2 minutes and I was a little panicked but in fact 2 minutes is a long time to get the test done."

- **Overcoming concerns & time taken:** If consumers had any concerns with self-monitoring these were quickly dismissed once they had performed a few tests by themselves. Thus the time to dispel concerns was spoken in terms of:

  "About three goes with the machine."

  "A couple of weeks of testing." (stroke patient)

  "It was ok after the first time."

- **Assistance provided:** Assistance to overcome any concerns was provided in the few cases by a GP, the pharmacists providing the training, a relative and a practice nurse connected to a GP surgery. Some consumers read more of the literature provided to reassure them. A telephone contact number was provided to all consumers and this offered considerable reassurance should they need information or assistance. It was also mentioned how important it was for GPs to have some education with self-monitoring machines.

  "GPs need to have some background on the machine."

- **Advice to overcome concerns:** There were suggestions made on ways to alleviate concerns patients may have when commencing INR self-monitoring. These included:

  - **No need to rush:** Should consumers feel panicked about the 2 minute time limit before they need to insert the strip into their machine, they need to be reassured and told that 2 minutes is more than enough time to go from blood collection to the reading phase;
- **Set up well**: Before testing it was important to have everything ready for each test and have a mini check list to assist with each step;

- **Practice**: Consumers valued the time spent with their trainer (accredited pharmacist). It was important for consumers to perform one or two tests while the trainer was watching as in most cases this dispelled any concerns consumers may have had about self-monitoring. It was also suggested that being supervised in a group setting may be useful as consumers could learn off each other, and

- **Expect some variance**: Some small difference may occur between laboratory and self-monitoring. Consumers should be advised that this is not unusual as one uses a venous sample and the other uses peripheral blood from the finger. Consumers might expect to see a small variation as a result.

"They should remember that 2 minutes is a long time and there is no need to panic. It is lots of time to get the test done."

"I was told that there was a difference in testing and that I should take an average."

"Have everything ready before starting, wait for the beep and remember there’s no need to feel rushed."

"The pharmacist should do more than show. They should do the test with the patient or watch the patient doing it himself."

"Read through the material and make yourself a mini check list with a simple structure and few words...the existing material has too many words at each step."

"It would be good to be supervised in a group as then you are able to learn from watching each other and listening to questions the others may have."

### 6.2.8 Health professional relationships

- **Initial relationship**: Consumers in the sample either had an established professional relationship with their GP and pharmacist or not. As would be expected an existing relationship seemed to depend on consumers’ previous medical needs. There were no mentions of a poor prior relationship; all reported good relationships.

- **Influence of self-monitoring**: It was important to note that from the consumers’ perspective there was no reduction in strength of the professional relationship with their
GP or pharmacist as a result of self-monitoring. Indeed some spoke of an improved relationship with their GP following their move to self-monitoring. One patient believed his GP seemed initially reluctant to accept self-monitoring and attributed this to the GP’s potential revenue reduction as the patient had been tested in the GP surgery by POCT. In most cases any relationships with community pharmacists were unchanged. The established relationships were good to start with and were unchanged while on INR monitoring. Only very few consumers had prior contact with the accredited pharmacist who performed the training. Once training and follow up had finished, all contact with the accredited pharmacist ceased as there was no need.

“I am not sure, maybe the GPs need to be enlightened on what happened (as a result of self-monitoring). Do some GPs have friends at Hobart Pathology? It saves them writing out blood test request slips. GPs should be told it will save them time as there will be no visits for purely lost slips.”

“The relationship with my GP is good. He is happy for me to have the machine as he can prescribe antibiotics and not be worried. So overall you could say it was better.”

“I think it is a stronger relationship with my GP. I think he is relieved of the tedium (of ordering and following up on INR test results) so he can concentrate on more important issues and be more productive.”

6.2.9 **Overall satisfaction**

Consumers were asked to comment on their satisfaction with all aspects of the move to self-monitoring:

- **Training:** All consumers were satisfied with the training provided by the accredited pharmacists. The training materials were well received. Most described them as comprehensive or very good. Consumers liked the easy to follow combination of diagrams and words. Some suggestions for improvements to the materials were made:
  - Provision of a short summary of the testing procedure so consumers could follow it without having to follow reading lots of words. It could be a picture and a few words telling users what to do;
  - A smaller recording booklet. The recording booklet (A4) used was too large for some; a smaller one would be more convenient and useful especially when away from home as it could fit into handbags or pockets; and
Potential users should complete a couple of INR tests with the trainer observing to ensure users were fully informed.

