

Community Pharmacist-led Anticoagulation Management Service

Final Report

Appendices

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14 December 2010

Professor John P Shaw
School of Pharmacy
Faculty of Medical and Health Science
University of Auckland
Private Bag 92 019 Auckland

Dear Professor Shaw

Re: Ethics ref: **MEC/10/10/105** (please quote in all correspondence)
Study title: Community Pharmacist-led Anticoagulation Management Service
Investigators: Professor John P Shaw, Dr Jeff Harrison

This study was given ethical approval by the Multi-region Ethics Committee on the 1st of December 2010. A list of members of the Committee is attached.

Approved Documents

- Protocol received with letter dated the 11th of November 2010
- Information sheet for general Practitioners, version 1, dated the 30th of September 2010
- Consent form for General Practitioners, version 1, dated the 30th of September 2010
- Information for Participants, version 1, dated the 30th of September 2010
- Consent form for participants, version 1, dated the 30th of September 2010

This approval is valid until 31 December 2011, provided that Annual Progress Reports are submitted (see below).

Access to ACC

For the purposes of section 32 of the Accident Compensation Act 2001, the Committee is satisfied that this study is not being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is being carried out. Participants injured as a result of treatment received in this trial will therefore be eligible to be considered for compensation in respect of those injuries under the ACC scheme.

Amendments and Protocol Deviations

All significant amendments to this proposal must receive prior approval from the Committee. Significant amendments include (but are not limited to) changes to:

- the researcher responsible for the conduct of the study at a study site
- the addition of an extra study site
- the design or duration of the study

- the method of recruitment
- information sheets and informed consent procedures.

Significant deviations from the approved protocol must be reported to the Committee as soon as possible.

Annual Progress Reports and Final Reports

The first Annual Progress Report for this study is due to the Committee by 1 December 2011. The Annual Report Form that should be used is available at www.ethicscommittees.health.govt.nz. Please note that if you do not provide a progress report by this date, ethical approval may be withdrawn.

A Final Report is also required at the conclusion of the study. The Final Report Form is also available at www.ethicscommittees.health.govt.nz.

Requirements for the Reporting of Serious Adverse Events (SAEs)

For the purposes of the individual reporting of SAEs occurring in this study, the Committee is satisfied that the study's monitoring arrangements are appropriate.

SAEs occurring in this study must be individually reported to the Committee within 7-15 days only where they:

- are *unexpected* because they are not outlined in the investigator's brochure, and
- are not defined study end-points (e.g. death or hospitalisation), and
- occur in patients located in New Zealand, and
- if the study involves blinding, result in a decision to break the study code.

There is no requirement for the individual reporting to ethics committees of SAEs that do not meet all of these criteria. However, if your study is overseen by a data monitoring committee, copies of its letters of recommendation to the Principal Investigator should be forwarded to the Committee as soon as possible.

Please see www.ethicscommittees.health.govt.nz for more information on the reporting of SAEs, and to download the SAE Report Form.

We wish you all the best with your study.

Yours sincerely



Jacqi Bartlett
Administrator
Multi-region Ethics Committee
Email: multiregion_ethicscommittee@MOH.govt.nz

STANDING ORDERS FOR THE MANAGEMENT OF WARFARIN

Dose adjustment and INR testing frequency

Applicable to: Pharmacists

Issued by: Pharmacy warfarin management
project medical advisor

Contact: Dr Paul Harper, Consultant
Haematologist, Palmerston North Hospital

Purpose

To improve the safety of Warfarin management by providing anticoagulant control through a pharmacist led service using point of care testing (CoaguChek XS Plus) and online computer decision support (INR Online Ltd).

Scope

Accredited pharmacists participating in the Pharmacy Warfarin Management project
The standing order is required to enable pharmacists to supervise anticoagulant management.

Medicine

Name of Medicine

Warfarin

Indications

Anticoagulation therapy initiated or confirmed by a doctor for;

1. Atrial Fibrillation
2. Deep vein thrombosis
3. Pulmonary Embolus
4. Tissue Heart valve
5. Mechanical Heart valve
6. Mural thrombus
7. TIA
8. Post myocardial infarction

Method of Administration: Oral

Dosage : see below

Contraindications

High risk of haemorrhage: active ulceration, overt bleeding of GI, genitourinary or respiratory tracts, cerebrovascular haemorrhage, cerebral aneurysm.

Pregnancy

Side effects

High incidence of drug interactions

Haemorrhage; GI upset; fever; dermatitis; urticaria; alopecia. hypersensitivity.

Test Procedure

Consent

All patients must be referred to the pharmacist anticoagulant management service by the prescribing doctor.

All patients must give informed consent

Safety

All patients are to be asked about signs and symptoms of bleeding (haematuria, blood in bowel motions, severe bruising, mucosal haemorrhage etc).

If minor bleeding the doctor should be informed and the patient reviewed if necessary.

If the patient has significant bleeding the doctor should be informed immediately.

All patients are to be asked about new medication since the previous INR test.

If a significant interaction is identified the doctor should be informed and the patient reviewed if necessary.

All patients are to be asked about warfarin compliance. If a significant number of doses have been omitted the doctor should be informed.

All patients are to be asked if they have been admitted to hospital since their previous INR test. Details of the reason for admission will be recorded.

Dose Adjustment

Dose recommendation

Dose recommendation and interval to next INR test to be determined using INR Online software at the time an INR result is entered from the point of care device (CoaguChek XS Plus with direct data connection).

The recommended dose can be accepted by the supervising pharmacists if the INR is within a specified range

Parameters for warfarin adjustment

- All patients must have a specified target INR and treatment range
- An upper and lower INR value that will trigger a REVIEW must be set for each patient.
- The default values: lower INR – 1.5 upper INR – 4.0 will be used unless otherwise specified by the doctor.
- The pharmacist can accept the dose recommendation made by INR Online for INR values between the lower and upper limits.
- INR values outside the upper and lower limits will be referred for review by the doctor.
- An INR >4.5 will automatically advise the patient to miss 1 dose of warfarin and recommend a test the following day.
- The pharmacist can contact the supervising doctor and discuss any dose recommendation if he or she believes that the dose recommendation is inappropriate for the patient.
- The pharmacist must document in the notes box in INR Online the reasons for any deviation in dose recommendation

Test interval

- A maximum test interval must be set for each patient. The default value of 28 days will be used unless otherwise specified by the doctor.

- The test interval varies depending on the patients anticoagulant control.
- The system defaults to 1 week when the INR is outside the treatment range. The interval increases by 1 week if the INR remains in range up to the maximum (28 days).
- The pharmacist can recommend a shorter test interval at anytime if he or she believes an earlier test is appropriate.
- The pharmacist must document in the notes box in INR Online the reasons for any deviation in the test interval recommendation.

The pharmacist will provide the patient with advice about the warfarin dose and the date of the next INR test, and provide a printed dosing calendar.

Starting warfarin

The INR Online software provides a protocol to assist with warfarin loading and initial stabilization.

This stage of treatment can be supervised by the pharmacist but close consultation with the supervising doctor is recommended.

Medical Review

Review process

Where the INR is outside the specified range, the INR-Online software will automatically set the result for review

- The pharmacist can accept the recommended dose from INR Online and advise the patient that the result has been sent for review by their doctor.
- The patient is advised to continue on the recommended dose unless they are informed otherwise. If their doctor wishes to modify the dose they will be informed of the change either by e-mail or by telephone by the pharmacist.

Medical review

If a patient has an INR result outside the specified safe range, the supervising doctor will be informed by e-mail. The contents of the message will include

- The latest INR result
- The recommended dose
- The date of the next test
- A graph showing recent warfarin control
- A list of previous results to enable the doctor to appropriately review the new dose.
- A link to open INR Online on the appropriate page to enable the doctor to edit the dose or date of the next test.

The doctor has two options on reviewing the result

1. Acknowledge result

- If the doctor agrees with the recommendation made by the INR Online software or the pharmacists, the doctor will need to acknowledge that the result has been seen by clicking on a link in the email. No further action will need to be taken. The patient will have been informed of the dose and the date of the next test.

2. Modify the recommendation

- If the doctor wishes to modify the dose or date of next test a web-page link is provided in the review message to take the doctor directly to the review page.
- The doctor can then change the dose or date of the next test and confirm the change.
- The pharmacist who entered the result will automatically be notified by e-mail that the dose or date has been changed. If the patient has e-mail the patient will also be informed.
- The doctor does not need to take any further action
- The responsibility to inform the patient rests with the pharmacist.

The review must be completed within 24 hours of the INR test.

