

# Community Pharmacist-led Anticoagulation Management Service

## Final Report

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## Executive Summary

This report details the evaluation of the Health Workforce New Zealand (HWNZ)-sponsored innovation project 'Community Pharmacist-led Anticoagulation Management Service (CPAMS)'. The project was led by the Pharmaceutical Society of New Zealand (PSNZ).

### Background

Warfarin is the most commonly used oral anticoagulant in New Zealand. Its successful use requires monitoring using a blood clotting test reported as an international normalised ratio (INR). Each patient is assigned a target INR within an acceptable range of  $\pm 0.5$  units. If the INR is below the target range the patient is at increased risk of a thromboembolic event (such as stroke); if the INR is above the target range the patient is at increased risk of bleeding.

The proportion of time in the therapeutic range (TTR) is a widely used measure of the quality of anticoagulation control. International guidelines recommend maintaining a TTR of 60% or above in order to maximise the benefits of warfarin and to limit adverse events. In New Zealand, warfarin treatment in primary care is usually managed by general practice, with venous blood sampling and testing by a laboratory. Results are communicated back to the general practice where a decision is made on dose adjustment. TTRs in studies using this model of care, both in New Zealand and elsewhere, have typically been less than 60%.

### CPAMS

The CPAMS project proposed a new model of care whereby accredited community pharmacists provided point-of-care INR testing (using a CoaguChek XS Plus device) by way of a capillary blood sample and adjusted warfarin doses with the aid of a decision support system (INR Online). Authority to perform testing, review results and implement dose adjustments was delegated to the pharmacist by the patient's general practitioner (GP); the GP retained overall responsibility for the patient's management and could intervene at any time.

The overall aim of the CPAMS project was to investigate whether the role of community pharmacists should be extended to provide a new service to patients for the monitoring of anticoagulant (warfarin) therapy. The aim of the evaluation was to ascertain whether this innovative model of care can provide safe, effective and cost-effective care that is acceptable to patients and other healthcare providers.

### Methods

Approval to conduct the study was granted by the Multi-region Ethics Committee in December 2010. Fifteen pharmacies were selected from interested sites, with a spread of urban, suburban and rural populations and a variety of socio-demographic and ethnic backgrounds. Pharmacists were trained and accredited on point-of-care testing and warfarin management.

General practitioner and patient recruitment took place during December 2010 and January 2011; informed consent was required from both GPs and patients. By the end of January 2011, 693 patients had been recruited across the 15 pharmacy sites and entered the service.

## **Finding 1: Effectiveness and Safety of the Service**

The INR Online database stored demographic data for each patient; treatment details including indication, INR target range and intended duration; and information collected at each visit, including test results, doses and details of adverse events and hospitalisations. The patients enrolled were predominantly male (62.4%), aged over 65 (70.6%) and were receiving warfarin for prevention of ischaemic stroke complicating atrial fibrillation (73.8%).

The mean TTR for the 671 patients whose results were evaluated was 78.6%, rising to 79.4% and 80.2% for patients who had been in the CPAMS for 16 weeks or 26 weeks respectively. All pharmacy sites achieved a mean TTR in excess of 70% (range 71.4% to 84.1%) well above the recommended target of 60%. Of the 693 patients enrolled, 587 remained in the service at 31 July, 2011. The majority of those who left the service had warfarin discontinued or returned to GP care.

The mean interval between tests across the whole study was 14.4 days; with more frequent testing in months 1 to 3 (every 9.7 days) but increasing to 16.7 days in months 4 to 6. Compliance with appointments was excellent with 83.1% of tests occurring on or before the due date.

Prior INR data (6 months) was obtained for 154 patients from six sites. For these patients, mean TTR for the CPAMS was 77.5% and for standard care was 60.4%; whereas the mean interval between tests was similar with 12.6 days for the CPAMS and 13.5 days for standard care.

There were 436 episodes of bleeding or bruising recorded during the study, of these seven were categorised as major bleeds. Three thromboembolic events were recorded during the study. There were 192 recorded hospitalisations during the study, of these 174 were judged to be unrelated to warfarin treatment and ten definitely related to warfarin treatment. Due to the small sample size it is not possible to conclude that there was a reduction in the number of warfarin-related adverse events for patients in the CPAMS. However, using TTR as a marker for the quality of anticoagulation control, it is reasonable to postulate a reduction in potential adverse events and hospitalisations.

## **Finding 2: Acceptability of the Service**

Patients, pharmacists, GPs and practice nurses were surveyed on their opinions of the CPAMS; in addition a number of interviews were conducted with each group. Questionnaire responses were recorded from 60% of patients; 83% of pharmacists; 24% of GPs; and nurses from 29% of practices. Although the latter percentages are small there was good consistency in the responses. Full analysis is presented in the text; overall responses are presented here.

The great majority of patients found the CPAMS to be convenient and accessible, preferable to the previous system, and expressed confidence in the pharmacist to perform the service. Many patients felt that it had increased their involvement with treatment. A small proportion of patients expressed a preference for GP care. Most patients wanted the service to continue but there was divided opinion on whether they would use it if they had to pay a fee.

Pharmacists were overwhelmingly positive about the service. All were pleased to play a much more patient-focused role. They felt that their relationships with both patients and other health professionals had improved and they were confident in their ability to provide a safe and effective service. They unanimously supported continuation of the service.

While the sample sizes were small, the majority of both GPs and practice nurses expressed confidence in pharmacists' ability to offer the service and felt that there were positive benefits for both patients (convenience) and themselves (time saved). Some concerns were expressed about

communication of results and possible fragmentation of services. The majority wished to see continuation of the service and wider availability.

### **Finding 3 Cost-benefit analysis**

The cost-benefit model for the CPAMS, submitted to HWNZ in the proposal, was evaluated and updated using data collected during the project, for example time taken to perform the service, frequency of testing, etc. An established tool (The Economic Model of Oral Anticoagulation Therapy (OAT)) was used to estimate cost-benefit. A full economic analysis was beyond the scope of this evaluation. The strengths and limitations of this approach are fully discussed in the report.

Using data generated from this study and from published research in New Zealand, the cost of standard care is estimated to be \$1301.76 per patient per year, and of the CPAMS to be \$908.16 per patient per year.

When the cost and frequency of hospital admissions and thromboembolic events are factored in to the OAT cost-benefit model, the predicted budget impact from a government perspective is a net reduction in anticoagulation-associated costs of approximately \$177 million over 5 years (for 80% of patients managed under the CPAMS), or approximately NZ\$111 million over 5 years (for 50% of patients managed under the CPAMS).

### **Conclusions**

The aim of the evaluation was to ascertain whether the CPAMS can provide safe, effective and cost-effective care that is acceptable to patients and other healthcare providers.

The most notable result in terms of safety and effectiveness is the mean TTR achieved in this study. In all sites this exceeded 70% and the mean TTR across the whole study was 78.6%, rising to 80.2% for patients with 26 weeks or more of tests. Using TTR as a measure of the quality of anticoagulation control, this result strongly suggests that community pharmacists, appropriately trained and accredited, can provide a high quality service. Other measures, such as compliance with appointments, are further evidence of the effectiveness of the service.

The limitations of cost-benefit analysis in a study such as this are acknowledged. Nevertheless, using data validated in this study, the cost per patient per year is about 30% less for the CPAMS than standard care. Economic modelling would further suggest that the improvements in anticoagulation control could lead to substantial cost savings through the reduction of both thromboembolic and major bleeding events.

In terms of the acceptability of the service, a large majority of those surveyed (patients, pharmacists, GPs and practice nurses) supported its implementation and continuation. Some useful perspectives on how it could be improved were received from all parties.

Our conclusion is that this is a safe, effective and cost-effective alternative to 'standard' anticoagulation management. Some valuable insights into future service provision have been gained. Our recommendation is that this model of care should be extended to allow all eligible patients in New Zealand to access it.

## Introduction

This is the final report on the evaluation of the Health Workforce New Zealand (HWNZ) innovation project 'Community Pharmacist-led Anticoagulation Management Service', referred to throughout this report as the CPAMS.

The innovation project was established to investigate whether the role of community pharmacists should be extended to provide a new service to patients for the monitoring of anticoagulant therapy; specifically the oral anticoagulant warfarin. The aim of the evaluation is to ascertain whether this innovative model of care can provide safe, effective and cost-effective care that is acceptable to patients and other healthcare providers.

## Background

### Anticoagulant therapy and monitoring

Anticoagulants are medications that slow the rate at which blood clots. They are used to prevent blood clots from forming in the blood vessels or to treat blood clots that have already formed and are prescribed for a range of indications including:

- prevention of ischaemic stroke in patients with atrial fibrillation,
- treatment and prevention of deep vein thrombosis and pulmonary embolism,
- prevention of clot formation on some types of replacement heart valves,
- prevention of further strokes in patients who have previously had an ischaemic stroke.

Warfarin is the most commonly used oral anticoagulant in New Zealand. It is also the drug most frequently associated with adverse drug events in New Zealand.(1). Warfarin requires careful individual titration because the potency of its effect varies from patient to patient. Too low a dose will put the patient at risk of inadequate protection or treatment, too high a dose can result in potentially dangerous bleeding. In addition, the dose a patient needs can change over time and is affected by factors such as alterations to diet or alcohol intake, other medications or concurrent illness. Regular blood tests and dose adjustment are essential to ensure safe management.

Results of blood tests for patients on warfarin are reported as an international normalised ratio (INR). This ratio compares the time taken for the patient's blood to form a clot with the time taken for untreated blood to form a clot. Each patient is assigned a target within an acceptable range of  $\pm 0.5$  units, typically a target of 2.5 allowing variation between 2.0 and 3.0. For prevention of ischaemic stroke in atrial fibrillation, an INR of greater than 2.0 is required for maximum efficacy but some benefit remains at an INR of 1.5 to 1.9.(2) The risk of bleeding increases exponentially as the INR rises and it becomes clinically unacceptable once the INR is greater than 5.0.(2)

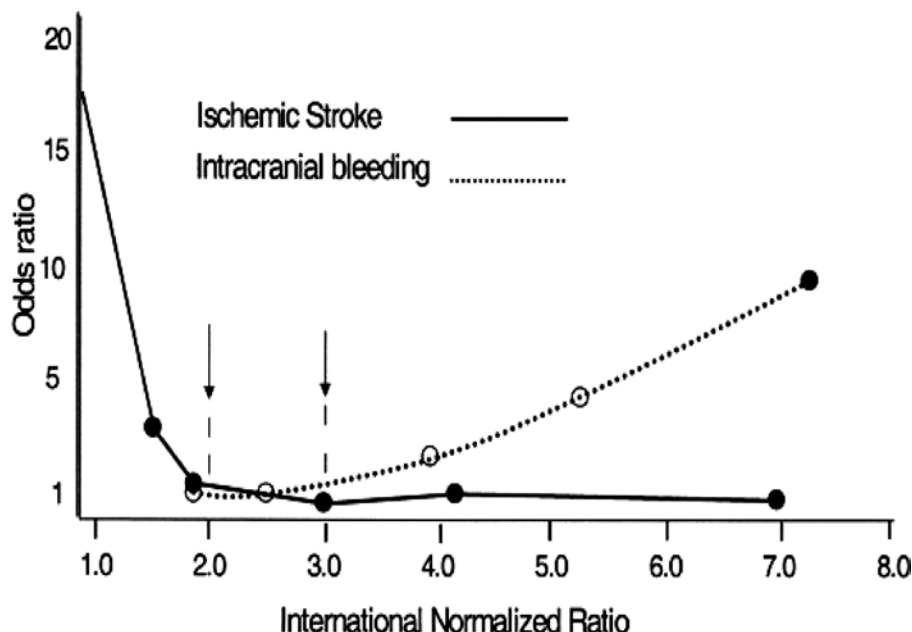


Figure 1: Optimal INR range based on balance of risks (intracranial bleeding) vs. benefits (prevention of ischaemic stroke). Adapted from Hylek et al.(3)



In the early stages of treatment, blood testing is required daily or every few days. Once treatment has been established and the INR has stabilised, the gap between tests can gradually be extended to four to six weeks. Some patients are more difficult to stabilise or are more at risk of adverse effects and will continue to require more frequent testing. The frequency of testing may also need to be increased when the patient has had a change to an interacting medication, reports a significant change to their diet or alcohol intake, or is suffering from concurrent illness.

### **Time in therapeutic range**

The proportion of time in therapeutic range (TTR) can be used as a measure of the quality of anticoagulation control at both an individual patient and practice or population level. The greater the TTR the better the balance is between the risks and benefits of warfarin treatment. In this evaluation, the TTR is calculated using the linear interpolation method described by Rosendaal et al.(4). Whilst there are a number of approaches to measuring the quality of anticoagulation control, there is a growing consensus supporting the use of TTR and the method described by Rosendaal is becoming widely adopted. Unlike alternative approaches, this method takes into account the time between tests. In effect, a line is drawn from the previous test to the current test and the number of days in which that line falls within the range is counted. International guidelines, such as those produced by the British Committee for Standards in Haematology (BCSH) (5), recommend maintaining a TTR of 60% or above in order to maximise benefits from treatment and to limit adverse events.

### **Utilisation of warfarin**

The most common indication for the use of warfarin is the prevention of stroke associated with atrial fibrillation. Warfarin has been shown to be highly effective, reducing the relative risk of ischaemic stroke by 67% and death by approximately 25%. (6) However, it is known that warfarin remains underutilised and that there are many more patients who could benefit from its use. (7) Multiple barriers to warfarin treatment have been identified, one of which is the need for regular blood testing. This can be inconvenient for patients, perhaps involving time off work, long waits at blood collection centres, or significant distances to travel. It may be supposed that if access to testing were improved, this would lead to increased uptake of warfarin treatment.

A second important barrier is the perception of the risks of warfarin treatment. The benefit from warfarin when used to prevent stroke in patients with atrial fibrillation is directly related to the patient's underlying risk of stroke. Age is a very strong factor in determining the risk of stroke. It follows that those most likely to benefit are older patients. However, due to concerns about the risks of warfarin therapy, both older patients and their doctors are often reluctant to consider warfarin treatment. Improved quality of anticoagulation care would be expected to lead to lower risks and therefore better utilisation of an effective therapy. (8)

It is also known that the number of New Zealanders with atrial fibrillation is likely to increase significantly as the population ages. The prevalence of atrial fibrillation in the general population is thought to be around 1%; however prevalence increases with age to almost 10% in those aged over 80. (9) Therefore it can be supposed that the number of patients on warfarin will also increase, leading to an increase in demand for testing and management services.

### **Current service provision**

In New Zealand, warfarin treatment in primary care is usually managed by general practices. Patients attend their local blood collection centre or surgery for testing and a venous blood sample is taken. The sample is sent to a laboratory for processing and the result is communicated to the practice, usually electronically. The result is reviewed and it is decided whether a dose adjustment is required. The patient contacts the practice later in the day to be told their INR, what their warfarin dose should

be until their next test and the date of their next test. Responsibility for co-ordinating the management of warfarin patients is often delegated to the practice nurse.

This model of care has been demonstrated, both overseas and in New Zealand, to deliver a TTR that is typically less than 60% (10, 11) . The process involves multiple parties and is often somewhat fragmented, characteristics that are associated with sub-optimal anticoagulation. (12)

### **Alternative models of care**

Dedicated anticoagulation management services (AMS), such as hospital-based anticoagulation clinics, are well-established particularly in the United States, Canada and the United Kingdom. They have been demonstrated to achieve better outcomes when compared to 'standard care' management by general practitioners. (11, 13) AMS are provided by a range of healthcare professionals: doctors, physicians' assistants, nurses and pharmacists. Examples of hospital anticoagulation clinics, led by doctors and run by nurses, exist in New Zealand but they are not widespread.

Studies overseas have shown that AMS involving pharmacists can lead to improved anticoagulation control, reduced frequency of warfarin-related hospital admission, lower frequency of drug interactions, and improved patient compliance and satisfaction. (14)

There are a few reports in the literature that describe the development of community-based models of anticoagulation care involving pharmacists; most of these are from Australia, Canada and the United Kingdom. (15-17) Some of these studies have investigated the use of point-of-care testing and/or the use of computer decision-support systems to enable community pharmacists to perform INR testing and carry out warfarin dose adjustment. These studies support the view that there are potential benefits of a community pharmacy-based service, including greater convenience for patients, improved access to testing and a reduction of the burden on general practice.

#### ***Point-of-care testing***

Point-of-care testing is defined as a diagnostic test at or near the site of the patient. It can provide immediate results, allowing more rapid decision making which may in turn lead to improved patient care. The use of point-of-care testing for the measurement of INRs is widespread overseas and is usually carried out using a capillary blood sample obtained by means of a finger prick, rather than a venous blood sample taken using a needle and syringe. (18) This method of sampling is known to be preferred by many patients. (19)

#### ***Computer decision-support systems***

Computer decision-support systems have been used successfully in AMS for many years to assist with dose adjustment and other aspects of patient management. Computer-assisted dosing has been shown to increase the time that patients' INRs are within the target range and to significantly reduce the risk of bleeding and thromboembolic events when compared to manual dosing. (20)

## The innovation service

### Development of innovation service

The proposal for the innovation project was developed following a trial undertaken by pharmacists Ian McMichael and Alice Littlewood at a community pharmacy in Hamilton in 2009. During the trial, patients on warfarin had their INR blood tests performed at the pharmacy using a point-of-care testing device (CoaguChek XS Plus). Dose adjustment was carried out by the pharmacist with the aid of an online decision-support system (INR Online). Results from the trial suggested a significant improvement in TTR and a reduction in INR results below 1.5 or above 4.0 when compared to the standard model of care. Patient, GP and pharmacist levels of satisfaction with the new service were assessed by questionnaire. The responses indicated that the service had been well received overall and that there was support for it to continue (personal communication, Ian McMichael, February 2010). The results of the study have not yet been published.