“Geoff (accredited pharmacist) was good as I got a deeper understanding of the interaction between food and my (INR) levels.”

“We went through the booklet together and it was very good.”

“The package (training) was excellent and we put together.”

“It was very adequate and detailed. In all it was pretty straight forward.”

“The training material was good but it was a lot of writing, especially for older people.”

“It was really interesting to have a face to face session and he (pharmacist) took his time to explain things. He told me that it was about 2 days between the effects of taking food and a change in the results.”

- **Session convenience**: In nearly all cases the training was completed at the consumers’ homes and at a time convenient to them. This approach was well received. The home setting was familiar and relaxed and thereby aided the learning experience.

- **Preferences for training location**: The most favoured training location was in the consumer’s home. Not only was this a familiar and relaxed setting, but was also where the testing would be subsequently conducted. The second favourite was a GP clinic where the practice nurse could provide the training. Pharmacies were suggested by only a few as possible training sites but with the caveat that private areas with no distractions were available.

  “It would be better to have the training at home as it is familiar surroundings but I expect it would be more cost effective if we all went to a centre somewhere... the next best option would be to go to a GP clinic as most pharmacies don’t have a private area... if they had a private area then it would be ok.”

  “It was good to have it done at home as that is where I self test anyway.”

- **Move to self-monitoring**: All consumers in the sample were very satisfied with their move to self-monitoring. Only one consumer had any lingering reservations concerning self-monitoring and that was one who had difficulties with temperature extremes when CoaguChek®BKS did not function. All others were very satisfied with self-monitoring many expressing a strong desire to continue with self-monitoring.
“It is the best thing since sliced bread; you do your testing on your schedule.”
“I am happy to continue monitoring myself until I drop off my perch.”
“I was over the moon to be included in the study.”
“I couldn’t be more satisfied with it”
“It is a very good thing.”
6.3 Pharmacists

6.3.1 Respondent Background

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<th>Pharmacist</th>
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Two pharmacists were from NSW and four were from Tasmania. As far as their respective roles in the study were concerned, two had provided consumer training, the rest worked as community pharmacists. Their pharmacy experience ranged from 4 years to 31 years (mean 15.9 yrs). All but one had previous experience with INR testing.

6.3.2 Coagulation testing

- **Frequency of INR testing:** It was the GPs’ role to set the INR testing routines and advise patients of their warfarin doses. Generally pharmacists did not suggest INR testing frequencies to consumers. Infrequently, when consumers’ test results were variable or unstable, pharmacists might suggest more frequent testing for a short time or suggest the patient contact the GP.

*I would suggest they contact their GP.*
“Generally patients are well controlled and they would test every fortnight.”

“Initially it is the GP’s domain but I might make a comment if the patient comes in with their test results.”

“The range and testing frequency are set by the GP. If the readings were not stable then I may recommend more frequent testing.”

• **Laboratory testing - strengths:** Pharmacists were asked to discuss the strengths of laboratory INR testing. Their comments were:
  
  o **Better assurance of result:** Laboratories have methodologies and quality checks to provide consistent testing. This means the results are accurate and reliable;

  o **No or low cost to consumer:** INR tests are often bulk billed so the cost to the consumer is minimal;

  o **Good back up to home testing:** Laboratory testing can be used as a backup if there was an aberrant INR self-monitoring result or if the CoaguChek®XS machine failed to function. This was especially helpful when CoaguChek®XS did not work because of temperature fluctuations in the environment; and

  o **Good communication of results:** Laboratories send test results to GPs electronically. This allows GPs to maintain an electronic record of patient’s INR levels within in prescribing software.

• **Laboratory testing – weaknesses:** Pharmacists were asked to discuss the weaknesses of laboratory INR testing. Their comments were:

  o **Difficult for some patients:** Some people have poor veins or dislike blood being taken: a trip to the laboratory for a venesection is not pleasurable experience;

  o **Delayed results:** It can be at least 24 hours before laboratory INR results are known so there is a waiting period. This delay in knowing results is absent with point of care testing; and

  o **Inconvenience to consumer:** A trip to the laboratory, collection point or GP requires driving or arranging transport. This represents a time commitment for those
in the workforce or living in rural settings and can be a significant problem for the elderly.