Warfarin Reversal

Managing High INR Results

- All INR results >4.0 will trigger a review message to the doctor
- If the INR is >4.5 INR Online will recommend missing a dose and repeating a test the following day
- If the INR is >5.0,
 - INR Online will provide advice for warfarin reversal in line with the Australasian Guidelines (Appendix 2).
 - All results should be discussed with the supervising doctor
 - If the guidelines recommend treatment with vitamin K, this must be discussed with the supervising doctor. Vitamin K can only be given with authorization from the supervising doctor.
- IF A PATIENT HAS SIGNIFICANT BLEEDING.
 - Refer to the hospital immediately.
 - Inform the supervising doctor.
 - Consider giving 10mg oral vitamin K if there is significant travel time to the nearest hospital. Vitamin K can only be given with authorization from the supervising doctor.

NB: Significant bleeds include: Blood in the urine, Blood in the bowel motions, A prolonged nose bleed, Large bruises (bigger than 4cm in diameter)

Many patients on warfarin have minor bleeds, such as gum bleeding, spotting from the nose, or easy bruising. These do not need urgent attention

Record keeping

Recording results

The INR result, dosage of warfarin and testing interval are to be recorded in the INR-Online software and the same information will be sent automatically to the doctor's patient management system via HealthLink.

INR Online automatically records the date, time and user, when results are entered or any changes made.

Adverse events are recorded during the assessment prior to each test and additional information can be recorded in a notes field with each INR test.

Countersign period	The Doctor initiating anti-coagulation therapy will sign off treatment. Sign off will take place every 3 months at the time a new warfarin prescription is provided.
Training and Competency Assessment	<p>Prior to administering Warfarin dose titration under this Standing Order, Accredited pharmacists are required to have:</p> <p>Attended a Standing Order education session.</p> <p>Completed the INR-Online training session.</p> <p>Completed CoaguChek XS Plus Competency Training</p>
Process for audit and review	<p>The correct operation of this Standing Order will be reviewed once per year</p> <p>The individual pharmacists competency in applying the order accurately will be assessed</p> <p>Adverse events related to Standing Orders will be monitored by Dr Paul Harper and reported to CARM or other relevant body.</p>
Responsibility for Review	Dr Paul Harper is responsible for the review of this Standing Order.
Time period for which the Standing Order is valid	<p>This Standing Order is valid for one year from the date of issue</p> <p style="text-align: center;">OR</p> <p>This Standing Order is valid until it is replaced by a new Standing Order or cancelled by the issuer.</p>
Limitations	This standing order only applies to Pharmacies participating in the Pharmacy based anticoagulant management service and is valid for the period of the evaluation of the study.
Consent	By signing this standing order you are also consenting to allowing your patients to participate in the Pharmacy based anticoagulant management service study

Standing order
Issued by:

_____ Date: _____
Dr Paul Harper

Standing order received and consent for study

Name of doctor:.....

Signed:.....Date:.....

See attached page for full listing of pharmacists covered by this standing order.

Standing order prepared by

Dr P L Harper. MD, FRCP, FRACP, MRCPATH.

Consultant Haematologist, Palmerston North Hospital

Honorary Senior lecturer, Auckland University.

In collaboration with

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Richard Townley, CEO, Pharmaceutical Society of New Zealand

Dale Griffiths, Pharmacist

Ian McMichael, Pharmacist

Amanda Kiss, Clinical facilitator.

Appendix 1

Summary of the testing process

The patient will attend their allocated pharmacy.

The patient will be interviewed by the pharmacist.

The patient will be identified on INR Online (search by NHI or name)

Safety questions

- Bleeding complications
- Compliance
- New medication - Drugs recorded - Potential interactions identified
- Adverse events - Hospital admission: Date of admission:

INR Test

- Performed on CoaguChek XS Plus. NHI number recorded on the device
- Result automatically transferred to INR Online
- Automatically calculate recommended dose and date of next test

INR within safe range

- Recommendation reviewed by pharmacists and accepted if appropriate.
- Calendar printed

INR outside safe range

- Recommendation reviewed by pharmacists and accepted if appropriate
- Calendar printed
- Patient informed that result has been sent to their doctor for review and may be altered.
- The patient should continue with the recommended dose unless told otherwise

Data storage

INR Result, Test date, Dose and date of next test sent to GP PMS

Review by doctor

- The GP will receive an email stating the INR result is outside the safe range.
- The email will display the latest result and recommended dose and a list of recent results.
- There will be a link taking the doctor directly to the review page.
- The doctor will have the option to alter the result or make no change

If result changed

- If the patient has requested email notification – the patient will receive an email
- Otherwise an email will be sent to the allocated pharmacy

Data storage

Amended result sent to GP PMS

Appendix 2

3 Guidelines for the management of an elevated international normalised ratio (INR) in adult patients with or without bleeding	
Clinical setting	Action
INR higher than the therapeutic range but < 5.0; bleeding absent	<ul style="list-style-type: none"> Lower the dose or omit the next dose of warfarin. Resume therapy at a lower dose when the INR approaches therapeutic range. If the INR is only minimally above therapeutic range (up to 10%), dose reduction may not be necessary.
INR 5.0–9.0;* bleeding absent	<ul style="list-style-type: none"> Cease warfarin therapy; consider reasons for elevated INR and patient-specific factors. If bleeding risk is high, give vitamin K₁ (1.0–2.0 mg orally or 0.5–1.0 mg intravenously). Measure INR within 24 hours,[†] resume warfarin at a reduced dose once INR is in the therapeutic range.
INR > 9.0; bleeding absent	<ul style="list-style-type: none"> Where there is a low risk of bleeding, cease warfarin therapy, give 2.5–5.0 mg vitamin K₁ orally or 1.0 mg intravenously. Measure INR in 6–12 hours, resume warfarin therapy at a reduced dose once INR < 5.0. Where there is high risk of bleeding,[‡] cease warfarin therapy, give 1.0 mg vitamin K₁ intravenously. Consider Prothrombinex-HT (25–50 IU/kg) and fresh frozen plasma (150–300 mL), measure INR in 6–12 hours, resume warfarin therapy at a reduced dose once INR < 5.0.
Any clinically significant bleeding where warfarin-induced coagulopathy is considered a contributing factor	<ul style="list-style-type: none"> Cease warfarin therapy, give 5.0–10.0 mg vitamin K₁ intravenously, as well as Prothrombinex-HT (25–50 IU/kg) and fresh frozen plasma (150–300 mL), assess patient continuously until INR < 5.0, and bleeding stops.[§] <p>OR</p> <ul style="list-style-type: none"> If fresh frozen plasma is unavailable, cease warfarin therapy, give 5.0–10.0 mg vitamin K₁ intravenously, and Prothrombinex-HT (25–50 IU/kg), assess patient continuously until INR < 5.0, and bleeding stops.[§] <p>OR</p> <ul style="list-style-type: none"> If Prothrombinex-HT is unavailable, cease warfarin therapy, give 5.0–10.0 mg vitamin K₁ intravenously, and 10–15 mL/kg of fresh frozen plasma, assess patient continuously until INR < 5.0, and bleeding stops.[§]
<p>*Bleeding risk increases exponentially from INR 5 to 9;¹³ INR ≥ 6 should be monitored closely. †Vitamin K effect on INR can be expected within 6–12 hours. ‡Examples of patients in whom the bleeding risk would be expected to be high include those with active gastrointestinal disorders (such as peptic ulcer or inflammatory bowel disease), those receiving concomitant antiplatelet therapy, those who underwent a major surgical procedure within the preceding two weeks, and those with a low platelet count. See Box 1 for a list of bleeding risk factors. §In all situations carefully reassess the need for ongoing warfarin therapy.</p>	

Ref: R I Baker, P B Coughlin, A I S Gallus, P L Harper, H H Salem and E M Wood. The Warfarin Reversal Consensus Group. Warfarin reversal: consensus guidelines, on behalf of the Australasian Society of Thrombosis and Haemostasis. MJA 2004; 181: 492–497

Appendix 3

Procedure to manage patients when unable to communicate with INR Online

The following procedure should be followed if access to INR Online is interrupted due to local computer problems, lost internet connection, problems with the INR Online server, or the INR Online program stops running.

1. Interview patient and record as a hard copy any missed medication, history of bleeding since the last visit, new medication since the last visit and any hospital admissions.
2. Perform the INR test as usual on the CoaguChek XS Plus. Enter the NHI number if known. If the patient does not know their NHI Number perform the INR test without a reference number.
3. Record the following information as a hard copy
 - Patient's name,
 - NHI number (if known) or date of birth
 - Present warfarin dose
 - INR result
 - Patient's GP details

INR within the therapeutic range

If the INR is within the therapeutic range, advise the patient to continue on the same dose and recommend a dose interval the same as the previous interval.