The Hamilton trial was supported by Roche Diagnostics New Zealand, manufacturers of CoaguChek XS Plus. After completion of the trial, Roche Diagnostics Product Manager, Bronwyn Sheppard, approached the Pharmaceutical Society of New Zealand Inc (PSNZ) with the idea of a larger study. PSNZ was already working with District Health Boards and the Ministry of Health to achieve better use of pharmacists' skills and knowledge through the National Pharmacist Services Framework. Led by Elizabeth Plant, the PSNZ National Executive sought advice from the Associate Minister of Health and began preparing a business case for a larger study. Discussions took place in early 2010 between PSNZ, Roche Diagnostics NZ, the developers of INR Online and the University of Auckland. A proposal was submitted to HWNZ in mid-2010 for consideration as an innovation demonstration project. Approval was given in July 2010 and contract negotiations between HWNZ and PSNZ for the implementation and evaluation of the project were begun.

A steering group was established in September 2010. Its role was to direct the project. Its members are listed in Table 1.

**Table 1: Steering group membership**

Name	Project role/expertise
Elizabeth Plant	President, PSNZ, chief pharmacist Taranaki DHB
Richard Townley	CEO, PSNZ
Dale Griffiths	Vice President PSNZ, community pharmacist
Ian McMichael	Community pharmacist
Alice Littlewood	Community pharmacist
Amanda Kiss	Clinical facilitator Midland Clinical Network, pharmacist
Anne Blumgart	Clinical pharmacist, Middlemore Hospital
Dr Paul Harper	INR Online developer, consultant haematologist
Prof Les Toop	Professor of General Practice, University of Otago
Dr Claire Hill	General practitioner
Alan Neal	Charge, Haematology, PathLab Waikato
Bronwyn Sheppard	Product manager, Roche Diagnostics NZ
Keryn Smith	Product specialist, Roche Diagnostics NZ
Janice Homan	Product specialist, Roche Diagnostics NZ
Prof John Shaw	Evaluator, Head of School of Pharmacy, University of Auckland

Bronwyn Sheppard was appointed as project manager to coordinate the day-to-day running of the project.

Ethics approval was sought from the Multi-region Ethics Committee in October 2010 and was granted on 1<sup>st</sup> December 2010 following the submission of additional documentation and the clarification of some aspects of the project (Appendix 1).

A Workforce Innovation Services Agreement was signed between HWNZ and PSNZ in October 2010.

The steering group convened once a month to monitor the progress of the innovation project. Amendments to protocols and documentation were made as the need arose.

### **Description of innovation service**

In the CPAMS, accredited community pharmacists provide supervision of warfarin treatment. Authority to perform testing, review results and implement dose adjustments is delegated to the pharmacist by the GP by means of a standing order (Appendix 2). The GP retains overall responsibility for the patients' management and for prescribing warfarin and can intervene at any time. Patients who wish to participate must sign a consent form and be referred by their GP.

Patients have their blood tested at the pharmacy using a point-of-care testing device and a capillary ('finger prick') sample. The INR results are available immediately and dose adjustments are made by the pharmacist with the aid of an online decision-support system. All test results and dosing information are sent automatically to the GP's patient management system (PMS) via HealthLink. Any results that fall outside the patient's specified range are referred for medical review.

A copy of the standing operating procedure for the CPAMS is included in the appendices (Appendix 3).

### **Point-of-care testing device: CoaguChek XS Plus**

The point-of-care testing device used in the CPAMS is the CoaguChek XS Plus, supplied by Roche Diagnostics NZ. A single-use test strip is inserted into the device and one drop of blood is squeezed onto it directly from the patient's finger. The result is available within one minute and can be downloaded directly from the device onto a computer. The device can measure INRs in the range 0.8 to 8.0. The accuracy of the device is well validated (21) and it has been used extensively both in New Zealand and overseas. It is approved for use by the FDA in the United States and is CE marked.

### **Decision-support system: INR Online**

INR Online is a web-based support tool for anticoagulant management developed by Dr Paul Harper (consultant haematologist, Palmerston North Hospital). It provides recommendations for warfarin dosing and testing, based on the patient's target INR; current and previous INR results; and current dose. Upper and lower INR values that will trigger a request for a medical review are entered for each patient. The default values of 1.5 and 4.0 are used unless otherwise specified by the referring GP. When new patients are entered into the system they are scheduled for weekly testing by default. If INR results are subsequently within range, the interval between tests is gradually increased up to a maximum interval of four weeks.

INR Online assists with scheduling and tracking patients by providing information on patients due or overdue for testing and listing those patients whose results are awaiting medical review. Patients can elect to receive email reminders when their next test is due. Anticoagulation control and compliance reports can be generated to further help with individual patient management.

The use of this system is described in a recent paper by Harper and Pollock. (22)

## The patient consultation

Before the INR test, the patient is asked four safety questions by the pharmacist and the answers are entered into INR Online. If the response to a question is 'yes', additional information is requested and/or advice is provided on the screen.

1. Has the patient missed any tablets since their last test?  
*'If the patient has only missed one or two doses continue with your INR check.  
If the patient has missed a dose within the last two days the INR may be unreliable.  
Consider referring the result to the supervising doctor.'*
2. Has the patient had any bleeding or bruising since their last test?  
*'If bleeding is minor, such as gum bleeding, spotting from the nose, or easy bruising, continue with the INR check.  
Consider referring the result to the supervising doctor.  
If the bleeding is more serious, refer to the doctor immediately.  
Serious bleeds include: blood in the urine, blood in the bowel motions, a prolonged nose bleed, large bruises (bigger than 4cm in diameter).'*
3. Has the patient started any new medication since their last test?  
*'Please enter drugs started.'*
4. Has the patient been admitted to hospital since their last test?  
*'Please enter the following information:  
Date admitted.  
Hospital name.  
Reasons.'*

The blood test is then carried out and the result is downloaded onto INR Online. A recommended dose and date for the next test are generated.

If the result is within the range 1.5 to 4.0, the recommended dose and date for the next test can be accepted by the pharmacist. If the pharmacist believes the recommendations are inappropriate, the system can be overridden and an amended dose or test date entered. The reason for the amendment must be documented. A calendar with dose and test information is printed from INR Online and given to the patient and the pharmacist provides any counselling required. The test result and dosing information are sent electronically to the GP's PMS.

INR results above 4.0 or below 1.5 are automatically referred to the GP for review. An email is generated by INR Online and includes:

- the latest INR result.
- the recommended dose.
- the date of the next test.
- a graph showing recent INR control.
- a list of previous results.

If the INR is below 1.5 or above 4.0, but not above 4.5, the pharmacist can still accept the recommended dose and test date but must tell the patient that the result has been sent for review by the GP. The patient is advised to continue with the recommended dose unless informed otherwise. If the GP agrees with the recommendations, there is a link provided in the email to acknowledge receipt. No further action is needed. If the GP wishes to change the dose or the date of the next test, there is a second link which leads directly to the patient's INR Online review page. The desired

changes can be made and the pharmacist is automatically informed by email. It is then the pharmacist's responsibility to contact the patient.

If the INR is above 4.5, INR Online will recommend that the patient misses that day's dose and returns for a repeat test the following day.

If the INR is above 5.0, the result must be discussed with the supervising GP. INR Online will provide advice on reversing the effects of warfarin in line with the Australasian Guidelines (2) but any treatment must be authorised by the GP.

### **Selection of pharmacy sites**

Community pharmacies were invited to apply to join the project. Over a hundred expressions of interest were received. Sites were selected by the steering group with the aim of providing a spread across the country; a mix of urban, suburban and rural populations; and a variety of socio-demographic and ethnic profiles. Sites had to be able to provide a suitable consultation area with adequate space; privacy; easy access for elderly or disabled patients; and a computer with an internet connection and printer. Evidence of support for the project from local GPs was desirable.

### **Accreditation of pharmacists**

To gain accreditation to provide the CPAMS, pharmacists attended a one day training programme approved by the New Zealand College of Pharmacists and underwent competency assessments on warfarin management and INR testing using the CoaguChek XS Plus. The first training day was held on 5<sup>th</sup> November 2010 and was attended by 30 pharmacists. A second training day, held on 13<sup>th</sup> December 2010 was attended by a further 10 pharmacists. One additional pharmacist was trained in April 2011 to replace an accredited pharmacist who was on extended leave.

### **Recruitment of general practitioners**

General practices close to the pharmacy sites were invited by the pharmacists to participate in the CPAMS. GPs were provided with an information pack explaining how the CPAMS would operate and what their role and responsibilities would be (Appendix 4). Those who agreed to take part were asked to complete a consent form (Appendix 5).

### **Recruitment of patients**

A list of patient selection criteria was agreed by the steering group (Appendix 6).

Patients on warfarin considered suitable to take part were identified and approached by their pharmacist, GP or practice nurse. Other patients became aware of the CPAMS and volunteered themselves. Potential patients were provided with verbal and written information about the service (Appendix 7). It was made clear that they were free to remain within the standard model of care if they preferred. Those who decided to take part in the CPAMS were asked to complete a consent form (Appendix 8). The aim was to recruit an average of 50 patients per site. Recruitment took place over the period November 2010 to January 2011.

The GP was then asked to complete a referral form for each patient who had consented to join the CPAMS. The forms requested information such as the indication for warfarin treatment; target INR; date of starting warfarin treatment; anticipated duration of treatment; and previous INR results (Appendix 9).

### **Quality assurance programme**

Advice was sought from IANZ (International Accreditation New Zealand) on developing a quality assurance (QA) programme for the CPAMS. IANZ recommended appointing a laboratory

representative to join the steering group; Alan Neal (PathLab Waikato) was approached and took up the position. A QA programme, based on the AACB (Australasian Association of Clinical Biochemists) guidelines for point-of-care testing, was implemented.

The CoaguChek XS Plus device has an in-built quality control (QC) system that checks each test strip prior to use. In addition, regular monthly QC was specified, to be carried out by the pharmacist using a control solution. The device was programmed to lock-out automatically, thereby preventing use, if the required QC had not been performed. Further QC testing was stipulated whenever a new batch of test strips was opened or if an operator lacked confidence in the result obtained for a patient.

As recommended by IANZ, inter-pharmacy comparisons were performed using the same batch of test strips and control solution. This was to allow identification of intra-operator or intra-device variation.

Responsibility for the scrutiny of QC results was delegated to the laboratory representative. It was decided by the steering group not to participate in a formal external quality assurance programme during the project.

## Aims and objectives of the evaluation

### Aims

To evaluate the innovation project to assess the safety and efficacy of the innovation and the degree to which the innovation has achieved its goals and objectives.

### Objectives

(a) To evaluate whether the following project goals, laid out in clause 3.2 of schedule 3 of the Workforce Innovation Services Agreement, have been met.

- Improve on current practice.
- Reduce warfarin-related adverse medication events.
- Improve accessibility and convenience for patients.
- Increase job satisfaction for pharmacists.
- Improve multidisciplinary management of atrial fibrillation patients in the community.
- Reduce the burden on general practice
- Builds on professional relationships and encourages further GP and pharmacist collaboration.
- Initiate the first step towards pharmacist-managed medication management.

(b) To answer the evaluation questions, laid out in clause 5.4 of schedule 3 of the Workforce Innovation Services Agreement.

- How was the innovation project implemented?
- Did the innovation project achieve the desired outcomes?
- Did the innovation project team learn from the innovation and made improvements?
- Did the innovation project represent value for money?
- Did the innovation project result in any unintended outcomes?
- Should the innovation project be generalised and spread.



## Section I -Method

### Data extraction and analysis

The INR Online database stores demographic details for each patient; treatment details including indication, INR target range and intended duration; and the information gathered at each visit, including test results, doses and details of adverse events and hospitalisations. Data captured up to and including 31<sup>st</sup> July 2011 were extracted for all patients managed under the CPAMS. INR Online system event logs and free-text clinical notes were also extracted.

### Enrolment and withdrawal data

The data were analysed to provide information on; age; gender; indication for treatment; date of and reason for withdrawal from the service, if applicable; number of patients per site; and general practice and DHB details.

### Adverse events and hospitalisations

The information on adverse events and hospitalisations was analysed to determine:

- i. the number, incidence and nature of adverse events reported
- ii. the number, incidence and nature of hospitalisations reported

Information on hospitalisation and bleeding events was extracted from the INR Online database using the internal coding system. The descriptive text relating to each event was reviewed.

Hospitalisations were allocated to one of three categories: hospitalisation related to warfarin treatment; hospitalisation potentially related to warfarin treatment; hospitalisation unrelated to warfarin treatment. Bleeding events were categorised as major or minor. Major bleeding was defined as bleeding requiring hospitalisation or blood transfusion.

In the absence of a separate code for thromboembolic events, these were identified by manual review.

The accuracy and completeness of the data were not independently verified as part of the evaluation. The data analysed were restricted to the information recorded by the pharmacist in INR Online. Data on hospitalisations were not obtained from discharge coding recorded in National Minimum Data Set collections held by the Ministry of Health.

The sample size of the study and low incidence of adverse events made it unlikely that a difference between the CPAMS and the standard model of care could be detected.

### INR test results

The INR results during the period of enrolment in the CPAMS were analysed in the following ways:

- i. INR results outside efficacy and safety thresholds.

The British Committee for Standards in Haematology (BCSH) (23) identifies thresholds to be used as safety indicators in the management of patients on oral anticoagulant treatment. These are: INRs more than 1.0 unit below target; INRs above 5.0; and INRs above 8.0. The proportion of tests and the number of patients with one or more tests outside each of these thresholds was calculated.

The day of treatment on which the patient's INR crossed each of these thresholds, in relation to the date of enrolment in the CPAMS, was also calculated. This was used to identify any potential risk period in the transition from standard care to CPAMS.

ii. Percentage time in therapeutic range (TTR).

The time in therapeutic range (TTR) was calculated for each patient based on each patient's target INR, as recorded in INR Online. In line with standard practice, the patient's therapeutic range was specified as the target INR plus or minus 0.5 INR units. Each patient's TTR was calculated as the cumulative number of days in range divided by the total number of days. The period analysed covered the first to the last recorded CPAMS tests. Sub-group analyses were performed for patients with CPAMS tests covering 16 and 26 weeks, irrespective of the number of tests.

CPAMS tests were defined as those occurring on or after the date of patient registration with the pharmacy. All tests occurring before this date were categorised as non-CPAMS tests and were excluded from the calculation of TTR. No adjustment was made to allow for patients who had started warfarin treatment under the CPAMS and would initially have had sub-therapeutic INRs.

### INR test dates

The test dates for each patient were analysed to determine:

- i. frequency of testing
- ii. compliance with appointments

### Collection of prior INR data

During the enrolment process, each patient's three most recent INR results were supplied to the pharmacist by the GP and were entered into INR Online. The calculation of TTR based on three results, representing two time periods, was felt to be insufficiently reliable for comparison with the TTR calculated for the CPAMS. To enable a meaningful comparison of INR control before and after enrolment in the CPAMS, it was decided to try to obtain additional INR data. Patient consent was sought to allow collection of a further six months' of INR results (Appendix 10).

For those patients who gave consent, results were requested either directly from the GP or via Pathology Associates Ltd. Results obtained up to the 10<sup>th</sup> August 2011 were included in the evaluation. Analyses were performed to compare INRs outside efficacy and safety thresholds, TTR and frequency of testing before and after enrolment in the CPAMS.

### Collection of ethnicity data

Ethnicity data was not recorded as part of the official enrolment process. It was decided to collect this information as part of the evaluation. Forms were provided to the sites and patients were asked to complete them during their pharmacy consultation.

## Section I - Results

### Enrolment and withdrawal data

Fifteen sites were selected but two withdrew from the project in its early stages. One of the sites had decided it no longer wished to participate and was replaced from a reserve list. The second site was substituted by another pharmacy under the same ownership. The final fifteen sites are shown in Table 2. Thirteen of the sites were located in the North Island and two in the South Island. Ten of the sites were in urban or suburban areas of larger centres and five were in rural or semi-rural towns. The populations served were diverse and included both lower and higher socioeconomic groups and a broad range of ethnicities.

**Table 2: Distribution of sites by DHB**

District Health Board	Number of sites	Name of sites
Bay of Plenty	2	Amcal Mount Dispensary, Mount Maunganui
		Kawerau Pharmacy
Canterbury	1	Elmwood Pharmacy, Christchurch
Capital and Coast	1	Miramar Unichem Pharmacy
Counties Manakau	2	Family Care 7 Day Pharmacy, Otara
		Papatoetoe City Centre Pharmacy
Hawke's Bay	1	Radius Pharmacy, Greenmeadows, Napier
Hutt	1	Owles Unichem, Lower Hutt
Taranaki	1	Devon West Pharmacy, New Plymouth
Waikato	3	Heslop Pharmacy, Putaruru
		Huntly West Pharmacy
		Tokoroa Unichem Pharmacy
Waitemata	2	All Seasons Pharmacy, Te Atatu South
		Westview Pharmacy, Glen Eden
West Coast	1	Olsen's Pharmacy, Greymouth

A total of 41 pharmacists were accredited to provide the CPAMS. Two pharmacists left their sites during the study period, one to take up new employment and one on extended leave.