- **Self-monitoring – strengths**: Pharmacists were asked to discuss the strengths of self-monitoring. Their comments were:
  
  - **Convenient**: Self-monitoring is convenient for the following reasons:
    
    ⇒ There is no need for people to travel as testing can be conducted anywhere.
    
    ⇒ Tests can be completed when desired. This is particularly important when a person is not feeling well and wishes to rule out any concerns related to blood clotting times.
  
  - **Instant reading**: There is no waiting for results with self-testing.
  
  - **Consumers learn more**: Consumers generally learn more about their condition once they have adopted INR self-monitoring. It allows them to see the effects of food on INR levels more readily, since they can test more frequently.
  
  - **Less invasive test**: A finger prick is less invasive than a venous puncture and for some would be more attractive.

- **Self-monitoring – weaknesses**: Pharmacists were asked to discuss the weaknesses of self-monitoring. Their comments were:
  
  - **Not for everyone**: Patients need to be selected for self-monitoring as it is not for everyone. Pharmacists agreed that several types of consumers would be poor candidates for self-monitoring: insufficiently dextrous, disinterested or unable to understand the minimum requirements;
  
  - **Non compliant consumers create risk**: Consumers who failed to communicate their test results to their GP, or who did not test often enough perhaps due to forgetfulness or who did not follow the testing instructions were unsuitable candidates for self-monitoring. All could create a potential risk for themselves and medico legal issues for the GP; and
• **Training required:** People need to have some understanding of blood coagulation and be well trained in the testing procedure to be capable of performing their own INR testing. To achieve this requires significant effort, resources and follow up.

• **Finger prick reluctance:** Some people may be reluctant to use Lancing devices for finger pricking.

• **Costs:** The INR testing machines and strips are not subsidised by Government and are expensive. This means that self-monitoring will be only be available to those who can afford it; and

• **Cross checking:** Self-monitoring need to be cross checked with laboratory testing from time to time to ensure levels and correct testing techniques.

*It can be painful to finger-prick yourself.*

• **Pharmacy-based point of care testing:** Half the pharmacist sample had considered pharmacy-based INR testing. Only one pharmacist had provided such a testing service. The others had not because of a number of hindrances: unsuitable layout to accommodate clinical services, lack of a separate professional area or insufficient manpower and time to devote to a service.

• **Criteria for self-monitoring:** The consensus was that self-monitoring was not for all people. Pharmacists may suggest to some patients that they should consider self-monitoring. The criteria used by the pharmacist sample in selecting consumers included:

  o **Adequate dexterity:** Consumers need to have adequate dexterity to be able to use the INR testing strips and machine;

  o **Motivated and take ownership:** To continue with self-monitoring consumers need to be sufficiently motivated and interested in their health care;

  o **Cognitively capable:** Consumers need to be able to understand the fundamentals of the clotting process and how to operate the CoaguChek®XS device; and

  o **Ability to afford the test:** The CoaguChek®XS machine and test strips are expensive for most consumers so only a few will be able to afford the machine and consumables.
• **Testing preferences:** All pharmacists in the sample preferred self-monitoring over laboratory testing with the proviso that the demands of self-monitoring could be coped with by the consumer. Some thought that the Government should make self-monitoring available to those consumers meeting some of the criteria above.

“If depends on the person, in a perfect world everyone on warfarin would be self-monitoring but some would not be able to manage it.”

“The convenience of a finger prick and immediate results is enough reason to support self-monitoring.”

### 6.3.3 Transition to self-monitoring

• **Training:** Two accredited pharmacists were interviewed, one each from NSW and Tasmania, and they were responsible for providing most of the training for consumers in the trial. There were no reports of any problems with the training materials or any complaints that the training sessions were inadequate. However, some of the more elderly consumers did require a little more time to absorb the information than others. Some patients had difficulty performing the initial test procedures but this issue was overcome easily with more practice.

“I always redemonstrated the machine and especially to the elderly to make sure the process was ok and they would not have any problems.”

“Once they had done it (a test) four or five times then they were OK.”

“I was quite impressed on how it was set up and with the information provided.”

• **Run-in phase:** Consumers undertook two self-obtained INR tests and compared them to a laboratory test result with the sample taken within four hours of the POC test. This was sufficient to allay any fears or apprehension consumers may have had with their ability to self-monitor and reassured them that the results were accurate and comparable to laboratory testing.