Record the dose recommended and the date of the next test

If the INR Is outside the therapeutic range

Warfarin dosing is the responsibility of the patient's general practitioner. You should therefore contact the GP practice, advise them that you are unable to contact INR Online and require dosing advice.

The dose recommendation from the doctor and the date of the next test should be recorded and the patient should be contacted with this information.

If the INR is >4.5, advise the patient to miss a warfarin dose and repeat the INR the next day.

When access is resumed

The missing results should be entered into INR online.

Enter the results by using the *add result* tab on the top of the left-hand column on the overview page.

This will ensure that the results are sent to the doctor's PMS and an e-mail will be sent to the patient.

When you enter a result the computer will recommend a new dose. Edit this to the dose you gave and edit the recommended date of the next test to the date you recommended. Then confirm the result.

DO NOT ENTER THE MISSING RESULT USING THE *EDIT RESULT* TAB. If you do, the result will not be sent to the doctor's PMS and the patient will not receive an e-mail.

Procedure for the management of non-compliant patients

Note: The responsibility for the patient's warfarin management rests with the supervising doctor.

It is important that the supervising doctor is informed if a patient is a regular poor complier. It may be appropriate for the doctor to reassess the risks and benefits of warfarin in such cases and may recommend discontinuing warfarin if the risk of poor compliance is assessed to be potentially dangerous.

The following is a recommended procedure for managing non-attenders. Where possible we suggest this is followed but individual patient circumstances must be considered with these recommendations. It is important to document all deviations from the procedure and to maintain good communication with the supervising doctor.

Procedure if patient fails to attend for INR testing on the specified date

- As a general rule the patient should go no more than 6 weeks between tests.
- If the patient fails to attend within 3 days of the specified test date, the patient should be contacted by phone to remind the patient that the test is due.
- If the patient fails to attend within 4 to 6 days of the first reminder, a second call should be made to the patient.
- If the patient fails to attend within 1 week of the second reminder, the patient should be contacted a third time and the patient's doctor should be informed that the test is 2 weeks over due & a maximum of 6 weeks since the last test and you will only send further reminders at the doctor's request. Further follow up of the patient is the responsibility of the doctor.
- Each contact with the patient and the doctor should be documented in INR Online.
- If a patient presents for a test more than 2 weeks after the expected date of the test, the test should be performed and the doctor should be informed.
- If a patient regularly fails to attend on time, discuss management with the supervising doctor.

STANDARD OPERATING PROCEDURE FOR PHARMACY BASED ANTICOAGULATION MANAGEMENT SERVICE

Version 1.2

EQUIPMENT

CoaguChek XS Plus Meter:

The CoaguChek XS Plus meter tests INR from a fingerprick blood test using 8µL of capillary whole blood. It conforms to the WHO PT standardisation scheme (INR).

CoaguChek XS Plus meters must be stored suitably, protected from dust and extreme temperatures and cleaned according to instructions.

Each meter has the ability to store Operator and Patient ID alongside 1000 test results and up to 500 Quality Control Results.

The base unit is used for data transfer of the patient result directly into INR Online and also used to charge the meter.

Test strips:

Test strips should be stored at room temperature and always keep test strips in the original container, replacing the vial cap after removing a test strip (exposure to moisture, heat and humidity will damage the strip and cause an error message on the CoaguChek XS Plus).

The test strips will come with a code chip in the bottom of the box also which hold all the test strip calibration, lot and expiry information. The code chip should be inserted into the CoaguChek XS Plus meter when a new lot of strips are being used. The code chip should be kept in the meter even after the meter has read the information as this will protect the contacts from any dust. Protect the code chip from any electromagnetic fields.

Capillary Blood Lancing Devices

A disposable single-use lancing device called the Accu-Chek Safe-T-Pro Plus is used for all individual patients, to prevent cross infection and minimise the risk of sharps injury. All pharmacy staff should be aware that pen lancing devices are also available for single patient use and are often provided with CoaguChek XS meters for patient self testing and also blood glucose meters purchased over the counter, such lancing devices are not suitable for use on multiple patients.

Quality Control Testing

Quality control refers to the routine testing of the CoaguChek XS Plus. This will ensure the device is working correctly and assure the operator of the reliability of patient results. Quality control testing should be performed on a monthly basis and with every new lot of test strips. The result will be stored in the meter.

The CoaguChek XS PT Control solution must be stored in the refrigerator and once must be used within 30 minutes of reconstitution.

The quality control solution results are interpreted on the basis of whether they fall within or outside acceptance limits, if the results of the control solution fall within its acceptance limits, then the performance of the meter and the current test strip can be said to be adequate. If however, it falls outside those quoted limits, then the performance of the meters and strips must be deemed unacceptable, and the meter should not be used pending further investigation.

The quality control test procedure must then be repeated, if the results are still found to be outside the acceptable limits withdraw the CoaguChek XS Plus from use and label with a do not use notice and contact Roche Diagnostics on 0508 69 5433.

SPECIMEN REQUIREMENTS

The blood drop must be a minimum of 8µL in volume. Low sample volume will cause an error message.

Possible interferences include:

- Presence of Anti Phospholipid Antibodies
- Haematocrit <0.25 or >0.55
- Triglycerides >11.4 mmol/L
- Haemolysis >0.31 mmol/L
- Bilirubin >513 µmol/L
- The presence of alcohol or soap at the lancing site
- Hirudin

The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU/mL antifactor Xa activity.

Please refer to CoaguChek XS PT Test Strip package insert for details.

TRAINING

It is essential that both the correct equipment is used and the pharmacist is trained and accredited by attending the Pharmaceutical Societies prescribed training day for Anticoagulation Management Services.

A competency assessment must be successfully completed before staff use the CoaguChek XS Plus and INR Online.

PROCEDURAL GUIDELINE – PHARMACY BASED ANTICOAGULATION MANAGEMENT SERVICE

Equipment

- CoaguChek XS Plus
- Base Unit
- Test Strips and Code Chip
- Quality Control Material
- Safe-T-Pro Plus Lancing Device
- Computer with Internet
- Printer

- Cotton swabs
- Disposable gloves

Procedural Guideline – Patient Testing & Dosing

Action	Rationale
1. Access INR Online via the internet and login using your name and password in the morning to check the clients due and overdue for an INR test under Due Test tab. Contact overdue patients.	Ensures patients are having their INR tests at the necessary intervals for best management.
2. Patients attend pharmacy for their INR test. If it is the patient's first consultation they must receive full warfarin counseling. Document any patient counseling given in INR Online.	Patient is aware of all aspects of their Warfarin Management
3. Gather items for testing: CoaguChek XS Plus, test strips and code chip, Safe-T-Pro Plus lancing device, alcohol wipes, plasters, gloves and tissues.	Making sure you have everything ready before testing will enhance workflow.
4. Take the CoaguChek XS Plus off the Base Unit and place in front of the patient on the edge of the table so when the strip is inserted it will be hanging over the edge of the table. Make sure the patient is facing the meter.	This is the best position for testing successfully, giving you room for placing the drop of blood on the side of the strip.
5. Go to the INR test wizard.	This will take you through the steps of testing with the CoaguChek XS Plus and entering results into INR Online.
6. Work your way through the INR Online test wizard, asking the patient all the safety questions until you come to the instructions for testing. Check for possible drug interactions in MIMS. <i>(If unsure of any drug interactions, contact the attending Pharmacist at Taranaki Base Hospital for advice).</i>	This records any necessary information for the study and patient file. Missed tablets, Bleeding or Bruising, New Medication and Hospital Admissions.
7. Touch and hold down the power button until the CoaguChek XS Plus beeps	This will turn the machine on.
8. Enter your initials as your operator ID.	This ensures a record of who did the testing is kept in the CoaguChek XS Plus next to each result.
9. Touch the Patient Test button and enter the patient NHI Number.	The NHI number is a unique identifier in which INR Online will use for each patient to transfer patient results.
10. Insert the test strip and code chip (if using a new lot of strips, the meter will request this automatically and you will be required to perform a Quality Control Test – see Procedural Guideline – Quality Control Testing). The meter will then warm up displaying an egg timer.	The code chip holds all the test strip lot information, expiry date and calibration information necessary to perform the test.
11. Put on gloves	To minimize the risk of cross-infection