The official recruitment period ended on 31<sup>st</sup> January 2011. A total of 693 patients were enrolled in the service, under the care of a total of 115 GPs in 52 practices.

**Table 3: Site characteristics**

Site	Number of accredited pharmacists	Number of general practices	Number of GPs	Number of patients enrolled
A	3	6	9	35
B	2	2	5	45
C	3	4	13	51
D	2	1	3	26
E	3	3	6	75
F	3	4	14	53
G	3	3	5	47
H	3	7	10	43
I	2	4	8	35
J	2	3	4	34
K	4	3	8	48
L	3	1	4	62
M	2	1	5	51
N	3	6	15	36
O	3	4	6	52
Total	41	52	115	693

Of the 693 patients enrolled, 22 were excluded from the analysis because they had insufficient CPAMS INR results recorded on the INR Online database. A minimum of two results was required to allow calculation of TTR. The remaining 671 patients were included in the analysis.

106 patients left the service before the end of the study period. This left a total of 587 patients enrolled as of 31<sup>st</sup> July, 2011. The median duration of follow-up for patients in the CPAMS was 197 days.

**Table 4: Patient numbers as of 31<sup>st</sup> July, 2011**

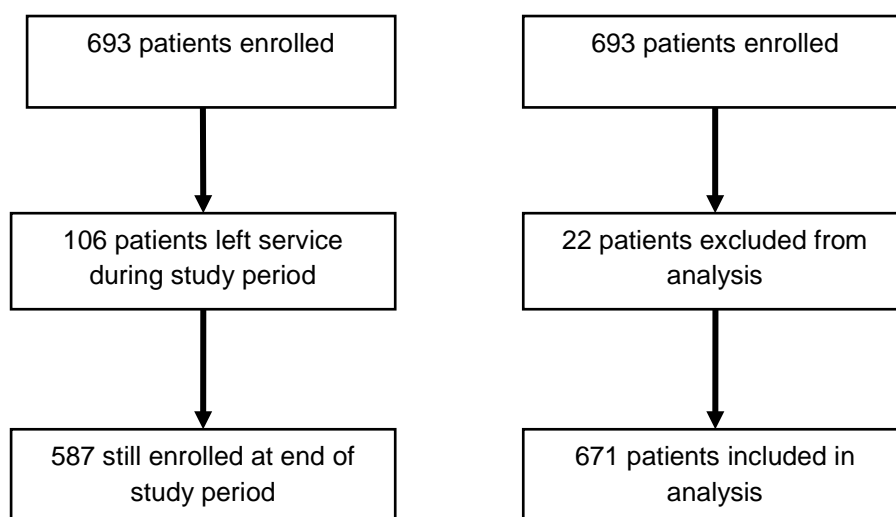
Site	Number of patients enrolled	Number of patients as of 31 <sup>st</sup> July 2011	Number of patients who left CPAMS before end of study period
A	35	30	5
B	45	39	6
C	51	42	9
D	26	19	7
E	75	66	9
F	53	43	10
G	47	37	10
H	43	33	10
I	35	29	6
J	34	29	5
K	48	45	3
L	62	54	8
M	51	43	8
N	36	31	5
O	52	47	5
Total	693	587	106

The reasons for patients leaving the CPAMS before the end of the study period are shown in Table 5.

**Table 5: Reasons for patients leaving the CPAMS**

Reason	Number of patients
Warfarin discontinued	37
Treatment changed to dabigatran	17
Returned to GP care <sup>1</sup>	24
Moved away or changed GP	11
Died	13
Unspecified	4
Total <sup>2</sup>	106
<sup>1</sup> To enable home testing (5); clinical reasons (6); blood tests in addition to INR required (1); patient preference (7); non-compliance with CPAMS (5).	
<sup>2</sup> Of these patients, five later returned to the CPAMS (three stopped dabigatran and restarted warfarin, one moved back to area covered by CPAMS and one was returned by the GP to CPAMS care). They are not included in the figure of 587 patients enrolled as of 31 <sup>st</sup> July 2011. Only INR results recorded during the first period of pharmacy management have been included in the analysis.	

Figure 2 summarises patient enrolment and follow-up.



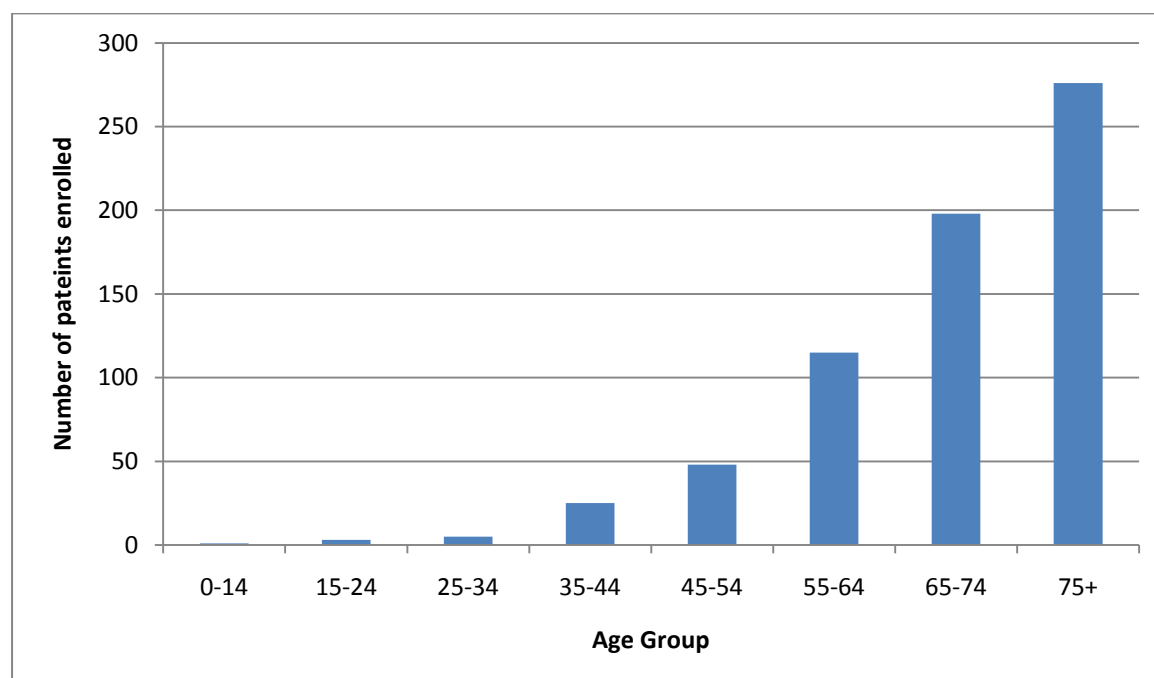
**Figure 2: Flow diagram of patient enrolment and follow-up.**

The demographic characteristics of patients enrolled in the CPAMS are shown in Table 6. Patients were predominantly male and over 65 years of age.

**Table 6: Patient demographics**

	Number of patients (n=671)	Percentage of patients
<b>Gender</b>		
Male	419	62.4%
Female	252	37.6%
<b>Age</b>		
Median (Range)	72 (13 to 97)	
<b>Age group</b>		
75+	276	41.1%
65-74	198	29.5%
55-64	115	17.1%
45-54	48	7.2%
35-44	25	3.7%
25-34	5	0.7%
15-24	3	0.4%
0-14	1	0.1%

Figure 3 shows the age distribution of patients in the study.



**Figure 3: Age distribution of patients enrolled in the CPAMS**

Table 7 shows that the majority (73.8%) of patients were prescribed warfarin for the prevention of ischaemic stroke complicating atrial fibrillation. Patients on warfarin for deep vein thrombosis and pulmonary embolism may have been prescribed it either short term for treatment of an individual event or long-term for prevention of recurrent events.

**Table 7: Indication for treatment**

Indication	Number of patients	Percentage of patients
Atrial fibrillation	495	73.8%
Mechanical heart valve	58	8.6%
Deep vein thrombosis	40	6.0%
Pulmonary embolus	24	3.6%
TIA	8	1.2%
Mural thrombus	4	0.6%
Post myocardial infarction	4	0.6%
Tissue heart valve	4	0.6%
Other	34	5.1%
Total	671	100.0%

### Adverse events and hospitalisations

There were 436 events recorded in the INR Online database in response to the question 'Has the patient had any bleeding or bruising since their last test?'. Two hundred and forty-six patients had one or more episodes of bleeding or bruising entered. The remaining 425 patients had no episodes documented.

Of the 436 events of bleeding or bruising recorded, seven were categorised as major events requiring hospitalisation or blood transfusion. One of these major events, a cerebral haemorrhage, resulted in the death of the patient.

The manual review of records found a total of three thromboembolic events, all of which resulted in hospitalisation. None of these events were recorded as resulting in the death of the patient.

**Table 8: Adverse events recorded for CPAMS patients**

Category of adverse event	Number	Incidence per 100 patient years of follow-up
Minor bleeding	429	125.0
Major bleeding	7	2.0
Thromboembolism	3	0.9

There were 192 hospital admissions recorded in the INR Online database in response to the question 'Has the patient been admitted to hospital since their last test?'. One hundred and fifty patients had one or more admissions. The remaining 521 patients had no admissions documented.

**Table 9: Hospitalisations recorded for CPAMS patients**

Category of hospitalisation	Number	Incidence per 100 patient years of follow-up
Related to warfarin treatment	10	2.9
Potentially related to warfarin treatment	8	2.3
Unrelated to warfarin treatment	174	50.7
Total <sup>1</sup>	192	56.0

<sup>1</sup> It was noted that some of the entries recorded under hospital admissions appeared to relate to outpatient appointments or visits to the emergency department, rather than inpatient stays.

## INR test results

### *INR results outside efficacy and safety thresholds*

Table 10 summarises the number of patients and individual tests that were outside recommended efficacy and safety thresholds. Patients with an INR more than 1.0 INR units below target are at increased risk of a thromboembolic event, those with an INR above 5.0 are at increased risk of a bleeding event and those with an INR above 8.0 are at high risk of a bleeding event.

**Table 10: INRs outside efficacy and safety thresholds**

Total number of patients	671		
Total number of CPAMS tests performed to 31 <sup>st</sup> July, 2011	9265		
	<b>INR &gt; 1.0 below target<sup>1</sup></b>	<b>INR above 5.0</b>	<b>INR 8.0 or above<sup>2</sup></b>
Number of test results	311	65	7
Percentage of test results	3.4%	0.7%	0.1%
Number of patients with one or more test results in band stated	152	43	5
Percentage of patients with one or more test results in band stated	22.7%	6.4%	0.8%

<sup>1</sup> This column may include test results from patients recently started or restarted on warfarin, whose INRs had not yet reached the therapeutic range.  
<sup>2</sup> The measure  $\geq 8.0$ , rather than  $>8.0$  as recommended in the guidelines of the BCSH (23), was used because the CoaguChek XS device has a maximum INR reading of 8.0.

Analysis of the number of days since enrolment on which patients crossed the efficacy and safety thresholds revealed no obvious pattern. There was no evidence of an increased risk period in the transition from standard care to CPAMS.



### Time in therapeutic range

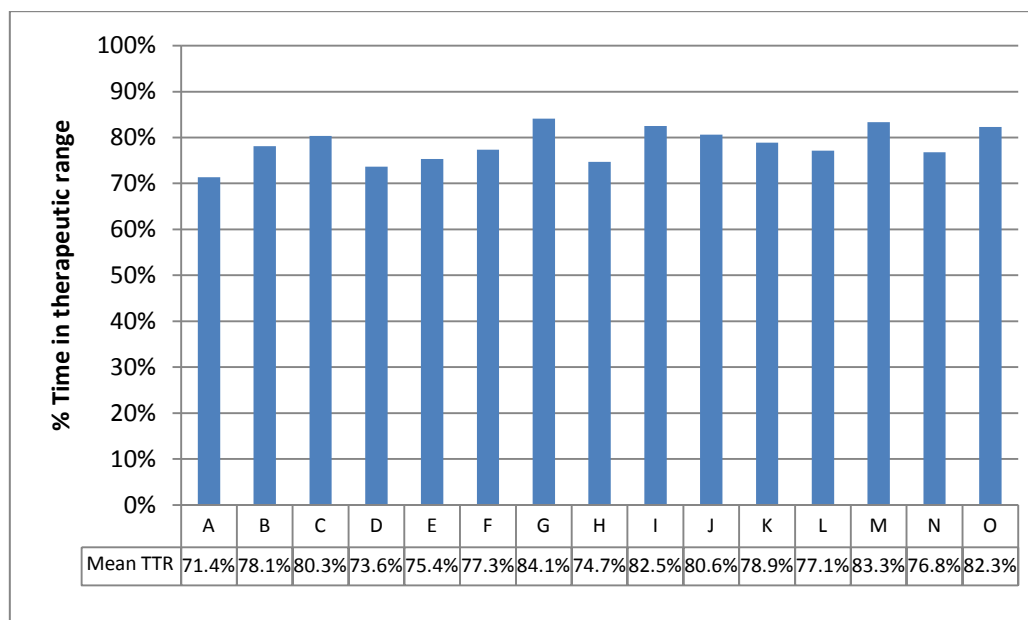
Table 11 shows the time in therapeutic range for patients during CPAMS follow-up. The mean TTR achieved was 78.6%. A small increase in mean TTR was observed when results were analysed for patients who completed 16 or 26 weeks in the CPAMS, to 79.4% and 80.3% respectively.

Of the 671 patients included in the analysis, 598 (89.1%) were found to have a TTR of 60% or greater.

**Table 11: TTR based on target +/- 0.5 units**

	Patients included in the analysis	Patients with 16 weeks or more of tests in the CPAMS	Patients with 26 weeks or more of tests in the CPAMS
Number of patients	671	624	421
Mean TTR	78.6%	79.4%	80.2%
95% Confidence Interval	49.3% to 100%	52.6% to 100%	55.0% to 100%
Number (percent) of patients with TTR ≥ 60.0%	598 (89.1%)	562 (90.1%)	385 (91.4%)
Number (percent) of patients with TTR ≥ 70.0%	514 (76.6%)	487 (78.0%)	338 (80.3%)
Number (percent) of patients with TTR ≥ 80.0%	375 (55.9%)	357 (56.3%)	249 (59.1%)

A further analysis was performed to calculate TTRs achieved at individual sites. The results are presented in Figure 4. All sites achieved a mean TTR for their patients of over 60%. The mean TTR ranged from 71.4% to 84.1%.



**Figure 4: Comparison of mean TTR by pharmacy site**

## INR test dates

### *Frequency of testing*

Table 12 shows the interval between tests for patients in the CPAMS. The mean interval for the whole period of patient follow-up was 14.4 days. There was an increase in the mean interval between tests over the study period from 9.7 days (3.1 tests per month) during the first three months of the service to 16.7 days (1.8 tests per month) in months four to six inclusive.

**Table 12: Interval between tests**

	<b>For whole period of CPAMS up to 31<sup>st</sup> July 2011</b>	<b>For months one to three of CPAMS</b>	<b>For months four to six of CPAMS</b>
Number of patients	671	671	635
Mean interval between tests	14.4 days	9.7 days	16.7 days
95% Confidence Interval	4 to 31 days	2 to 22 days	4 to 31 days
Median interval between tests	10	8	15
Inter-quartile range	8 to 21	7 to 12	8 to 27

### *Compliance with appointments*

Table 13 shows that over the study period, the majority of tests (83.1%) were performed on or before the due date. During the period covered by the interim report (up to 31<sup>st</sup> May, 2011), 85.1% of tests were performed on or before the due date. Comparison of these results indicates that compliance remained high throughout the study period.

**Table 13: Compliance with appointments**

Timing of test	Period to 31 <sup>st</sup> May 2011		Period to 31 <sup>st</sup> July 2011	
	Number of tests	Proportion of tests	Number of tests	Proportion of tests
Before due date	909	12.7%	1302	14.1%
On due date	5199	72.4%	6394	69.0%
1 to 3 days overdue	710	9.9%	1010	10.9%
4 to 7 days overdue	248	3.5%	372	4.0%
More than 7 days overdue	114	1.6%	187	2.0%
Total	7180	100%	9265	100%

### Prior INR data

Consent to request prior INR results was obtained from 403 patients. Results were then sought from two sources: general practices and Pathology Associates Ltd.

Results were obtained for 154 patients from six sites; 134 via Pathology Associates Ltd and 20 from a single GP practice. The median duration of follow-up under usual care and under the CPAMS was 162 days and 211 days respectively.

Table 14 summarises the number and proportion of INR tests outside recommended efficacy and safety thresholds for those patients for whom both standard care and CPAMS data were available. In addition, the number and proportion of patients who had one or more test outside these safe ranges is presented. There was no statistically significant difference between CPAMS and standard care, although it should be noted that there is limited power to detect such differences with this small group of patients.