“Two tests were the way to go.”
- **Barriers to self-monitoring:** Some consumers had difficulty getting used to a new testing system. The main issues causing problems related to the test: fear of not completing the test in time, inability to turn on the machine, inability to reset the date/time, not obtaining sufficient blood for testing and not being fully comfortable performing the test.

- **Overcoming barriers:** There were some suggestions for overcoming these barriers:
  
  o **Machine practice:** All the identified barriers were overcome once consumers had used the CoaguChek®XS machine several times. It was suggested that some consumers should complete 4 to 5 tests if they were experiencing problems with the testing procedure e.g. using the lancet, obtaining a blood sample and then placing the strip in the machine;

  o **Training with no distractions:** It was important for the training to be conducted in an environment free from interruptions or distractions: the consumer’s home was ideal, and

  o **Telephone support/ follow up:** The accredited pharmacists also provided support through telephone calls and in some cases extra visits. Consumers could be guided through most parts of the testing process by telephone. Some consumers received up to 4 follow up calls to address any issues and to provide support. This was a time to reinforce the testing protocol to ensure consumers were completing all the necessary steps. It consumers were coping well then a monthly telephone call was all that was needed. For those not coping well with self-monitoring a weekly telephone call may be needed.

  > "There should be more structured follow up after the training to ensure patients are ok. It could be weekly for 2 weeks then monthly."

### 6.3.4 Satisfaction with INR self-monitoring

- **Reservations regarding INR self-monitoring:** There were some concerns regarding self-monitoring:

  o **Misuse of device:** Over the longer term consumers may become less stringent with the proper testing steps. This could have the outcome of reducing the accuracy of
the test. This possible scenario was a concern and could mean that tests should be verified by regular laboratory test comparisons;

- **Over confidence**: Some consumers could become overly confident. This might mean they rely too much on the machine or that they fail to communicate with their GP as regularly as they should; and

- **Not for all patients**: If consumers were not able to manage testing then they should not perform self-monitoring.

> "If patients are screened by their GP correctly to pick up those suitable for testing, it would be a great thing."

> "I don't have any concerns. If the criteria are followed, they are trained well and they are told who to contact if there is a problem then you don't have concerns."

- **Training Materials**: No pharmacists who had seen or used the training materials provided offered any complaints about content or appropriateness.

- **Patient satisfaction**: Comments made by consumers to the pharmacists in the sample indicated that they were satisfied with the transition to self-monitoring.

> "One loves it as they are young and they travel a lot. She thinks it is fantastic."

> "They were happy with it (training) and not one said they needed any more."

> "One was most complimentary about the training..."

### 6.3.5 Viability of a nationally conducted INR self-monitoring program

- **Target segments**: The consumers who could be included in a national program were suggested to be:
  - Cognitively capable;
  - Adequately dextrous;
  - With regular GP contact;
  - Interested in own healthcare;
  - With relatively stable INR levels; and
- Ability to afford self-monitoring consumables.

- **Likelihood:** All pharmacists in the sample supported a national program for self-monitoring of INR levels. Recruitment for the program should be based on recommendations by GPs. Pharmacists could make suggestions to consumers to consider self-monitoring but this would be best done in consultation with the GP.

  "I think it would be a great benefit (for consumers) to regularly monitor themselves. The GPs will see how easy it is for patients... it is of great benefit to patients."

  "In the short term it may be a lot of work. But patients will get better management of their warfarin so there will be fewer people outside their ranges (INR)."

  "Recruitment would be best through GPs. If the GP is confident a patient can do their own testing then that patient should be made aware of self testing."

- **Communications strategy:** In any national program consumers should be directed to contact their GP for more information. Pharmacy could contribute to a national program by suggesting to selected consumers that they consider self-monitoring and to consult their GP if interested. There would need to be development of specific criteria or indicators of appropriate consumers for use by pharmacists.
7 APPENDICES

7.1 Appendices 1 – General practitioner discussion guide

Patient Self-Monitoring of Warfarin Project (IIG)

GP Discussion GUIDE

Background: Explain purpose of research: To determine the acceptance of INR self-monitoring in the Australian situation

Note: This represents a guide rather than a set of specific questions. The purpose of the guide is to provide a framework for interviews, and to provide a list of the issues to be covered.