12. If necessary swab the patients finger with an alcohol swab and tissue dry or get them to wash their hands with warm soapy water for a good 30 seconds making sure they wash off all soap residue.	Minimises the risk of infection. Washing hands in warm water increases circulation.
13. Prepare the patients finger for lancing by massaging gently from the base of the finger to the tip, making sure you get good colour in the tip.	Enables good blood sample size.
14. Using the disposable Accu-Chek Safe-T-Pro Plus dial to the deepest setting and twist off the end cap.	Deepest setting enables good blood sample size.
15. When the meter beeps and the 180 second countdown begins prick the top side of the patients finger, holding their hand upright as though they were about to shake someone's hand.	Side of the fingertip is less painful and by pricking the top side you can then balance the drop of blood easily.
16. Milk the finger from the base to the tip until you obtain the biggest drop of blood you can balance on the top side of the finger. Always use the first drop of blood for testing and apply the drop to the test strip within 15 seconds of lancing.	Obtaining the biggest drop ensures you have enough blood for testing and avoiding a blood application error. As soon as you lance the finger the clotting process has begun. By using the first drop of blood and applying the drop within 15 seconds you eliminate any shortened INR results.
17. Making sure the patient is relaxed and you are in control of the finger take the drop of blood to the strip and touch it to the edge of the transparent area of the strip until you hear the CoaguChek XS Plus beep.	Allows control of dosing the strip. Side dosing gives you full view of dosing and more control. Beep tells you strip has sufficient dose of blood.
18. Dispose of Safe-T-Pro Plus into sharps bin.	To comply with waste regulations.
19. Wipe blood off finger with a tissue and apply a plaster if required.	To minimize contamination and ensure patient comfort.
20. INR Result appears within a few seconds. Touch the 'speech bubble' symbol if you would like to add comments. Result is then stored in the meter memory.	Then enables data to be transferred electronically to INR Online.
21. Dispose of used test strip, gloves, and tissues in biohazardous waste bin.	To comply with waste regulations
22. Dock meter back onto base unit and click on next on INR test wizard	Enables transmission of result from the CoaguChek XS Plus to INR Online
23. Confirm the NHI number, result and date and time and click on send. Send button then changes to sent when result has been transmitted. Click on Go to INR Online icon.	This transmits the result into the patient file and takes you to the patient file.

24. Follow instructions on INR Online and standing order. Educate patient around result and their patient file.	Allows appropriate dose recommendation.
25. Add any comments relevant to the result if necessary. Confirm result by clicking on confirm button.	Enables a record of all relevant information to do with patient results and treatment. Takes you to the current result page.
26. If a review of the result is not necessary click on Contacted. If result has gone off for GP review click on Contact later. If a review is necessary communicate to the patient that they will be contacted only if their GP has changed their dose. It is the Pharmacists responsibility to contact the patient with any dose changes.	This will prompt you to follow up any results that need to be reviewed.
27. Click on treatment calendar and print off for patient. Discuss with them the dosage they are to take each day and when they are due back for there next test. Advise them to keep it somewhere visible to them and mark off each day as they have taken their medication.	Gives patient a visual prompt on when to take their medication.
28. Log out of INR Online	Ensures no unauthorized use of INR Online and access to patient files.
29. On a daily basis make sure you 'clean up' the Due Test, Need Review and Uncontacted tabs in INR Online.	This ensures all patients under these tabs need genuine actioning.

Procedural Guideline – Quality Control Testing

Action	Rationale
1. Take the CoaguChek XS PT Controls out of the fridge.	Storing the controls in the fridge ensures stability.
2. Remove 1 vial of CoaguChek XS PT Control, 1 dropper of diluent and the code chip.	Necessary items to perform the Quality Control test.
3. Carefully remove the screw cap and rubber stopper from the vial of QC material and make sure none of the dried powder is removed with the stopper.	Removing any powder could lead to an erroneous result.
4. Holding the dropper at the bottom of the stem use scissors to cut off the tip of the dropper at the marked upper end of the stem. Do not squeeze the bulb of the dropper.	Allows measured amount of diluent to be added to powder.
5. Insert the dropper tip first, into the control solution bottle. Gently squeeze the bulb to dispense the entire contents of the dropper onto the dried powder. Do not touch the dried material and the dropper.	To reconstitute the QC Material.

6. Gently swirl a number of times and allow to stand for at least 1 minute before testing. Do not shake. Once reconstituted the QC material must be used within 30 minutes.	Shaking may cause the formation of foam which could lead to an error on the CoaguChek XS Plus.
7. Take the CoaguChek XS Plus off the Base Unit and touch and hold down the power button until the CoaguChek XS Plus beeps.	This will turn the meter on.
8. Enter your initials as your operator ID.	This ensures a record of who did the QC testing is kept in the CoaguChek XS Plus next to each result.
9. Touch the Control Test button and either select the corresponding code in the list that appears or touch NEW CODE and insert QC code chip. The code number of the lot of control you are using can be found on the side of the box and also on the side of the vial of QC material.	The code chips holds the lot specific information to perform a QC test including the QC range the the result should lie within. The CoaguChek XS Plus must read this code chip with every new lot of QC material.
10. The meter will then warm up displaying an egg timer. While it is warming up gently swirl the QC material again.	Ensures the QC material is properly mixed.
11. When the dropper icon flashes and you see the 180 second countdown begin the meter is ready to perform the test. Draw the solution into the dropper and apply one large hanging drop of QC solution to the clear target area of the strip.	The INR measurement will then begin.
12. The result will appear and the QC range will be underneath in brackets. You can add comments by touching the 'speech bubble' button. If the result is out of range, indicated by an up arrow or down arrow next to the result, repeat the test mixing a fresh vial of QC material. If it's still out of range, contact Roche Diagnostics on 0508 MY LIFE (0508 69 5433).	The likely cause of a QC result to be out of range is inadequate mixing of the QC material. Roche Diagnostics need to find the cause of the problem and the meter needs to stop testing patients until the cause has been found and remedied.
13. The result will be stored in the CoaguChek XS Plus memory alongside the Operator ID and QC lot information.	Important record of the QC data for audit purposes.
14. Dispose of used test strip, gloves, QC Material and dropper into the biohazardous waste bin.	To comply with waste regulations.

Supporting Documents

- CoaguChek XS Plus Operator's Manual
- CoaguChek XS Plus Quick Reference Guide
- INR Online Quick Guide
- Standing Order for Warfarin Management, Dose Adjustment and INR Testing Frequency
- CMDHB Warfarin Education Flipchart. (NB: For other Warfarin Education resources and information visit: <http://www.cmdhb.org.nz/warfarin/default.htm>)
- CoaguChek XS PT Test Strip Package Insert

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PHARMACY BASED ANTICOAGULANT SERVICE

Information for General Practitioners

Introduction

Health Workforce New Zealand in collaboration with the Pharmaceutical Society of New Zealand and the Royal New Zealand College of General Practitioners, have approved funding for a pilot study to evaluate a community pharmacist-led anticoagulation management service. Fifteen pharmacies around New Zealand have been selected as pilot sites and one of these pharmacies is in your area. You are invited to participate in this study. This would enable your patients on warfarin to have INR testing at the pharmacy with treatment supervised by an accredited pharmacist as an alternative to their current anticoagulant monitoring and management.

This leaflet has further information about the study. If after reading it you have further questions please contact one of the study co-ordinators.

Background

Overseas anticoagulant services are often provided by pharmacists or specialist nurses. In Canada, the UK and some parts of the US pharmacy based services have proved successful achieving a high standard of care. Pharmacists are ideally placed to supervise anticoagulant management as they are in a position to counsel patients, understand drug interactions and encourage compliance. Published studies have confirmed that this method of management often achieves safer anticoagulant control than that achieved in conventional anticoagulant clinics. In this country the quality of anticoagulant management is variable and difficult to assess as it is hard to get audit data. International guidelines recommend that the INR should be within the therapeutic range for at least 60% of the time but several audits in New Zealand have shown that we rarely achieve this level of control.

A pharmacy based model potentially has a number of advantages.

- It provides a convenient service for patients. There is easy access to a local pharmacy, the test result is available within minutes and the patient receives printed treatment advice immediately.

- It is convenient for you. The vast majority of care is provided by the pharmacist. The pharmacist interviews the patient each time a test is performed and asks four standard safety questions. The dose adjustment is made by the pharmacists acting under a standing order using the decision support software recommendation.
- It allows you to monitor unstable patients. Although the pharmacist will be able to manage all patients using the decision support software, you will also be informed automatically if the INR is outside a set range. In addition all INR results and dosing information will be sent to your PMS automatically via HealthLink.
- It is beneficial for pharmacists. This service is making use of highly trained health care professionals ideally placed to manage warfarin. It also likely to improve job satisfaction for pharmacists by involving them in direct patient care

How will it work?

Your patient will attend the pharmacy for their blood test

Safety questions

Each time the patient will be asked four safety questions; have they experienced any bleeding; have they missed taking any warfarin tablets; have they started any new medication and have they been admitted to hospital since their last test? The answers will be recorded in the computer system.

The blood test

The blood test is performed using a finger-prick sample on the CoaguChek XS Plus. The result is automatically fed into the computer system and a dose recommendation is calculated. The pharmacist will review the result and then print out a small dosing calendar for the patient and provide the patient with the date of their next test.