**Table 14: Comparison of INRs outside efficacy and safety thresholds for standard care and CPAMS**

	Standard care			CPAMS		
Number of patients	154			154		
Number of tests	1921			2637		
	INR > 1.0 below target	INR above 5.0	INR 8.0 or above	INR > 1.0 below target	INR above 5.0	INR 8.0 or above
Number of test results	165	19	8	103	21	2
Percentage of test results	8.6%	1.0%	0.4%	3.9%	0.8%	0.1%
Number of patients with one or more test results in band stated	62	10	4	52	16	1
Percentage of patients with one or more test results in band stated	40.3%	6.5%	2.6%	33.8%	10.4%	0.7%

Table 15 summarises the time in therapeutic range data for the 154 patients for whom prior results were available. There was a mean difference in TTR of 17.1% (95% CI 13.3% to 20.9%). Statistically, there was a highly significant difference in TTR between the two groups (related-samples Wilcoxon sign rank test, 7.343,  $p < 0.001$ ).

For the six sites from which paired patient pre-post data were available, there was no statistically significant difference between sites in terms of the change in TTR (Kruskal-Wallis test, 8.026,  $df=5$ ,  $p=0.155$ ).

**Table 15: Comparison of TTR during standard care and under CPAMS**

	Standard care	CPAMS
Number of patients	154	154
Mean TTR	60.4%	77.5%
95% Confidence Interval	9.9% to 100%	51.8% to 100%

Table 16 summarises the frequency of testing during standard care and under the CPAMS. There was significant variation in the interval between tests; however, the overall pattern of testing for the two models of care was broadly similar.

**Table 16: Comparison of interval between tests during standard care and under the CPAMS**

	<b>Standard care</b>	<b>CPAMS</b>
Number of patients	154	154
Mean interval between tests	13.5 days	12.6 days
95% Confidence Interval	2 days to 34 days	3 days to 28 days
Median interval between tests	8 days	8 days
Inter-quartile range	6 days to 19 days	7 days to 17 days
Mean number of tests per month	2.3	2.4
Median tests per month	3.8	3.8

### **Ethnicity data**

The ethnicity data obtained were incomplete and are not presented as part of the evaluation.

Ethnicity data provided by respondents to the patient questionnaire were analysed and have been included in Section II, results.

## Section II -Method

### Questionnaires

Questionnaires were developed to send to patients, accredited pharmacists, GPs and practice nurses (Appendices 11, 12, 13, and 14). A number of revisions were made after consultation with the steering group and distribution took place in June and July 2011.

The questionnaires were designed to collect opinions on:

- i. the accessibility and convenience of the CPAMS for patients
- ii. the safety of the CPAMS
- iii. the impact of the CPAMS on patients' anticoagulant control
- iv. participants' confidence in pharmacists' ability to take on this additional role
- v. the impact of the CPAMS on the workload of general practices
- vi. the effect of the CPAMS on the relationship between patients and pharmacists
- vii. the effect of the innovation service on professional relationships
- viii. the performance of the point-of-care testing device
- ix. the performance of the decision-support system
- x. whether the service should be continued
- xi. whether the service should be made more widely available

In addition, patients who completed the questionnaire were asked to record their gender, age range and ethnicity.

All questionnaires returned by 16<sup>th</sup> August 2011 were included in the evaluation.

### Interviews and site visits

Each of the sites was visited by a member of the evaluation team. A semi-structured interview outline was developed and one or more of the accredited pharmacists at each site was interviewed using this as a guide. The member of the evaluation team was also able to view the pharmacy premises, in particular the area used to provide the CPAMS.

The aim of the interview was to gather more detailed information about how the CPAMS had worked in practice and to identify any changes that would be needed if the service were to be continued or expanded. It was also designed to allow an assessment of the service's impact on pharmacists' job satisfaction and on multidisciplinary team functioning.

A letter requesting GP, practice nurse and patient volunteers for interviews was distributed with the questionnaires. A sample of those who replied was contacted by telephone with the aim of canvassing a range of opinions from across the sites.

## Section II - Results

### Patients

By 16<sup>th</sup> August 2011, completed questionnaires had been returned by 412 of the 693 patients originally enrolled in the service, a response rate of 60%. Questionnaires continued to be returned after this date.

Seven patients from seven different sites were interviewed. It was decided not to interview more patients because a large amount of information had already been collected via the questionnaires and the interviews were not providing significant additional information.

The responses to the questionnaire are shown in Table 17.

**Table 17: Patient questionnaire responses (n=412)**

I find it more convenient to have my blood test at the pharmacy	<p>Strongly agree 71.8%</p> <p>Agree 25.1%</p> <p>Neither agree nor disagree 2.2%</p> <p>Disagree 0.7%</p> <p>Strongly disagree 0.2%</p>	
I would rather have a finger-prick blood test than have blood taken from my arm using a needle	<p>Strongly agree 73.5%</p> <p>Agree 24.6%</p> <p>Neither agree nor disagree 1.7%</p> <p>Disagree 0.0%</p> <p>Strongly disagree 0.2%</p>	
I feel confident that the results from the pharmacy blood test are reliable	<p>Strongly agree 59.5%</p> <p>Agree 39.0%</p> <p>Neither agree nor disagree 1.0%</p> <p>Disagree 0.2%</p> <p>Strongly disagree 0.2%</p>	
I like knowing my test result and dose immediately, rather than having to wait until later	<p>Strongly agree 72.6%</p> <p>Agree 26.7%</p> <p>Neither agree nor disagree 0.5%</p> <p>Disagree 0.2%</p> <p>Strongly disagree 0.0%</p>	
I find it useful to be able to discuss my warfarin treatment with the pharmacist when I go for my test	<p>Strongly agree 58.7%</p> <p>Agree 36.7%</p> <p>Neither agree nor disagree 4.1%</p> <p>Disagree 0.0%</p> <p>Strongly disagree 0.5%</p>	
I find it helpful to be given a calendar showing me what dose of warfarin to take	<p>Strongly agree 63.3%</p> <p>Agree 30.6%</p> <p>Neither agree nor disagree 5.4%</p> <p>Disagree 0.2%</p> <p>Strongly disagree 0.5%</p>	

I am not confident that the pharmacist can manage my warfarin treatment safely	Strongly agree 8.0% Agree 9.0% Neither agree nor disagree 4.3% Disagree 38.8% Strongly disagree 39.8%	
Using the warfarin service at the pharmacy has meant that the pharmacist has also been able to help me with other aspects of my healthcare	Strongly agree 34.2% Agree 44.5% Neither agree nor disagree 17.4% Disagree 3.2% Strongly disagree 0.7%	
I feel less in control of my warfarin treatment now that I go to the pharmacy for testing	Strongly agree 5.6% Agree 5.8% Neither agree nor disagree 5.8% Disagree 47.6% Strongly disagree 35.2%	
It saves me time having my warfarin managed by the pharmacist	Strongly agree 58.4% Agree 35.2% Neither agree nor disagree 4.2% Disagree 1.7% Strongly disagree 0.5%	
I would prefer to have my warfarin managed by my family doctor	Strongly agree 2.8% Agree 5.1% Neither agree nor disagree 31.7% Disagree 45.2% Strongly disagree 15.2%	
I would still want to use the warfarin service at the pharmacy even if I had to pay a fee	Strongly agree 13.8% Agree 32.5% Neither agree nor disagree 24.5% Disagree 21.5% Strongly disagree 7.7%	
Being involved in the pharmacy warfarin management service has changed my view on how the pharmacist can help people with their healthcare	Yes 71.2% Agree 28.8%	
<b>KEY: Strongly agree – SA, Agree – A, Neither agree nor disagree N, Disagree – D, Strongly disagree - SD</b>		

Table 18 shows the gender, age range and ethnicity of questionnaire respondents.

**Table 18: Gender, age and ethnicity distribution of patient questionnaire respondents (n=412)**

Gender	Male Female Unspecified	52.7% 42.5% 4.8%	<p>A bar chart showing the gender distribution of respondents. The y-axis represents percentage from 0% to 100% in 20% increments. The x-axis lists Male, Female, and Unspecified. The bars show Male at approximately 53%, Female at approximately 43%, and Unspecified at approximately 5%.</p>
Age range	15 to 24 25 to 34 35 to 44 45 to 54 55 to 64 65 or over Unspecified	0.2% 0.5% 1.9% 5.1% 13.8% 74.5% 3.9%	<p>A bar chart showing the age range distribution of respondents. The y-axis represents percentage from 0% to 100% in 20% increments. The x-axis lists age ranges: 15 to 24, 25 to 34, 35 to 44, 45 to 54, 55 to 64, 65 or over, and Unspecified. The bars show 65 or over as the highest at approximately 75%, followed by 55 to 64 at approximately 14%, and Unspecified at approximately 4%.</p>
Ethnicity (prioritised)	NZ European Maori Samoan Cook Island Maori Tongan Chinese Indian Other Unspecified	71.1% 14.8% 1.0% 2.2% 0.2% 1.0% 0.7% 5.3% 3.6%	<p>A bar chart showing the ethnicity distribution of respondents. The y-axis represents percentage from 0% to 100% in 20% increments. The x-axis lists NZ European, Maori, All others, and Unspecified. The bars show NZ European as the highest at approximately 71%, followed by Maori at approximately 15%, All others at approximately 5%, and Unspecified at approximately 4%.</p>

Approximately 15% of respondents reported their ethnicity as Maori. Analysis of patient responses by ethnicity showed no important differences between Maori and NZ European respondents.

Selected quotes from the interviews and written comments from the questionnaires are provided below.

### **Convenience and accessibility**

The majority of questionnaire respondents (96.9%) found it more convenient to have their blood test at the pharmacy. Many people commented that they liked being able to have testing done at a time that suited them. Most patients found the CPAMS saved time (93.6%) and some indicated that there was improved access to testing.

*"No time off work. Can go in any time and day."*

*"There are no time frames in which you must have the tests done by if you want same-day results."*

*"I am very happy with service as there are no long queues waiting for blood to be taken and the pharmacists are very competent."*

*"..... the pharmacy is in the shopping mall, helping me to get everything done in the same area, saving time and travel."*

*"If it stops I will have further to travel."*



### **Reduced fragmentation of care**

A number of respondents commented that the testing process had been streamlined and that the potential for delays and miscommunications had been reduced. Others felt they had greater peace of mind, knowing that any results outside their target range could be dealt with straightaway.

*"This is such a helpful way to have these tests. It is so simple all at once. The other way sometimes you couldn't get through to the doctor's for ages, then sometimes the doctor had been so busy he hadn't read [the result] and sometimes you forgot! This way it is done and decided there and then."*

*"The doctor's system is in four stages i.e. blood taken, to lab, lab faxes to doctor's reception, to duty nurse, then doctor approves. Too many/much room for mistakes."*

*"It's good. I get a result straightaway. If it was off the range the pharmacist can get something done about it straightaway."*

*"Having the test done at the pharmacy has been great. Having it done at the hospital meant I could wait five days to get the results from my doctor. The pharmacy option has given me peace of mind, quick, easy and more regular testing has been great."*

A number of patients were keen to point out that they had not been unhappy with service from their GP practice; they realised how busy the staff were and how heavy their workload was. However, many of them appreciated the CPAMS one-on-one attention and the opportunity to discuss any concerns about their treatment.

*"The medical practice I attend is most efficient and helpful but at times it is extremely busy – results of test can take time or get missed. My experience with the pharmacy has been and is brilliant for my needs."*

*"I see a pharmacy with trained staff can lighten the load on overcrowded doctors' rooms and stretched out appointment times."*

*"It is nice to be able to talk and ask questions of the people involved with your treatment. Someone who understands what you are saying."*

*"Personal touch. A sounding board when you aren't sure about things. Explain things better in terms I can understand."*

*"At the pharmacy you can ask about anything, the doctors don't seem to have enough time."*

*"[The pharmacy service] has put my mind at rest re warfarin as I was quite scared of it initially and fought taking it for approx four years."*

### **Method of testing**

Almost all respondents (98.1%) preferred to have their blood sample taken using the finger prick method. For some patients, this brought relief after years of struggling with poor venous access.

*"This has been a godsend for me, a finger prick works each and every time, whereas at the lab they would have to have two or three attempts and leave me bruised and sore."*

*"I always had trouble them trying to find a vein. Sometimes they had about four or five stabs before they found a vein, this is so much better."*

### **Increased involvement with treatment**

The majority of respondents (93.9%) found it helpful to be given a printed dose calendar and many patients liked being able to track their INR control using the INR Online graph. A number of patients commented that they now felt more involved with their treatment.

*"I like being able to see how my readings are going."*

*"Getting a printout showing dosage and INR record is good for my understanding of my progress."*

*"I get the feeling of being involved in my treatment."*

### **The patient-pharmacist relationship**

Many respondents stated that they had already had a good relationship with their pharmacist before enrolling in the CPAMS and had been aware of how the pharmacist could help people with their healthcare. Other respondents (71.2%) felt that their view on how the pharmacist could help people with their healthcare had changed. A large proportion (78.7%) felt that the pharmacist had been able to offer help and advice for other health problems they experienced.

*"I was not aware until recently the pharmacist could be so helpful, especially in explaining the ins and outs of prescribed medication."*

*"I have come to understand my healthcare a lot better now after talking to the pharmacist and I am more at ease with my health problems."*

*"I can enquire about other ailments if needed. I find going to your local chemist you feel more relaxed and can talk about any other issues."*

*"Lots of little problems along the way that are not worth going to the doctor for can be talked over and advice given."*

### **Confidence in the service**

Almost all respondents (98.5%) had confidence that the pharmacy blood tests were reliable. The majority (78.6%) disagreed with the statement "I am not confident that the pharmacist can manage my warfarin treatment safely". Many patients commented that the pharmacist was working closely with their GP and said this gave them confidence in the service.

*"He's the man with the finger on the button and can fix it if things aren't right, immediately."*

*"The pharmacist and I will discuss the computer dosage and quite often will adjust that because of my history. As the GP receives the results, he will occasionally overrule that, so I feel I am well cared for and monitored."*

*"The pharmacy and my doctor work together so I feel very happy that my treatment is well managed."*

*"I feel more comfortable knowing I can discuss my warfarin along with my medications and side-effects etc. with my pharmacist – anything contentious would also be discussed with my GP and I know my pharmacist would insist on it."*

### **Patient concerns**

A minority of respondents were less confident in the service or had less trust in the pharmacist. Some were uncertain as to whether their GP was kept fully informed; some were unhappy with the

recommendations provided by the computer; some lacked trust in the pharmacist's qualifications or motivations.

*"It is more convenient but I do not think my doctor knows the results and I do go up and down considerably."*

*"The pharmacist does not manage my warfarin treatment – a computer programme does (its decisions are relayed by the pharmacist). I am not confident of the programme's decisions."*

*"I feel micromanaged and wonder if the programmes can be adapted to avoid this. Happily the pharmacist is willing to listen to my concerns and will override the programme recommendations."*

*"The qualifications of – and trust in – the pharmacist in running these tests may need better development and explanation. I trust my doctor; I am not sure about someone who is trying to sell me deodorant."*

*"I prefer my doctor to manage my warfarin. Pharmacy too pushy, if one day late they are ringing you all the time. It's all about money."*

A few patients felt that their INRs had been less well controlled in the CPAMS, particularly in the early weeks. However, overall only a minority of respondents (11.4%) agreed with the statement "I feel less in control of my warfarin treatment now I go to the pharmacy for testing".

*"My INR had been between 2 and 3 for three years but when I moved to the pharmacy service it was 4.1 and then 1.2."*

### ***Paying for the service***

Some patients said that they had been paying a fee to their GP for managing their warfarin. Others said that their GP and lab had been providing the service free-of-charge. Respondents' opinions on paying a fee to use the CPAMS were divided. Some said that they wouldn't or couldn't pay a fee and would return to GP-led care. Others said they would struggle to pay a fee but felt that the service was worth paying for. A third group said they would be happy to pay to continue to use the service.

*"I would go back to lab if I did have to pay a fee for pharmacy."*

*"As a pensioner, every dollar counts. If it is free at the medical centre I'd go there."*

*"As a pensioner I would prefer not to pay fee but if I had to I would."*

*"Because the results are instant and it's much more convenient going to the pharmacy I would pay a reasonable fee."*

*"Fee would have to be small and if tested once a month fine but if one needed testing weekly even a small fee x 4 could mount up."*

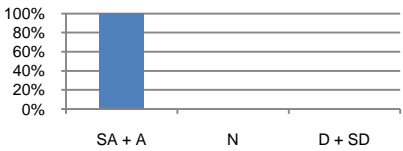
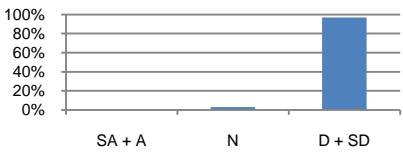
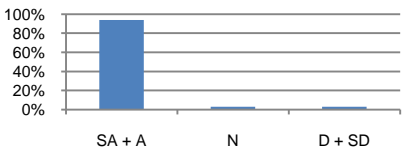
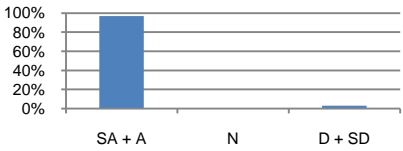
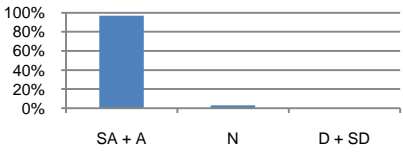
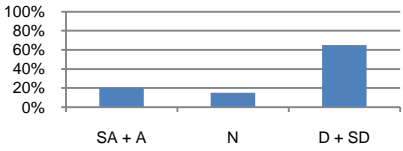
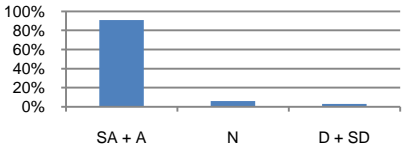
## Pharmacists

Completed questionnaires were returned by 34 of the 41 pharmacists, a response rate of 83%.