Briefly explain the following points:
• Research objectives: To determine:
  o The weaknesses and strengths of laboratory and point of care INR testing
  o Patient expectations for the management of anticoagulation therapy
  o The initial and ongoing acceptance of point of care testing and any reasons for patient apprehension
  o The drivers and barriers of self-monitoring of INR by point of care testing
  o The effects on point of care testing on the relationship of patients with General Practitioners
  o The viability of a nationally conducted POCT INR programme

• Confidentiality and anonymity, privacy
• Timing: interview will take about 20 minutes.
• Honorarium: General Practitioners: $150

1. Participant profile – General Practitioner

The aim here is to get an overview of the respondent. Encourage respondents to describe themselves and situation, including:
- Years in GP practice
- Type of practice (city, regional, number GPs in practice, any specialties)
- An estimate of the number of their patients needing regular INR testing;
- The percentage or number using POCT in their practice;

2. Expectations of anticoagulant therapy

Obtain a detailed picture of the GPs’ thoughts on INR levels and targets.

Specifically with General practitioners explore:
- The INR levels (range) in what diagnoses do they aim to achieve;
- If and what they recommend as the frequency of testing, in what situations and the rationale;
- Do they advise patients specifically the frequency of INR testing or is it negotiated between patient and GP?

3. INR testing options

Explain to the patient that as they now have experienced both self-monitoring and laboratory testing we would like to obtain their opinion on the strengths and weaknesses of both.

Specifically with General Practitioners explore:
- What they feel are the strengths of laboratory testing for patients and GPs;
- What were weaknesses of laboratory testing in their view;
- If they encourage patients to self-monitor their INR;
- Is it all patients or do they have a patient criteria before suggesting it to patients?
- What do they feel are the strengths of Point of Care INR testing;
- Are there any weaknesses with Point of Care INR testing and what are they?
- What is the GPs preference for INR testing; do they lean towards laboratory or self testing, and does it depend on the patient type.

4. Initiation of Point of Care INR testing

Here we want to learn what problems or issues patients may have when moving over to Point of Care INR testing.
Specifically with General practitioners explore:

- Patients had a run-in phase comparing two test results with pathology testing before self-monitoring their INR – do they feel this is sufficient? Feelings about this;
- What issues/barriers do patients have to overcome in order to commence testing their own INR? (fears, apprehension etc);
- What or who assisted patients in overcoming these barriers;
- Did the GP have to provide assistance or reassurance and was this onerous for them;
- How long does it generally take to overcome these barriers;
- Any suggestions they have to help patients overcome any barriers (support etc).

5. Health Professional relationships

Obtain an understanding of any changes in the relationships with the respondent’s medical practitioners or community pharmacy since moving to POCT.

Explore:

- The extent which POCT may have changed the relationship with his/her patient;
- How would they describe this relationship now after moving to POCT;
- Do they see their patients more or less than previously and is that good or bad;
- Would they say the relationships were better or worse than before (if not already mentioned);
- If there were any negative aspects to this relationship now, what suggestions would they have to minimize or overcome these negative aspects?

6. Level of Satisfaction with POCT

If not already covered explore this GP’s satisfaction with POCT.

Explore:

- Do they have any reservations with POCT;
- Any impression of POCT training (may have received impression from patients’ comments);
- Overall how satisfied this GP is with their patients’ move to POCT;
- The likelihood that this program of training and POCT could be used nationally;
- The areas or segments which may benefit more from POCT (is it for all patients or just some. Which types);
- Confidence with the accuracy and reliability of the point of care INR device;
- Would they consider offering self-monitoring as an option to other patients? Why/why not!
• Do they feel a scheme such as the one in this project could be rolled out nationally? Reasons for their view and any changes they would make to the project.

Thank the GP for their time and take contact details for the GP to receive the incentive of $150. Terminate interview.
7.2 Appendices 2 – Consumer discussion guide

Patient Self-Monitoring of Warfarin Project
(IIG)

Consumer Discussion GUIDE

Background: Explain purpose of research: To discuss their feelings about warfarin self-monitoring.

Note: This represents a guide rather than a set of specific questions. The purpose of the guide is to provide a framework for interviews, and to provide a list of the issues to be covered.