Keeping you informed

All INR results and dose recommendations will be sent to your PMS.

What is your role?

You remain responsible for the patient

You will continue to prescribe warfarin as required and can intervene with treatment at any time. The pharmacist is acting under your delegated authority under the provisions of the standing order.

Patient referral

The patient must be referred by you to the pharmacy service. A referral form will be provided.

Review results

The pharmacists will take primary responsibility for supervising treatment, however the computer system is set-up so you will automatically receive an e-mail if the INR is above 4.0 or below 1.5. You will have to acknowledge receipt of these but will not need to take any further action unless you wish to alter the dose or date of the next test. The emails are primarily for information but they give you the option to intervene if necessary. There will be a link in the e-mail to take you directly to the correct webpage in the decision support software.

If you change the dose or the date of the next test, the pharmacist is automatically informed and the pharmacist will contact the patient with the revised advice.

Using e-mail

We have elected to use e-mail in this study. Patients agree to data being sent in this way as part of the consent process. The e-mail only contains INR results, the INR target range and warfarin dosage and no other clinical information. Some doctors are uncomfortable about receiving medical information by e-mail, this will be evaluated as part of the study. The reason for using e-mail is that it allows you to directly link to the online warfarin management system from an e-mail message. This cannot be done from mail sent to your PMS.

What do I need to do to take part?

If you would like to offer this service to your patients you need to

- Sign the attached standing order and consent form allowing accredited pharmacists to manage your patients on warfarin.
- Provide an e-mail address for the study

At the end of the evaluation period you will be asked to complete a questionnaire about the service.

If you offer this service to your patients they will have the option of taking part or continuing with their present method of warfarin monitoring. A patient information sheet will be provided for your patients when you discuss this project with them.

Is the system safe?

Safety is the top priority for this type of service. There are several safe guards in place to make the system as safe as possible.

Pharmacist training

All accredited pharmacists providing this service must attend a training course to learn about warfarin treatment and how to use the testing device and the computer system. The pharmacist must be assessed as competent in order to provide the service.

The testing device

The CoaguChek XS Plus will be used to measure the INR. The device has an in built quality control process that checks each test-strip prior to an INR test. Regular quality control measurements will be performed to ensure the machine is functioning correctly.

Are the results reliable?

There are a number of comparative studies published that confirm that the results from the CoaguChek XS Plus are comparable to laboratory results over a wide range of INR values including high INRs. If you would like further information about this or to see study data please ask the trial co-ordinator.

Data storage

All results are linked to the patient's NHI number. Results are automatically transferred from the CoaguChek XS Plus to the computer system. All data are encrypted and stored on a secure server protected by a digital certificate. The results are automatically transferred to your PMS via HealthLink. The computer system is backed up daily.

Decision support software

The dose recommendation is calculated using an algorithm that takes into account previous INR results and the level of control overtime. The algorithm has been tested in three previous studies and achieves anticoagulant control comparable to that achieved by a doctor. If you would like to see a detailed evaluation please contact the trial co-ordinator.

The pharmacist or the doctor can over-ride the computer recommendation at any time.

The computer has additional safe guards and automatically gives advice to the pharmacist if the INR too high. The advice is in line with the Australasian Guidelines.

Why is this study being done?

The study is being done to ensure that warfarin management provided through a pharmacy based service is as safe as standard warfarin control. An assessment of the acceptability of the service and a cost benefit analysis will be carried out to establish if it would be cost effective service if provided nationally.

How many people will take part in the study and how long is the study?

The study will involve 15 pharmacies with up to 50 people at each pharmacy and will continue for 6 months.

How is the evaluation carried out?

This is an evaluation to assess that this is a safe acceptable service. The following parameters will be measures; the time in therapeutic range, the number of INR results >4.0 and > 5.0; adverse events including bleeding, thrombosis and hospital admissions. The results will be compared to historical audit data to assess that the management is at least comparable to the present standard of care. Preliminary results from a small pilot and other published data would suggest that this type of management achieves significantly better control than conventional methods of control.

The patients, pharmacists and doctors will be asked to complete a questionnaire at the end of the study to evaluate the acceptability of the service. A cost analysis will also be performed to assess the viability of continuing this type of service.

What happens at the end of the study?

This is a pilot study to evaluate the potential for offering this type of service to patients throughout New Zealand, however continuing access to the service will depend on funding. If a funding model is agreed and funding approved during the trial period the intention is to continue the service. However at this stage there is no guarantee that funding will be available. If funding is not approved, patients will have to transfer back to their previous form of warfarin supervision.

How will information about the study be disseminated?

It is proposed that the results will be submitted as a publication in both a Medical and Pharmacy journal. A report will be available for all participants at the end of the study.

Thank you for considering participation

Trial co-ordinator

Professor John P Shaw

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This study has been approved by the Multi-region Ethics Committee, reference number MEC/10/10/105



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CONSENT FORM FOR GENERAL PRACTITIONERS

Pharmacy Based Anticoagulation Management Service

Investigator: Prof John Shaw, Principal Investigator, University of Auckland.

Name of Doctor

I have received an information sheet about the study and had an opportunity to discuss it with a trial coordinator

I understand the following

- My patients will be attending the following pharmacy
Name of pharmacy:.....
- My patients warfarin management will be supervised by:
Accredited pharmacist
- All patients must sign a consent form before participating in the study.
- Patients have the opportunity to choose to continue with their present form of warfarin management.
- Patients can withdraw from the study at any time and this will not affect their treatment in any way.
- All patients must be referred to the participating pharmacy on the relevant referral form before they can use the pharmacy based service.
- All INR results and dosing information will be sent directly to my patient management system via HealthLink.
- I will receive information about INR results outside a specific treatment range by e-mail.

The following e-mail address should be used during this study (an e-mail address must be provided to participate in the study).

e-mail address for trial.....

I (full name) hereby consent to take part in this study.

Date:

Signature: (or proxy consent)

Full names of Researchers: Prof John Shaw, University of Auckland

Contact Phone Number for researchers: 09 923 3778 Or 021 455 068 (after hours)

Project explained by:

Project role:

Signature:

Date:

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Pharmacy Anticoagulation Management Service Patient Selection Criteria

Inclusion

- 1. Chronic treatment with warfarin in stabilized patient.**
- 2. Medically stable patients being initiated on warfarin.**
- 3. Treatment with warfarin requiring LMWH overlap.**
- 4. Patient is mobile and able to access the Pharmacy.**

Exclusion

- 1. Anti-phospholipid syndrome, anti-cardiolipid syndrome, lupus anticoagulant syndrome.**
- 2. Active anti-neoplastic treatments.**

Cautions

Following conditions need to be notified by referring GP to Pharmacist on referral form:

- 1. Alcoholism**
- 2. Persistent unstable INRs**

Other conditions may be listed on the referral form at the discretion of the GP.



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INFORMATION FOR PARTICIPANTS OF THE PHARMACY BASED ANTICOAGULANT SERVICE

Introduction

You are invited to take part in a pilot study to evaluate a new method of monitoring the blood thinning drug warfarin. During this pilot you will be able to go to a local pharmacy for your blood test. The test will be performed on a finger-prick blood sample on a small machine in the pharmacy, the result will be fed into a computer system which will provide treatment advice which will be printed out in the form of a calendar to help you keep track of your treatment. The computer system is directly linked to your doctor's surgery so that your doctor can supervise your treatment and keep a record of your results. If you have internet access you will be able to receive e-mail reminders when your next test is due and even go online and check your dose and see previous results.

This leaflet has further information about the study. If after reading it you have further questions please contact the study co-ordinator.

Information about warfarin

Warfarin is an anticoagulant. This type of drug slows normal blood clotting and reduces the possibility of you developing a blood clot in the circulation. Warfarin is used to treat many conditions including clots in the legs or lungs and several heart conditions. Warfarin has been used for more than 40 years and is a very effective drug, however all patients taking warfarin require regular blood tests to check that the dose is correct. The blood test is called the INR. This stands for the International Normalised Ratio. This is a measure of how quickly the blood clots. In a person not taking warfarin the INR should be 1.0. In a person taking warfarin the ideal INR in most conditions is between 2.0 and 3.0, although some patients may need a slightly higher dose. Your doctor will tell you if your results should be in a higher INR range.

Why do I need frequent tests?

Unfortunately warfarin is an unpredictable drug and the INR result can vary considerably even if the dose of warfarin remains stable. We know that warfarin is

affected by other medication, but it also appears to be affected by diet, alcohol use, exercise and other minor illnesses like coughs and colds. Therefore it is important to regularly check the INR and change the warfarin dose if necessary.