Face-to-face interviews were carried out with 24 pharmacists; at least one from each site.

The responses to the questionnaire are shown in Table 19.

**Table 19: Pharmacist questionnaire responses (n=34)**

I find the CoaguChek XS Plus easy to use	Strongly agree 65% Agree 35% Neither agree nor disagree 0% Disagree 0% Strongly disagree 0%	
I often have to repeat tests with the CoaguChek XS Plus because there is an error message	Strongly agree 0% Agree 0% Neither agree nor disagree 3% Disagree 44% Strongly disagree 53%	
I usually find it easy to obtain a blood sample from the patient's finger	Strongly agree 26% Agree 68% Neither agree nor disagree 3% Disagree 3% Strongly disagree 0%	
I am confident that the INR results from the CoaguChek XS Plus are reliable	Strongly agree 59% Agree 38% Neither agree nor disagree 0% Disagree 0% Strongly disagree 3%	
I find it easy to use INR Online	Strongly agree 59% Agree 38% Neither agree nor disagree 3% Disagree 0% Strongly disagree 0%	
I am not confident that the dosing recommendations obtained from INR Online are appropriate	Strongly agree 0% Agree 20% Neither agree nor disagree 15% Disagree 59% Strongly disagree 6%	
I have enough information about my patients' medical history to enable me to provide them with appropriate management of their warfarin treatment	Strongly agree 29% Agree 62% Neither agree nor disagree 6% Disagree 3% Strongly disagree 0%	

I am confident that the review system I have in place with my GPs for INRs above 4.0 or below 1.5 is effective	Strongly agree 29% Agree 62% Neither agree nor disagree 6% Disagree 3% Strongly disagree 0%	
Providing a warfarin management service has improved my relationship with the patients involved	Strongly agree 79% Agree 21% Neither agree nor disagree 0% Disagree 0% Strongly disagree 0%	
As a direct result of seeing patients for their INR testing, I have been able to help them with other aspects of their healthcare	Strongly agree 67% Agree 27% Neither agree nor disagree 3% Disagree 3% Strongly disagree 0%	
I don't feel confident managing my patients' warfarin treatment	Strongly agree 3% Agree 0% Neither agree nor disagree 0% Disagree 50% Strongly disagree 47%	
I find it difficult to make time for the CPAMS because of the other demands of my work	Strongly agree 3% Agree 15% Neither agree nor disagree 21% Disagree 29% Strongly disagree 32%	
I would like to be able to continue to offer a warfarin management service to my patients	Strongly agree 79% Agree 21% Neither agree nor disagree 0% Disagree 0% Strongly disagree 0%	

**KEY: Strongly agree – SA, Agree – A, Neither agree nor disagree N, Disagree – D, Strongly disagree - SD**

The information obtained from the site visits and interviews is summarised below.

### *Motivation for participating*

Pharmacists felt their clinical skills were currently underutilised and they wanted to see the profession continue to expand its role. Many of them were already offering additional clinical services such as Medicines Use Review and smoking cessation support. The CPAMS project was seen as a natural extension of the warfarin counselling and dispensing services already provided by pharmacists, and offering the opportunity to develop a new model of care.

Some of the pharmacists felt there was a particular need for the service in their area. At one rural site, two of the GPs had recently left and had not yet been replaced, meaning that the practice was very busy and glad of help with its workload. At another site, the local blood collection centre had been closed, making it more difficult for many of their patients to access testing.

### *Relationship with patients*

Pharmacists reported that some patients were initially unsure about joining a pharmacist-led service. They required reassurance that the GP would receive their results and still be involved in their care. Some patients elected to remain with GP-led care because they felt confident with a system they were familiar with and were reluctant to opt for change.

Pharmacists stated that their relationships with patients had improved, often greatly, as a result of providing the CPAMS. Patients had gained a better understanding of the pharmacists' skills and knowledge and their levels of trust and confidence had increased. Many had become more open about their lifestyles and more likely to ask questions about their treatment. As a result, the pharmacists had been able to show them the effects that changes to their diet, alcohol intake, missing doses or taking other medications had had on their INR control. In addition, pharmacists had been able to identify other health problems and had been able to offer treatment or refer the patient to their GP. These interview findings were supported by the responses to the questionnaire.

Some pharmacists commented that patients who had previously become 'edgy' if required to wait for prescriptions were now more patient because they had a better understanding of what the pharmacist's job involved.

### *Relationship with GPs and practice nurses*

The majority of pharmacists said that they had already had a good professional relationship with the practices they invited to participate in the project. This was seen as being vital to the project's success.

Pharmacists reported a range of responses from GPs and practice nurses when the service was proposed. Some were fully supportive from the start while others were more hesitant. The pharmacists worked at increasing the confidence of those who were unsure by various methods including providing information sessions at practices and discussing with GPs how they were currently managing their warfarin patients. Some of the nurses were reluctant because they saw the service as taking work away from them but others enthusiastically welcomed a potential reduction in workload.

Some of the GPs did still decline to be involved. Reasons for this included having experienced serious problems with warfarin patients in the past; being prepared to allow the pharmacist to perform testing but not dose adjustment; and feeling it was unfair that only one of the local pharmacies was able to offer the service. Some of the pharmacists felt there might have been higher levels of GP support had the initial proposal been made via a GP organisation.

Many of the pharmacists believed that their relationships with GPs and practice nurses had been strengthened by their involvement in the CPAMS. For some there was increased contact, trust and a greater sense of working together. Pharmacists were being asked to manage medications, rather than just dispense them, and there was a feeling of more professional respect towards what they could contribute. Several pharmacists said that they were now considered to be the 'warfarin experts' and were asked for advice on managing drug interactions and reducing INRs prior to surgery.

Some sites felt that they had benefited from working with just one practice, whereas other sites believed that they had managed successfully to work with multiple practices.

### *Other relationships*

Some sites reported that their local blood collection centres had initially been unsure about the new service and the effect it would have on them. Subsequent feedback indicated that some centres had been glad of the reduction in their workload and that some of their patients with poor venous access could now have capillary sampling.

One of the sites recruited patients who had previously been managed by an anticoagulant clinic at the local hospital. This was a clinic run by nurses and overseen by haematologists. Relations were initially difficult because patients were transferred to the CPAMS by the GP without the knowledge of the clinic. However, these problems were overcome and good relationships were established, enabling additional patients to be transferred from the clinic to CPAMS care.

### *Communication*

None of the sites relied solely on the emails generated by INR Online to inform GPs of INR results that were below 1.5 or above 4.0. Additional arrangements were put in place for each practice, taking into account individual preferences. Methods included faxing, phoning, texting and hand-delivery. Questionnaire responses indicated that most pharmacists (91%) were confident that their review system was effective.

Some sites experienced problems with GPs not being able to identify which of the INR results on their computer records had come from the CPAMS, rather than from the laboratory. CPAMS results were labelled with the pharmacist's name but this was not sufficient to avoid confusion in all cases, especially when a locum GP was involved. It was requested that the CPAMS results could be marked more clearly with their source.

Pharmacists reported that some, but not all, patients were still using their 'red books' to keep a record of INR results and warfarin doses. Others preferred to use only the calendar printed from INR Online at each CPAMS visit.

Communication between the sites and hospitals about patients' warfarin management was thought by many pharmacists to be sub-optimal. Some reported that there was little or no direct communication. Information on admission and discharge was usually relayed via the GP or the patient. A number of pharmacists identified the need for formal processes to be put in place to ensure adequate exchange of information, and for hospital staff to be made aware of the existence of the CPAMS. In one instance, a patient was discharged from hospital and didn't have her INR checked for two weeks because of a communication breakdown; her INR was significantly elevated. In another case, a patient was taken off a waiting list for a procedure because the hospital had not received any INR results. Pharmacists in the Auckland region were keen for CPAMS results to be made available on TestSafe.

When patients went away on holiday, where possible the pharmacists adjusted test dates to accommodate this. However, alternative testing arrangements sometimes had to be made. Usually this involved patients going to a blood collection centre and having a venous sample taken for processing at a laboratory. Often the laboratory staff were unwilling to deal directly with the pharmacist and results were sent to the GP instead. Pharmacists then had to liaise with the GP to obtain the result before the dose could be adjusted and the patient informed.

One pharmacist thought that communications could be aided by providing patients with a small card stating they were on warfarin treatment, managed by the CPAMS, and giving the contact details of the pharmacy.

### *Point-of-care testing device: CoaguChek XS*

The responses to the questionnaire indicated that pharmacists found it easy to obtain blood samples and use the point-of-care testing device. The majority of respondents (97%) were confident that the INR results obtained were reliable.



### *Decision-support system: INR Online*

A large amount of feedback was provided on the decision-support system. The parts most relevant to the evaluation are reported here; other comments will be forwarded directly to the developers of INR Online.

The majority of respondents to the questionnaire (97%) found it easy to use INR Online. However 20% indicated that they were not confident that the dosing recommendations obtained from the system were appropriate.

A number of pharmacists commented that some patients whose INR had been stable under GP care had been less stable once being dosed using INR Online. It was noted that the system appeared to become more successful at achieving stable INRs later in the study period when there were more prior results and doses in the system. Therefore they suggested that more INR results and previous doses, perhaps six months' worth, should be obtained on enrolment to enable a smoother transition.

Some pharmacists felt that INR Online was more 'aggressive' in its dose recommendations than the GPs had been, recommending higher doses than patients had previously been used to. However, the pharmacists believed that this was probably beneficial because the patients' prior results suggested that their INRs had been at sub-optimal levels under GP-led care.

There were different attitudes amongst the pharmacists to overriding the INR Online recommendations on doses and test dates. Some pharmacists believed strongly that the system was simply a tool to assist with decision making; it was the pharmacist's clinical judgement that was important. They commented that there were often factors that the system was not able to allow for such as patients missing doses or taking a different dose from the one prescribed. Other pharmacists were more cautious in their approach, expressing concern that they might leave themselves open to criticism if they overrode recommendations and the patient came to harm.

Some of the pharmacists said that in the early stages of the project they were more likely to discuss dose-overrides with the patient's GP. Later in the project, as their confidence increased and they were more familiar with patients' individual requirements, they were less likely to refer to the GP.

### *Training*

The majority of pharmacists felt that the training provided was good overall and prepared them adequately. Some would have liked more time to practise taking and testing blood samples. Several commented that it wasn't until they started operating the CPAMS that they realised the gaps in their knowledge; they were pleased that there was a high level of support, both technical and clinical, available to them at that stage. A number of pharmacists would have welcomed a follow-up session a few months into the service. It was suggested that pharmacists undergoing accreditation in the future might benefit from working alongside an experienced CPAMS pharmacist as part of their training.

### *Other comments*

One of the sites operated an appointment system for consultations, the other fourteen sites performed tests on a drop-in basis. Testing was usually available from Monday to Friday only; some sites offered weekend testing on a limited basis e.g. if clinically necessary.

Most of the pharmacists thought that a broad-range of patients had been referred to them for management in terms of previous compliance and stability of results. Some pharmacists commented that GPs who had initially had strong reservations about the service had later referred their more difficult patients, once confidence had been gained.



The majority of questionnaire respondents felt they had enough information about their patients' medical history to provide them with appropriate management of their warfarin treatment.

Some respondents to the questionnaire (18%) indicated that they found it difficult to make time for the CPAMS because of the other demands of their work. Many of the pharmacists who were interviewed said that the workload associated with the CPAMS had been high in the early stages when patients were being enrolled and all patients were on weekly testing. The amount of time taken up by the service gradually reduced as patients moved onto less frequent testing. A number of pharmacists suggested that an electronic referral system should be developed to reduce the time and paperwork needed to enrol patients.

All of the pharmacists indicated that they would like the CPAMS to continue.

## General practitioners

Completed questionnaires were returned by 28 of the 115 GPs with patients involved in the CPAMS, a response rate of 24%. The GPs were based at 21 of the 52 practices in the study, and were linked with 12 of the 15 pharmacy sites.

Telephone interviews were carried out with seven GPs from different practices. The seven practices were linked with five of the fifteen pharmacy sites.

The responses to the questionnaire are shown in Table 20.

**Table 20: General Practitioner questionnaire responses (n=28)**

I am confident that the INR results from the CoaguChek XS Plus device used in the pharmacy are reliable	Strongly agree 25% Agree 64% Neither agree nor disagree 7% Disagree 4% Strongly disagree 0%	
I find it easy to access information about the warfarin treatment of my patients involved in the CPAMS, using INR Online	Strongly agree 19% Agree 33% Neither agree nor disagree 41% Disagree 7% Strongly disagree 0%	
I am not confident that the dosing recommendations obtained from INR Online are appropriate	Strongly agree 4% Agree 28% Neither agree nor disagree 14% Disagree 43% Strongly disagree 11%	
How does the pharmacist inform you of INRs above 4.0 or below 1.5? Please tick all that apply:	By email 46% By phone 25% By fax 29% Other 18%	
I am confident that this method of informing me about INRs above 4.0 or below 1.5 is effective	Strongly agree 30% Agree 44% Neither agree nor disagree 4% Disagree 22% Strongly disagree 0%	
I am confident that the pharmacist can manage my patients' warfarin treatment safely	Strongly agree 32% Agree 57% Neither agree nor disagree 7% Disagree 4% Strongly disagree 0%	

As a direct result of seeing my patients for warfarin management, the pharmacist has helped them with other aspects of their healthcare	Strongly agree 11% Agree 25% Neither agree nor disagree 60% Disagree 4% Strongly disagree 0%	
Having my patients enrolled in the CPAMS has saved me time	Strongly agree 53% Agree 32% Neither agree nor disagree 4% Disagree 11% Strongly disagree 0%	
Having my patients enrolled in the CPAMS has saved time for my practice nurse and/or receptionist	Strongly agree 64% Agree 25% Neither agree nor disagree 7% Disagree 4% Strongly disagree 0%	
Since my patients have been involved in the CPAMS, their warfarin treatment has been less well controlled	Strongly agree 0% Agree 7% Neither agree nor disagree 25% Disagree 54% Strongly disagree 14%	
I would like the CPAMS to continue to be available to my patients	Strongly agree 43% Agree 39% Neither agree nor disagree 14% Disagree 0% Strongly disagree 4%	
I think the CPAMS should be made available to patients throughout New Zealand	Strongly agree 46% Agree 29% Neither agree nor disagree 21% Disagree 0% Strongly disagree 4%	
<b>KEY: Strongly agree – SA, Agree – A, Neither agree nor disagree N, Disagree – D, Strongly disagree - SD</b>		

The information collected during the telephone interviews and from the additional written comments on the questionnaires is summarised below.

### *Benefits of CPAMS*

Most of the GPs interviewed felt that their patients had benefited from being enrolled in the CPAMS and reported high levels of patient satisfaction. Advantages to patients included not having to wait for test results; immediate notification of dose changes; and provision of printed dose instructions. A number of GPs commented that some of their patients who had been non-compliant with testing had been much more compliant with the CPAMS and had achieved better control of their treatment as a result.

The majority of GPs interviewed thought that the CPAMS had saved time for their practices, particularly for their nurses. The main areas in which time had been saved were contacting patients

who hadn't attended for testing and informing patients of test results and dose changes. The questionnaire responses supported these findings: 89% of respondents agreed that the CPAMS had saved time for other practice staff.

Some of the GPs commented that they themselves now spent less time on warfarin management, particularly on reviewing results and deciding doses. They were pleased that the pharmacist was doing this; it was something less they had to think about. The majority of questionnaire respondents (85%) agreed that the CPAMS had saved them time.

One GP noted that the pharmacists were better placed to manage warfarin because the way the CPAMS operated gave them better access to patients. If test results were outside the target range the pharmacist could easily discuss the reasons for this with the patient.

One GP had found that having INR testing performed in the nearby pharmacy had allowed flexibility for extra testing when required, for example before a minor procedure at the surgery.

### *Disadvantages of CPAMS*

Some GPs remained cautious about removing the monitoring of INRs from general practice. Concerns included the GP potentially lacking familiarity with their patients' anticoagulation, leading to an increased risk of problems such as drug interactions; uncertainty over where responsibility lay when results were out-of-line and if things went wrong; and pharmacists being unaware of changes in patients' medical conditions which might necessitate adjustment of their anticoagulant therapy.

### *Relationships*

All of the GPs interviewed said that they had a good professional relationship with the pharmacists before the CPAMS started. Some felt that their relationship had improved; others felt that there had been no noticeable change.