Briefly explain the following points:
- Research objectives: To determine
  - The weaknesses and strengths of laboratory and point of care INR testing
  - Consumer expectations for the management of warfarin therapy
  - The initial and ongoing acceptance of point of care testing and any reasons for patient apprehension
  - The drivers and barriers of self-monitoring of INR by point of care testing
  - The effects on point of care testing on the relationship of patients with General Practitioners and pharmacists
  - The level of satisfaction with point of care testing training provided in the study

- Confidentiality and anonymity, privacy
- Timing: interview will take about 30 to 40 minutes and definitely no longer than one hour.
- Honorarium: Patients: $50

1. Participant profile - Consumer

The aim here is to get an overview of the respondent. Encourage respondents to describe themselves and situation, including:

- Patients: Ascertain:
  - Family status (married, single etc., children);
2. Expectations of warfarin therapy

Obtain a detailed picture of the respondent's thoughts on their INR levels and target aims.

Specifically with consumers explore:
- Overall impressions of warfarin therapy including perceptions of safety, effectiveness, and fears
- Their knowledge of blood clotting and INR levels they regard to be acceptable
- What INR levels (range) they aim to achieve
- How often they need to test and the rationale (could be GP instruction Generally every 2 to 4 weeks)
- Do they test themselves or do they receive assistance from a family member or friend?
- Is there a level of competency which they hope to attain with INR testing which they have not achieved yet and what is this?

3. INR testing options

Explain to the consumer that as they now have experienced both self-monitoring and laboratory testing we would like to obtain their opinion on the strengths and weaknesses of both.

Specifically with consumers explore:
- Encourage the respondents to discuss their history of any laboratory INR testing (where and by whom)
- What they feel are the strengths of laboratory testing
- What were weaknesses to them?
- What were the main reasons (drivers) for them wanting to consider Point of Care INR testing
- What they feel are the strengths of Point of Care INR testing
- Are there any weaknesses with Point of Care INR testing and what are they?
4. Initiation of Point of Care INR testing

Here we want to learn what problems or issues consumers had when moving over to Point of Care INR testing.

Specifically with patients explore:

- What were their feelings when they were about to start their own INR testing?
- Did the run-in phase where two results were compared to pathology results assure them that they could use the monitor appropriately?
- What issues did the patient have to overcome in order to commence testing their own INR? (fears, apprehension etc)
- What or who assisted them in overcoming these barriers;
- How long did it take to overcome these barriers;
- What suggestions do they have to help others overcome these barriers which they did not use or mention above;

5. Health Professional relationships

Obtain an understanding of any changes in the relationships with the respondent’s medical practitioners or community pharmacy since moving to POCT.

- Ask the consumer to describe what their relationship were like with their (1) GP and (11) community pharmacist before they commenced with POCT;
- How would they describe these relationships now after moving to POCT?
- Would they say the relationships were better or worse than before (in not already mentioned);
- If there were any negative aspects to these relationships now, what suggestions would they have to minimize or overcome these negative affects?
- Relationship with accredited pharmacist (who performed training)

6. Level of Satisfaction with Self-Monitoring and training
If not already covered explore this patient’s satisfaction with POCT

Explore:
- Do they have any lingering reservations with testing themselves?
- When, where and who provided the training on self-monitoring?
- How well the respondent understood the training and was it necessary to go over some points a few times before the patient was confident they understood?
- What was the quality of the material provided and could it be improved?
- Where there any inadequacies in other parts of the training and if so how could this be improved?
- Where the sessions convenient to them or would another time have suited them better?
- Do they feel the training would be best delivered in the home, the pharmacy or the GP clinic?
- Overall how satisfied this patient is with their move to POCT and their testing.

Thank the respondent for their time and take contact details for the patient to receive the incentive of $50.

Terminate interview.
7.3 Appendices 3 – Pharmacist discussion guide

Patient Self-Monitoring of Warfarin Project (IIG)

Pharmacist Discussion GUIDE

Background: Explain purpose of research: To determine the acceptance of INR self-monitoring in the Australian situation

Note: This represents a guide rather than a set of specific questions. The purpose of the guide is to provide a framework for interviews, and to provide a list of the issues to be covered.

Briefly explain the following points:
- Research objectives: To determine:
  - The weaknesses and strengths of laboratory and point of care INR testing
  - Patient expectations for the management of anticoagulation therapy
  - The initial and ongoing acceptance of point of care testing and any reasons for patient apprehension
  - The drivers and barriers of self-monitoring of INR by point of care testing
  - The effects on point of care testing on the relationship of patients with General Practitioners
  - The viability of a nationally conducted POCT programme

- Confidentiality and anonymity, privacy
- Timing: interview will take about 20 minutes.
- Honorarium: Pharmacists $100

1 Participant profile – Pharmacist

The aim here is to get an overview of the respondent. Encourage respondents to describe themselves and situation, including:

- Years in community pharmacy practice
- Type of practice (city, regional, number of staff)
- Involvement with INR testing
- Role in the project – accredited pharmacist in a training role, community pharmacist, etc

Commercial in Confidence
2. Expectations of anticoagulant therapy

Obtain a detailed picture of the PhC’s thoughts on INR levels and targets.