Why is the INR important?

If the INR is too high there is a risk of bleeding. This is a rare complication. It can range from minor bruising problems to major internal bleeding in the stomach or most seriously in the brain. If blood tests are performed regularly and the INR is well controlled the risk is very small.

If the INR is too low you are at risk of developing a blood clot.

How is warfarin normally managed in New Zealand?

There are different ways of monitoring warfarin in different parts of the country. In some cities warfarin is managed by your own General Practitioner and in others it is controlled through the hospital or local laboratory. In all cases the blood tests are collected at a local laboratory or collection centre. A venous sample taken from a vein in the arm is used for the INR test. The sample is sent to the laboratory for processing and later in the day you get treatment advice. The process can be time consuming with a long wait for a blood test and sometimes it is difficult to get the treatment advice from your doctor or the hospital.

Why change warfarin management?

This study is being carried out to help both you and your doctor. For you there will be greater convenience and potentially safer warfarin control. Providing testing through a pharmacy means that the process can be much quicker. The test only takes a few minutes and you will be given advice immediately. There is also evidence from studies overseas that using this type of testing device with computer decision support improves the level of anticoagulant control making treatment safer.

There are also advantages for your doctor. This study is funded as a Health Workforce project. These projects are designed to help relieve the doctor's workload by using other skilled health professionals to assist with specific management. In this study experienced accredited pharmacists will be managing your treatment, but it will still be supervised by your doctor through a computer link.

How will it work?

When your blood test is due you will go to the pharmacy instead of the laboratory.

Safety questions

There will be an area in the pharmacy where you can privately talk with the pharmacist. Each time you go for a test you will be asked four safety questions; have you experienced any bleeding; have you missed taking any of your warfarin tablets;

have you started any new medication and have you been admitted to hospital since your last test? Your answers will be recorded in the computer system.

The blood test

The blood test is performed using a finger-prick sample. The pharmacist will squeeze your finger and use a special device to prick your finger. A drop of blood is placed on a test strip in a small testing device. Within a few seconds you will get the INR result. The result is automatically fed into the computer system and a dose recommendation is calculated. The pharmacist will review the result and then print out a small calendar for you which shows what dose of warfarin to take each day until your next test. If the result is outside a set range the result will automatically be sent to your doctor for review. If your doctor changes the dose or the date of your next test you will be contacted later in the day by the pharmacist. All your INR results are automatically sent to your doctors surgery and recorded in your doctor's computer system. If at any time the pharmacist is concerned about your symptoms or the dose recommendation he or she will contact your doctor directly.

e-mail and internet access

You do not need e-mail or internet access to take part in this study, but we can offer additional services if you have the internet. You can choose to receive an e-mail every time your result is entered or changed, you can receive an e-mail reminder on the day your next test is due and you can have online access to check your own results and dose at anytime.

What do I need to do to take part?

If you are interested in taking part you will need to complete a consent form. Your doctor will need to complete a referral form to provide us with information about your warfarin treatment. When we have received this, you will be contacted by the trial co-ordinator or pharmacist and told when to attend for your first blood test.

During the evaluation period you will be asked to complete a questionnaire about the service.

Is the system safe?

Safety is the top priority for this type of service. There are several safe guards in place to make the system as safe as possible.

Pharmacist training

All accredited pharmacists providing this service must attend a training course to learn about warfarin treatment and how to use the testing device and the computer system.

The computer system

The computer is referred to as 'Decision support', this means that it is used as an aid to the pharmacist and doctor. Each time a result is entered, the computer will calculate a dose recommendation but this has to be reviewed by the pharmacist and accepted before you are told the result. Therefore the pharmacist is in charge of treatment under the supervision of your doctor. The pharmacist or the doctor can over-ride the computer recommendation at any time.

The computer has additional safe guards and automatically gives advice to the pharmacist if your result is too high. The advice is in line with the Australasian Guidelines used by medical staff.

The computer system has been used in three other studies. Evaluation of these results confirms that the computer dosing is as good as standard dosing.

What if the computer fails?

Your results are copied onto another computer every day and each time a result is entered, it is automatically sent to your doctor. If the computer system stops working, your pharmacist will be able to recommend a dose or consult with your doctor to get advice.

Are the results reliable?

There are a number of studies published that confirm that the results from the testing device are comparable to laboratory results.

Why is this study being done?

The study is being done to ensure that warfarin management provided through a pharmacy based service is as safe as standard warfarin control. We will also be assessing the acceptability of the service and carrying out a cost benefit analysis to ensure that it would be cost effective if provided as a national service.

How many people will take part in the study?

The study will involve 15 pharmacies with up to 50 people at each pharmacy

What are the risks to me of being in the study?

There are virtually no additional risks. Warfarin is a necessary part of your treatment that you would be taking anyway and regular blood tests are a standard part of your care. The pharmacist's management will be very closely supervised. If you develop any complications from your warfarin therapy, the pharmacist will contact your doctor and these will be dealt with by your GP in the normal way.

Are there benefits to taking part in this study?

The pharmacy based service potentially has some advantages over the present method of monitoring warfarin. Access to testing will be more convenient and it is potentially safer. If the system is shown to be as safe as standard management it could be made available at pharmacies throughout New Zealand.

What happens at the end of the study?

This is a pilot study to evaluate the potential for offering this type of service to patients throughout New Zealand, however continuing access to the service will depend on funding. It is very unlikely that ongoing funding will be immediately available, so at the end of this pilot study you **will** have to transfer back to supervision by your general practitioner or the laboratory based system, whichever you were using prior to the study.

How will information about me be kept private?

All aspects of the study, including results, will be kept confidential and only your doctor and the staff directly involved in the study will have access to your information. A report of the study may be submitted for publication, but individual participants will not be identifiable in such a report. The following information about you will be needed to manage your warfarin therapy. Your name, date of birth, contact details, reason for taking warfarin, recommended INR range, other medication, previous history of bleeding, present warfarin dose and INR results. This information will be stored on a secure computer protected by firewalls and virus protection software. The trial data will be accessible only by staff members directly related to the trial.

Do I have to take part in this study? (Your rights as a study participant)

Your participation is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part you will receive the usual warfarin monitoring. Your decision whether or not to participate will not affect your rights to medical treatment in any way. If you decide to participate, you are free to withdraw your consent and to discontinue participation at any time without affecting your future medical treatment. If you withdraw from the study, you will still be offered all available care that suits your needs and medical condition.

Compensation

In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

Who can I call if I have questions or problems?

For questions about the study, you can contact the trial co-ordinator Professor John Shaw at 09 923 3778 (during office hours) or at 021 455 068 (after hours). Alternatively you can contact your trial pharmacist (insert name) at (insert telephone numbers).

For questions about your rights as a research subject, you may wish to contact a Health and Disability Advocate. The listed advocacy services are free and are independent of the study. The telephone number is ***Free Phone: 0800 555 050***

If you would like advice or support from the Maori Health Services please contact the Maori Liaison Co-ordinator at (will be inserted)

Thank you for considering participation

Trial co-ordinator

Professor John P Shaw

Contact details

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CONSENT FORM

Pharmacy Based Anticoagulation Management Service

Investigator: Prof John Shaw, Principal Investigator, University of Auckland.

Name of participant:

English	I wish to have an interpreter.	Yes	No
Maori	E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.	Ae	Kao
Samoan	Oute mana'o ia iai se fa'amatala upu.	Ioe	Leai
Tongan	Oku ou fiema'u ha fakatonulea.	Io	Ikai
Cook Island	Ka inangaro au i tetai tangata uri reo.	Ae	Kare
Niuean	Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu.	E	Nakai
Mandarin Cantonese	我需要一個翻譯	是	否

I have read and I understand the information sheet dated 30th September 2010 for volunteers taking part in the pilot study to evaluate the pharmacy based anticoagulant management service. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

I have had the opportunity to use whānau support or a friend to help me ask questions and understand the study.

I have had time to consider whether to take part.

I know who to contact if I have any side effects from the study.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing health care.

I understand that my participation in this study is confidential and that no material, which could identify me will be used in any reports on this study.

I know who to contact if I have any questions about the study.

«ReviewStatement»

	Yes	No
I have decided of my own free will to be a participant in this study:	<input type="checkbox"/>	<input type="checkbox"/>
I consent to the researchers contacting my GP or accessing my medical records for information in relation to this research if I cannot be contacted in person:	<input type="checkbox"/>	<input type="checkbox"/>
I consent to my INR results and relevant dosing advice being transmitted to my general practitioner by e-mail.	<input type="checkbox"/>	<input type="checkbox"/>
I wish to receive a copy of the results:	<input type="checkbox"/>	<input type="checkbox"/>

I (full name) hereby consent to take part in this study.