### *Communication*

Overall, the GPs interviewed felt that they had been kept well-informed of their patients' progress. However, a number of them had experienced a few problems, particularly in the early stages of the project. Some commented that results had been received onto the surgery computer system but that it hadn't been clear whether they were from the pharmacy or the laboratory.

The majority of questionnaire respondents (74%) were confident that the pharmacist's method of informing them about results below 1.5 or above 4.0 was effective.

### *Point-of-care testing device: CoaguChek XS Plus*

The majority of questionnaire respondents (89%) agreed that they were confident the INR results from the point-of-care testing device were reliable.

### *Decision-support system: INR Online*

Some GPs commented that they weren't always happy with the doses recommended by the decision-support system, observing that it didn't take into account patient factors such as non-compliance. One GP commented that it took a long time and a lot of testing to stabilise their patients' INR in the CPAMS, especially considering that all the patients referred had been stable on transfer. Approximately one-third of questionnaire respondents indicated that they were not confident in the dosing recommendations obtained from INR Online.

One GP reported that initially he had been unable to log into INR Online and felt that some training would have been beneficial, as had been provided to the pharmacists.

One GP, who did not have patients enrolled in the CPAMS but was interested in the service, suggested that GPs should be able to inform pharmacists via INR Online when potentially-interacting medications were started or stopped and request more frequent testing.

#### *Confidence in the service*

The majority of questionnaire respondents (89%) agreed that they were confident that the pharmacist could manage their patients' warfarin treatment safely.

Only 7% of respondents agreed that their patients' warfarin treatment had been less well controlled since enrolment in the CPAMS.

One GP, who responded to the questionnaire but chose not to be interviewed, felt very strongly that warfarin management should be left in GPs' hands. During the study period, one of their patients was admitted to hospital with a cerebral haemorrhage and died shortly afterwards. The GP reported that the patient's INR had been greater than 6 on admission to hospital.

#### *Other comments*

Some of the GPs said they had referred all their warfarin patients to the CPAMS, except those who were medically unstable or were having frequent dose adjustments at the hospital. Others had only referred those who were considered more compliant with treatment.

A number of GPs would have liked to have been able to offer CPAMS home-testing for their less-mobile patients or those who were unreliable at attending for testing.

#### *Future of the service*

All of the GPs interviewed agreed that they would like the CPAMS to continue to be available to their patients. There was also strong support for the CPAMS from questionnaire respondents: 81% wanted the CPAMS to continue and 75% thought the CPAMS should be made available throughout New Zealand.

## Practice nurses

Completed questionnaires were returned by 22 nurses, based at 15 of the 52 GP practices involved in the study, a response rate of 29% of practices. Those 15 practices were linked with 11 of the 15 pharmacy sites.

Telephone interviews were carried out with five nurses from different practices. The nurses selected for interview were from separate practices to the GPs selected for interview. In addition, a senior nurse at a hospital anticoagulant clinic was interviewed. The six nurses were linked with 6 of the 15 pharmacy sites.

The responses to the questionnaire are shown in Table 21.

**Table 21: Practice nurse questionnaire responses (n=22)**

It is more convenient for patients to have their INR blood test at the pharmacy	Strongly agree 50% Agree 41% Neither agree nor disagree 9% Disagree 0% Strongly disagree 0%	<table><thead><tr><th>Category</th><th>Percentage</th></tr></thead><tbody><tr><td>SA + A</td><td>91%</td></tr><tr><td>N</td><td>9%</td></tr><tr><td>D + SD</td><td>0%</td></tr></tbody></table>	Category	Percentage	SA + A	91%	N	9%	D + SD	0%
Category	Percentage									
SA + A	91%									
N	9%									
D + SD	0%									
It is better for patients to be told straight away what their warfarin dose should be, rather than having to contact the practice later	Strongly agree 77% Agree 23% Neither agree nor disagree 0% Disagree 0% Strongly disagree 0%	<table><thead><tr><th>Category</th><th>Percentage</th></tr></thead><tbody><tr><td>SA + A</td><td>100%</td></tr><tr><td>N</td><td>0%</td></tr><tr><td>D + SD</td><td>0%</td></tr></tbody></table>	Category	Percentage	SA + A	100%	N	0%	D + SD	0%
Category	Percentage									
SA + A	100%									
N	0%									
D + SD	0%									
I am confident that the pharmacist can manage our patients' warfarin treatment safely	Strongly agree 63% Agree 32% Neither agree nor disagree 5% Disagree 0% Strongly disagree 0%	<table><thead><tr><th>Category</th><th>Percentage</th></tr></thead><tbody><tr><td>SA + A</td><td>95%</td></tr><tr><td>N</td><td>5%</td></tr><tr><td>D + SD</td><td>0%</td></tr></tbody></table>	Category	Percentage	SA + A	95%	N	5%	D + SD	0%
Category	Percentage									
SA + A	95%									
N	5%									
D + SD	0%									
Since our patients have been involved in CPAMS their warfarin treatment has been less well controlled	Strongly agree 5% Agree 0% Neither agree nor disagree 27% Disagree 41% Strongly disagree 27%	<table><thead><tr><th>Category</th><th>Percentage</th></tr></thead><tbody><tr><td>SA + A</td><td>5%</td></tr><tr><td>N</td><td>27%</td></tr><tr><td>D + SD</td><td>68%</td></tr></tbody></table>	Category	Percentage	SA + A	5%	N	27%	D + SD	68%
Category	Percentage									
SA + A	5%									
N	27%									
D + SD	68%									
As a direct result of seeing our patients for warfarin management, the pharmacist has been able to help them with other aspects of their healthcare	Strongly agree 9% Agree 41% Neither agree nor disagree 45% Disagree 0% Strongly disagree 5%	<table><thead><tr><th>Category</th><th>Percentage</th></tr></thead><tbody><tr><td>SA + A</td><td>50%</td></tr><tr><td>N</td><td>50%</td></tr><tr><td>D + SD</td><td>75%</td></tr></tbody></table>	Category	Percentage	SA + A	50%	N	50%	D + SD	75%
Category	Percentage									
SA + A	50%									
N	50%									
D + SD	75%									
As a direct result of our warfarin patients being involved in the CPAMS, they have missed out on help I could give them	Strongly agree 0% Agree 0% Neither agree nor disagree 52% Disagree 29% Strongly disagree 19%	<table><thead><tr><th>Category</th><th>Percentage</th></tr></thead><tbody><tr><td>SA + A</td><td>0%</td></tr><tr><td>N</td><td>52%</td></tr><tr><td>D + SD</td><td>41%</td></tr></tbody></table>	Category	Percentage	SA + A	0%	N	52%	D + SD	41%
Category	Percentage									
SA + A	0%									
N	52%									
D + SD	41%									

Having our patients enrolled in the CPAMS has saved me time	Strongly agree 90% Agree 5% Neither agree nor disagree 0% Disagree 5% Strongly disagree 0%	
Having our patients enrolled in the CPAMS has saved time for the GPs	Strongly agree 72% Agree 14% Neither agree nor disagree 14% Disagree 0% Strongly disagree 0%	
I would like the CPAMS to continue to be available to our patients	Strongly agree 82% Agree 18% Neither agree nor disagree 0% Disagree 0% Strongly disagree 0%	
I think the CPAMS should be made available to patients throughout New Zealand.	Strongly agree 77% Agree 18% Neither agree nor disagree 5% Disagree 0% Strongly disagree 0%	
<b>KEY: Strongly agree – SA, Agree – A, Neither agree nor disagree N, Disagree – D, Strongly disagree - SD</b>		

The information collected during the telephone interviews and from the additional written comments on the questionnaires is summarised below.

### *Benefits of CPAMS*

The majority of nurses interviewed believed that having their patients' warfarin managed by the CPAMS had saved time both for them and the GPs at their practice. Most of the nurses interviewed felt that the time-savings were considerable and had freed them to perform other tasks. Estimates of how much nurse time had been saved ranged from 30 minutes per week up to five hours per week. The principal areas of time-saving were informing patients of test results and dose changes; and following-up patients who hadn't attended for testing. The majority of questionnaire respondents (95%) agreed that the CPAMS had saved them time and 86% agreed that the CPAMS had saved time for their GPs.

All the nurses interviewed said that the service had been very popular with the majority of their patients. Feedback they had received showed that patients liked the convenience of having the whole process of testing and dose-adjustment completed during a single, short appointment. A number of nurses from rural practices commented that previously there had often been a delay of two days or more before test results were received from the laboratory. These findings were supported by the responses to the questionnaire: 91% of respondents agreed that it was more convenient for patients to have their blood test at the pharmacy and all agreed that it was better for patients to be told their dose straightaway.

The CPAMS was seen as being particularly helpful for those who had been non-compliant with testing under GP-led care and for those who had poor venous access. The pharmacists were perceived by

some nurses as offering better follow-up of patients who didn't attend for testing than they were able to provide themselves.

Some of the nurses commented that the pharmacists were well-placed to manage drug interactions with warfarin and could easily instigate more frequent testing when required.

### *Disadvantages of CPAMS*

One respondent raised concerns about potentially increasing the fragmentation of care by involving another health professional (the pharmacist) in the management of warfarin patients. Other nurses commented that they now had patients being managed under two different systems.

At one of the practices, nurses had previously been carrying out point-of-care INR testing for some of their warfarin patients. These nurses commented that they were possibly now seeing those patients less and therefore missing out on the opportunity to monitor their health. However, it was also noted that the pharmacists had contacted them with any concerns and had referred patients back to the GP when necessary.

None of the questionnaire respondents agreed with the statement "As a direct result of our warfarin patients being involved in the CPAMS, they have missed out on help I could give them".

### *Relationships*

The practice nurses interviewed stated that they had already had a good relationship with the pharmacists involved; they believed that this relationship was key to the success of the CPAMS. Some felt that the nurse-pharmacist relationship had not changed in any way as a result of the service but others observed that it had improved.

A number of the nurses noted that some patients, particularly those who were older, were uncertain about their warfarin care being transferred away from their GP or felt it was disloyal to have testing done elsewhere. Those patients had to form a relationship with the pharmacist and some had chosen to remain with GP-led care.

### *Communication*

The practice nurses interviewed felt that communication between the pharmacy and the practice had been good and that they had been kept well-informed about their patients. They felt confident that the pharmacist would contact the practice if any results needed to be reviewed urgently.

The nurse from the anticoagulant clinic commented that some of the clinic's patients had been transferred to the CPAMS without the clinic's knowledge but that this had not been the pharmacists' fault. She believed that the CPAMS was a good idea but that communications needed to be worked on, particularly those between the pharmacy and the hospital.

### *Confidence in the service*

The majority of questionnaire respondents (95%) agreed that they were confident that the pharmacist could manage their patients' warfarin treatment safely.

Only 5% of questionnaire respondents agreed that their patients' warfarin treatment had been less well controlled since enrolment in the CPAMS.

### *Other comments*

One of the nurses commented that the CPAMS computer programme didn't include sufficient history which led to patients who had been stable on four to six weekly testing going back to weekly testing.



Some nurses noted that the enrolment process had been quite time-consuming but that the service saved time in the long-run.

#### *Future of the service*

There was a high level of support for both continuation and expansion of the service. Many of the nurses commented that both they and their patients would be very disappointed if the service did not continue. All questionnaire respondents agreed that the CPAMS should continue to be available to their patients and 95% agreed that the service should be made available throughout New Zealand.

A number of respondents and interviewees commented that not all patients would be suitable to join the CPAMS; some required blood tests for other indications as well as INR; and some preferred to be cared for by their GP. They felt it was important that the GP-led model of care remained available for those groups of patients.

## Section III - Method

### Cost-benefit analysis

The cost-benefit model for the CPAMS, submitted to HWNZ as part of the PSNZ business case, was evaluated and updated using data collected during the project.

Cost-benefit analyses are a form of economic analysis that compares inputs (in this case, cost of care) and outputs (in this case, thromboembolic and haemorrhagic events) in monetary terms. A full economic analysis was beyond the scope of the evaluation. The analysis presented here was conducted using the Economic Model of Oral Anticoagulation Therapy (OAT) developed by Oblikue Consulting. This tool is based on a published decision analysis and Markov model (24) that compares the costs of anticoagulation management with the costs of thromboembolic events and bleeding. The model takes the perspective of the payer, in this case the government. Only direct costs accrued by the health system are included. Costs to the patient, whether direct costs (such as out-of-pocket expenses for travel), or indirect costs (such as lost earnings due to taking time off work), are not accounted for.

The cost-benefit outcomes of two scenarios are presented: one where 80% of patients are managed under CPAMS and one where 50% of patients are managed under CPAMS. In both scenarios all non-CPAMS patients are assumed to be managed under standard care.

### Costs of providing anticoagulation management

Pharmacist staff costs entered into the model for the CPAMS arm were calculated using data on timings collected in the time and motion study, described in Appendix 15, and professional fees for an equivalent service obtained from the NZ National Pharmacist Services Pricing Guidance. (25) Nurse and GP time spent reviewing warfarin management during the CPAMS was not measured; for the purposes of the cost-benefit evaluation this time was estimated at 10% of what was required under standard care. The cost of consumables was based on acquisition costs. The cost of the point-of-care testing device was included as a cost per test based on the acquisition cost depreciated over 5 years. Overhead costs that were considered essential to the delivery of CPAMS, including internal and external quality assurance programmes and computer decision support, were included as a cost per test. All cost per test variables in the CPAMS arm were based on the assumption that each pharmacy had 80 patients enrolled and conducted two tests per patient per month. No allowance was made in the model for the additional staff costs incurred during the CPAMS enrolment process and initial consultation.

Comparative data on staff costs incurred under the standard model of care (including GP time, nurse time and professional fees) were derived from a published study of warfarin management in general practice in New Zealand. (26) The cost of laboratory testing was based on a published report from one DHB. (27) Costs of laboratory consumables and the cost of laboratory quality control programmes were assumed to be overheads included in the laboratory test fee and were not added to the model for the standard care arm. No costs for blood collection at the general practice were included. No costs for quality assurance of practice management (practice audits) were included.

The frequency of testing in the CPAMS arm was derived from an analysis of the CPAMS data; the average number of tests per month across the entire CPAMS follow-up was used (Table 12). If CPAMS becomes an established model of care there will be a mix of new and established patients and it was felt that the average frequency across the whole period of follow-up best reflected this. The frequency of testing in the standard care arm was based on an analysis of prior INR data from a sub-set of the CPAMS group (see Table 16) and from published research from New Zealand (10); these data indicate that test frequencies in standard care and the CPAMS are broadly similar.

A summary of the costs included in the model is provided in Table 22. The cost of warfarin itself is assumed to be the same in both groups and is not included in the model.

**Table 22: Costs of anticoagulation management**

Standard care	Cost in NZ\$	CPAMS	Cost in NZ\$
<b>Laboratory testing<sup>1</sup></b>	<b>9.39</b>	<b>Point-of-care testing<sup>2</sup></b> INR test strip Consumables (lancing device, gloves, tissue, plaster, medical waste charges) Cost of POC-INR device (based on depreciation over 5 years)	<b>7.32</b> 6.12 0.84   0.36
<b>Quality assurance/quality control</b> Laboratory QA/QC costs assumed included in tests fee. Practice audit not currently required.	-.-	<b>Quality assurance/quality control<sup>2</sup></b> Coaguchek XS quality control test (monthly <i>plus</i> at change of batch) External Quality Assurance Programme (based on Royal College of Pathologists of Australasia (RCPA) programme)	<b>0.54</b> 0.28  0.26
<b>Computer decision support system</b> Not routinely used	-.-	<b>Computer decision support system</b> Fee for service (based on INR Online commercial pricing)	<b>0.50</b> 0.50
<b>Professional fees</b> Pharmacist time GP time <sup>3</sup> (8.8 min @ \$200/hr) Nurse time <sup>3</sup> (18.6 min @ \$50/hr)	<b>44.85</b> -.- 29.33  15.50	<b>Professional fees</b> Pharmacist time <sup>4</sup> (10 minutes, comprising 7 min consultation and 3 min administration and follow-up, @ \$150/hr) GP time (assumed 10% of standard care) Nurse time (assumed 10% of standard care)	<b>29.48</b> 25.00   2.93  1.55
<b>Cost</b> (per patient per visit)	<b>54.24</b>	<b>Cost</b> (per patient per visit)	<b>37.84</b>
<b>Total cost<sup>5</sup></b> (per patient per year)	<b>1301.76</b>	<b>Total cost<sup>5</sup></b> (per patient per year)	<b>908.16</b>
<sup>1</sup> . Based on Canterbury Laboratory Services Consultation Report.(27) <sup>2</sup> . Based on pharmacy enrolling 80 patients and conducting 2 tests per month; total 1920 tests per year. <sup>3</sup> . Derived from Geevasinga et al 2004 (Table 1). <sup>4</sup> . Derived from time and motion study (Appendix 15). <sup>5</sup> . Based on mean test frequency of 2 tests per month (see text).			

### Costs of thromboembolic and haemorrhagic events

New Zealand specific data on age-specific mortality rates, thromboembolic and haemorrhagic event rates and costs per event were entered into the cost-benefit model. These data were obtained from researchers in the Centre for Health Service Research, School of Population Health, The University of Auckland [Personal communication]. The data were sourced from DHB hospital cost data and analysis of discharge codes reported to the National Minimum Data Set. All patients admitted to hospital were followed-up for three years to identify ongoing costs.