Specifically with Pharmacists explore:
- The INR levels (range) targeted for patients;
- If and what they recommend as the frequency of testing, in what situations and the rationale;
- Do PhC advise patients on the frequency of INR testing to be used or is it negotiated between patient and GP?

3. INR testing options

Explain to the PhC we would like to obtain their opinion on the strengths and weaknesses of both self-monitoring and laboratory testing of INRs.

Specifically with PhC explore:
- What they feel are the strengths of laboratory testing for patients;
- What were weaknesses of laboratory testing in their view;
- If they actively suggest to patients to self test their INR;
- Is it all patients or do they have a patient criteria before suggesting self-monitoring INRs?
- What they feel are the strengths of Point of Care INR testing;
- Are there any weaknesses with Point of Care INR testing and what are they?
- Do they have a preference between laboratory and self-monitoring;
- Have you considered offering Point of Care INR testing in your pharmacy? Why/why not?

4. Initiation of Point of Care INR testing and Patient Training

Here we want to learn what problems or issues patients may have when moving over to Point of Care INR testing.

Specifically with PhC explore:
5. Level of Satisfaction with POCT

If not already covered explore this P&Co satisfaction with POCT

- Do they have any reservations regarding POCT;
- Any impression of POCT training (may have received impression from patients’ comments);
- Do they have contact with patients after they have moved to POCT;
- Do patients feel happy after moving to POCT (if applicable);
- The likelihood that this program of training and POCT could be used nationally;
- The areas or segments which may benefit more from POCT (is it for all patients or just some. Which types)
- Would you now consider offering anticoagulation services to your patients? Such as in pharmacy INR testing, training for self-monitoring, outreach services involving monitoring a patient’s INR in their home e.g. as part of an HMR

6. National Scheme for POCT

If not already covered explore likelihood for national scheme

- What is the likelihood that this scheme could be used nationally?
- What areas of the program would work well and what ones would need improvement?
- How could improvements be made;
- What communication strategy would most likely work!
Thank the PkC for their time

Terminate interview.
Appendix 15: EQ5D Quality of Life Instrument

Health Questionnaire

By placing a tick in one box in each group below, please indicate which statements best describe your own health state today.

**Mobility**
- I have no problems in walking around
- I have some problems in walking around
- I am confined to bed

**Personal Care**
- I have no problems with personal care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

**Usual Activities** *(e.g. work, study, housework, family or leisure activities)*
- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

**Pain/Discomfort**
- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

**Anxiety/Depression**
- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

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To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.
Appendix 16: Adapted Oral Anticoagulation Knowledge Test

Warfarin Knowledge Questionnaire

Section One

Please place an X in the box(es) that best describe you and your situation

Sex:  ☐ Male    ☐ Female
Age:  ☐ under 30  ☐ 31-50  ☐ 51-60  ☐ 61-70  ☐ 71-80  ☐ above 80

What year did you start taking warfarin? ..................................................
(if you can’t remember exactly when, about how long have you been taking it for?)

Where were you started on warfarin?
  ☐ In hospital
  ☐ By your family doctor/general practitioner

When were commenced on warfarin, were you given a “warfarin booklet”?
  ☐ Yes    ☐ No    ☐ Not sure

As far as you know, which of the following are reasons for your present warfarin treatment?
  ☐ Deep vein thrombosis (DVT) – blood clot in leg vein
  ☐ Heart surgery
  ☐ Atrial fibrillation (AF)
  ☐ Peripheral arterial disease
  ☐ Stroke
  ☐ Prosthetic (artificial) heart valves
  ☐ Pulmonary embolism (PE) – blood clot in lung
  ☐ Heart disease
  ☐ Unknown/unable to tell

Do you know what your most recent INR was?
  ☐ Yes    ☐ No

What was it? ..........................................................................................
Section Two

For each question, place an X in the box next to the answer you think is correct or best completes the sentence correctly. Please answer all questions.