Date:

Signature: (or proxy consent)

Full names of Researchers: Prof John Shaw, University of Auckland

Contact Phone Number for researchers: 09 923 3778 or 021 455 068 (for after hours contact)

Project explained by:

Project role:

Signature:

Date:

Interpreter's name:

This study has been approved by the Multi-region Ethics Committee, reference number MEC/10/10/105



PHARMACEUTICAL SOCIETY
of New Zealand Incorporated



THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND
HEALTH SCIENCES

Referral Form for Pharmacy-led Anticoagulation Management Service

PATIENT IDENTIFICATION	
Name:	
Date of Birth:	Age:
NHI Number:	
Street Number & Name:	
Suburb:	
City/Town:	Postcode:
Home Phone:	
Work Phone:	
Cell Phone:	
Email Address:	

- INDICATION:**
- Atrial Fibrillation
 - Deep Vein Thrombosis
 - Pulmonary Embolism
 - Tissue Heart Valve
 - Mechanical Valve Prosthesis
 - Mural Thrombus
 - TIA
 - Myocardial Infarction
 - other: _____

- TARGET INR:**
- 2.5 (2.0-3.0)
 - 3.0 (2.5-3.5)
 - other: _____

WARFARIN STRENGTH USED:

Marevan

- Only use 1's
- Only use 1's & 5's

Coumadin

- Only use 1's
- Only use 1's & 5's

ANTICOAGULATION THERAPY STARTED ON (DATE): _____

- ANTICIPATED DURATION:** 6 weeks
 3 months
 6 months
 1 year
 life-time

PATIENT ACCESS

Allow patients to view their own results on line? No
 Yes

3 MOST RECENT INR RESULTS & WAFARIN DOSES:

Date of INR test	INR Result	Warfarin Dose

PRESCRIPTION: According to the Standing Order for the Management of Warfarin Dose adjustment and INR testing frequency.

CAUTIONS

Please indicate if your patient has any of the following:

- Problems with excess alcohol intake No Yes
 Persistent unstable INRs No Yes

Details and Additional Cautions:

Dr:	
Surgery:	
Street Number & Name:	
Suburb:	
City/Town:	Postcode:
Phone:	
Fax:	
Cell Phone:	
email:	

Signed: _____
 Date: _____

Patient consent form for collection of previous INR results

The School of Pharmacy at the University of Auckland has been asked to evaluate the warfarin management service you have been receiving through your pharmacy.

As part of this evaluation, we would like to compare your INR blood results now with the results you had before you joined the pharmacy service. If you agree, we will ask your doctor's surgery to provide us with these results. The only information we will be requesting will be the dates of the tests and the test results. All the information will be kept strictly confidential and will not be identifiable in any reports.

You do not have to agree to allow us to have access to your previous results if you do not want to. It will not affect your warfarin management in any way if you decide to say no and you will still be able to use the pharmacy service.

If you have any questions or concerns about your doctor providing this information, you can either ask your pharmacist or contact me, Jenny Harrison, on je.harrison@auckland.ac.nz or 021 167 3233.

Name: _____

NHI: (*pharmacist to complete*) _____

- I do** consent to the School of Pharmacy requesting my previous INR results
- I do not** consent to the School of Pharmacy requesting my previous INR results

Signature: _____

Date: _____

Community Pharmacist-led Anticoagulation Management Service (CPAMS)

Patient Survey

The School of Pharmacy at the University of Auckland has been asked to evaluate the warfarin management service you have been receiving from your pharmacy. The information collected in this survey will help in planning how warfarin treatment is managed in the future for patients throughout New Zealand. Your responses will be kept strictly confidential and will not be identifiable in any reports. As a person using the service, your opinions are very important. Thank you for your time taken to complete this survey.

Please return the completed survey in the prepaid envelope provided.

If you have any questions about this survey please contact:

Jenny Harrison
Research Fellow
School of Pharmacy
Faculty of Medical and Health Sciences
The University of Auckland
Private Bag 92019
Auckland
je.harrison@auckland.ac.nz

Please circle **one** response to show how strongly you agree or disagree with each statement.

I find it more convenient to have my blood test at the pharmacy.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I would rather have a finger-prick blood test than have blood taken from my arm using a needle.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I feel confident that the results from the pharmacy blood test are reliable.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I like knowing my test result and dose immediately, rather than having to wait until later.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I find it useful to be able to discuss my warfarin treatment with the pharmacist when I go for my test.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I find it helpful to be given a calendar showing me what dose of warfarin to take.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I am not confident that the pharmacist can manage my warfarin treatment safely.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

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 **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I feel less in control of my warfarin treatment now that I go to the pharmacy for testing.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

It saves me time having my warfarin managed by the pharmacist.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I would prefer to have my warfarin managed by my family doctor.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I would still want to use the warfarin service at the pharmacy even if I had to pay a fee.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Please add any comments you have about paying a fee.

Being involved in the pharmacy warfarin management service has changed my view on how the pharmacist can help people with their healthcare.

Yes **No**

If yes, please give details here.

If you have any additional comments you would like to make about the pharmacy warfarin management service, please add them here.

Please complete the following information by ticking the relevant boxes.

Gender **Male** **Female**

Which ethnic group do you belong to?

Mark the space or spaces which apply to you.

Age group **15-24**
 25-34
 35-44
 45-54
 55-64
 65 or over

- New Zealand European**
- Maori**
- Samoan**
- Cook Island Maori**
- Tongan**
- Niuean**
- Chinese**
- Indian**
- Other (such as DUTCH, JAPANESE, TOKELAUAN)**

Please state: _____

Community Pharmacist-led Anticoagulation Management Service (CPAMS)

Pharmacist Questionnaire

The School of Pharmacy at the University of Auckland has been contracted to evaluate the CPAMS pilot study. Your opinions are a very important part of the evaluation and we would be grateful for you taking the time to complete this questionnaire. Your responses will be kept strictly confidential and will not be identifiable in any reports.

If you have any questions about this questionnaire please contact:

Jenny Harrison
Research Fellow
School of Pharmacy
Faculty of Medical and Health Sciences
The University of Auckland
Private Bag 92019
Auckland
je.harrison@auckland.ac.nz

Please circle **one** response to show how strongly you agree or disagree with each statement.

I find the CoaguChek XS Plus easy to use.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I often have to repeat tests with the CoaguChek XS Plus because there is an error message.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I usually find it easy to obtain a blood sample from the patient's finger.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I am confident that the INR results from the CoaguChek XS Plus are reliable.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I find it easy to use INR Online.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I am not confident that the dosing recommendations obtained from INR Online are appropriate.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I have enough information about my patients' medical history to enable me to provide them with appropriate management of their warfarin treatment.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

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 **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Providing a warfarin management service has improved my relationship with the patients involved.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

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 **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I don't feel confident managing my patients' warfarin treatment.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I find it difficult to make time for the CPAMS because of the other demands of my work.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I would like to be able to continue to offer a warfarin management service to my patients.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Over the course of the pilot study, has your relationship with the GPs involved improved, deteriorated or remained unchanged? (Please estimate how many fall into each category)

Improved _____

Deteriorated _____

Unchanged _____

Over the course of the pilot study, has your relationship with the practice nurses involved improved, deteriorated or remained unchanged? (Please estimate how many fall into each category)

Improved _____

Deteriorated _____

Unchanged _____

If you have any additional comments you would like to make about the CPAMS, please add them here.

Thank you again for your time.

Please return the completed questionnaire in the prepaid envelope provided.

Community Pharmacist-led Anticoagulation Management Service (CPAMS)

General Practitioner Questionnaire

The School of Pharmacy at the University of Auckland has been contracted to evaluate the CPAMS pilot study in which some of your patients have been involved. The results of the evaluation will be used to assist in planning how pharmacists can contribute to the management of warfarin for patients throughout New Zealand. Your opinions on the service are a very important part of the evaluation and we would be grateful for you taking the time to complete this questionnaire. Your responses will be kept strictly confidential and will not be identifiable in any reports.

Please return the completed questionnaire by 15th July, 2011

If you have any questions about this questionnaire please contact:

Jenny Harrison
Research Fellow
School of Pharmacy
Faculty of Medical and Health Sciences
The University of Auckland
Private Bag 92019
Auckland
je.harrison@auckland.ac.nz

Please circle **one** response to show how strongly you agree or disagree with each statement.

I am confident that the INR results from the CoaguChek XS Plus device used in the pharmacy are reliable.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I find it easy to access information about the warfarin treatment of my patients involved in the CPAMS, using INR Online.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I am not confident that the dosing recommendations obtained from INR Online are appropriate.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

How does the pharmacist inform you of INRs above 4.0 or below 1.5?