The cost data included in the model are summarised in Table 23.

**Table 23: Cost and frequency of hospital admissions for thromboembolic and haemorrhagic events**

Complication	Year 1		Subsequent years	
	Cost (NZ\$)	Proportion of event category	Cost (NZ\$)	Proportion of event category
<b>Thrombotic event</b>				
Thrombotic stroke (ICD-10 codes: I63.0, I63.3, I63.6)	10,846.47	62	7685.55	57
Transient Ischaemic Attack (ICD-10 codes: G45)	6,186.34	28	8542.57	33
Pulmonary embolism (ICD code: I26)	10,447.98	10	8476.45	10
<b>Haemorrhagic Event</b>				
Cerebral haemorrhage (ICD-10 codes: I60.x; I61.x; I62.x)	14,067.47	48	7611.88	28
GI Bleed (ICD-10 codes: K92.-)	8401.64	52	7500.74	72

### Estimation of the effect of improved anticoagulation control

The size of the patient group enrolled in the project was not sufficiently large to detect small differences in adverse event rates between the CPAMS and those reported in the literature. The time in therapeutic range (TTR) was therefore used as a surrogate measure of event rates. This is justified on the basis of a number of studies showing an association between increased TTR and reduced complication rates. One such study (28) concluded that, on the basis of meta-analysis of 47 studies, a 7% improvement in TTR was associated with one fewer major haemorrhagic event per 100 patient years of treatment. Similarly, a 12% improvement in TTR was associated with one fewer thromboembolic event per 100 patient years of treatment.

Extrapolating the mean improvement in TTR achieved in the innovation project to a reduction in event rates, based on the assumptions above, suggests that the expected thromboembolic event rate in the CPAMS group would be 1.9% (95% CI 0.5% to 5.1%) per year compared to an assumed rate of 4.6% (95% CI 3.0 to 6.5%) for standard care. Similarly, the rate of haemorrhagic complications would be expected to fall to 2.1% (95% CI 0.2 to 8.9%) from an assumed rate of 3.7% (95% CI 1.4% to 7.0%). The assumed rates for standard care were derived from a large systematic review and meta-analysis. (29)

There are no data on which to base a predicted reduction in mortality from a change in TTR. Mortality rates in the CPAMS group were assumed to be the same as that shown in a meta-analysis of trials of patient self-management of warfarin therapy (29) since the improvement in TTR seen in the CPAMS project exceed those seen in the meta-analysis. The mortality rates used in the model were 2.4% (95% CI 0.8% to 4.2%) in the CPAMS group and 3.9% (95% CI 3.0% to 5.1%) for standard care.

### Prevalence of warfarin treatment in New Zealand

Data published by BPAC<sup>NZ</sup> indicate that 34 137 patients were taking long-term warfarin in 2009/10 (30); this is in line with recent PHARMAC estimates. (31) The model assumes that 46 000 patients are treated with warfarin at any given time; this figure is taken from the model for the CPAMS, submitted to HWNZ as part of the PSNZ business case.

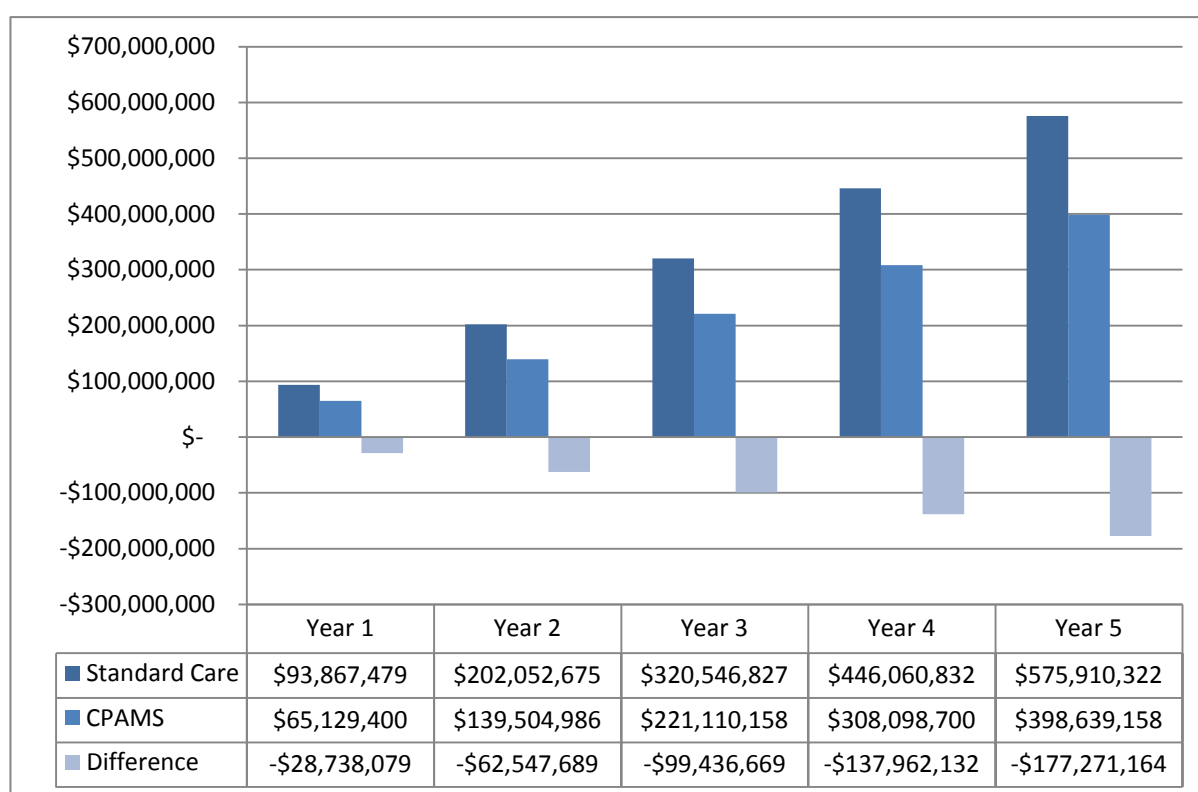
## Section III - Results

### Cost-benefit analysis

From a government-payer perspective, the cost of delivering the CPAMS is 30% lower than the cost of the standard care model (\$908.16 versus \$1301.76 per patient per year). The main cost in both models of care is the cost of staff time. The economic analysis is therefore potentially sensitive to changes in both the time spent on delivering the service and on professional pay rates.

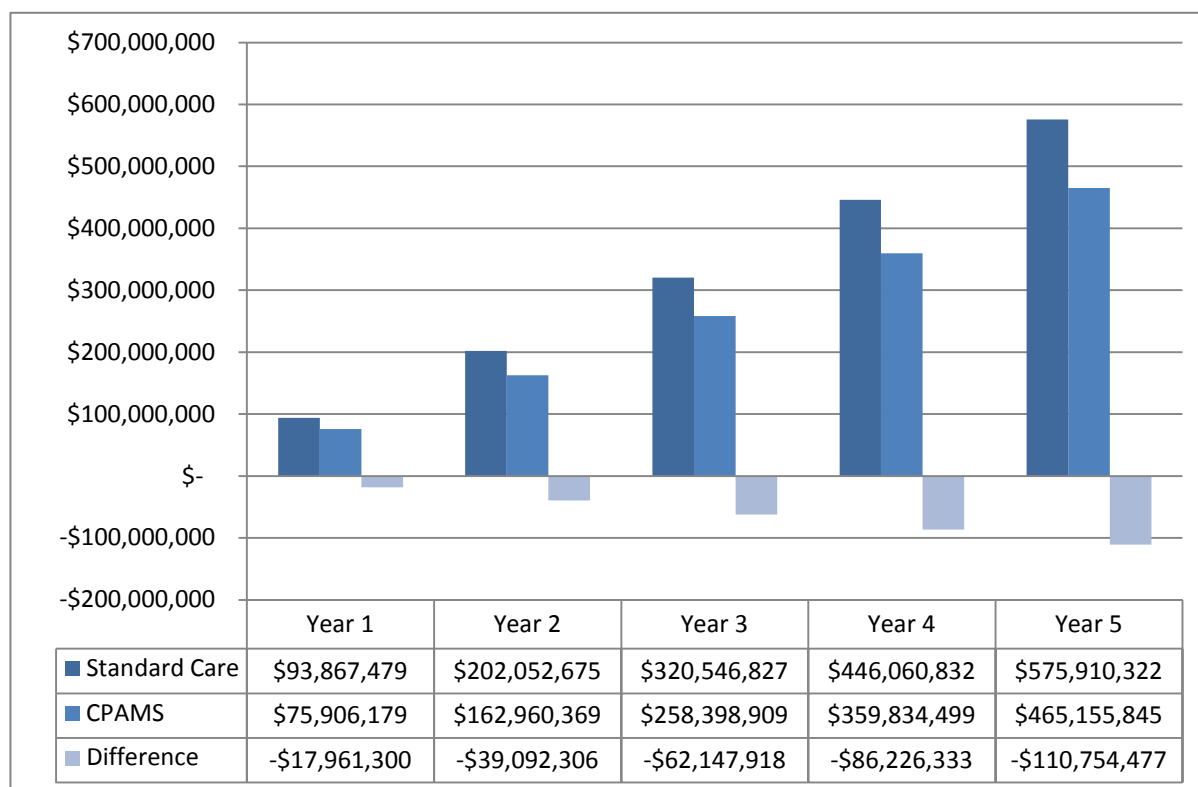
When considering the improvement in anticoagulation control and extrapolating this to a reduction in both thromboembolic and major bleeding complications, the CPAMS model appears to offer substantial cost savings. The economic analysis is driven by the high costs of both thromboembolic, particularly stroke, and major bleeding events.

In scenario one, where 80% of patients are managed under CPAMS and the remaining 20% under standard care, the predicted budget impact from a government perspective is a net reduction in anticoagulation-associated costs of approximately \$177M over 5 years (Figure 5).



**Figure 5: Cost-benefit analysis (80% of eligible patients managed under CPAMS)**

In scenario two, where 50% of patients are managed under CPAMS and the remaining 50% under standard care, the predicted budget impact from a government perspective is a net reduction in anticoagulation-associated costs of approximately \$111M over 5 years (Figure 6).



**Figure 6: Cost-benefit analysis (50% of eligible patients managed under CPAMS)**

## Discussion

The discussion is structured on the project goals and evaluation questions laid out in schedule 3 of the Workforce Innovation Services Agreement (see Aims and Objectives).

## Project goals

### Improvement on current practice

#### *Quality of anticoagulation control*

The quality of anticoagulation control, as measured by the TTR, was shown to be improved for patients enrolled in the CPAMS when compared with outcomes for standard care in the literature, and with pre-enrolment data.

The mean TTR achieved for patients in the CPAMS was 78.4%. Further improvements in the mean TTR were observed as the duration of enrolment in the CPAMS increased; a mean TTR of 80.2% was achieved for patients with 26 weeks or more of management. All sites involved in the project achieved mean TTRs well in excess of the BCSH standard of 60%; mean TTRs ranged from 71.4% to 84.1%. For those patients for whom pre- and post-enrolment data were available, the mean TTR increased from 60.3% with standard care to 77.4% in the CPAMS.

There is some evidence from the literature to support the hypothesis that higher TTRs may be associated with more frequent testing. (32) However, the difference in mean test frequency seen in the pre-post enrolment sub-study was not significant and is unlikely to explain the difference in TTRs seen in this project.

Statistically significant differences in mean TTR were seen between pharmacy sites; however these were not deemed to be clinically important and were not adjusted for patient mix. Further analysis is needed to compare risk-adjusted TTRs (33) before any conclusions about between-site variations can be drawn.

#### *Compliance with monitoring and adherence to treatment*

A high level of compliance with appointments was achieved by the CPAMS with the majority of tests (83.1%) performed on or before the due date. Factors contributing to the high level of compliance with monitoring are likely to have included the convenience of having testing done at the pharmacy; increased accessibility of testing; patient preference for capillary sampling; and improved tracking and follow-up of patients known to be poor attendees. Comments made during pharmacist, GP and practice nurse interviews support this view, indicating that a number of patients who had been non-compliant with monitoring under standard care had become more compliant under the CPAMS and had achieved better anticoagulation control as a result.

Adherence to treatment was not measured directly; however the high TTRs achieved by the CPAMS may in part be due to higher adherence rates. There is a well documented link between patient knowledge, adherence to treatment, anticoagulation control and bleeding rates.(34-37) The majority of patient respondents said that they found it useful to be able to discuss their warfarin treatment with the pharmacist when going for their test; this may have led to an increased understanding of their treatment and therefore better adherence to it and therefore better control. Patient and pharmacist feedback indicated that the CPAMS had led to increased patient involvement with their treatment; this is also likely to have contributed to adherence. In addition, the questionnaire responses showed that many patients found it helpful to be given a printed calendar showing the dose of warfarin to be taken on each day; this was provided to aid adherence.

### **Reduced fragmentation of care**

The CPAMS reduced fragmentation of care by the incorporation of sampling, testing and dose adjustment into one consultation involving a single health professional. Results found to be outside the patient's target range could be dealt with immediately and patients were given a printout of their dose instructions. Under the standard model of care, management often involved a blood collection centre, laboratory, practice nurse and/or receptionist, and GP. Results were sometimes delayed; follow-up of non-attendees was sometimes sub-optimal; and dose instructions were often given over the phone, leading to the possibility of miscommunication.

The CPAMS itself has the potential to fragment care. Some GPs and practice nurses felt that their reduced involvement with patients taking warfarin might result in a lack of familiarity with their treatment or lead to other medical problems being missed. Practices had to cope with warfarin patients being managed under two different systems; some by the CPAMS and others remaining with standard care. There were also reports from pharmacists of sub-optimal communication between the sites and secondary care. To limit the potential for fragmentation of care, pharmacists and practices worked together to develop good communication and ensure that all those involved were kept fully informed. Patients were referred back to the GP whenever the pharmacist considered it necessary.

The CPAMS incorporated many of the key components identified by Garcia et al as supporting the delivery of optimised anticoagulant therapy, namely scheduling, testing, decision-support and use of a tracking system to minimise the likelihood of a patient being lost to follow-up.(12) However communication, another key component, was not always optimal and this has the potential to affect patient outcomes.

### **Reduction in warfarin-related adverse medication events**

No conclusions can be drawn about whether there was a change in the incidence of warfarin-related adverse events for patients in the CPAMS. The incidence of adverse events in the literature is in the order of 5%; (38, 39) therefore a very large sample of patients could be required to show a clinically significant difference. Furthermore, the information collected via INR Online lacked detail and it could not be verified that all events had been identified and documented. However, using TTR as a marker for the quality of anticoagulation control, it can be postulated that the increase in TTR seen for patients enrolled in the CPAMS would have resulted in a reduction in the incidence of adverse events and hospitalisations when compared to standard care.

As would be expected, a large majority of the adverse events reported were minor bleeding or bruising not requiring medical intervention. There were a number of serious adverse events reported, one of which resulted in the death of the patient. It was beyond the scope of the evaluation to investigate these events other than by using the information available from INR Online. However, the incidence rates calculated would not appear to suggest that adverse events for patients in the CPAMS fell outside expected ranges.

The data obtained for hospitalisations, like those for adverse events, are of limited value. However, when evaluated only 18 of the 192 documented hospital admissions were categorised as being potentially or definitely related to warfarin treatment.

### **Improved accessibility and convenience for patients**

Whilst those involved in the CPAMS were a self-selected cohort, they were consistently positive about its benefits in terms of accessibility and convenience.

Accessibility to testing was improved for many patients. They found it helpful to be able to go to the pharmacy at any time during opening hours rather than having to attend the blood collection centre by



a certain time. Some now had less far to travel or could visit the pharmacy when they were doing their shopping.

The majority of participants who responded (patients, pharmacists, GPs and practice nurses) thought that the CPAMS model of care offered greater convenience for patients. A large majority of patients reported that having their warfarin managed by the pharmacist had saved them time. Many of them commented that there were no long queues, unlike at the blood collection centres. They also found it convenient to find out their result and dose straightaway, removing the need to contact their GP practice later.

### **Increased job satisfaction for pharmacists**

Pharmacists derived satisfaction from the expansion of their role to involve the management of warfarin as well as its dispensing. Many of them felt that their clinical skills and knowledge were being underutilised and they welcomed the challenge of developing a new model of care that made better use of these.

Pharmacists enjoyed the opportunity to develop a closer relationship with their patients. Trust and confidence were increased, enabling them to provide more help with many aspects of their patients' care. Similarly, many pharmacists derived satisfaction from strengthened relationships with GPs and nurses, and a perception of greater professional respect towards what they could contribute.

### **Improved multidisciplinary management of atrial fibrillation patients in the community**

The evaluation was designed to assess the management of warfarin treatment rather than the management of atrial fibrillation patients. However, over 70% of patients enrolled in the project were being treated with warfarin for the management of atrial fibrillation. The majority of these patients were 65 years or older (70.6%) and therefore at a high baseline risk of stroke. Warfarin treatment is known to be very effective at preventing ischaemic stroke but in order to be effective the TTR needs to be greater than 60%. (40) It can therefore be postulated that the increase in mean TTR seen under CPAMS management will have contributed to the improved management of atrial fibrillation patients.