1. Missing one dose of warfarin:
   - Has no effect
   - Can alter the drug’s effectiveness
   - Is permissible as long as you take a double dose next time
   - Is permissible as long as you watch which foods you eat

2. You can distinguish between different strengths of warfarin tablets by what?
   - Colour
   - Shape
   - Size
   - Weight

3. A person on warfarin therapy should contact their doctor (or the healthcare provider who monitors their therapy) when:
   - Another physician adds a new medication
   - Another physician stops a current medication
   - Another physician changes a dose of a current medication
   - All of the above

4. Occasionally eating a large amount of leafy green vegetables while taking warfarin can:
   - Increase your risk of bleeding from warfarin
   - Reduce the effectiveness of warfarin
   - Cause upset stomach and vomiting
   - Reduce your risk of having a blood clot

5. Which of the following vitamins interacts with warfarin?
   - Vitamin B12
   - Vitamin A
   - Vitamin B6
   - Vitamin K

6. When is it safe to take a medication that interacts with warfarin?
   - If you take the warfarin in the morning and the interacting medication at night
   - If your healthcare provider is aware of the interaction and checks your INR regularly
   - If you take your warfarin every other day
   - It is never safe to take a medication that interacts with warfarin
7. The INR test is:
   - A blood test used to monitor your warfarin therapy
   - A blood test that is rarely done while on warfarin
   - A blood test that checks the amount of vitamin K in your diet
   - A blood test that can determine if you need to be on warfarin

8. Warfarin may be used to:
   - Treat people that already have a blood clot
   - Treat people that have high blood sugar levels
   - Treat people with high blood pressure
   - Treat people with severe wounds

9. A patient with an INR value below their target range:
   - Is at an increased risk of bleeding
   - Is at an increased risk of developing a clot
   - Is more likely to have a skin rash from warfarin
   - Is more likely to experience side effects from warfarin

10. Taking medication containing aspirin or other non-steroidal anti-inflammatory medications such as ibuprofen (Nurofen®, Advil®) while on warfarin will:
    - Reduce the effectiveness of warfarin
    - Increase your risk of bleeding from warfarin
    - Cause a blood clot to form
    - Require you to increase your dose of warfarin

11. A person on warfarin should seek immediate medical attention:
    - If they skip more than two doses of warfarin in a row
    - If they notice blood in their stool when they go to the bathroom
    - If they experience a minor nosebleed
    - If they develop bruises on their arms or legs

12. Skipping even one dose of warfarin can:
    - Cause your INR to be above the ‘target range’
    - Increase your risk of bleeding
    - Cause your INR to be below the ‘target range’
    - Decrease your risk of having a clot
13. Drinking alcohol while taking warfarin:
   - ☐ Is safe as long as you separate your dose of warfarin and the alcohol consumption
   - ☐ May affect your INR
   - ☐ Does not affect your INR
   - ☐ Is safe as long as you are on a low dose

14. Once you have been stabilised on the correct dose of warfarin, about how often should your INR value be tested?
   - ☐ Once a week
   - ☐ Once a month
   - ☐ Once every other month
   - ☐ Once every 3 months

15. It is important for a person on warfarin to monitor for signs of bleeding:
   - ☐ Only when their INR is above the target range
   - ☐ At all times
   - ☐ Only when their INR is below the target range
   - ☐ Only when they miss a dose

16. The best thing to do if you miss a dose of warfarin is to:
   - ☐ Double up the next day
   - ☐ Take the next scheduled dose and tell your healthcare provider
   - ☐ Call your healthcare provider immediately
   - ☐ Discontinue warfarin altogether

17. When it comes to diet, people taking warfarin should:
   - ☐ Never eat foods that contain large amounts of vitamin K
   - ☐ Keep a diary of all of the foods they eat
   - ☐ Be consistent and eat a diet that includes all types of food
   - ☐ Increase the amount of vegetables they eat

18. Each time you get your INR checked, you should:
   - ☐ Skip your dose of warfarin on the day of the test
   - ☐ Avoid eating high fat meals on the day of the test
   - ☐ Avoid foods high in vitamin K on the day of the test
   - ☐ Let your doctor know if you missed any doses of warfarin
19. Which of the following over-the-counter products is most likely to interact with warfarin?

- Nicotine replacement therapies
- Herbal/dietary supplements
- Allergy medications
- Calcium supplements

20. A patient with a INR value above the ‘target range’:

- Is at an increased risk of having a clot
- Is more likely to have drowsiness and fatigue from warfarin
- Is at an increased risk of bleeding
- Is less likely to experience side effects from warfarin