Please tick all that apply:

by email **by phone** **by fax** **other:** _____

I am confident that this method of informing me about INRs above 4.0 or below 1.5 is effective.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I am confident that the pharmacist can manage my patients' warfarin treatment safely.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

As a direct result of seeing my patients for warfarin management, the pharmacist has helped them with other aspects of their healthcare.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Having my patients enrolled in the CPAMS has saved me time.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Having my patients enrolled in the CPAMS has saved time for my practice nurse and/or receptionist.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Since my patients have been involved in the CPAMS, their warfarin treatment has been less well controlled.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I would like the CPAMS to continue to be available to my patients.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I think the CPAMS should be made available to patients throughout New Zealand.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Have you experienced any problems with the CPAMS? If yes, please give details here.

If you have any additional comments you would like to make about the CPAMS, please add them here.

Thank you again for your time.

Please return the completed questionnaire in the prepaid envelope provided by 15th July, 2011.

Community Pharmacist-led Anticoagulation Management Service (CPAMS)

Practice Nurse Questionnaire

The School of Pharmacy at the University of Auckland has been contracted to evaluate the CPAMS pilot study in which some of the patients from your practice have been involved. The results of the evaluation will be used to assist in planning how pharmacists can contribute to the management of warfarin for patients throughout New Zealand.

Your opinions on the service are a very important part of the evaluation and we would be grateful for you taking the time to complete this questionnaire. Your responses will be kept strictly confidential and will not be identifiable in any reports.

Please return the completed questionnaire by 15th July, 2011

If you have any questions about this questionnaire please contact:

Jenny Harrison
Research Fellow
School of Pharmacy
Faculty of Medical and Health Sciences
The University of Auckland
Private Bag 92019
Auckland
je.harrison@auckland.ac.nz

Please circle **one** response to show how strongly you agree or disagree with each statement.

It is more convenient for patients to have their INR blood test at the pharmacy.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

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 **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I am confident that the pharmacist can manage our patients' warfarin treatment safely.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Since our patients have been involved in the CPAMS their warfarin treatment has been less well controlled.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

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 **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

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 **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Having our patients enrolled in the CPAMS has saved me time.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Having our patients enrolled in the CPAMS has saved time for the GPs.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I would like the CPAMS to continue to be available to our patients.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

I think the CPAMS should be made available to patients throughout New Zealand.

Strongly agree **Agree** **Neither agree
nor disagree** **Disagree** **Strongly disagree**

Have you experienced any problems with the CPAMS? If yes, please give details here.

If you have any additional comments you would like to make about the CPAMS, please add them here.

Thank you again for your time.

Please return the completed questionnaire in the prepaid envelope provided by 15th July, 2011.

Time and motion study

A time and motion study was carried out in May and June 2011 to collect data on the time and activities required to provide the CPAMS. Pharmacists were asked to record the time taken to perform each activity related to the CPAMS for a period of one working week. In addition, they were asked to estimate the time taken for those activities which took place during the earlier parts of the innovation project but were no longer being performed during the period of the time and motion study. These were activities relating to the patient enrolment process and the first testing and counselling visit at the pharmacy.

Table 1 shows the results obtained during the time and motion study. There was wide variation in the timings recorded at the different sites.

The average consultation time was 7 minutes per patient with a range of average times for individual sites of 4 to 14 minutes. The median consultation time was 6 minutes. The consultation time was defined as the time the pharmacist spent with the patient at each visit and included performing the test; determining the dose and next test date; and any counselling.

The average number of consultations during the week was 18, with a range of 7 to 30.

The average time per site spent on CPAMS-related activities that were not part of the consultation was 54 minutes per week with a range of 5 to 128 minutes. Activities recorded included contacting patients overdue for testing; liaising with GP practices; and performing quality control procedures.

Table 1: Current activity – data collected for one week in May or June 2011

Current activity¹	Time in minutes (to nearest minute)
Average consultation time for all sites	7
Median consultation time for all sites	6
Maximum average consultation time	14
Minimum average consultation time	4
Average number of consultations per week	18
Maximum number of consultations per week	30
Minimum number of consultations per week	7
Average time spent on CPAMS per week, excluding consultations	54
Maximum time spent on CPAMS per week, excluding consultations	128
Minimum time spent on CPAMS per week, excluding consultations	5
¹ Includes data from 14 sites	

The estimated timings recorded for activities relating to the patient enrolment process and the first testing and counselling visit at the pharmacy are shown in Table 2. The average total time across the sites was 48 minutes per patient, with a range of 21 to 73 minutes for individual sites.

Table 2: Data for service set-up – estimated timings only

Previous activity¹	Average time in minutes per patient
Explanation of CPAMS to potential patient	9
Completing consent form with patient	6
Liaising with GP to arrange patient referral	12
Entering new patient details into INR Online	8
First CPAMS consultation with new patient	13
Total time	48
Minimum average total time	21
Maximum average total time	73
¹ Includes data from 15 sites	

Sites were asked to list other activities that had taken place while the CPAMS service was being set-up. They included:

- Meeting with or writing to GPs, nurses and other practice staff to explain how the service would work.
- Identifying and contacting potential patients.
- Liaising with practice staff to obtain additional or missing enrolment details
- Liaising with patients to coordinate transfer from laboratory testing.
- Providing warfarin counselling.
- Explaining the service to other members of pharmacy staff.
- Setting up a consulting room
- Ordering sharps bins and disposables (e.g. gloves and plasters).
- Paperwork including photocopying and filing



Date: _____

MISSED APPOINTMENT

Mr./Mrs./Ms.: _____

NHI: _____

: _____

Dear Mr./Mrs./Ms _____


You are now overdue for your INR test. It is extremely important that you attend for your regular INR tests to ensure that the warfarin dose you are taking is safe.

The last INR we have on record was taken ____/____/____ and was _____

We have failed in our attempts to contact you, and thus have notified your General Practitioner as we cannot be responsible for your INR control and warfarin dosing if you do not attend.

We would be happy to hear from you to arrange an appointment or discuss & resolve any issues you have with our service.

Sincerely,

Pharmacist : _____



Date: _____

MISSED APPOINTMENT

Mr./Mrs./Ms.: _____

NHI: _____

: _____

Dear Doctor,

This is to advise you that Mr./Mrs./Ms. _____ referred to our pharmacy for warfarin anticoagulation management, missed his/her INR test appointments.

Despite repeated calls and explanation of the importance of ongoing care, this patient has not complied with the requisite follow-up.

The last INR was taken ____/____/____ and was _____

We cannot be responsible for the INR control and warfarin dosing of non-compliant patients. We have therefore suspended follow-up for the time being and have not made any future appointments for this patient with the Community Pharmacy Anticoagulation Management Service and hand warfarin management back to your service. In the meantime if the patient presents for a test we will process them and you will be notified in the usual manner.

Please feel free to contact us if you wish to discuss management of this patient or require further information.

Sincerely,

Pharmacist : _____

Community Pharmacist-led Anticoagulation Management Services

Manual INR Result Record Sheet

Date Time	Name NHI or DOB	Safety Questions	INR	Current Dose	Recommended dose and date of next test	Operator
		<input type="checkbox"/> Missed dose <input type="checkbox"/> Bleeding or bruising <input type="checkbox"/> Medication changes <input type="checkbox"/> Hospital Admission				
		<input type="checkbox"/> Missed dose <input type="checkbox"/> Bleeding or bruising <input type="checkbox"/> Medication changes <input type="checkbox"/> Hospital Admission				
		<input type="checkbox"/> Missed dose <input type="checkbox"/> Bleeding or bruising <input type="checkbox"/> Medication changes <input type="checkbox"/> Hospital Admission				

INR within the therapeutic range

If the INR is within the therapeutic range, advise the patient to continue on the same dose and recommend a dose interval the same as the previous interval.

Record the dose recommended and the date of the next test

If the INR Is outside the therapeutic range

Warfarin dosing is the responsibility of the patient's general practitioner. You should therefore contact the GP practice, advise them that you are unable to contact INR Online and require dosing advice.

The dose recommendation from the doctor and the date of the next test should be recorded and the patient should be contacted with this information.

If the INR is >4.5, advise the patient to miss a warfarin dose and repeat the INR the next day.

When access is resumed

The missing results should be entered into INR online.

Enter the results by using the add result tab on the top of the left-hand column on the overview page.

This will ensure that the results are sent to the doctor's PMS and an e-mail will be sent to the patient.

When you enter a result the computer will recommend a new dose. Edit this to the dose you gave and edit the recommended date of the next test to the date you recommended. Then confirm the result.

DO NOT ENTER THE MISSING RESULT USING THE EDIT RESULT TAB. If you do, the result will not be sent to the doctor's PMS and the patient will not receive an e-mail.