It may be the case that if the CPAMS becomes established it will facilitate increased utilisation of warfarin in patients with atrial fibrillation, hence contributing to improved management. Better access to testing, increased convenience and a more acceptable method of blood sampling may help to remove some of the patient barriers to treatment seen with standard care. In addition, if GPs have confidence in the service and believe that it provides high quality anticoagulation management, it may encourage wider prescribing of warfarin.

### **Reduced burden on general practice**

The majority of GPs and practice nurse respondents thought that the CPAMS had saved time for them and for other members of staff at their practices. It was difficult for them to quantify how much time was saved because the workload related to warfarin management varied from week to week and often involved multiple members of staff at a practice. Some practices reported significant time-savings, with one nurse estimating that she was saved as much as five hours each week.

Some GPs were pleased to have the responsibility for day-to-day management taken on by the pharmacist because it meant that they had one less thing to think about.

It was thought by some participants that the CPAMS was of particular benefit in rural areas where GP shortages meant that there were very heavy workloads for practice staff.

## **Improved professional relationships and increased GP-pharmacist collaboration**

As discussed above, pharmacists felt that professional relationships had been strengthened by their involvement in the CPAMS. Responses from GPs and practice nurses indicated that they had already enjoyed good relationships with the pharmacists involved. Changes to these relationships, if any, were positive.

A high level of GP-pharmacist collaboration was required to allow implementation of the CPAMS model of care. Pharmacists and GPs had to work together throughout including organising enrolment of patients; managing out-of-range results; and sharing information about changes to patients' treatment or medical conditions.

## **Initiation of first step towards pharmacist-managed medication management**

One of the objectives of the innovation project was to demonstrate the contribution community pharmacists can make to patient care beyond their accepted role of medicines provision, medication counselling and treating minor ailments. The evaluation clearly demonstrated that both patients and primary care practitioners accepted this extended role. Pharmacists reported high levels of satisfaction with being able to put their clinical knowledge to use in direct patient care.

These findings may, in part, be the result of selection bias. Pharmacies that participated in the project were selected from a pool of pharmacies expressing interest. For this reason, pharmacies that participated may be more progressive, with better existing relationships, than is the case for community pharmacy at large. Notwithstanding this, the feedback from all groups was predominantly positive. Some concerns were raised and these are important to address when considering extending the CPAMS.

## **Evaluation questions**

### **How was the innovation project implemented?**

The implementation of the project has been summarised in the introductory section of this report.

### **Did the innovation project achieve the desired outcomes?**

The innovation project was established to investigate whether the role of community pharmacists should be extended to provide a new service to patients for the monitoring of anticoagulant therapy, specifically the oral anticoagulant warfarin. The model of care established needed to provide safe, effective and cost-effective care that was acceptable to patients and other healthcare providers.

### **Safety**

The greater the TTR, the better the balance is between the risks and benefits of warfarin treatment. TTR can therefore be used as a proxy for safety. As discussed above, the mean TTR achieved by the CPAMS was higher than that typically reported for standard care. Using this measure, CPAMS care would be considered safer than standard care. Based on published estimates of the correlation between TTR and event rates, (28) it could be expected that the mean increase in TTR seen in the CPAMS project might translate to 2.4 major haemorrhages saved per 100 patient-years of treatment.

A second proxy for safety is the number of INRs above 5.0 or above 8.0. At this level of INR, the risk of bleeding is considered to be clinically unacceptable. A comparison was made of the percentage of INRs results above 5.0 and above 8.0 for patients for whom pre- and post-enrolment data were available (Table 14). This found that 1.0% and 0.4% of results under standard care, and 0.8% and 0.1% of results under CPAMS care were above 5.0 and above 8.0 respectively. However, the size of the patient group meant that the difference was not statistically significant and could not be used to compare the relative safety of the two models of care.

Concerns were raised by some participants (patients, pharmacists and GPs) that patients who had had stable INRs under standard care were less stable in the early stages of CPAMS enrolment. An analysis of INR results during the transition period between standard care and CPAMS care did not reveal an increase in the number of results outside safety thresholds when compared to the rest of the study period. However, participants did suggest that management during this period could be improved if pharmacists were provided with more than three prior INR results and doses for each patient.

It may be the case that management of the transition period will be smoother once pharmacists have gained experience in the CPAMS. The information gathered by the evaluation relates to patients who were enrolled at the start of a new service when pharmacists will have been less familiar with warfarin management than at the end of the study period.

### *Effectiveness*

TTR can also be used as a proxy for effectiveness of care. Using this measure, CPAMS care would be considered more effective than standard care. Based on published estimates of the correlation between TTR and event rates, (28) it could be expected that the mean increase in TTR seen in the CPAMS project might translate to 1.4 additional thromboembolic events prevented per 100 patient-years of treatment.

A second proxy for effectiveness of care is INRs more than 1.0 below target. At this level of INR, there is likely to be inadequate protection against thromboembolism. A comparison was made of the percentage of INR results more than 1.0 below target for patients for whom pre- and post-enrolment data were available (Table 14). This found that 8.6% of results under standard care and 3.9% of results under CPAMS care were more than 1.0 below target. However, the size of the patient group meant that the difference was not statistically significant and could not be used to compare the relative effectiveness of the two models of care.

### *Cost-effectiveness*

The evaluation did not seek to undertake an extensive health economic analysis. The project was not designed with a comparator group and the patient group was not sufficiently large to be able to detect a difference in adverse event rates. Using the TTR to estimate a reduction in event rates, a cost-benefit model was used to evaluate the impact of wider adoption of the CPAMS on the total costs of anticoagulation-related health care costs. The model indicated that substantial net savings could be achieved.

It is important to note that the cost-benefit analysis takes the view of the payer, in this case the government. It assumes that all costs and all benefits are accrued in the same system. In reality, costs are accrued in one place and benefits elsewhere. Similarly, cost-benefit analyses are frequently criticised for promising savings that cannot be realised without, for example, withdrawing funding from other services. The analysis should perhaps be viewed as describing discretionary spending. In theory, money saved on the costs of managing anticoagulation and its related complications, and by avoiding thromboembolic events, can be redirected to other areas of care.

In the project, all patients were initially tested weekly as a requirement of the transition to dosing using the decision-support system. For some patients this meant more frequent testing than under standard care; however the interval between tests gradually reverted to a more 'normal' pattern. The economic model assumes that the same number of tests is performed per patient, per year for both models of care. This assumption appears to be justified both by the literature (10) and by data collected during the study period.

Irrespective of the cost-benefit analysis, a simple analysis of the cost of management indicates that the CPAMS offers a cost-effective alternative to the standard model of care.

#### ***Acceptability to patients and other healthcare providers***

The CPAMS was well accepted by the majority of patients and primary healthcare providers.

Patient opinions, obtained via questionnaires and interviews, showed that there were high levels of confidence in the pharmacy test results and in the pharmacist's ability to manage their warfarin treatment safely. The majority of patients did not feel less in control of their warfarin treatment, nor did they express a preference for having their warfarin managed by their GP.

Whilst the response rate to questionnaires by GPs and practice nurses was low (less than 30%), which may imply responder bias, there was consistency in the responses to many questions. Likewise, only a small sample of GPs and practice nurses was interviewed but there were many commonalities in the opinions expressed.

The majority of GPs who responded were confident that the pharmacist could manage their patients' warfarin treatment safely. However, opinions were divided on whether the dosage recommendations obtained from the decision-support system were appropriate. As discussed previously, some GPs remained concerned about the potential for their lack of familiarity with patients' treatment to cause problems. Others were uncertain where responsibility would lie if something went wrong. Despite these reservations, 82% of respondents to the questionnaire, and 100% of interviewees, agreed they would like the CPAMS to continue to be available to their patients.

The majority of practice nurses also had confidence in the pharmacist to manage their patients' warfarin treatment safely. There were some concerns raised about possible fragmentation of care that have been discussed previously. However, all of the respondents to the questionnaire, and all of the interviewees, agreed they would like the CPAMS to continue to be available to their patients.

There was also support amongst GPs and nurses for expansion of the service. Seventy-five percent of GP respondents and 95% of practice nurse respondents thought that the CPAMS should be made to patients throughout New Zealand.

Acceptability to secondary healthcare providers was not assessed as part of the evaluation.

#### ***Did the innovation team learn from the innovation and make improvements?***

The steering group met regularly throughout the innovation project to monitor its progress. Patient enrolments, TTRs, QC results and the performance of the decision-support system were kept under review and feedback from the sites was discussed.

It was clear that GP support for the project was crucial to its success. Some sites had difficulty in enrolling the target number of patients and this was partly due to some GPs withdrawing or withholding their support. Feedback from pharmacists suggested that some GPs would have been more willing to be involved if they had been approached via a GP organisation rather than by the pharmacist directly.

The technical and clinical support provided to pharmacists proved important, particularly in the early stages of the project. Although the training provided as part of the accreditation process was rated highly, it was not possible to prepare pharmacists for everything they would encounter in practice. Discussions were begun on the re-accreditation processes that might be required in the future.

The intention was that results below 1.5 or above 4.0 would be communicated to GPs via email and that GPs would use the decision-support system if they wanted to adjust the dose specified by the

pharmacist. It became clear that the majority of GPs did not want to rely on results being communicated to them in this way, nor did they want to make dose adjustments electronically. Pharmacies instead made individual arrangements with practices for dealing with out-of-range results.

Improvements to communications with both primary and secondary care providers were discussed. A request was received from Auckland sites for results to be sent to TestSafe, the regional laboratory results electronic repository, and efforts to make this possible were begun.

Additional documentation was developed to formalise the management of patients who were non-compliant with appointments (Appendices 16 and 17). A protocol was established for the manual recording and management of results when the decision-support system was unavailable, for example if there was no internet connection (Appendix 18). The standing order was amended to incorporate these changes. Feedback about the enrolment process highlighted the need for paperwork to be kept to a minimum. Some participants suggested that an electronic system should be developed.

A number of improvements were made to the decision-support system based on requests from the sites. These included a function to generate lists of due and overdue patients to assist with scheduling and tracking.

As described in the introduction, the QA processes for the service were developed and improved over the course of the project. Monitoring of QC results revealed that the results at one site were slightly lower than at other sites. This was investigated and it was found that the QC control sample had been incorrectly reconstituted. The operator was given additional training and the site's results were subsequently consistent with those from other sites. Patient results were not affected. In a second incident, a patient was admitted to hospital with a clot on a valve and was found to have a sub-therapeutic INR on admission. An investigation was carried out at the pharmacy responsible for his care. The pharmacy testing processes, test strips and device were examined to ensure that the INR results provided by the pharmacy were reliable. None of the findings to date indicate that the CPAMS management was erroneous. The point-of-care testing device was returned to Germany for further analysis and was found to be functioning correctly.

### **Did the innovation project represent value for money?**

As discussed above, both the cost-benefit analysis and a simple analysis of the cost of management indicate that the CPAMS offers a cost-effective alternative to the standard model of care.

### **Did the innovation project result in any unintended outcomes?**

The evaluation did not find that any unintended outcomes had resulted from the project.

### **Should the innovation project be generalised and spread?**

The findings of the evaluation support the view that there is the potential for significant benefits for patients and the health system from spreading the innovation.

The innovation project developed a new model of care that was demonstrated to be safe, effective, cost-effective and acceptable to patients and other healthcare providers. There was widespread support for its continuation and expansion.

## Barriers to wider implementation

### *Acceptance of extended role*

A key part of the success of any role expansion will not only be the skills of the pharmacists offering the extended service but their recognition and acceptance by other health professionals. Current models of extended pharmacy service focus on collaboration and it is important that CPAMS is seen in this light. The project was designed as a collaborative arrangement between patient, pharmacist and general practice. If the service is to be generalised and spread, it will require the support of GP and nursing organisations; some GPs and nurses may accept the service more readily if it is advocated for by their professional organisations.

Not all patients will find it acceptable to have their warfarin management taken on by the pharmacist. Some may need reassurance that the GP will remain involved in their care; if GPs demonstrate confidence in the service, this is likely to build patient confidence. If the service gains support from patient organisations, this may increase its acceptance. However, those who prefer to remain with the standard model of care should be allowed to do so.

### *Legislation*

Amendments to legislation may be required. The current legislation was not designed to cover models of care of this type; the CPAMS used standing orders to allow pharmacists to make dose adjustments and manage warfarin treatment. It may also be necessary to address the question of who is legally responsible for what, as was raised by some participants in the project.

Proposed changes to the Medicines Act include the creation of 'delegated prescribers'. This new category of prescriber may lend itself to the role being carried out by accredited pharmacists in the CPAMS.

### *Funding*

The funding model will need further development. Support for the service from DHBs will be required as they will be the primary funders of pharmacy services. There may be resistance from laboratory services and GP organisations if funds are re-allocated from them to the CPAMS. Feedback from patients indicates that some would be prepared to pay a small fee towards the CPAMS but many others would be unwilling or unable to do so; the majority of patients enrolled in the service were over 65 and many will have been on low incomes.

## Recommendations for future service development

### *Selection of pharmacies and patient enrolment*

Not all pharmacists will be capable of offering the service, nor will all want to. The sites involved in the project were carefully chosen because of their well-established professional relationships; many were already providing additional clinical services or had participated in other pilot projects. The pharmacists were highly motivated and demonstrated great commitment to developing a high quality service for their patients. There was a strong feeling amongst them that the service should not be compromised by making it available to all pharmacies or by too fast a roll-out.

Additional pharmacists and pharmacies will need to be carefully selected. There should be evidence of strong professional relationships that will allow collaborative management of patients. The GPs and nurses involved will require a good understanding of how the service works and must be supportive of it. Practices may need to make changes to their record systems so that it is clear which patients are managed under the CPAMS and which are under GP-led care.



Patient numbers should be built up gradually. Limits may need to be placed on the number of patients per site so that the benefits of the service are not compromised. The types of patients enrolled in the service will reflect the level of confidence that GPs have in it; as with the innovation project, some GPs may wish only to refer patients who are stable on warfarin and compliant with treatment while others may believe that the CPAMS can offer better management of more difficult patients than they can provide themselves. It is accepted that the CPAMS is not suitable for all patients and, additionally, consideration should be given to assessing which patients would benefit most from the service if there are limited resources.

Whilst accepting that not all pharmacies or patients will be willing or able to participate in the service, in principle all eligible patients should have the opportunity to enrol and, therefore, there should be an adequate geographical spread of participating pharmacies. Initially however, it may be appropriate to concentrate resources in areas of higher need such as rural areas experiencing GP shortages.

### *Training and support*

Development of training, accreditation and reaccreditation processes will need to be continued. Technical and clinical support should remain available to sites; the way this is provided may have to be adapted as site and patient numbers increase.

### *Communication*

The work that has been started on making CPAMS results available to other healthcare providers e.g. via TestSafe, should be continued. Pharmacy test results should be made more readily distinguishable from other test results to avoid confusion.

Awareness of the CPAMS service amongst secondary healthcare providers should be increased. Communication should be improved so that CPAMS providers are informed of hospital discharges and have access to records as necessary.

Consideration should be given to encouraging the use of 'red books' (the patient-held anticoagulant record). These are an established method of recording INR results and warfarin doses that can aid communication between healthcare providers. Some sites stopped using them and relied solely on the printed dosage calendar. However, the calendar does not provide a complete record of previous doses and INR results.

### *Quality assurance and standard setting*

Work has begun on implementing a quality assurance programme, to include accredited external assessment.

It will be necessary to develop a set of service standards; this will allow individual pharmacies to monitor their performance and will assist with external review. Examples of the types of standards that may be appropriate have been published by the BCSH (23). They include monitoring of TTRs, INRs outside safety thresholds and adverse event rates. With this in mind, changes should be made to the decision-support system to enable more accurate collection of data on adverse events and hospitalisations. There should also be a requirement for a formal collaborative review of patients' warfarin treatment by the GP and the pharmacist, perhaps on an annual basis.

## Impact of new medications on the demand for warfarin management services

There are a number of new oral anticoagulants emerging; these include rivaroxaban, apixaban and dabigatran. These new medications are not without their problems but they do offer an alternative to treatment with warfarin. One of the perceived advantages for these new treatments is a more predictable dose-response relationship. In practice this means there is no need for the regular blood testing associated with warfarin. However, they do still carry a substantial risk of bleeding, particularly in the elderly.

Currently, only rivaroxaban and dabigatran are available in New Zealand. Both agents are licensed for short-term use to prevent thromboembolic complications following major surgery; only dabigatran is licensed and funded for long-term treatment and its use is currently limited to the prevention of stroke in patients with atrial fibrillation. Recently presented clinical trial data appear to show that apixaban, like dabigatran, provides a safe and effective alternative to warfarin for patients with atrial fibrillation. Rivaroxaban does not, based on the data available to date, offer a clear advantage over warfarin for these patients.

As more information on the effectiveness of these new agents becomes available, and prescribers become more familiar with the slightly different set of problems they present, it is likely that there will be a reduction in the number of patients receiving warfarin treatment. However, because these new medications are not suitable for all patients, nor are they licensed for as wide a range of indications as warfarin, there will be a place for anticoagulation using warfarin for the foreseeable future and warfarin management services will continue to be required. Furthermore, on the basis of re-analysis of trial data, it appears that patients who are well-controlled on warfarin are unlikely to benefit from switching to one of the newer agents.



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